

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-_____

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

DECLARATION OF DR. MARTIN MARTZ, D.D.S., M.S.

ALIGN - EXHIBIT 2017
ClearCorrect Operating, LLC. v. Align Technology, Inc.
IPR2025-00816

I, Dr. Martin Martz, D.D.S., M.S. declare as follows:

I. INTRODUCTION

1. Based on my background, being over the age of eighteen (18), and being of sound mind, I am competent to make this Declaration.

2. ClearCorrect Operating, LLC (“Clearcorrect”) has retained me to provide my opinion on U.S. Patent No. 6,699,037 (“the ‘037 patent”) for a Declaration in support of a Petition for Inter Partes Review (“IPR”) of the ‘037 patent. The opinion set forth in this Declaration addresses the ‘037 patent, the state of the art at the time of the ‘037 patent, and the scope and content of the prior art to the ‘037 patent.

3. I have reviewed and am familiar with the '037 patent, which was filed on February 21, 2001 and issued on March 2, 2004, and its prosecution history.

4. I have reviewed and am familiar with: (1) U.S. Patent No. 6,068,482 to Snow (“Snow”); (2) U.S. Patent No. 6,217,334 to Hultgren (“Hultgren”); (3) U.S. Patent No. 2,467,432 to Kesling (“Kesling”); and (4) U.S. Patent No. 5,011,405 to Lemchen (“Lemchen”).

5. I am familiar with the technology at issue as of June 20, 1997, the earliest filing date to which the '037 patent claims priority.
6. I have been asked to provide my technical review, analysis, insights, and opinions regarding the above-noted references that form the basis for the grounds of rejection set forth in the IPR Petition of the '037 patent.

A. Qualifications

7. I earned both my D.D.S. and M.S. in orthodontics from Loma Linda University in 1976 and 1981, respectively. I attended Pacific Union College with minor studies in physics, computer science, chemistry, and biology from 1969 to 1972. Before receiving a bachelor's degree from Pacific Union College, I was accepted into the dental school at Loma Linda University.
8. I am currently a lecturer for the Clinical Faculty of the UCLA Section of Orthodontics. As a lecturer, I teach a class on orthognathic surgery where complex cases are discussed involving orthodontic treatments and jaw surgery, an advanced treatment planning seminar that evaluates treatments and outcomes, and a seminar that combines orthodontics and plastic surgery for treatment of congenital deformities,

such as cleft palates. I also attend and supervise a clinic where residents develop treatment plans for patients and perform that treatment.

9. Prior to my work as a lecturer, I spent approximately 30 years working in private practice limited to orthodontics. My areas of expertise include orthodontic education, treatment of cleft palate and craniofacial deformities, orthodontic finishing, orthognathic surgery, complex multi-discipline cases, and orthodontic treatment with modified clear aligners.

10. As part of my private practice work in orthodontics, I have been a member of the American Association of Orthodontists and a member of the American Dental Association since 1984. I have also been a member of both the California Association of Orthodontists and the California Dental Association since 1989.

11. In relation to treatment with aligners, I have been the sole or lead inventor of three patents relating to removable tooth appliances, all filed and issued between 1987 and 1992. I am also the lead inventor on two pending patent applications that relate to tooth positioning appliances. Based on the technology of my pending patent application,

I am currently developing and testing a new removable clear aligner system to solve problems encountered with currently available commercial aligner appliances. Clinical testing of this new aligner system is underway using thermoformed aligners with 3-D printed aligner development ongoing.

12. A copy of my curriculum vitae is attached to this Declaration as Appendix A. My curriculum vitae lists in detail my educational background and my professional experience.

B. Basis of My Opinion and Materials Considered

13. The opinion set forth in this Declaration is based on my entire background including my education and professional experience as well as my knowledge and research activities. In making this opinion, I reviewed the '037 patent, its file history, the prior art and other background documents. Appendix B provides a full list of the documents that I considered in making this opinion.

C. Legal Standards for Patentability

14. A patent claim is invalid if the differences between the patented subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person of ordinary skill in the art. I am informed that this standard is set forth in 35 U.S.C. § 103(a).

15. When considering the issues of obviousness, I am to do the following: (i) determine the scope and content of the prior art; (ii) ascertain the differences between the prior art and the claims at issue; (iii) resolve the level of ordinary skill in the pertinent art; and (iv) consider objective evidence of non-obviousness. I appreciate that secondary considerations must be assessed as part of the overall obviousness analysis (i.e. as opposed to analyzing the prior art, reaching a tentative conclusion, and then assessing whether objective indicia alter that conclusion).

16. Put another way, my understanding is that not all innovations are patentable. Even if a claimed product or method is not explicitly described in its entirety in a single prior art reference, the patent claim will still be denied if the claim would have been obvious to a person of ordinary skill in the art at the time of the patent application filing.

17. In determining whether the subject matter as a whole would have been considered obvious at the time that the patent application was filed, by a person of ordinary skill in the art, I have been informed of

several principles regarding the combination of elements of the prior art:

- a. First, a combination of familiar elements according to known methods is likely to be obvious when it yields predictable results.
- b. Second, if a person of ordinary skill in the art can implement a “predictable variation” in a prior art device, and would see the benefit from doing so, such a variation would be obvious. In particular, when there is pressure to solve a problem and there are a finite number of identifiable, predictable solutions, it would be reasonable for a person of ordinary skill to pursue those options that fall within his or her technical grasp. If such a process leads to the claimed invention, then the latter is not an innovation, but more the result of ordinary skill and common sense.

18. The “teaching, suggestion, or motivation” test is a useful guide in establishing a rationale for combining elements of the prior art. This test poses the question as to whether there is an explicit teaching, suggestion, or motivation in the prior art to combine prior art elements in a way that realizes the claimed invention. Though useful to the obviousness inquiry, I understand that this test should not be treated as a rigid rule. It is not necessary to seek out precise teachings; it is permissible to consider the inferences and creative steps that a person of ordinary skill in the art (who is considered to have an ordinary level of creativity and is not an “automaton”) would employ.

II. DESCRIPTION OF THE RELEVANT FIELD AND THE RELEVANT TIMEFRAME

19. To determine the relevant field, I reviewed the '037 patent and its file history.

20. To determine the scope of the prior art, I understand the prior art must be earlier than the earliest priority date for the '037 patent. The '037 patent issued from U.S. Patent Application No. 09/791,650, which was filed on February 21, 2001 and was a continuation of U.S. Patent Application No. 09/298,268, filed Apr. 23, 1999. U.S. Patent Application No. 09/298,268 was itself a division of U.S. Patent Application No. 08/947,080, which was filed on Oct. 8, 1997 and claimed priority to Provisional Application No. 60/050,342, filed on Jun. 20, 1997.

21. Based on this history, the '037 patent has at least a claim to the June 20, 1997 filing date of provisional U.S. Patent Application No. 60/050,342 as its earliest priority date. Without confirming or acknowledging that the '037 patent is entitled to this priority date, the following opinion relies on prior art that is prior art to the June 20, 1997 priority date.

22. Based on my review of this material, I believe that the relevant field for the purposes of the '037 patent is, in general, tooth realignment and,

more specifically, the design, manufacture, and use of tooth appliances for realigning teeth.

III. THE PERSON OF ORDINARY SKILL IN THE RELEVANT FIELD IN THE RELEVANT TIMEFRAME

23. I have been informed that “a person of ordinary skill in the relevant field” is a hypothetical person to whom an expert in the relevant field could assign a routine task with reasonable confidence that the task would be successfully carried out. I have been informed that the level of skill in the art is evidenced by prior art references. The prior art discussed herein demonstrates that a person of ordinary skill in the field, at the time the ‘037 patent was effectively filed, would have a doctorate in dental science and three to five years of training and practical experience in orthodontics.

24. My background education and professional experience provide me with a strong understanding of the abilities and knowledge of a person of ordinary skill in the art for the relevant field of the ‘037 patent. Not only do I have such abilities and knowledge, but I have also worked with and overseen the work of others with such abilities and knowledge.

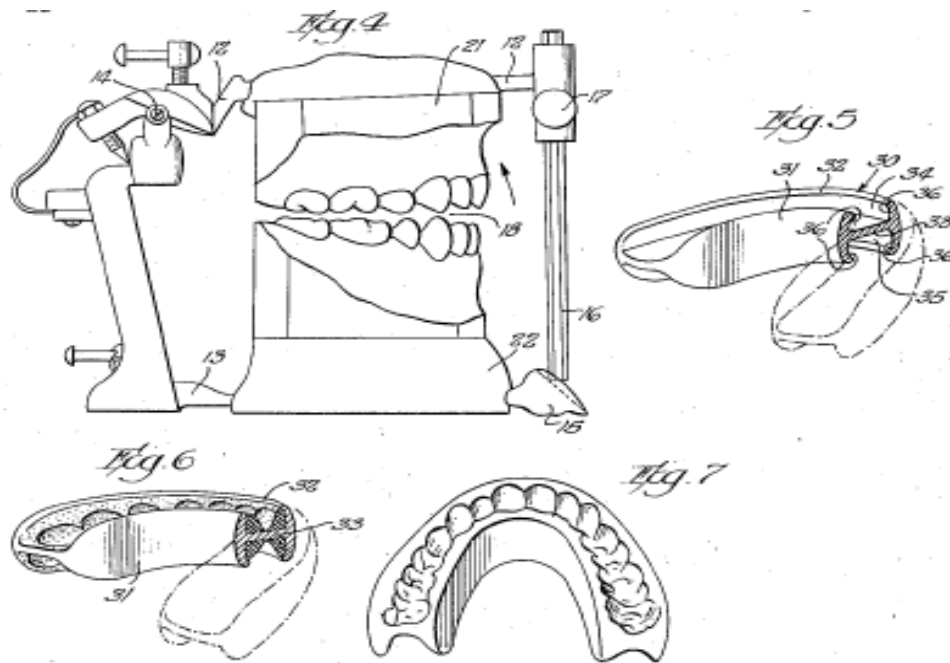
IV. STATE OF THE ART FOR THE '037 PATENT

25. For a number of decades extending back to the 1940s, dental practitioners have manufactured and used dental appliances to reposition patients' teeth. The technology for making such appliances can be traced back at least to the work of H.D. Kesling, as illustrated in his U.S. Patent No. 2,467,432 ("Kesling") filed in 1943. Kesling disclosed a system for changing the position of teeth using a plurality of tooth positioning appliances in which each appliance moves the teeth only a fraction of the way toward a desired final position. (Ex. 1005, 2:50 – 3:1).

26. To make the appliances, Kesling taught making plaster casts of a patient's teeth, dissecting or cutting out the teeth from the upper and lower bases of the plaster casts, and repositioning or reassembling the teeth on the bases in a proper or desired position for the patient using wax to secure the teeth to the bases. (*Id.* at 3:13-60). Using the bases with the repositioned teeth, Kesling formed the tooth positioning appliance by using a suitable tray filled with an impression material to make an impression of the teeth on the bases. (*Id.* at 4:8-47). The appliance is then produced by making a mold from the tray and

impression and filling the mold with a resilient material such as live rubber, which is shaped and cured to make the appliance. (*Id.* at 4:48-58).

27. Figs. 4-7 reproduced below show the bases with the repositioned teeth (Fig. 4), the tray (Fig. 5), the impression of the teeth (Fig. 6), and the resulting appliance (Fig. 7).



28. Although Figs. 4-7 described the technique for producing the appliance for the last or final change to the desired ideal position, Kesling explicitly taught that this technique can be used with a plurality of steps that move the teeth step by step from any extreme position to the desired and final position. (*Id.* at 5:22-28). To

accomplish the movement in a plurality of steps, Kesling disclosed it would be necessary to make a number of different appliances, each appliance representing one step of movement toward the final positioning of the teeth. (*Id.* at 5:29-32).

29. Kesling's innovative system for generating tooth positioning appliances inspired improvements from others in the field including Henry Nahoum. In his 1964 paper "The Vacuum Formed Dental Contour Appliance" ("Nahoum"),¹ Nahoum disclosed a system for constructing dental appliances very similar to Kesling but using a vacuum forming process capable of forming separate upper and lower appliances instead of the single appliance for upper and lower teeth as taught by Kesling. (Ex. 1014, 385). Like Kesling, Nahoum taught making a model with a plaster cast, sawing off the teeth, and repositioning the teeth on the model with wax. (*Id.* at 386). The appliance, which can be made of elastic plastic, is then formed using heat and a vacuum to reshape the plastic sheet over the model with the repositioned teeth. (*Id.*)

¹ Exhibit 1014 (Henry I. Nahoum, D.D.S. The New York State Dental Journal (1964) 30(9):385-390).

30. Nahoum also taught that the model could be used over and over again to make several appliances. (*Id.* at 387). In particular, depending upon the amount of correction needed, Nahoum taught making the adjustment in two or more phases with each appliance making a partial and progressive adjustment. (*Id.*) Nahoum's system improved the speed of production of appliances and was inexpensive. (*Id.* at 390) Moreover, the Nahoum appliances could be worn at all times including during eating, an improvement over the Kesling design. (*Id.*)

31. While the appliance systems of Kesling and Nahoum provided a useful and capable alternative for repositioning teeth as compared to braces or brackets, these systems required significant manual efforts and were both cumbersome and time-consuming to implement. Of course at the time Kesling and Nahoum developed their systems, computers and computer-controlled automation had not yet been developed or were at most in their infancy. But like most other industries, practitioners in the dental field recognized the possible advantages and efficiencies that could be obtained through the use of digital technology and automation.

32. Dianne Rekow documented early efforts to capitalize on digital technology and automation to design and produce dental devices and prostheses. For example, in “Computer-aided design and manufacturing in dentistry: A review of the state of the art” (“Rekow 1987”),² Rekow describes multiple efforts to use computer-aided design and computer-aided manufacturing (CAD/CAM) in an effort to integrate engineering applications of automation for generating dental prostheses. (Exhibit 1015, 512). The disclosed systems used optical-based real-time data acquisition devices to create three-dimensional models of a patient’s mouth and teeth in a CAD/CAM environment. (*Id.* at 512-13). The CAD/CAM system was then used to design the prosthesis to fit the unique requirements of the patient. (*Id.* at 513). The prosthesis design controlled a multi-axis milling machine to produce the prosthesis. (*Id.*)³

² Exhibit 1015 (Rekow, *The Journal of Prosthetic Dentistry*, vol. 58, No. 4 (Oct. 1987), pp. 512-516.)

³ *See also* Exhibit 1016 (Rekow, “A Review of the Developments in Dental CAD/CAM Systems,” *Dental Clinics: Prosthodontics and Endodontics*, pp. 25-

33. More particularly in relation to orthodontics, Craig Andreiko described the use of digital imaging and design for orthodontic appliances. (Exhibit 1017, Abstract). In U.S. Patent No. 6,244,861 (“Andreiko”), Andreiko taught a computerized system and method in which the finish positions of the teeth of a patient are derived from digitized information of the anatomical shapes of the patient's mouth. (*Id.* at 4:14-18). An orthodontic appliance was automatically designed from the digitized shape information and the derived tooth finish positions. (*Id.* at 4:18-19). Machine code was then generated for production of the orthodontic appliance and communicated to machines that automatically fabricate the appliance based on the machine code. (*Id.* at 4:20-24) Andreiko taught that the digitized information can be generated from measurements from the mouth of the patient that are taken directly or from a model of the mouth. (*Id.* at 4:25-28). The digitized information preferably included information of the shapes of the individual teeth of the patient and of the patient's jaw. (*Id.* at 4:28-30).

33, 1992) (describing the use of CAD/CAM systems for generating dental restorations).

34. Through this system, Andreiko provided a practical, reliable and efficient automated design and manufacturing system for custom appliances. (*Id.* at 3:38-42). Andreiko designed it to be easily and reliably used by practicing orthodontists to make the best use of their skills, knowledge and experience. (*Id.* at 3:43-47). The system thus increased the accuracy of the orthodontist's treatment, rendered the use of the orthodontist's time more efficient, eliminated sources of error and guesswork from the orthodontist's treatment of patients, and efficiently, repeatedly and reliably performed automatically many of the routine steps in the diagnosis, prescription and implementation of orthodontic treatment and in the design and manufacture of orthodontic appliances. (*Id.* at 3:48-56).

35. As explained by the prior art systems above and as further demonstrated by the prior art described in more particularity herein, the use of digital technology and automation to design and generate tooth appliances, as well as other dental products including dental prosthetics and restorations, was a natural development in dental practice that provided cost savings and increased efficiency.

V. OVERVIEW OF THE '037 PATENT

36. 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).

37. 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" and is reproduced hereinbelow. (Ex. 1001, 7:42-45). FIG. 2 of the '037 patent "illustrat[es] the steps of the present invention for producing a system of incremental position adjustment appliances" and is also reproduced hereinbelow. (Ex. 1001, 7:46-48).

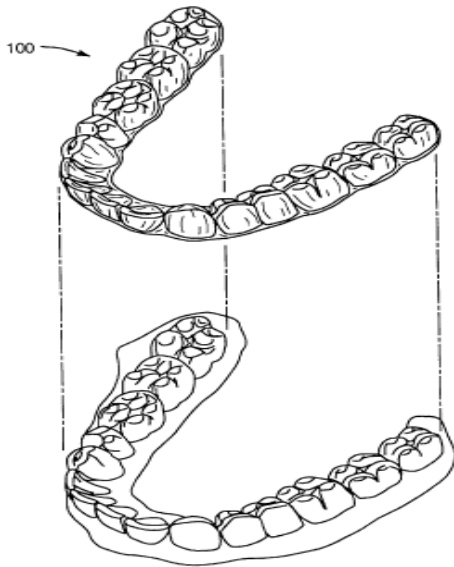


FIG. 1C

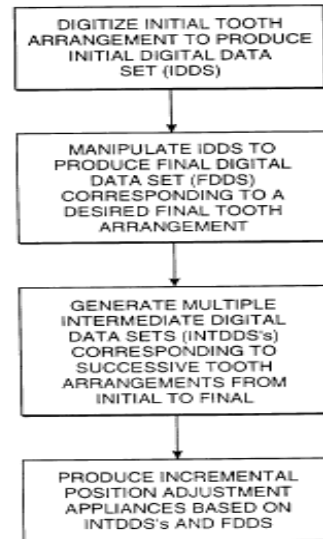


FIG. 2

38. 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).

39. Instead of using a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the IDDS, the '037 patent discloses that the dental appliances can be produced by non-computer-aided techniques. (*Id.* at 10:14-23). For example, plaster casts of a patient may be cut to permit repositioning of individual teeth within the casting with the disconnected teeth held in place by soft wax. (*Id.* at 10:23-27). A plurality of intermediate tooth arrangements can then be prepared using the modified plaster casting of the patient's teeth with the different arrangements used to prepare sets of multiple appliances using pressure and vacuum molding techniques. (*Id.* at 27-33). The '037 patent teaches that the manual creation of the appliances come within the scope of the alleged invention. (*Id.* at 10:33-36).

VI. CLAIM INTERPRETATION

40. In proceedings before the U.S. Patent and Trademark Office, I understand that the claims of an unexpired patent are to be given their

broadest reasonable interpretation (“BRI”) in view of the specification from the perspective of one skilled in the art. I have been informed that the ‘037 patent has not expired. In comparing the claims of the ‘037 patent to the known prior art, I have carefully considered the ‘037 patent and the ‘037 patent file history based upon my experience and knowledge in the relevant field. In my opinion, the broadest reasonable interpretation of the claim terms of the ‘037 patent is generally consistent with the term’s ordinary and customary meaning, as one skilled in the relevant field would understand them, subject to the terms identified below.

41. One of the limitations recited in both claims 1 and 9 of the ‘037 patent is that the plurality of digital data sets are provided “at the outset of treatment.” Although the specification of the ‘037 patent does not define this limitation, www.dictionary.com defines the term “outset” as the “beginning” or “start” and the term “treatment” as “the application of medicines, surgery, psychotherapy, etc., to a patient or to a disease or symptom.” Consistent with these definitions, the ‘037 patent discloses 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). Since the digital data set is generated “prior to treatment,” one of ordinary skill in the art would understand that generating the digital data sets is not part of the “treatment,” but rather that “treatment” begins when a patient starts using the dental adjustment appliances. Based on these definitions and the disclosure of the ‘037 patent, one of ordinary skill in the art would understand that the broadest reasonable interpretation of the limitation “at the outset of treatment” to be a point in time when a patient starts to use a dental adjustment appliance.

VII. THE PRIOR ART

A. Snow

42. 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). Snow teaches that this simulated movement can be generated as a plurality of digital data sets that map movements from the current state of the patient’s teeth to the idealized second position. (Id. at 14:45-48). Since the plurality of digital data sets map

the movements from the initial or current position of a patient's teeth to the idealized second position, it would be understood that the plurality of digital data sets can be generated at any point in time during treatment including at the outset or later in treatment. As a result, all or some of the appliances corresponding to the digital data sets can be fabricated for an individual patient and given to the treating professional or patient at the outset of treatment. In addition, because the movements are mapped from the current state of the patient's teeth, the plurality of digital data sets necessarily represent successive tooth arrangements that have been customized and created for each individual patient.

43. Snow also teaches creating individualized brackets based on the produced digital data sets. In particular, Snow teaches that each individualized model can be used to fabricate an individualized bracket "having accurate measurements with the surface of each bracket accurately profiled to match the corresponding surface in the individualized tooth." (*Id.* at 5:49-54). For the actual fabrication, the bracket structure can be output in a standard stereo lithographic

format (STL) that is used to create the customized bracket or brace. (*Id.* at 54-56).

B. Hultgren

44. Hultgren discloses controlling a fabrication machine based on digital data to produce a positive model. In particular, Hultgren discloses a fabrication device 507 connected directly to a computer 500 or a remote computer 505 in which the fabrication device 507 may be any type of device capable of creating a three-dimensional object from computer generated data. (Ex. 1004, 7:28-32). For example, the fabrication device 507 can be one that uses stereo lithography technology such as the SLA-250⁴ and SLA-500 manufactured by 3-D Systems of Valencia, California. (*Id.* at 7:32-36). I note that the ‘037 patent also discloses using the SLA-250. The fabrication device 507 can alternatively use the FDM-1500, which is a filament technology (also known as fused deposition modeling) manufactured by Stratasys Corporation of Minneapolis, Minnesota. (*Id.* at 7:36-39).

⁴ Petitioner notes that the ‘037 patent uses the same SLA-250 stereolithography machine as Hultgren to print the models.

45. Based on the teachings of Hultgren, it would have been understood that the “three-dimensional object” can be a positive model of a patient’s teeth arrangement. (*Id.* at Abstract). To create the positive model, an array of negative image scan data can be created by scanning a patient’s dental impression or casting. (*Id.*) Positive image data is converted from the negative image scan data and transmitted to the fabrication device 507 to create the three-dimensional object, such as a positive model of a patient’s teeth. (*Id.*)

46. Hultgren teaches using the processor 501 to provide scans of each of the upper and lower impressions and the bite registration impression of a patient where the scans provide the information necessary to create an electronic equivalent of the prior art physical casts. (*Id.* at 7:57-61). Through its use of negative image impressions and a line scanner, Hultgren teaches that fabrication device 507 can generate high quality study casts faster and which have higher resolution than older methods. (*Id.* at 7:61-65). Accordingly, the data used to create the three-dimensional, physical objects in Hultgren are generated by the electronic equivalent of the prior art physical casts. Moreover, in

comparison to older study cast production methods, Hultgren's teaches a system providing higher resolution and greater speed.

C. Kesling

47. Kesling discloses a system for fabricating a plurality of polymeric shell tooth positioning appliances for an individual patient. (Ex. 1005, 2:50 – 3:1, 4:54-58). To form the tooth positioning appliances, Kesling teaches forming them as a negative of a positive model. (*Id.* at 4:8-58).

48. Kesling teaches a manual method for preparing modified positive dental models. In particular, Kesling discloses that respective teeth carried by the upper base 21 and the lower base 22 of a casting of a patient's teeth are dissected from the bases using, for example, a small scroll saw or vibrating scroll saw. (*Id.* at 3:30-35). Wax or another suitable material is placed upon each of the bases, and the teeth are reassembled in the proper, desired or ideal position on the bases with the wax holding them in place. (*Id.* at 3:43-52). The position of the teeth to the ideal position is performed in consideration of the formation of the jaw structure and the facial characteristics of the patient. (*Id.* at 3:51-56). Fig. 3 of Kesling 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. (*Id.* at 3:30-64).

49. After making the plaster cast and reassembling the teeth, Kesling teaches using a tray to make an impression of the patient's teeth and to make a pattern for making the tooth positioning appliance. (*Id.* at 4:8-12). With the upper and lower grooves of the tray filled with an impression material, the tray is placed between the teeth of the plaster cast to make a true and accurate impression of the teeth in the desired position. (*Id.* at 4:39-47). Subsequently, a mold or casting is made from the tray and impression. (*Id.* at 4:53-54). Finally, the mold or casting is filled with a resilient material, such as live rubber, that is shaped and cured in the mold to make the tooth positioning appliance. (Ex. 1005, 4:55-58).

D. Lemchen

50. Lemchen discloses a method for creating a model of a patient's teeth arrangement by generating digital information representing negative image scan data through the use, for example, of laser scanning or digital video scanning. (Ex. 1006, 2:56-63). Lemchen teaches that Computer Aided Design ("CAD") can use that digitized information to

generate a model representing a positive, digital dental model. (*Id.* at 3:1-5). The model includes a full representation of the upper and lower dental arches and associated jaw structure of the patient. (*Id.* at 3:10-16). From this model, the “finish” or desired final position of a maloccluded tooth or teeth can be calculated. (*Id.* at 3:20-23).

51. This model can also be provided to known fabrication devices to create customized brackets. In particular, Lemchen teaches that customized brackets may be provided to the practitioner by a dental laboratory, where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion. (*Id.* at 5:31-35). Accordingly, Lemchen demonstrates the equivalence between the computer generation of the positive, digital dental model for manufacturing appliances with previously known manual techniques for creating incremental positive models, from which appliances are produced. With respect to previously known manual techniques, Lemchen notably references Kesling’s physical cast model of a patient’s teeth, specifically disclosing that Kesling teaches forming a full physical model of the upper and lower

dental arches and associated jaw structure, including in a desired final or finishing position. (*Id.* at 3:13-19; 3:41-46).

VIII. THE PRIOR ART IN RELATION TO CLAIMS OF THE '037 PATENT

A. Snow in Combination with Hultgren and Kesling

52. I have been asked whether a person of ordinary skill in the art would be inclined to combine the system of Snow with the systems discussed in Hultgren and Kesling. I have considered this combination with respect to claims 1, 2, 9, and 10 of the '037 patent.

53. As I explained above, Snow teaches a method for providing a plurality of digital data sets that includes 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. As I also explained, these digital data sets of Snow can be provided at any time during treatment including at the outset of treatment.

54. As I also explained above, Hultgren teaches controlling a fabrication machine to produce positive dental casts. In particular, the fabrication

machine produces a plurality of dental casts of successive tooth arrangements based upon the plurality of digital data sets. Kesling correspondingly teaches fabricating a plurality of dental incremental position adjustment appliances based on those positive casts. As a result, Kesling's appliances would therefore be produced "based on" the digital data sets because Hultgren teaches that the digital data sets are used to form the physical casts that are used by Kesling to produce the appliances.

55. The combination of Snow, Hultgren, and Kesling represent the natural progression of using digital technology to assist in the fabrication of dental appliances. In particular, it would have been understood that a practitioner could use Snow's plurality of digital data sets for digitally repositioning teeth to control a fabrication machine to produce a plurality of positive casts of the successive tooth arrangements, as taught by Hultgren. Correspondingly, based on the teachings of Kesling, it would have been understood that those positive casts can be used to produce the plurality of tooth positioning appliances as negatives of the positive casts. Given the detailed disclosures of Snow, Hultgren and Kesling and the predictability of this

technology, it would have been understood that this combination would be reasonably likely to succeed.

56. Not only is this combination a natural progression with the development of digital technology and automation, but the combination would also provide cost savings by avoiding the need for labor intensive efforts to make the modified tooth arrangements on physical casts.

Indeed, using automation to replace manual efforts is commonly sought to achieve cost savings and improve efficiency.

B. Snow in Combination with Lemchen and Kesling

57. I have also been asked whether a person of ordinary skill in the art would be inclined to combine the system of Snow with the systems discussed in Lemchen and Kesling. I have considered this combination with respect to claims 1, 2, 9, and 10 of the '037 patent.

58. As I explained above, Snow teaches a method for providing a plurality of digital data sets that includes 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. As I

also explained, these digital data sets of Snow can be provided at any time during treatment including at the outset of treatment.

59. As I also explained above, Lemchen teaches using the plurality of digital data sets representing the repositioned teeth to generate modified positive, digital dental models of the successive tooth arrangements. Moreover, not only does Lemchen recognize that these digital models are equivalent to manually-created, physical dental casts, Lemchen also discloses controlling a fabrication machine to produce dental appliances based on those digital models. Accordingly, since Lemchen teaches that the physical casts are equivalent to the digital models, and Kesling teaches fabricating a plurality of tooth positioning appliances based on the physical casts, it follows that the combination of Lemchen and Kesling teaches fabricating a plurality of tooth positioning appliances based on the positive, digital model data sets.

60. The combination of Snow, Lemchen, and Kesling represent the natural progression of using digital technology to assist in the fabrication of dental appliances. In particular, it would have been understood that a practitioner could use Snow's plurality of digital data

sets for digitally repositioning teeth to control a fabrication machine to produce a plurality of positive casts of the successive tooth arrangements, as taught by Lemchen. Correspondingly, based on the teachings of Kesling, it would have been understood that those positive casts can be used to produce the plurality of tooth positioning appliances as negatives of the positive casts. Given the detailed disclosures of Snow, Lemchen and Kesling and the predictability of this technology, it would have been understood that this combination would be reasonably likely to succeed.

61. Not only is this combination a natural progression with the development of digital technology and automation, but the combination would also provide cost savings by avoiding the need for labor intensive efforts to make the modified tooth arrangements on physical casts. Indeed, using automation to replace manual efforts is commonly sought to achieve cost savings and improve efficiency.

C. Snow in Combination with Admitted Prior Art and Kesling

62. In addition, I have been asked whether a person of ordinary skill in the art would be inclined to combine the system of Snow with the systems discussed in the Admitted Prior Art (“APA”) and Kesling. I

have considered this combination with respect to claims 1, 2, 9, and 10 of the '037 patent.

63. As I explained above, Snow teaches a method for providing a plurality of digital data sets that includes 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. As I also explained, these digital data sets of Snow can be provided at any time during treatment including at the outset of treatment.

64. Admitted Prior Art (“APA”) acknowledges that it was known in the art to transform digital image data into a positive model or cast through the use of fabrication machines under the control of the image data. Kesling correspondingly teaches fabricating a plurality of dental incremental position adjustment appliances based on those positive casts. Kesling’s appliances are therefore produced “based on” the digital data sets because APA teaches that the digital data sets are used to form the physical casts that Kesling uses to produce the appliances.

65. The combination of Snow, APA, and Kesling represent the natural progression of using digital technology to assist in the fabrication of dental appliances. In particular, it would have been understood that a practitioner could use Snow's plurality of digital data sets for digitally repositioning teeth to control a fabrication machine to produce a plurality of positive casts of the successive tooth arrangements, as taught by APA. Correspondingly, based on the teachings of Kesling, it would have been understood that those positive casts can be used to produce the plurality of tooth positioning appliances as negatives of the positive casts. Given the detailed disclosures of Snow, APA and Kesling and the predictability of this technology, it would have been understood that this combination would be reasonably likely to succeed.

66. Not only is this combination a natural progression with the development of digital technology and automation, but the combination would also provide cost savings by avoiding the need for labor intensive efforts to make the modified tooth arrangements on physical casts. Indeed, using automation to replace manual efforts is commonly sought to achieve cost savings and improve efficiency.

IX. SECONDARY CONSIDERATIONS

67. Prior to working on this declaration, I have never heard anyone offer praise for the '037 patent, nor am I aware of any commercial success attributable to the '037 patent. I am also unaware of any copying of the alleged invention of the '037 patent.

68. By the time the application for the '037 patent was filed, the industry had already naturally evolved to the use of digital technology and automation to design and manufacture tooth repositioning appliances, without knowing the patent owner had passed off an obvious combination of pre-existing, commercially-available technology as their own "invention."

69. Thus, I am unaware of any secondary considerations supporting the nonobviousness of the '037 patent.

X. CONCLUSION

70. In connection with the above, I have reviewed, had input into, and endorse as set forth fully herein the claims charts in the accompanying petition showing that each element of claims 1, 2, 9 and 10 is disclosed by the combinations set forth therein, and that, as set forth above, a

person of ordinary skill in the art would have combined the teachings of the references as claimed.

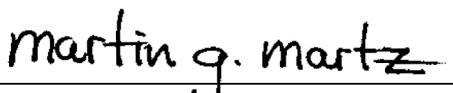
71. For my efforts in connection with the preparation of this declaration I have been compensated at my standard hourly rate for this type of consulting activity. My compensation is in no way contingent on the results of these or any other proceedings relating to the above-captioned patent.

72. In signing this declaration, I understand that the declaration will be filed as evidence in a review proceeding before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

73. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section

1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the results of these proceedings.

Executed on: November 30, 2015


Dr. Martin Martz, D.D.S., M.S.

APPENDIX A

CURRICULUM VITAE

Name: Martin G. Martz, D.D.S., M.S.

Position: Lecturer, Section of Orthodontics, UCLA School of Dentistry

Address: 8421 Blue Heron Drive, Bakersfield, CA 93312

Telephone: Home 661-368-2259, Cell 661-204-8123

Email: martz8421@sbcglobal.net

EDUCATION:

- 1979-1981 Loma Linda University, Graduate School, Dept of Orthodontics
Masters Degree in Orthodontics
- 1972-1976 Loma Linda University, School of Dentistry, Loma Linda, CA
Doctor of Dental Surgery
- 1969-1972 Pacific Union College, Angwin, CA
Minors in Physics, Computer Science, Chemistry, Biology
Accepted into Dental School early without earning a degree

LICENSES, CERTIFICATION:

- 1977-Present CA Dental License, California State Board of Dental Examiners

PRINCIPAL POSITIONS HELD:

- 2010-Present Lecturer, Clinical Faculty, UCLA Section of Orthodontics
- 1991-2010 Solo Orthodontic Private Practice, Bakersfield, CA
- 1988-1991 Orthodontic Associateship, Bakersfield, CA
- 1981-1988 Solo Orthodontic Private Practice, Aspen, CO
- 1977-1978 General Dentistry Associateship, Victoria, B.C., Canada

HONORS AND AWARDS:

- 2015 UCLA Section of Orthodontics Faculty of the Year Award
- 2012 UCLA Section of Orthodontics Faculty of the Year Award
- 2010 UCLA Section of Orthodontics Faculty of the Year Award
- 1972-1975 California State Graduate Fellowship
- 1969-1972 California State Scholar

KEYWORDS/AREAS OF INTEREST:

Orthodontic Education, Treatment of Cleft Palate and Craniofacial Deformities,
Orthodontic Finishing, Orthognathic Surgery, Complex Multi-Discipline Cases,
Orthodontic Treatment with modified Clear Aligners

PROFESSIONAL ORGANIZATIONS

Memberships

- 1984-Present American Association of Orthodontists
- 1984-1989 Rocky Mountain Society of Orthodontists
- 1989-Present Pacific Coast Society of Orthodontists

Professional Organizations, Continued

Memberships

1989-Present California Association of Orthodontists
1984-Present American Dental Association
1989-Present California Dental Association
1989-Present Kern County Dental Society

Service to Professional Organizations

1995-2002 Board of Directors, Kern County Dental Society
2001 Served as President, Kern County Dental Society

INVITED PRESENTATIONS

1998 International Association of Orofacial Myology Annual Session, San Diego
1991 Kern County Dental Hygiene Association

CDE COURSES ATTENDED

1997-1999 Roth-Williams Center, 2-yr advanced continuing education 280 hours
Taught by Ron Roth and Robert Williams, Burlingame, CA
Additional numerous routine CDE Courses were attended in order to maintain CA dental license
50 Hours minimum are required for each 2-yr renewal,
Hours obtained were mainly by attending the AAO Annual Sessions each year

TEACHING

2009-Present Attending Faculty, UCLA Craniofacial Clinic every week
Two orthodontic residents are assigned to attend the clinic each week
Clinic hours are 1PM to 5 PM, Conference follows from 5:15PM to 6:30PM
2010-Present Attending Faculty, UCLA Graduate Orthodontic clinic every week
Thurs Clinic hours are 9AM to 12 AM, 2PM to 5 PM
I also frequently cover clinic on Wednesday 9AM to 12AM
2010-Present Attending Faculty, Craniofacial Seminar
Wed 12AM-1 PM twice monthly
Attended by all Ortho residents, Plastic surgery fellow, and 3 plastic surgeons
2010-Present Attending Faculty, Orthognathic Surgery Seminar
Wed 7AM to 8AM every week, attended by all Ortho residents, Oral Surg residents
One or two Ortho Faculty, and 3 to 5 Oral Surgery Faculty
2012-Present Attending Faculty (not assigned), Advanced Treatment Planning Seminar
Thurs 1PM to 2PM every week, attended by all Ortho residents, 2 Ortho Faculty

RESEARCH AND CREATIVE ACTIVITIES

PEER REVIEWED PUBLICATIONS:

“Maxillary Hypoplasia in Cleft Cases: Contribution of Orthodontic Dental Space Closure to Orthognathic Surgery”. Justine C. Lee, Ginger Slack, Ryann Walker, Lindsay Graves, Sandra Yen, Jessica Woo, Rishal Ambaram, **Martin Martz**, Henry Kawamoto, Jr., James P. Bradley. Presented at 58th Annual Meeting Plastic Surgery Research Council, May 2-4-2013. Plastic and Reconstructive Surgery 2014 Feb; 133 (2); 355-361
“Lateral Incisor Agenesis Predicts Maxillary Hypoplasia and Le Fort 1 Advancement Surgery in Cleft Patients.” Kenneth K. Kao, Li Han Lai, Brian K. Hui, , Phong D. Nguyen, Kristen Yee, **Martin G. Martz**, James P. Bradley, Justine C. Lee; Plastic and Reconstructive Surgery 2014 Sep; 134(4 Suppl 1): 8-9

Publication in Preparation

“Case Report: Combined Surgical and Orthodontic Management of a Patient with Antley-Bixler Syndrome.” Christian Solem, Henry Kawamoto, Jr., Justine Lee, **Martin Martz**, Jeremy Barrett. Submitted for publication, Cleft Palate Craniofacial Journal

ADDITIONAL ACTIVITIES

2013 Expert Witness, Align Technology vs. ClearCorrect, ITC Hearings

2011 Writing Team, UCLA Orthodontics Self-Study Report for CODA, Accreditation Site Visit

PATENTS ISSUED

US 4,793,803 Removable Tooth Positioning Appliance and Method
Filed: 10-8-1987 Published: 12-27-1988

US 4,880,380 Orthodonture Appliance Which May Be Manually Installed and Removed by
the Patient
Filed: 10-13-1987 Published: 11-14-1989

US 5,145,364A Removable Orthodontic Appliance
Filed: 5-15-1991 Published: 9-8-1992

PATENTS PENDING

US 61/914,832 Tooth Positioning Appliance with U-Shaped Interconnecting Elements
Filed: 12-11-2013

US 61/952,364 Tooth Positioning Appliance for Closing Spaces
Filed: 3-13-2014

Development work and testing is underway for a new removable clear aligner system to solve problems encountered with commercial aligner appliances currently available. Current clinical testing is underway with thermoformed aligners, but 3-D printed aligner development is ongoing. New printable materials are currently being tested.

APPENDIX B

MARTZ DECLARATION APPENDIX B

Information considered includes the following Exhibits:

- | | |
|---------------------|--|
| Exhibit 1001 | U.S. Patent No. 6,699,037 to Chishti et al. |
| Exhibit 1002 | Prosecution history of U.S. Patent Application No. 09/791,650, which matured into the '037 patent ("650 Patent Application"). |
| Exhibit 1003 | U. S. Patent No. 6,068,482 to Snow ("Snow") |
| Exhibit 1004 | U.S. Patent No. 6,217,334 to Hultgren ("Hultgren") |
| Exhibit 1005 | U.S. Patent No. 2,467,432 to Kesling ("Kesling") |
| Exhibit 1006 | U.S. Patent No. 5,011,405 to Lemchen ("Lemchen") |
| Exhibit 1014 | Nahoum, H. I., "The Vacuum Formed Dental Contour Appliance," <i>The New York State Dental Journal</i> , 30(9):385-390 (1964). |
| Exhibit 1015 | Rekow, D., "Computer-aided design and manufacturing in dentistry: A review of the state of the art," <i>The Journal of Prosthetic Dentistry</i> , vol. 58, No. 4, pp. 512-516 (Oct. 1987). |
| Exhibit 1016 | Rekow, D., "A Review of the Developments in Dental CAD/CAM Systems," <i>Dental Clinics: Prosthodontics and Endodontics</i> , pp. 25-33 (1992). |
| Exhibit 1017 | U.S. Patent No. 6,244,861 to Andreiko ("Andreiko") |