UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC

Petitioner,

v.

ALIGN TECHNOLOGY, INC.

Patent Owner.

Case IPR2016-00270

U.S. Patent No. 6,699,037

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,699,037 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

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LIST OF EXHIBITS

No.	Exhibit
1001	U.S. Patent No. 6,699,037 ("the '037 patent").
1002	Prosecution History for U.S. Patent Application No. 09/791,650, which matured into the '037 patent ("'650 Patent Application").
1003	U.S. Patent No. 6,068,482 to Snow ("Snow") with a copy of parent U.S. Patent Application No. 08/785,664.
1004	U.S. Patent No. 6,217,334 to Hultgren ("Hultgren").
1005	U.S. Patent No. 2,467,432 to Kesling ("Kesling").
1006	U.S. Patent No. 5,011,405 to Lemchen ("Lemchen").
1007	Declaration of Dr. Martin Martz, D.D.S., M.S. ("Martz Declaration").
1008	Declaration of Dr. James Mah, D.D.S., M.Sc., D.M.Sc. ("Mah Declaration").
1009	Declaration of Diana Bowen
1010	U.S. Patent No. 6,217,325 ("the '325 patent"), parent of the '037 patent.
1011	Excerpts of Reexamination Prosecution History for U.S. Patent No. 6,217,325 (Control No. 90/013,457)
1012	Feder, Barnaby J., "Orthodontics Via Silicon Valley; A Start-Up Uses Computer Modeling and Venture Capital to Reach Patients," *N.Y. Times* (Aug. 18, 2000).
1013	Align SEC filing 11/14/2000 and SEC 10-K FY 2000- FY 2013.
1014	Nahoum, H. I., "The Vacuum Formed Dental Contour Appliance," *The New York State Dental Journal*, 30(9):385-390 (1964).
1015	Rekow, D., "Computer-aided design and manufacturing in dentistry: A review of the state of the art," *The Journal of Prosthetic Dentistry*, vol. 58, No. 4, pp. 512-516 (Oct. 1987).
1016	Rekow, D., "A Review of the Developments in Dental CAD/CAM Systems," *Dental Clinics: Prosthodontics and Endodontics*, pp. 25-33 (1992).
1017	U.S. Patent No. 6,244,861 to Andreiko ("Andreiko")
1018	Biggerstaff, R. H. "Computerized Diagnostic Setups and Simulations." *Angle Orthodontist*. 40(1), 28-36 (1970).

1019	Burstone, C. J. "JCO Interviews Dr. Charles J. Burstone on the Uses of the Computer in Orthodontic Practice, Part 2." *J Clin Orthod*. 13(8), 539-551 (1979).
1020	U.S. Patent No. 5,338,198, "Dental Modeling Simulator." ("Wu")
1021	U.S. Patent No. 5,605,459, "Method of and Apparatus for Making a Dental Set-up Model." ("Kuroda")
1022	Kuroda, M. N., et al. "Three-Dimensional Dental Cast Analyzing System Using Laser Scanning." *Am J Orthod Dentofac Orthop*. 110:365-369, at 366, col. 2 (1996).
1023	Hemayed, E.E., et al. "Three Dimensional Model Building in Computer Vision with Orthodontic Applications, Technical Report (TR)." *Computer Vision and Image Processing Laboratory (CVIP Lab)*. 1-27 (1996).
1024	Faber, R.D., et al. "Computerized Interactive Orthodontic Treatment Planning." *Am J Orthod*. 73(1), 36-46 (1978).
1025	U.S. Patent No. 4,478,580, "Process and Apparatus for Treating Teeth." ("Barrut")
1026	Marsh, J. L., et al. "Surface Reconstructions From Computerized Tomographic Scans for Evaluation of Malignant Skull Destruction." *Am J Surg*. 530-533 (1984).
1027	Guyuron, B., et al. "Computer-Generated Model Surgery: An Exacting Approach to Complex Craniomaxillofacial Disharmonies." *J Craniomaxillofac Surg*. 17:101-4 (1989).
1028	Frohberg, U., et al. "3D-CT Model Surgery for Orthognathic Surgery." *J Oral Maxillofac Surg*. 49(Suppl. 1):118 (1991).
1029	Stoker, N. G., et al. "Stereolithographic Models for Surgical Planning: Preliminary Report." *J Oral Maxillofac Surg*. 50:466-471 (1992).
1030	Fuhrmann, R. A. W., et al. "Treatment Prediction with Three-Dimensional Computer Tomographic Skull Models." *Am J Orthod Dentofac Orthop*. 106:156-60 (1994).
1031	Cacciafesta, V., et al. "Bending Art System – State of the Art and First Impressions." *Kieferorthop*. 9:247-254 (1995).
1032	Sassani, F., et al. "Computer-Assisted Fabrication of Orthodontic Appliances: Considering the Possibilities." *JADA*, 126:1296-1300 (Sept. 1995).
1033	Kesling, H. D. "The Philosophy of the Tooth Positioning Appliance." *Am J Orthod Oral Sur*. 31(6):297-304 (1945). ("Kesling 1945")
1034	Kesling, H. D. "The Diagnostic Setup with Consideration of the Third Dimension." *Am J Orthod*. 42(10):740-748 (1956). ("Kesling 1956")

1035	Elsasser, W. A. "Some Observations on the History and Uses of the Kesling Positioner." *Am J Orthod*. 136(5):368-374 (1950).
1036	*Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1306 (2006).
1037	Bunch, W. B. "Orthodontic Positioner Treatment During Orthopedic Treatment of Scoliosis." *Am J Orthod*. 47(3):174-204, 196 (1961).
1038	U.S. Patent No. 4,793,803, "Removable Tooth Positioning Appliance and Method." ("Martz")
1039	U.S. Patent No. 4,348,178 to Kurz ("Kurz")
1040	Vaughan, P. P. "Evaluation of Orthodontic Positioners." University of Sydney, Dept. of Preventive Dentistry, 1-237, at 118 (1986).
1041	Gottlieb, E. L. et al. "JCO Interviews Dr. James A. McNamara, Jr., on the Frankel Appliance, Part 2: Clinical Management." *J Clin Orthod*. 16(6), 390-407 (1982).
1042	Sheridan, J. J. "Air-Rotor Stripping." *J Clin Orthod*. 19(1):43-59 (1985).
1043	Cottingham, L. L. "Gnathologic Clear Plastic Positioner." *Am J Orthod.* 55(1):23-31 (1969).
1044	Intentionally Blank
1045	Intentionally Blank
1046	Modlin, S. S. "Realignment of Incisors with Vacuum-Formed Appliances." *J Clin Orthod*, 8(5):277-281 (1974).

I. INTRODUCTION

ClearCorrect Operating, LLC ("ClearCorrect Operating" or "Petitioner") requests that the Patent Trial and Appeal Board (the "Board") institute *inter partes* review of U.S. Patent No. 6,699,037 (the "'037 patent", Ex. 1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 et seq.

The claims of the '037 patent are directed to an age old idea: a method for fabricating a plurality of dental incremental position adjustment appliances for repositioning teeth. In particular, a plurality of digital data sets representing a plurality of successive tooth arrangements are provided at the outset of treatment for controlling a fabrication machine to produce the plurality of appliances. Manually producing modified tooth arrangements on physical casts and fabricating corresponding dental incremental position adjustment appliances therefrom has been known for almost an entire century, at least since the 1940's. With the passage of time and the advent of modern computer technology, the manual methodology was soon replaced by an automatic digital and mechanical means for accomplishing the same result. In fact, Patent Owner admits in its own patent that these concepts were well-established by providing examples of suitable models of rapid prototyping machines and conventional pressure or vacuum molding equipment which can be purchased to carry out the fabrication of the appliances. Hence, it is clearly evident that the '037 patent was improvidently granted.

The charts in Section VII, *infra*, demonstrate that claims 1, 2, 9 and 10 of the '037 patent are unpatentable over the prior art,[1] and that Petitioner has a reasonable likelihood of prevailing with respect to the same.

II. MANDATORY NOTICES

Petitioner ClearCorrect Operating, LLC ("ClearCorrect Operating" or "Petitioner") respectfully requests *inter partes* review for claims 1, 2, 9 and 10 of U.S. Patent No. 6,699,037 ("the '037 patent," attached as Ex. 1001) in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq*. Pursuant to 37 C.F.R. § 42.8(a)(1), ClearCorrect Operating provides the following mandatory disclosures.

A. Real Party-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that ClearCorrect Operating is the real party-in-interest. In addition, the parent company of ClearCorrect Operating is ClearCorrect Holdings, Inc.

B. Related Matters

The '037 patent is asserted in a co-pending litigation captioned as *Align Technology, Inc. v. SmileCareClub, LLC, et al.*, N.D.Cal., Case No. 5-15-cv-

[1] Review of the prosecution history of the '037 patent shows that much of the applied prior art was not before the Examiner, the remaining art discussed herein was not explicitly discussed by the Examiner during *ex parte* prosecution. (Ex. 1002 at 40, 42)

04864, the complaint in which was filed on October 22, 2015. Further, the '037 patent is a direct continuation of U.S. Patent No. 6,217,325 ("the '325 patent"), which is a division of U.S. Patent No. 5,975,893 ("the '893 patent"). Both the '325 patent and the '893 patent are currently involved in *ex parte* reexamination proceedings, Control Nos. 90/013,457 and 90/013,581, respectively, before the Office.

C. Lead and Back-Up Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner provides the following designation of counsel:

Lead counsel is Scott A. McKeown (Reg. No. 42,866) and back-up counsels are Michael L. Kiklis (Reg. No. 38,939) and Ruby J. Natnithithadha (Reg. No. 71,684).

D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), papers concerning this matter should be served in accordance with the following.

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III. PAYMENT OF FEES

The undersigned authorizes the Office to charge the fee required by 37 C.F.R. § 42.15(a) for this Petition for *inter partes* review to Deposit Account No. 15-0030. Any additional fees that might be due are also authorized.

IV. REQUIREMENTS FOR *INTER PARTES* REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '037 patent is satisfied.

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner hereby certifies that the '037 patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '037 patent on the grounds identified herein. The '037 patent has not been subject to a completed estoppel based proceeding of the AIA, and the complaint referenced above in Section II.B. was served within the last 12 months. None of the Petitioner, the Petitioner's real party-in-interest, or the Petitioner's privies, have been served with a complaint alleging infringement of the '037 patent.

B. Claims For Which Review is Requested

Pursuant to 37 C.F.R. §§ 42.104(b) and (b)(1), Petitioner requests *inter partes* review of claims 1, 2, 9 and 10 of the ‘037 patent, and that the Board cancel the same as unpatentable.

1. Statutory Grounds of Challenge

Pursuant to 37 C.F.R. § 42.204(b)(2), *inter partes* review of the ‘037 patent is requested in view of the following references, each of which is prior art to the ‘037 patent under 35 U.S.C. §§ 102(b), 102(e):

(1) U.S. Patent No. 6,068,482 to Snow (“Snow,” attached as Ex. 1003) issued on May 30, 2000, was filed on January 19, 1999, and claims priority to continuation Application No. 08/785,664, filed on January 17, 1997, which is prior to the earliest priority date claimed by the ‘037 patent. Therefore, Snow is prior art to the ‘037 patent under 35 U.S.C. § 102(e). Snow was not considered during the original prosecution of the ‘037 patent, nor is it cumulative of any prior art considered by the original patent examiner;

(2) U.S. Patent No. 6,217,334 to Hultgren (“Hultgren,” attached as Ex. 1004) issued on April 17, 2001 and was filed on January 28, 1997, which is prior to the earliest priority date claimed by the ‘037 patent. Therefore, Hultgren is prior art to the ‘037 patent under 35 U.S.C. § 102(e). Hultgren was included as one of

114 references cited by the Patent Owner in an Information Disclosure Statement ("IDS") during the original prosecution of the '037 patent;[2]

(3) U.S. Patent No. 2,467,432 to Kesling ("Kesling," attached as Ex. 1005) issued on April 19, 1949, which is prior to the earliest priority date claimed by the '037 patent. Therefore, Kesling is prior art to the '037 patent under 35 U.S.C. § 102(b). Kesling was not considered during the original prosecution of the '037 patent, nor is it cumulative of any prior art considered by the original patent examiner;

(4) U.S. Patent No. 5,011,405 to Lemchen ("Lemchen," attached as Ex. 1006) issued on April 30, 1991, which is prior to the earliest priority date claimed by the '037 patent. Therefore, Lemchen is prior art to the '037 patent under 35 U.S.C. § 102(b). Lemchen was included as one of 114 references cited by the Patent Owner in an Information Disclosure Statement ("IDS") during the original prosecution of the '037 patent;[3]

The grounds of unpatentability presented in this petition are as follows:

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[2] Ex. 1002 at 42. This prior art reference was never discussed on the record previously, and was found to raise a substantial new question of patentability (SNQ) in the reexamination of the parent '325 patent (Control No. 90/013,457).

[3] Ex. 1002 at 40. Although submitted to the Office, this reference was also never discussed on the record.

i. Claims 1, 2, 9 and 10 of the '037 patent are rendered obvious by Snow in view of Hultgren and Kesling under 35 U.S.C. § 103(a).

ii. Claims 1, 2, 9 and 10 of the '037 patent are rendered obvious by Snow in view of Lemchen and Kesling under 35 U.S.C. § 103(a).

iii. Claims 1, 2, 9 and 10 of the '037 patent are rendered obvious by Snow in view of Applicants' Admitted Prior Art ("APA")[4] and Kesling under 35 U.S.C. § 103(a).

2. How the Construed Claims are Unpatentable under the Statutory Grounds Identified in 37 C.F.R. § 42.204(b)(2) and Supporting Evidence Relied upon to Support the Challenge

Pursuant to 37 C.F.R. § 42.204(b)(4), an explanation of how claims 1, 2, 9 and 10 of the '037 patent are unpatentable under the statutory grounds identified

[4] The Board has recognized that Admitted Prior Art can be considered a "patent or printed publication" under 35 U.S.C. § 311(b). as has been the case for decades in patent reexamination, which conforms to the same "patents and printed publications" jurisdictional limitation. *Intri–Plex Technologies, Inc. and MMI Holdings, Ltd., v. Saint–Gobain Performance Plastics Rencol Limited*, IPR2014–00309 (Paper 83), *Berk-Tek, LLC v. Belden Inc.*, IPR2013-00057, 2014 WL 1253012 (PTAB Mar. 18, 2014); *Tasco, Inc. v. Pagnani*, IPR2013-00103, 2013 WL 5947703 (PTAB May 23, 2013); *Google Inc. v. B.E. Tech., LLC*, IPR2014-00038, 2014 WL 1410533 (PTAB Apr. 9, 2014); *Pride Solutions, LLC v. Not Dead Yet Mfg., Inc.*, IPR2013-00627, 2014 WL 1477696 (PTAB Mar. 17, 2014).

above, that the Petitioner has at least a reasonable likelihood of prevailing on these grounds, including the identification of where each element of the claim is found in the prior art, is provided in Section VII, below, in the form of claims charts. Pursuant to 37 C.F.R. § 42.204(b)(5), the exhibit numbers of the supporting evidence relied upon to support the challenges and the relevance of the evidence to the challenges raised, including identifying specific portions of the evidence that support the challenges, are provided in Section VII, below, in the form of claim charts.

V. FACTUAL BACKGROUND

A. Declaration Evidence

This Petition is supported by the Declaration testimony of Dr. Martin G. Martz, D.D.S., M.S. ("Martz Declaration") and Dr. James Mah, D.D.S., M.Sc., D.M.Sc. ("Mah Declaration"), which describe the scope and content of the prior art at the time of the application of the '037 patent. *See* Exs. 1007, 1008.

The level of skill in the art is generally evidenced by the prior art references. *See Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed.Cir. 1983). *See* also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001). The '037 patent discloses and claims a computer implementation of an age old idea: to incrementally move and reposition teeth by using a plurality of dental appliances, each of which shifts the teeth into a new position over time. There is nothing new disclosed or claimed in the '037 patent. The '037 patent represents nothing more than an automatic or mechanical means for replacing a manual activity which accomplishes the same result. See *In re Veener*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

B. Overview of the '037 Patent

The '037 patent, entitled "Method and System for Incrementally Moving Teeth," is generally directed to a system and method for repositioning teeth using a plurality of individual appliances, with the appliances incrementally repositioning the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, to a final tooth arrangement. (Ex. 1001, Abstract)

FIG. 1C illustrates the jaw of a patient "together with an incremental position adjustment appliance which has been configured according to the methods of the present invention" (Ex. 1001, 7:42-45) and is reproduced hereinbelow. "The appliances are intended to effect incremental repositioning of individual teeth in the jaw . . . The systems . . . will provide a plurality of such appliances intended to be worn by a patient successively in order to achieve the gradual tooth repositioning." (*Id.* at 8:46-57)

FIG. 2 of the '037 patent "illustrat[es] the steps of the present invention for producing a system of incremental position adjustment appliances" (Ex. 1001, 7:46-48) and is also reproduced hereinbelow. As a first step, a digital data set representing an initial tooth arrangement is obtained and referred to as the IDDS. (*Id.* at 9:23-25) After the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. (*Id.* at 10:36-38) For example, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. Once the user is satisfied with the final arrangement, the final tooth arrangement is incorporated into a final digital data set or FDDS. (*Id.* at 10:36-48) Next, based on both the IDDS and FDDS, a plurality of intermediate digital data sets (INTDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDDS's. (*Id.* at 10:50-55)

After production or fabrication, the plurality of appliances is supplied to the treating professional all at one time. The appliances will be marked in some manner to indicate their order of use. (Ex. 1001, 15:9-15)

C. The Prosecution History of the '037 Patent

The '037 patent issued from U.S. Patent Application No. 09/791,650, which was originally filed on February 21, 2001, with claims 1-9. (Ex. 1002 at 24-25) A copy of the file history of the application which matured into the '037 patent is attached to this Petition as Exhibit 1002.

Independent claims 1 and 9 are reproduced hereinbelow:

1. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:

providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement **for an individual patient**; and

controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances **for the individual patient**.

9. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:

providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement; and

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

In an initial, non-final Office Action dated April 19, 2002, (1) claim 1-4, 6, 8 and 9 were rejected under 35 U.S.C. § 102(e) as being anticipated by the Chishti ‘893 or ‘325 patents; (2) claims 1 and 2 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Miura (U.S. Patent No. 5,017,133) in view of Andreiko et al. (U.S. Patent No. 5,431,562); (3) claims 5 and 7 were rejected under 35 U.S.C.

§ 103(a) as being obvious over the Chishti '893 or '325 patents; (4) claims 1-9 were rejected under obviousness-type double patenting as being unpatentable over claims of the Chishti '325 patent; and (5) claims 3-9 were indicated as containing allowable subject matter. (Ex. 1002 at 46-49)

Over the course of the prosecution history of the '037 patent, one of the rejections that the Examiner maintained was the 35 U.S.C. § 103(a) obviousness rejection over Miura in view of Andreiko et al. (Ex. 1002 at 70, 112, 125, 139, 152-155, 163) Just before allowance of the '037 patent, Patent Owner scheduled a personal interview with the Examiner on October 8, 2003, in order to discuss claims 1 and 10 and the Miura and Andreiko et al. prior art references. The Examiner indicated that "[l]anguage that limits the claims to providing all of the plurality of data sets at once before fabrication would overcome the rejections." (*Id.* at 165)

As a result, Patent Owner filed an Amendment After Final on November 3, 2003, amending claims 1 and 10, as suggested by the Examiner. Specifically, Patent Owner amended independent claim 1, and similarly independent claim 10 (which was renumbered as claim 9 upon allowance), to recite "providing <u>at the outset of treatment</u> a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient." (Ex. 1002 at 170)

In turn, the Examiner issued a Notice of Allowance on November 19, 2003, allowing claims 1, 2, 4-21 and 23. (Ex. 1002 at 176) These claims issued as claims 1-21 of the '037 patent. The Examiner did not set forth any statement of reasons for allowance.

D. The Prosecution History of the '325 Patent Reexamination

As discussed in Section II.B., *supra*, the '037 patent is a direct continuation of U.S. Patent No. 6,217,325 ("the '325 patent"). On March 23, 2015, the Office ordered reexamination of claims 1-3, 11-14, 18, 20, 21, 23, 27-35 and 37-39 of the '325 patent, finding a substantial new question of patentability raised by some of the same grounds as in the current petition and substantially similar claims as the '037 patent. (Ex. 1011 at 58-69) In particular, the Examiner found that "Snow in view of Hultgren or the APA and Kesling raises a substantial new question of patentability in the '325 patent." (*Id.* at 66) An exemplary claim of the '325 patent, substantially similar in scope to claims 1 and 9 of the '037 patent, is reproduced below:

> 35. A method for fabricating a plurality of successive dental incremental position adjustment appliances, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> providing a final digital data set representing the final tooth arrangement;

providing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the successive dental appliances as negatives of the positive models.

Soon after reexamination of the '325 patent was ordered, an Office Action issued on June 11, 2015, with the Examiner adopting the rejection of claims 1-3, 11-14, 18, 20, 21, 23, 27-35 and 37-39 under 35 U.S.C. § 103(a) as being unpatentable over Snow in view of Hultgren and Kesling. (Ex. 1011 at 48-57) As will be discussed in greater detail in Section VII.B., *infra*, Patent Owner's response to the Examiner's Office Action was largely non-responsive to the applied rejection.

VI. CLAIM CONSTRUCTION

In an *inter partes* review, a claim in an unexpired patent is given its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). In determining their scope, claim terms receive their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

As required by the Board's rules, this Petition applies the broadest reasonable interpretation standard for claim terms, although the broadest reasonable interpretation standard may be, and often is, different from a claim construction in district court. *See, e.g.*, *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1297 (Fed. Cir. 2007). Thus, the claim interpretations presented in this Petition, including where Petitioner does not propose an express construction, do not necessarily reflect the claim constructions that Petitioner believes should be adopted by a district court under the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

Claims 1 and 9 of the '037 patent recite, *inter alia*, "at the outset of treatment." The meaning of the term "outset" is "the beginning or start" and the term "treatment" is "the application of medicines, surgery, psychotherapy, etc., to a patient or to a disease or symptom." The disclosure of the '037 patent states that "[u]sually, the initial digital data set is provided by producing a plaster cast of the patient's teeth (prior to treatment) by conventional techniques." (Ex. 1001, 5:46-48) Accordingly, based on the above, the term "treatment" does not include the generation of digital data sets representing a plurality of tooth arrangements and the production of positive casts/models based on such digital data sets. Rather, "treatment" begins with the patient wearing/using the dental incremental position adjustment appliances. Therefore, the broadest reasonable interpretation of the phrase "at the outset of treatment" denotes a point in time when a patient begins/starts to wear/use a dental incremental position adjustment appliance. (Ex. 1007, ¶ 41; Ex. 1008, ¶¶ 68-70)

In view of the above, claim interpretations submitted herein for the purpose of demonstrating a Reasonable Likelihood of Prevailing are neither binding upon litigants in any litigation, nor do such claim interpretations correspond to the construction of claims under the legal standards that are mandated to be used by the courts in litigation. The interpretation of the claims presented either implicitly or explicitly herein should not be viewed as constituting, in whole or in part, Petitioner's own interpretation and/or construction of such claims for the purposes of any future litigation. Instead, such constructions in this proceeding should be viewed only as constituting an interpretation of the claims under the "broadest reasonable construction" standard.

All claim terms have been accorded their broadest reasonable interpretation in light of the patent specification including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.

VII. GROUNDS OF UNPATENTABILITY SHOWING THAT PETITIONER HAS A REASONABLE LIKELIHOOD OF PREVAILING

A. Snow in View of Hultgren and Kesling Renders Claims 1, 2, 9 and 10 of the '037 Patent Unpatentable Under 35 U.S.C. § 103(a)

Snow generally discloses a method for creating and utilizing an individualized, digital three-dimensional ("3D") teeth model for simulating the movement of a patient's teeth during orthodontic treatment from an initial position to an "idealised second position." (Ex. 1003, 1:45-48; 4:7-23) As further discussed in Snow, a plurality of digital data sets representing a plurality of successive tooth arrangements are automatically generated at the outset of treatment:

> the computer graphic model preferably has the ability to automatically produce a sequence of images mapping movements of teeth from a first position corresponding to the patient's current state to an idealised second position. (*Id.* at 1:45-58)

As explained in Dr. Martz's and Dr. Mah's declarations, the "idealised second position" in Snow can be any point in time during treatment, either at the final stage of treatment or during the middle or intermediate stage of treatment. (Ex. 1007, ¶ 42; Ex. 1008, ¶ 93) Further, the plurality of digital data sets representing the successive tooth arrangements are customized and created for each individual patient, with each set representing one of the successive tooth arrangements. (*Id.* at ¶ 42; *Id.* at ¶¶ 93-94) Moreover, as would be understood be understood by a person of ordinary skill in the art, all or some of the appliances corresponding to the digital data sets can also be fabricated for an individual patient and given to the treating professional or patient at the outset of treatment. (*Id.* at ¶ 42; *Id.* at ¶ 95)

Indeed, Snow teaches creating individualized brackets based on the produced digital data sets:

> [t]he individualised 3D model can then be utilised to create an individualized bracket with accurate measurements with the surface of each bracket accurately profiled to match the corresponding surface in the individualised tooth. The bracket structure can be output in a standard stereo lithographic format (STL) and later used to create a corresponding customized brackets/braces. (Ex. 1003, 5:49-56)

Hultgren specifically discloses controlling a fabrication machine based on the digital data sets to produce a positive model:

> [f]abrication device 507 may be connected directly to the computer 500 or may be connected to a remote computer 505. **The fabrication device 507 may be any number of devices which can utilize computer generated data and create a three-dimensional object from such data.** One example of such a machine are the devices utilizing stereo lithography technology manufactured by 3-D Systems of Valencia, Calif. under the model designations SLA-250[5] and SLA-

[5] Petitioner notes that the '037 patent uses the same SLA-250 stereolithography machine as Hultgren to print the models.

> 500. Another example is the device utilizing filament technology (fused deposition modeling) manufactured by Statasys Corporation of Minneapolis, Minn. under the model designation FDM-1500. (Ex. 1004, 7:28-39) (emphasis added)

As explained in Dr. Martz's and Dr. Mah's declarations, the "three-dimensional object" in Hultgren teaches a positive model of a patient's teeth arrangement created by first generating an array of negative image scan data from scanning a patient's dental impression or study cast. (Ex. 1004, Abstract; Ex. 1007, ¶¶ 45-46; Ex. 1008, ¶ 97) The negative image scan data is then converted to positive image data, which is transmitted to known fabrication devices that utilize such data to create three-dimensional objects, such as positive models of the patient's teeth therefrom. (*Id.*; *Id.*)

Hultgren further discloses that the data used to create the three-dimensional, physical objects are generated by the electronic equivalent of the prior art physical study casts:

> [t]he programming operation of the processor 501 provides for scanning each of the upper and lower impressions and the bite registration impression. These scans provide the information necessary to create an electronic equivalent of the prior art physical study casts. By using negative image impressions and a line scanner, high resolution and speed are gained **wherein high quality study casts may be generated by a fabrication device 507** thereby

> replacing older methods of constructing the same. (Ex. 1004, 7:57-65) (emphasis added)

Accordingly, Hultgren's contribution to the dental art is that high resolution and speed are gained compared to older study cast production methods. (*Id.*; Ex. 1007, ¶ 46; Ex. 1008, ¶ 96)

Additionally, Kesling discloses fabricating a plurality of polymeric shell dental incremental position adjustment appliances for an individual patient as a negative of the positive model generated by Hultgren, for example. (Ex. 1007, ¶ 47; Ex. 1008, ¶ 98) Specifically, Kesling discloses that the dental appliances may be fabricated to move the teeth in a plurality of different steps and making intermediate tooth positioning devices. (Ex. 1005, 2:50 – 3:1) A plaster cast is made and the teeth are sawed off and repositioned. This step is performed multiple, successive times until the final, desired position of the teeth is achieved. (*Id.* at 3:30-60) In particular, Kesling states:

> [t]he next step in the making of this appliance and in the technique is that the respective teeth carried by the upper base 21 and the lower base 22 are dissected from the bases. This dissection may be accomplished by means of a small scroll saw or vibrating scroll saw as follows: A cut may be made down between each of the teeth with the saw. The saw is then turned laterally at the base of one of these cuts, and a cut may be made along the horizontal dotted lines 23, 24. This will separate each tooth from the other teeth and from the base,

> and the teeth may then have their lower portions cut down to resemble the natural root for that particular tooth. A sufficient amount of wax or other suitable material may be placed upon each of the bases, and the teeth reassembled with the bases, and held in place by the wax, the wax being indicated by numeral 25 in the spaces between the tooth roots. Each of the plaster teeth is then preplaces on its proper base and in its proper position; but the position of the tooth is so altered by the operator as to assume the ideal position for that particular tooth in that particular assembly, bearing in mind the formation of the jaw structure of the patient and the facial and racial characteristics of each patient.
>
> The teeth are secured in place by means of wax or some to her suitable material which is initially plastic and which has suitable qualities for adhering to the plaster.
>
> Fig. 3 then is a plaster cast of the teeth after they have been reassembled with their plaster bases in the ideal position in which it is desired to position the teeth. (Ex. 1005, 3:30-64)

1. Motivation to Combine

Snow provides a method for providing, at the outset of treatment, a plurality of digital data sets, including an initial data set representing an initial tooth arrangement, a final data set representing a final tooth arrangement, and a plurality of successive data sets representing a plurality of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

Hultgren further offers controlling a fabrication machine based on digital data sets to produce modified positive casts or models of a plurality of successive tooth arrangements. Kesling discloses the non-computerized, manual method of preparing positive dental models of the modified, successive tooth arrangements. Further, Kesling fabricates a plurality of dental incremental position adjustment appliances as negatives of the positive dental casts or models.

In fabricating the plurality of dental incremental position adjustment appliances for repositioning teeth, one of ordinary skill in the art would have been motivated to combine the teachings of the above prior art references. That is, a skilled artisan would have been motivated to create a plurality of digital data sets and digitally reposition the teeth, as taught by Snow, and to use the digital data sets representing the repositioned teeth to control a fabrication machine to produce a plurality of positive casts of the successive tooth arrangements, as described by Hultgren. The positive casts would then be used for producing the plurality of dental incremental position adjustment appliances well known in the art, as negatives of the positive casts taught by Kesling. (Ex. 1007, ¶¶ 54-55; Ex. 1008, ¶¶ 101-102) All of the prior art references are from the field of dentistry, and all concern the creation and manipulation of or use of three-dimensional models of patients' teeth. Moreover, the combination would result in the fabrication of more precise positive casts or models, and, in turn, more precise dental position adjustment appliances, as the digital data sets from Snow, representing more precise tooth arrangements, would be used to control the fabrication machine in Hultgren. Further, the combination would save manufacturing costs by eliminating the laborious hand creation of modified tooth arrangements on physical casts.

Since Kesling's manual method of producing modified positive models is labor intensive, one of ordinary skill would want to reduce this cost and would recognize that the use of modern computer technology is advantageously efficient. It has long been considered obvious and within ordinary skill to provide an automatic or mechanical means to replace a manual activity which accomplishes the same result. *In re* Veener, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958); *Leapfrog Enterprises, Inc. v. Fisher-Price*, 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007) ("applying modern electronics to older mechanical devices has been commonplace in recent years, since person of ordinary skill in art would have found it obvious to combine two prior art devices at issue in order to update mechanical device using modern electronic components."); Ex. 1007, ¶¶ 34, 55-56; Ex. 1008, ¶¶ 101, 103-104) Further, because of the predictability of the art and the detailed disclosures of Snow, Hultgren and Kesling, these references would have suggested to one of ordinary skill that this combination would be reasonably likely to succeed. (Ex. 1007, ¶ 55; Ex. 1008, ¶ 105)

In summary, Snow describes producing digital data sets representing a plurality of successive tooth arrangements for the purpose of developing a dental appliance treatment regimen. This treatment contemplated fabrication of customized dental appliances, such as brackets, for repositioning teeth. Hultgren, in turn, provides detailed steps for transforming digital data sets into incremental, positive models/casts, by controlling conventional appliance fabrication machines. More specifically, Hultgren describes converting negative image scan data into positive image data, and transmitting such data to known fabrication machines for producing positive models/casts of the successive tooth arrangements. Modifying Snow with the teachings of Hultgren would provide a set of incremental, positive models/casts for repositioning teeth, manufactured in accordance with the digital data sets. Finally, modifying the positive models/casts of Hultgren is simply a matter of applying the teachings of Kesling (known for almost a century) of creating dental appliances as negatives of the positive models.

2. Identification of Where Each Element of Claims 1, 2, 9 and 10 is Found in Snow in View of Hultgren and Kesling

U.S. Patent No. 6,699,037	Snow in View of Hultgren and Kesling
1. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:	*See* Ex. 1003 at 1:45-48; 4:7-23; 5:49-55.
providing at the outset of treatment a plurality of digital data sets representing a	**Snow** provides, at the outset of treatment, a plurality of digital data sets: "[T]he computer graphic model . . . has the ability

plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient; and	to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position" (emphasis added). (Ex. 1003, 1:45-58; Ex. 1007, ¶ 42; Ex. 1008, ¶¶ 92-93) The plurality of digital data sets includes an initial data set representing an initial tooth arrangement: "Referring to FIG. 1, the usual 2D plaster cast model 1 taken from a patient is digitally rendered by placing it on a Twain compatible flatbed scanner or equivalent device to produce a scanned 2D image of both the upper and lower jaws. Further, the usual side medical images 2, such as X-rays, are also digitally rendered into the computer system by scanning." (Ex. 1003, 2:59-65; Fig. 1) The plurality of digital data sets also includes a final data set representing the final tooth arrangement: "[T]he position of an individual's teeth is first measured and reflected in the 3D model . . . The location and rotation of each tooth in the individualized 3D tooth model relative to the standard model is then noted. Next, a mapping from the position of each individual tooth in the 3D individualised model 4 to the corresponding position of the tooth in the 3D standard model 3 is determined by means of a series of interpolation steps between the two models, with the distance between interpolation steps being preferably a user defined parameter." (Ex. 1003, 4:12-22) The plurality of digital data sets also includes a plurality of intermediate digital data sets

	representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement: "The computer system is then programmed to "animate" the movement of teeth from the 3D individualized model 4 to the 3D standard model **through the series of steps from one model to the next model, rendering each step in turn for the specialist or patient to view**" (emphasis added). (Ex. 1003, 4:16-28; Ex. 1007, ¶ 42; Ex. 1008, ¶ 93)
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances for the individual patient.	**Snow** teaches creating individualized brackets based on the produced digital data sets but does not specifically disclose controlling a fabrication machine in order to produce the plurality of dental appliances: "[t]he individualised 3D model can then be utilised to create an individualized bracket with accurate measurements with the surface of each bracket accurately profiled to match the corresponding surface in the individualised tooth. The bracket structure can be output in a standard stereo lithographic format (STL) and later used to create a corresponding customized brackets/braces." (Ex. 1003, 5:49-56) **Hultgren** specifically discloses controlling a fabrication machine based on the digital data sets to produce positive casts or models of the plurality of successive tooth arrangements: "The programming operation of the processor 501 provides for scanning each of the upper and lower impressions and the bite registration impression. These scans provide the information necessary to create an electronic equivalent of the prior art physical study casts. By using negative image impressions and a line scanner, high resolution

	and speed are gained **wherein high quality study casts may be generated by a fabrication device 507** thereby replacing older methods of constructing the same" (emphasis added). (Ex. 1004, 7:57-65) **Kesling** discloses the non-computerized, manual method of preparing positive dental models of the modified, successive tooth arrangements. Further, Kesling teaches fabricating a plurality of dental incremental position adjustment appliances as negatives of the positive dental casts or models. "[t]he next step in the making of this appliance and in the technique is that the respective teeth carried by the upper base 21 and the lower base 22 are dissected from the bases. This dissection may be accomplished by means of a small scroll saw or vibrating scroll saw as follows: A cut may be made down between each of the teeth with the saw. The saw is then turned laterally at the base of one of these cuts, and a cut may be made along the horizontal dotted lines 23, 24. This will separate each tooth from the other teeth and from the base, and the teeth may then have their lower portions cut down to resemble the natural root for that particular tooth. A sufficient amount of wax or other suitable material may be placed upon each of the bases, and the teeth reassembled with the bases, and held in place by the wax, the wax being indicated by numeral 25 in the spaces between the tooth roots. Each of the plaster teeth is then preplaces on its proper base and in its proper position; but the position of the tooth is so altered by the operator as to assume the ideal position for that particular tooth in that particular assembly, bearing in mind the formation of the jaw structure of the patient and the facial and racial characteristics of each patient.

	The teeth are secured in place by means of wax or some to her suitable material which is initially plastic and which has suitable qualities for adhering to the plaster. Fig. 3 then is a plaster cast of the teeth after they have been reassembled with their plaster bases in the ideal position in which it is desired to position the teeth." (Ex. 1005, 3:30-64)
2. A method as in claim 1, wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements.	**Snow** provides, at the outset of treatment, a plurality of digital data sets, each of which represents one of the successive tooth arrangements: "[T]he computer graphic model . . . has the ability to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position" (emphasis added). (Ex. 1003, 1:45-58; Ex. 1007, ¶ 42; Ex. 1008, ¶ 106)
9. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:	*See* analysis of claim 1.
providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement; and	*See* analysis of claim 1.
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances.	*See* analysis of claim 1.
10. A method as in claim 9,	*See* analysis of claim 2.

wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements.	

Accordingly, the evidence presented above demonstrates that Petitioner has clearly addressed the following *Graham* factors to resolve the issue of obviousness, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed invention and the prior art, and has at least a reasonable likelihood of prevailing on the above ground. *Graham v. John Deere Co.,* 383 U.S. 1 (1966). The fourth *Graham* factor, relating to secondary evidence of nonobviousness, is addressed next in the section below.

B. Detailed Rebuttal of the '325 Reexamination Arguments

The Office has established that Petitioner has carried its burden in presenting a prima facie case of unpatentability in the reexamination of the parent '325 patent, based on the grounds of rejections presented in the Request for Reexamination of the '325 patent filed by Petitioner on February 20, 2015, by issuing an Office Action on June 11, 2015. (Ex. 1011 at 48-57) In its Response to the Examiner's Office Action, Patent Owner, however, has failed to provide any evidence that can be reasonably considered "secondary evidence [or indicia] of nonobviousness." This is not surprising given the Federal Circuit and the International Trade

Commission ("ITC") has held the same. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312–13 (Fed. Cir. 2006); *Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same* (Inv. No. 337-TA-833) Petitioner addresses the alleged evidence of secondary indicia submitted by Patent Owner in the parent reexamination record as follows, evidence which Petitioner anticipates will be presented in the instant proceeding in the event trial is instituted.

1. Patent Owner's Secondary Indicia is Deliberately Incomplete

Patent Owner has introduced evidence of secondary indicia or secondary considerations in its Response to the Office Action issued in the reexamination of the parent '325 patent, specifically alleging "commercial success" among other considerations, by citing to its gross revenue numbers, while at the same time concealing its substantial sales and marketing expenditures and the fact that it employed a shift in advertising, targeting consumers through television. (Ex. 1011 at 37-41) Patent Owner, however, fails to provide substantive evidence of a nexus between the commercial sales and any patented feature of the '325 patent. The limited "evidence" that Patent Owner does provide is from its paid advocate or salesman, Dr. Valley.[6] Additionally, Patent Owner states that the commercial

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[6] http://www.valleyorthodontics.net/#!meet-dr-valley/c17sd

success is directly tied to an unclaimed feature. Specifically, Patent Owner asserts that the commercial success is tied to "the production of a three-dimensional representation of initial and final tooth arrangements, as well as successive arrangements in between," that which is not recited in any claims of the parent '325 patent. As the Federal Circuit determined in *Ormco Corp. v. Align Tech., Inc.*, Align's arguments "that the commercial success is due 'partially' to claimed features … is inadequate …." 463 F.3d 1299, 1312–13 (Fed. Cir. 2006); *see also Id.* at 1312 ("if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant."). Moreover, Patent Owner's attempt to argue that the commercial success is due "to the process of producing intermediate digital data sets representing successive tooth positions and then producing dental appliances based on those digital data sets" fails because the prior art teaches these features. *See J. T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (holding that commercial success must be "due to the merits of the claimed invention beyond what was readily available in the prior art"); *see also Ormco Corp.*, 463 F.3d at 1312 (holding that "if the feature that creates the commercial success was known in the prior art, the success is not pertinent").

Further, Patent Owner fails to even acknowledge or discuss the lack of profitability for almost a decade, losing $20 Million - $97 Million, seven of the last

15 years, and having become profitable only in 2013 (when gains finally covered all the losses). Patent Owner's own SEC filings indicate "Sales and Marketing" spending for 1999 - 2013 of $1.3 Billion, that generated profits of a mere $35 Million. Second, there is ample evidence to support the fact that Patent Owner's sales data is actually driven by an intentional and aggressive marketing campaign (*see* table below: spending 34.4% of its gross revenue on "Sales and Marketing") and by a "shift in advertising" and not any patented feature. As noted in a New York Times article, which Patent Owner has failed to provide a copy of to the Office, Patent Owner's sales were driven by "the most aggressive consumer advertising plan the dental profession has ever seen" and was "the first effort by an orthodontics products company to appeal directly to consumers through television."[7] Specifically, as noted in the table below, Patent Owner expended a staggering amount of resources on advertising and marketing efforts.[8]

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[7] Feder, Barnaby J., "Orthodontics Via Silicon Valley; A Start-Up Uses Computer Modeling and Venture Capital to Reach Patients," *N.Y. TIMES* (Aug. 18, 2000). (Ex. 1012)

[8] MPEP § 716.03(b) instructs that when "considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising…."

Fiscal Year[9]	**Revenue**	**Profit/Loss**	**Spending on "Sales and Marketing"**	**"Sales and Marketing" As % of Revenue**
1999	$411,000	$15,415,000 (loss)	$5,688,000	1383.9%
2000	$6,741,000	$88,748,000 (loss)	$40,445,000	600.0%
2001	$46,384,000	$97,474,000 (loss)	$50,581,000	109.0%
2002	$75,395,000	$68,121,000 (loss)	$45,313,000	60.1%
2003	$122,725,000	$20,122,000 (loss)	$43,689,000	35.6%
2004	$172,830,000	$9,765,000 (gain)	$55,932,000	32.4%
2005	$207,125,000	$1,413,000 (gain)	$80,068,000	38.7%
2006	$206,354,000	$34,963,000 (loss)	$81,993,000	39.7%
2007	$284,332,000	$35,724,000 (gain)	$98,231,000	34.5%
2008	$303,976,000	$79,987,000 (gain)	$115,062,000	37.9%
2009	$312,333,000	$31,269,000 (loss)	$112,542,000	35.9%
2010	$387,126,000	$74,253,000 (gain)	$114,013,000	29.5%
2011	$479,741,000	$66,716,000 (gain)	$142,174,000	29.6%
2012	$560,041,000	$58,691,000 (gain)	$152,041,000	27.1%
2013	$660,206,000	$64,295,000 (gain)	$180,046,000	27.3%
TOTALS	$3,825,720,000	$34,732,000 (gain)	$1,317,818,000	34.4%

Nonetheless, even if Patent Owner were able to establish any type of evidence of secondary considerations, such evidence would not be enough to outweigh the strong showing of obviousness set forth for the claims at issue in the '037 patent. *Leapfrog v. Fisher-Price*, 485 F.3d 1157, 1160–61 (Fed. Cir. 2007).

[9] Align SEC filing 11/14/2000 and SEC 10-K FY 2000- FY 2013. (Ex. 1013)

Patent Owner has commercially implemented their claimed invention. However, none of the commercial embodiments can be tied directly to the claimed features of the ‘037 patent. In fact, it has been previously adjudicated that Patent Owner’s efforts in this regard have been insufficient in showing a nexus and commensurateness in scope of the commercial embodiment to the claims of the parent ‘325 patent. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312-13 (Fed.Cir. 2006)[10] (holding that any commercial appeal of the patentee’s techniques and appliances is due to <u>unclaimed benefits</u> of aligners that are well established in the art). That is, aligners offer long known benefits such as efficacy, convenience, and aesthetic appeal. *(See Id.)* Accordingly, such objective evidence is not probative of non-obviousness as to the ‘037 patent claims at issue, nor would such evidence matter even if properly presented relative to the significant art provided herein. *See, e.g., Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (“secondary considerations of nonobviousness … simply cannot overcome a strong prima facie case of obviousness”); *Exer-Genie, Inc. v. McDonald*, 453 F.2d 132, 136 (9th Cir. 1971) (“when patentable invention is clearly lacking, secondary considerations cannot fill the gap”).

[10] Although the *Ormco* litigation did not involve the ‘037 patent, or the parent ‘325 patent, it involved closely related patents with claims of overlapping scope which were ultimately held invalid.

2. Other Arguments in Reexamination History

Patent Owner's response to the Examiner's Office Action in the '325 patent reexamination completely ignores the testimony of Requester's expert, Dr. Mah, ignores explicit admissions highlighted in the specification of the '325 patent, and ignores the proposed obviousness *combinations* used for rejecting the claims at issue. Instead, Patent Owner erroneously focuses on and attacks each of the prior art references individually. *See* M.P.E.P. § 2145 ("One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." (citing *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). Accordingly, rather than providing rebuttal arguments directed toward the obviousness rationales for each of the proposed *combination* of prior art references, Patent Owner follows a piece-meal approach, attacking each of the prior art references individually. Thus, it is readily apparent that Patent Owner struggles to find any deficiencies in the proposed obviousness combinations.

C. Snow in View of Lemchen and Kesling Renders Claims 1, 2, 9 and 10 of the '037 Patent Unpatentable Under 35 U.S.C. § 103(a)

The teachings and disclosures of the Snow and Kesling references are discussed in Section VII.A, *supra*. Lemchen discloses a method for creating a model of a patient's teeth arrangement, for example, the shape and location of a malocclused tooth with respect to a patient's jaw, by generating negative image scan data, or digital information, in any number of ways, such as electromechanically, by laser scanning, digital video scanning or magnetically. (Ex. 1006, 2:56-63) In turn, the digitized information is used to generate a positive, digital mathematical dental model using Computer Aided Design ("CAD"). (*Id.* at 3:1-5) The mathematical model is preferably a complete "model" including a full replication of the upper and lower dental arches and associated jaw structure. (*Id.* at 3:10-16) The model can then be used to calculate the "finish" position of the malocclused tooth or teeth, with respect to their positions in the mathematical model. (*Id.* at 3:20-23)

Lemchen also discloses transmitting the digitized information to known fabrication devices that utilize such data to create customized brackets:

> customized brackets may be provided to the practitioner by a dental laboratory, where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion. (Ex. 1006, 5:31-35)

Lemchen further highlights the equivalence between the computer generation of the positive, digital mathematical dental model for manufacturing appliances and previously known manual techniques for creating incremental positive models, from which appliances are produced. (Ex. 1007, ¶ 51; Ex. 1008, ¶¶ 113-114) In fact, Lemchen specifically references Kesling's physical cast model of a patient's teeth:

> in many applications of the preferred embodiment, a complete 'model', as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Patent No. 2,467,432[, which is the Kesling reference]. (Ex. 1006, 3:13-19)

Lemchen again mentions Kesling's manual methodology for calculating the "finish" position of the repositioned teeth:

> [i]n the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a [physical] model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No 2,467,432. (Ex. 1006, 3:41-46)

Kesling discloses precisely the non-computerized, manual method of preparing the modified positive dental models. As discussed above in Section VII.A., Kesling also discloses fabricating a plurality of polymeric shell dental incremental position adjustment appliances for an individual patient as a negative of the positive dental model, similar to the one generated by Lemchen, for example. (*See* Ex. 1005, 3:30-64; 4:8-60; Ex. 1007, ¶¶ 54-55; Ex. 1008, ¶ 115)

1. Statement of Non-Redundancy

The grounds raised in the present section are meaningfully distinct from and <u>not</u> redundant to the grounds detailed in Section VII.A. above. The grounds detailed in each of the Sections VII.A. and VII.C. rely upon fundamentally different combinations of the cited prior art. Namely, the grounds detailed in Section VII.A. rely upon Hultgren as one of the secondary references, whereas the grounds detailed in Section VII.C. rely upon Lemchen as one of the secondary references.

Hultgren's disclosure focuses specifically on "a system of dental modeling and imaging, which creates digital images of teeth topography; and more particularly relates to scanning a dental impression wherein a set of negative image electronic data of the patient's teeth and surrounding soft tissue is created which can be electronically manipulated, displayed, stored and transmitted for uses relating to creating dental appliances and diagnosis." (Ex. 1004, 1:5-12) Lemchen is directed to a comprehensive, 3-dimensional digital system for orthodontists to use in diagnosis, treatment planning and therapy. Specifically, Lemchen replaces Kesling's labor intensive, manual manipulation of tooth repositioning. Further, Lemchen's simulation includes the modeling of tooth movement. (Ex. 1006, 3:20-29) Hence, Hultgren is more particular to the actual electronic scanning methodology and apparatus used for generating a set of electronic data from a dental impression or study cast, whereas Lemchen is more particular to using digital mathematical modeling for designing customized dental appliances.

Accordingly, both grounds of rejections, Grounds A and C, are necessary to fairly demonstrate the Petitioner's case.

2. Motivation to Combine

Snow provides a method for providing, at the outset of treatment, a plurality of digital data sets, including an initial data set representing an initial tooth arrangement, a final data set representing a final tooth arrangement, and a plurality of successive data sets representing a plurality of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement. Lemchen further offers controlling a fabrication machine based on digital data sets to produce modified positive, digital mathematical dental models of a plurality of successive tooth arrangements, which Lemchen highlights as being equivalent to the manually created, positive, physical dental models. Kesling discloses the non-computerized, manual method of preparing positive dental models of the modified, successive tooth arrangements. Further, Kesling teaches fabricating a plurality of dental incremental position adjustment appliances as negatives of the positive dental models.

In fabricating the plurality of dental incremental position adjustment appliances for repositioning teeth, one of ordinary skill in the art would have been motivated to combine the teachings of the above prior art references. That is, a skilled artisan would have been motivated to create a plurality of digital data sets and digitally reposition the teeth, as taught by Snow, and to use the digital data sets representing the repositioned teeth to control a fabrication machine to generate a plurality of positive, digital mathematical dental models of the successive tooth arrangements, as described by Lemchen. The positive, digital mathematical dental models, which Lemchen equates to the manually created, positive physical dental models, would then be used for producing the plurality of dental incremental position adjustment appliances well known in the art, as negatives of the positive models taught by Kesling. (Ex. 1007, ¶¶ 54-55; Ex. 1008, ¶¶ 116-117) All of the prior art references are from the field of dentistry, and all concern the creation and manipulation of or use of three-dimensional models of patients' teeth. Moreover, the combination would result in the fabrication of more precise positive casts or models, and, in turn, more precise dental position adjustment appliances, as the digital data sets from Snow, representing more precise tooth arrangements, would be used to control the fabrication machine in Lemchen. Further, the combination would save manufacturing costs by eliminating the laborious hand creation of modified tooth arrangements on physical casts.

Since Kesling's manual method of producing modified positive models is labor intensive, one of ordinary skill would want to reduce this cost and would recognize that the use of modern computer technology is advantageously efficient. It has long been considered obvious and within ordinary skill to provide an automatic or mechanical means to replace a manual activity which accomplishes the same result. *In re* Veener, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958);

Leapfrog Enterprises, Inc. v. Fisher-Price, 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007) ("applying modern electronics to older mechanical devices has been commonplace in recent years, since person of ordinary skill in art would have found it obvious to combine two prior art devices at issue in order to update mechanical device using modern electronic components."); Ex. 1007, ¶¶ 34, 55-56; Ex. 1008, ¶¶ 116, 118-119) Further, because of the predictability of the art and the detailed disclosures of Snow, Lemchen and Kesling, these references would have suggested to one of ordinary skill that this combination would be reasonably likely to succeed. (Ex. 1007, ¶ 55; Ex. 1008, ¶ 120)

In summary, Snow describes producing digital data sets representing a plurality of successive tooth arrangements for the purpose of developing a dental appliance treatment regimen. This treatment contemplated fabrication of customized dental appliances, such as brackets, for repositioning teeth. Lemchen, in turn, provides detailed steps for transforming digital data sets into dental appliances, by controlling conventional appliance fabrication machines. More specifically, Lemchen describes converting negative image scan data into positive, digital mathematical models, equivalent to manually created, positive models/casts. Modifying Snow with the teachings of Lemchen would provide a set of incremental, positive digital mathematical models for repositioning teeth, equivalent to physical, positive models/casts, manufactured in accordance with the digital data sets. Finally, modifying the positive models/casts of Lemchen is simply a matter of applying the teachings of Kesling (known for almost a century) of creating dental appliances as negatives of the positive models.

3. Identification of Where Each Element of Claims 1, 2, 9 and 10 is Found in Snow in View of Lemchen and Kesling

U.S. Patent No. 6,699,037	Snow in View of Lemchen and Kesling
1. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:	*See* Ex. 1003 at 1:45-48; 4:7-23; 5:49-55.
providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient; and	**Snow** provides, at the outset of treatment, a plurality of digital data sets: "[T]he computer graphic model . . . has the ability to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position" (emphasis added). (Ex. 1003, 1:45-58; Ex. 1007, ¶ 42; Ex. 1008, ¶¶ 92-93) The plurality of digital data sets includes an initial data set representing an initial tooth arrangement: "Referring to FIG. 1, the usual 2D plaster cast model 1 taken from a patient is digitally rendered by placing it on a Twain compatible flatbed scanner or equivalent device to produce a scanned 2D image of both the upper and lower jaws. Further, the usual side medical images 2, such as X-rays, are also digitally rendered into the computer system by scanning." (Ex. 1003, 2:59-65; Fig. 1) The plurality of digital data sets also includes a final data set representing the final tooth

	arrangement: "[T]he position of an individual's teeth is first measured and reflected in the 3D model . . . The location and rotation of each tooth in the individualized 3D tooth model relative to the standard model is then noted. Next, a mapping from the position of each individual tooth in the 3D individualised model 4 to the corresponding position of the tooth in the 3D standard model 3 is determined by means of a series of interpolation steps between the two models, with the distance between interpolation steps being preferably a user defined parameter." (Ex. 1003, 4:12-22) The plurality of digital data sets also includes a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement: "The computer system is then programmed to "animate" the movement of teeth from the 3D individualized model 4 to the 3D standard model **through the series of steps from one model to the next model, rendering each step in turn for the specialist or patient to view**" (emphasis added). (Ex. 1003, 4:16-28; Ex. 1007, ¶ 42; Ex. 1008, ¶ 93)
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances for the individual patient.	**Snow** teaches creating individualized brackets based on the produced digital data sets but does not specifically disclose controlling a fabrication machine in order to produce the plurality of appliances: "[t]he individualised 3D model can then be utilised to create an individualized bracket with accurate measurements with the surface of each bracket accurately profiled to match the corresponding surface in the individualised tooth.

	The bracket structure can be output in a standard stereo lithographic format (STL) and later used to create a corresponding customized brackets/braces." (Ex. 1003, 5:49-56) **Lemchen** specifically discloses controlling a fabrication machine to produce dental appliances based on the digital data sets: "customized brackets may be provided to the practitioner by a dental laboratory, where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Ex. 1006, 5:31-35) Further, **Lemchen** teaches using the plurality of digital data sets representing the repositioned teeth to generate modified positive, digital mathematical dental models of the successive tooth arrangements. First, negative image scan data or digital information defining the shape and location of the malocclused tooth with respect the patient's jaw is generated by laser scanning, digital video scanning or magnetically. (Ex. 1006, 2:56-63) In turn, the digitized information is used to generate a positive, digital mathematical dental model using Computer Aided Design ("CAD"). (*Id.* at 3:1-5) The mathematical model may be a complete "model" including a full replication of the upper and lower dental arches and associated jaw structure. (*Id.* at 3:10-16) The model can then be used to calculate the "finish" position of the malocclused tooth or teeth, with respect to their positions in the mathematical model. (*Id.* at 3:20-23) **Lemchen** further highlights the equivalence between the computer generation of the positive, digital mathematical dental model for manufacturing appliances and previously known

	manual techniques for creating physical dental casts or models. In particular, Lemchen references Kesling and states: "in many applications of the preferred embodiment, a complete 'model', as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Patent No. 2,467,432[, which is the Kesling reference]." (Ex. 1006, 3:13-19) **Kesling** discloses the non-computerized, manual method of preparing positive dental models of the modified, successive tooth arrangements. Further, Kesling teaches fabricating a plurality of dental incremental position adjustment appliances as negatives of the positive dental casts or models. "[t]he next step in the making of this appliance and in the technique is that the respective teeth carried by the upper base 21 and the lower base 22 are dissected from the bases. This dissection may be accomplished by means of a small scroll saw or vibrating scroll saw as follows: A cut may be made down between each of the teeth with the saw. The saw is then turned laterally at the base of one of these cuts, and a cut may be made along the horizontal dotted lines 23, 24. This will separate each tooth from the other teeth and from the base, and the teeth may then have their lower portions cut down to resemble the natural root for that particular tooth. A sufficient amount of wax or other suitable material may be placed upon each of the bases, and the teeth reassembled with the bases, and held in place by the wax, the wax being indicated by numeral 25 in the spaces between the tooth roots. Each of the plaster teeth

	is then preplaces on its proper base and in its proper position; but the position of the tooth is so altered by the operator as to assume the ideal position for that particular tooth in that particular assembly, bearing in mind the formation of the jaw structure of the patient and the facial and racial characteristics of each patient. The teeth are secured in place by means of wax or some to her suitable material which is initially plastic and which has suitable qualities for adhering to the plaster. Fig. 3 then is a plaster cast of the teeth after they have been reassembled with their plaster bases in the ideal position in which it is desired to position the teeth." (Ex. 1005, 3:30-64)
2. A method as in claim 1, wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements.	**Snow** provides, at the outset of treatment, a plurality of digital data sets, each of which represents one of the successive tooth arrangements: "[T]he computer graphic model . . . has the ability to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position" (emphasis added). (Ex. 1003, 1:45-58; Ex. 1007, ¶ 42; Ex. 1008, ¶ 121)
9. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:	*See* analysis of claim 1.
providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to	*See* analysis of claim 1.

a final tooth arrangement; and	
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances.	*See* analysis of claim 1.
10. A method as in claim 9, wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements.	*See* analysis of claim 2.

D. Snow in View of Applicants' Admitted Prior Art ("APA") and Kesling Renders Claims 1, 2, 9 and 10 of the '037 Patent Unpatentable Under 35 U.S.C. § 103(a)

The teachings and disclosure of the Snow and Kesling references are discussed in Section VII.A, *supra*. Applicants' Admitted Prior Art ("APA") evidences that it is known in the art to transform three-dimensional image data into a three-dimensional physical model. Specifically, APA in the '037 patent admits that the machines and methods for producing and fabricating positive models and aligners formed therefrom are known and conventional. Further, it is conventional to use digital data sets to control fabrication machines. (Ex. 1007, ¶ 64; Ex. 1008, ¶ 127) In particular, the '037 patent discloses:

> Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrangements. The dental appliances are then produced as negatives of the positive

> models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of nonhardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines. (Ex. 1001, 6:64 -7:10)

> Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, Calif. The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances. Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. (*Id.* at 14:46-63)

> After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minn. 55902. Suitable pressure molding equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc. (*Id.* at 14:63 – 15:8)

Such admission, however, does not encompass a digital data set which represents a positive model of a modified tooth arrangement. Importantly, however, APA admits the equivalence between computer generation of the intermediate [or modified] digital data sets for manufacturing appliances and previously known manual techniques for creating incremental positive models, from which appliances are produced. (Ex. 1007, ¶¶ 64-65; Ex. 1008, ¶ 128) In particular, APA states:

> While the methods will rely on computer manipulation of digital data, the systems of the present invention comprising multiple dental appliances having incrementally differing geometries may be produced by non-computer-aided techniques. **For example, plaster casts obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may**

> **then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare sets of multiple appliances,** generally as described below, using pressure and vacuum molding techniques. While such manual creation of the appliance systems of the present invention will generally be much less preferred, systems so produced will come within the scope of the present invention. (emphasis added) (Ex. 1001, 10:19-35)

Kesling discloses precisely the non-computerized, manual method of preparing modified positive dental models, suggested by APA. (*See* Section VII.B., *supra*; Ex. 1005, 3:30-64) Further, as discussed in Section VII.A., *supra*, Kesling discloses fabricating a plurality of polymeric shell dental incremental position adjustment appliances for an individual patient as a negative of the positive model. (*See Id.* at 4:8-60; Ex. 1007, ¶ 47; Ex. 1008, ¶ 129)

1. Statement of Non-Redundancy

The grounds raised in the present section are meaningfully distinct from and <u>not</u> redundant to the grounds detailed in Sections VII.A. and VII.C. above. The grounds detailed in each of the Sections VII.A., VII.C. and VII.D. rely upon fundamentally different combinations of the cited prior art. Namely, the grounds detailed in Section VII.A. rely upon Hultgren as one of the secondary references, the grounds detailed in Section VII.C. rely upon Lemchen as one of the secondary references, whereas the grounds detailed in Section VII.D. rely upon Applicants' Admitted Prior Art ("APA") as one of the secondary references.

As discussed above in Section VII.C.1., Hultgren is more particular to the actual electronic scanning methodology and apparatus used for generating a set of electronic data from a dental impression or study cast, whereas Lemchen is more particular to using digital mathematical modeling for designing customized dental appliances. Different and apart from both Hultgren and Lemchen, APA is directed to a variety features known in the art at the time of filing the application for the '037 patent, some of which are claimed, such as a suitable elastomeric polymeric for forming polymeric appliances (Ex. 1001, 9:8-11), techniques for obtaining a plaster cast of the patient's teeth and generating digital models (*Id.* at 9:25-48), different types of range acquisition systems (*Id.* at 9:49 – 10:6), different data structures, such as a quad edge data structure (*Id.* at 10:56 – 11:6), a suitable rapid prototyping device (*Id.* at 14:44-63), and a conventional pressure or vacuum molding machine (*Id.* at 14:63 – 15:8).

Accordingly, all three grounds of rejections, Grounds A, C and D, are necessary to fairly demonstrate the Petitioner's case.

2. Motivation to Combine

In summary, Snow provides a method for providing, at the outset of treatment, a plurality of digital data sets, including an initial data set representing an initial tooth arrangement, a final data set representing a final tooth arrangement, and a plurality of successive data sets representing a plurality of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement. Applicants' Admitted Prior Art ("APA") further offers that it was known in the art to transform three-dimensional digital image data into a three-dimensional physical, positive model, and it was conventional to use such digital data to control fabrication machines. Kesling, in turn, discloses the non-computerized, manual method of preparing positive dental models of the modified, successive tooth arrangements. Further, Kesling fabricates a plurality of dental incremental position adjustment appliances as negatives of the positive dental models.

In fabricating a plurality of dental incremental position adjustment appliances for repositioning teeth, one of ordinary skill in the art would have been motivated to combine the teachings of the prior art references. That is, a skilled artisan would have been motivated to create a plurality of digital data sets and digitally reposition the teeth, as taught by Snow, and to use the digital data sets representing the repositioned teeth to control a fabrication machine to produce a plurality of physical, positive models of the successive tooth arrangements, as described by APA. The positive models would then be used for producing the plurality of dental incremental position adjustment appliances, as negatives of the positive models taught by Kesling. (Ex. 1007, ¶¶ 34, 54-55; Ex. 1008, ¶¶ 130-131) All of the prior art references are from the field of dentistry, and all concern the creation and manipulation of or use of three-dimensional models of patients' teeth. Moreover, the combination would resulting in the fabrication of more precise positive casts or models, and, in turn, more precise dental position adjustment appliances, as the digital data sets from Snow, representing more precise tooth arrangements, would be used to control the fabrication machine in APA. Further, the combination would save manufacturing costs by eliminating the laborious hand creation of modified tooth arrangements on physical casts.

Since Kesling's manual method of producing modified positive models is labor intensive, one of ordinary skill would want to reduce this cost and would recognize that the use of modern computer technology is advantageously efficient. It has long been considered obvious and within ordinary skill to provide an automatic or mechanical means to replace a manual activity which accomplishes the same result. *In re* Veener, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958); *Leapfrog Enterprises, Inc. v. Fisher-Price*, 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007) ("applying modern electronics to older mechanical devices has been commonplace in recent years, since person of ordinary skill in art would have found it obvious to combine two prior art devices at issue in order to update mechanical device using modern electronic components."); Ex. 1007, ¶¶ 55-56;

Ex. 1008, ¶¶ 130, 132-133) Because of the predictability of the art and the detailed disclosures of Snow, APA and Kesling, these references would have suggested to one of ordinary skill that this combination would be reasonably likely to succeed. (Ex. 1007, ¶ 55; Ex. 1008, ¶ 134)

In summary, Snow describes producing digital data sets representing a plurality of successive tooth arrangements for the purpose of developing a dental appliance treatment regimen. This treatment contemplated fabrication of customized dental appliances, such as brackets, for repositioning teeth. APA, in turn, provides detailed steps for transforming digital data sets into incremental, positive models/casts, by controlling conventional appliance fabrication machines. More specifically, APA describes converting negative image scan data into positive image data, and transmitting such data to known fabrication machines for producing positive models/casts of the successive tooth arrangements. Modifying Snow with the teachings of APA would provide a set of incremental, positive models/casts for repositioning teeth, manufactured in accordance with the digital data sets. Finally, modifying the positive models/casts of APA is simply a matter of applying the teachings of Kesling (known for almost a century) of creating dental appliances as negatives of the positive models.

3. Identification of Where Each Element of Claims 1, 2, 9 and 10 is Found in Snow in View of Applicants' Admitted Prior Art ("APA") and Kesling

U.S. Patent No. 6,699,037	Snow in View of APA and Kesling
1. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:	*See* Ex. 1003 at 1:45-48; 4:7-23; 5:49-55.
providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement for an individual patient; and	**Snow** provides, at the outset of treatment, a plurality of digital data sets: "[T]he computer graphic model . . . has the ability to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position" (emphasis added). (Ex. 1003, 1:45-58; Ex. 1007, ¶ 42; Ex. 1008, ¶¶ 92-93) The plurality of digital data sets includes an initial data set representing an initial tooth arrangement: "Referring to FIG. 1, the usual 2D plaster cast model 1 taken from a patient is digitally rendered by placing it on a Twain compatible flatbed scanner or equivalent device to produce a scanned 2D image of both the upper and lower jaws. Further, the usual side medical images 2, such as X-rays, are also digitally rendered into the computer system by scanning." (Ex. 1003, 2:59-65; Fig. 1) The plurality of digital data sets also includes a final data set representing the final tooth arrangement: "[T]he position of an individual's teeth is first measured and reflected in the 3D model . . . The location and rotation of each tooth in the

	individualized 3D tooth model relative to the standard model is then noted. Next, a mapping from the position of each individual tooth in the 3D individualised model 4 to the corresponding position of the tooth in the 3D standard model 3 is determined by means of a series of interpolation steps between the two models, with the distance between interpolation steps being preferably a user defined parameter." (Ex. 1003, 4:12-22) The plurality of digital data sets also includes a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement: "The computer system is then programmed to "animate" the movement of teeth from the 3D individualized model 4 to the 3D standard model **through the series of steps from one model to the next model, rendering each step in turn for the specialist or patient to view**" (emphasis added). (Ex. 1003, 4:16-28; Ex. 1007, ¶ 42; Ex. 1008, ¶ 93)
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances for the individual patient.	**Snow** teaches creating individualized brackets based on the produced digital data sets but does not specifically disclose controlling a fabrication machine in order to produce the plurality of appliances: "[t]he individualised 3D model can then be utilised to create an individualized bracket with accurate measurements with the surface of each bracket accurately profiled to match the corresponding surface in the individualised tooth. The bracket structure can be output in a standard stereo lithographic format (STL) and later used to create a corresponding customized

	brackets/braces." (Ex. 1003, 5:49-56) **APA** specifically discloses controlling a fabrication machine based on the digital data sets to produce a three-dimensional physical, positive model: Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrangements. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of nonhardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines. (Ex. 1001, 6:64 -7:10) Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, Calif. The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances. Generally, because the

	rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. (*Id.* at 14:46-63) After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minn. 55902. Suitable pressure molding equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc. (*Id.* at 14:63 – 15:8) **Kesling** discloses the non-computerized, manual method of preparing positive dental models of the modified, successive tooth arrangements. Further, Kesling teaches fabricating a plurality of dental incremental position adjustment appliances as negatives of the positive dental casts or models. "[t]he next step in the making of this appliance and in the technique is that the respective teeth carried by the upper base 21 and the lower base 22 are dissected from the bases. This dissection may be accomplished by means of a small scroll saw or vibrating scroll saw as follows: A cut may be made down between each of the teeth with the saw. The saw is then turned laterally at the base of one of these cuts, and a cut may be made along

	the horizontal dotted lines 23, 24. This will separate each tooth from the other teeth and from the base, and the teeth may then have their lower portions cut down to resemble the natural root for that particular tooth. A sufficient amount of wax or other suitable material may be placed upon each of the bases, and the teeth reassembled with the bases, and held in place by the wax, the wax being indicated by numeral 25 in the spaces between the tooth roots. Each of the plaster teeth is then preplaces on its proper base and in its proper position; but the position of the tooth is so altered by the operator as to assume the ideal position for that particular tooth in that particular assembly, bearing in mind the formation of the jaw structure of the patient and the facial and racial characteristics of each patient. The teeth are secured in place by means of wax or some to her suitable material which is initially plastic and which has suitable qualities for adhering to the plaster. Fig. 3 then is a plaster cast of the teeth after they have been reassembled with their plaster bases in the ideal position in which it is desired to position the teeth." (Ex. 1005, 3:30-64)
2. A method as in claim 1, wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements.	**Snow** provides, at the outset of treatment, a plurality of digital data sets, each of which represents one of the successive tooth arrangements: "[T]he computer graphic model . . . has the ability to **automatically produce a sequence of images mapping movements of teeth** from a first position corresponding to the patient's current state to an idealised second position" (emphasis added). (Ex. 1003, 1:45-58; Ex. 1007, ¶ 42; Ex. 1008, ¶ 135)

9. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:	*See* analysis of claim 1.
providing at the outset of treatment a plurality of digital data sets representing a plurality of successive tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement; and	*See* analysis of claim 1.
controlling a fabrication machine based on individual ones of the digital data sets to produce the plurality of appliances.	*See* analysis of claim 1.
10. A method as in claim 9, wherein providing the digital data comprises providing a plurality of digital data sets, wherein each set represents one of the successive tooth arrangements.	*See* analysis of claim 2.

VIII. CONCLUSION

Substantial, new and noncumulative technical teachings have been presented for each of claims 1, 2, 9 and 10 of the '037 patent, which claims are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioner will prevail as to each of these claims. *Inter Partes* review of claims 1, 2, 9 and 10 is accordingly requested.

Respectfully submitted,
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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner by Express Mail of a copy of this Petition for *Inter Partes* Review and supporting materials at the correspondence address of record for the '037 patent to:

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