

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALIGN TECHNOLOGY, INC.,

Petitioner,

v.

DENTAL MONITORING SAS,

Patent Owner.

Case No. IPR2024-00052

U.S. Patent No. 11,049,248

**DECLARATION OF DR. BUDI KUSNOTO IN SUPPORT OF PATENT
OWNER'S RESPONSE**

TABLE OF CONTENTS

	Page
I. INTRODUCTION & SUMMARY OF OPINIONS	1
II. BACKGROUND	3
A. Qualifications	3
B. Compensation	8
C. Materials and Other Information Considered	8
III. RELEVANT LEGAL PRINCIPLES	9
A. Person of Ordinary Skill in the Art	9
B. Date of Invention.....	10
C. Prior Art.....	11
IV. DENTAL PHOTOGRAPH ACQUISITION	11
V. ALIGNER TREATMENT	27
A. Diagnosis	27
B. Treatment.....	29
1. Wearing the Aligners	29
2. Assessing the Aligner Treatment.....	30
3. Adjusting the Treatment Plan	34
VI. PERSON OF ORDINARY SKILL IN THE ART WITH RESPECT TO THE '248 PATENT	35
VII. ALIGN'S REFERENCES	37
A. The Invisalign Clinical Monitoring Guide ("Invisalign").....	37
B. U.S. Patent Publication No. 2017/0281313 to Kim ("Kim").....	46
C. PCT Publication No. WO2016066651 to Salah et al. ("Salah").....	53
VIII. DEEP LEARNING IN DENTAL PHOTOGRAPHY.....	57
IX. CONCLUSION.....	60

EXHIBIT LIST

Exhibit Number	Description
2007	Rui Zhao et al., <i>Changing Clear Aligners Every 10 Days or 14 Days? A Randomised Controlled Trial</i> , 39(1) Australasian Orthodontic J. (2023)
2010	J. Liu et al., <i>Machine learning in orthodontics: Challenges and perspectives</i> , 30(10) Advances in Clinical and Experimental Medicine 1065
2022	Timothy T. Wheeler, <i>Orthodontic Clear Aligner Treatment</i> , 23(1) Seminars in Orthodontics 83 (2017)
2023	Emilia Taneva, Budi Kusnoto, Carla A. Evans, Chapter 9: 3D Scanning, Imaging, and Printing in Orthodontics, Issues in Contemporary Orthodontics (Farid Bourzgui 2015)
2024	Orhan Tuncay et al., <i>Effectiveness of a Compliance Indicator for Clear Aligners</i> , 43(4) J. Clin. Orthod. 263 (2009)
2025	Silvia Caruso, Sara Caruso, et al., <i>A Knowledge-Based Algorithm for Automatic Monitoring of Orthodontic Treatment: The Dental Monitoring System. Two Cases</i> , 21(5) Sensors (Basel) 1856 (2021)
2026	Barry J. Glaser, <i>The Insider's Guide to Invisalign Treatment</i> , (3L Publishing, 2017)
2031	Updated Curriculum Vitae of Budi Kusnoto, D.D.S., M.S.
2033	American Board of Orthodontists, <i>Ideal Photographs and Radiographs</i>
2034	Institute of Medical Illustrators, <i>IMI National Guidelines: Orthodontic Photography</i> (Feb. 2008).
2035	Canon, <i>Canon Dental Photography Guide</i> (2015)
2036	Excerpts from Transcript of Deposition of Dr. Maureen A. Valley in IPR2019-00132 (Dec. 18, 2019)
2037	Excerpts from Declaration of Dr. Maureen A. Valley in <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , 3:22-cv-07335-WHA (Dkt. 104-5)
2038	R. Kaplan, <i>Standardization for Serial Intraoral Photography</i> , The C.V. Mosby Co. 431 (1979)

2040	S. Samawi, <i>Clinical Digital Photography in Orthodontics: Professional Photographic Records in Daily Practice</i> , 18 Jordan Dental J. 20 (2012)
2046	I. Ahmad, <i>Digital Dental Photography, Part 2: Purposes and Uses</i> , 206(9) British Dental J. 459 (May 2009)
2047	S. Finlay, <i>Photographic Analysis and Diagnosis: Step One</i> , 2(3) Inside Dentistry (Oct. 2009)
2054	Excerpts from Transcript of Deposition of Hassan Foroosh, Ph. D, in IPR2024-00110 and IPR2024-00052 (June 28, 2024)
2055	<i>Making Sure Your Invisalign Aligners Fit Correctly</i> , Morita Orthodontics (2016)
2056	Apple, <i>Apple Reinvents the Phone with iPhone</i> , Apple Newsroom (Jan. 9, 2007)
2063	N. Smith, <i>Clear aligner therapy: An esthetic approach to total patient care</i> , Dentistry IQ (Sept. 25, 2017)

I. INTRODUCTION & SUMMARY OF OPINIONS

1. I have been retained by counsel for Patent Owner Dental Monitoring SAS as an expert witness in the above-captioned proceeding. I have been asked to provide my opinions relating to aspects of the state of the art described in U.S. Patent No. 11,049,248 (“the ’248 patent”) (EX1001), as well as certain references relied upon by Petitioner Align Technology, Inc., and its expert witness, Dr. Hassan Foroosh. The following is my written declaration on these issues.

2. In summary my opinions are as follows:

- As of 2017, dental photographs captured by dental professionals during in-office patient consultations were part of the standard of care. Training was required to capture high-quality dental photographs using sophisticated cameras and controlled lighting.
- As of 2017, prior to treatment with clear aligners, dental professionals would perform an in-office inspection of a patient’s dental condition (“dentition”) and would typically collect detailed scans of the patient’s teeth for purposes of the design and manufacture of a series of aligners.
- Once the aligners were manufactured, treatment proceeded in three general steps: (1) a patient wearing a series of aligners according to the treatment plan of their orthodontist; (2) an orthodontist assessing

the progress of that treatment at regular intervals; and (3) an orthodontist adjusting the treatment plan as necessary. Step (2) required frequent in-person examinations and did not involve quantitative measurements, but rather, qualitative holistic assessments of the alignment of teeth and the aligner fit.

- The Invisalign reference relates exclusively to in-person treatment and instructs orthodontists to perform steps at each appointment that can only be performed in-person. Invisalign does not suggest acquisition of images showing an aligner on patient's teeth for the purposes of assessing aligner treatment or any method for remote assessment of aligner fit in between in-office orthodontist check-ins. Invisalign further does not provide a method of measuring the separation between the teeth and the aligner to a precision of 1 mm or less, and making such measurements was not the standard of care in 2017.
- The Kim reference relates to a method for a dental professional to remotely determine the alignment of teeth for purposes of assessing treatment progress and not aligner fit. Contrary to Dr. Foroosh's interpretation, it does not disclose taking images of a patient wearing an aligner.

- The Salah reference describes a method of monitoring tooth movement over time, not aligner fit. The single image in Salah that shows a device fitted on teeth shows a bonded expander—which is physically affixed and not removable by the patient, unlike a clear aligner.
- The use of deep learning or machine learning in the acquisition and/or analysis of dental photographs had not been accepted by the dental community as of 2017.
- Obtaining a learning base for training a deep learning device comprising thousands of images of aligners in the service position taken on a cellphone would have been a tremendous undertaking in 2017. I am not aware of any collection of such images that existed at the time, and even if the images were available, they would need to be labeled and anonymized in accordance with ethical, regulatory, and legal requirements.

II. BACKGROUND

A. Qualifications

3. My qualifications are summarized below and are presented in more detail in my updated professional CV (EX2031). Additionally, the following

overview of my background pertains to my qualifications for providing expert testimony in this matter.

4. I have worked as a practicing clinician, researcher, and academic in orthodontics for twenty-five years. I have extensive experience with dental monitoring technology in clinical, patient care, and research settings.

5. I obtained a D.D.S. from the University of Indonesia in 1994. In 1998, I obtained a Master's degree in oral sciences and a specialty certificate in orthodontics from the University of Illinois at Chicago ("UIC"). I completed my fellowship at the University of Illinois at Chicago Craniofacial Center in 1999. In addition, I obtained a second D.D.S. from UIC in 2002. I previously obtained my Bachelor's degree in Computer Science Engineering from the Computer Science Institute in Indonesia in 1993.

6. I am currently a tenured Professor of Orthodontics, Program and Clinical Director as well as Coordinator of the Digital Imaging Laboratory in the Department of Orthodontics at UIC. I also run a private orthodontic clinic, and I am a consultant in several group practices.

7. As part of my work in the Department of Orthodontics at UIC, I have been deeply involved in the implementation of digital technology for dental treatment purposes. I am also actively involved in research and teaching on the subject of orthodontic diagnosis, treatment, and planning, as well as biomechanics.

More specifically, I am actively involved in research relating to (a) the management of craniofacial patients and orthognathic cases, and (b) orthodontic diagnosis, treatment planning, and treatment, including through the use and implementation of 3D imaging technology, teledentistry, artificial intelligence, and machine learning. I am actively involved in benchmark, evidence-based, and translational research in these areas. My knowledge on the growth and development of the human craniofacial complex is complementary to my research and teaching in the field of orthodontic diagnosis, treatment planning, and treatment.

8. My orthodontics work has been published in numerous peer-reviewed journals. See, *e.g.*, Fernandes, E.C. et al., “The 100 Most-Cited Articles in Orthodontic Journals in the Last 20 Years,” *Am. J. Orthod. Dentofac. Orthop.* (2021). I am also an active member in good standing of the American Association of Orthodontists, Illinois Society of Orthodontists, Midwest Society of Orthodontists, Chicago Dental Society, American Dental Association, and American Dental Educator Association. In addition, I am a Diplomat of the American Board of Orthodontics.

9. Below are examples of publications concerning my work with digital technology, remote dental monitoring, and artificial intelligence.

- Morris R, Hoyer L, Elnagar M, Atsawasuwon P, Galang-Boquiren M, Caplin J, Viana G, Obrez A, Kusnoto B., “Accuracy of Dental

Monitoring™ 3D Digital Dental Models Using Photo and Video Mode,” American Journal of Orthodontics and Dentofacial Orthopedics, 156(3), 420-428 (2019).

- Elnagar MH, Aranovich S, Kusnoto B., “Digital Workflow for Combined Orthodontics and Orthognathic Surgery,” Oral and Maxillofacial Surgery Clinics of North America, 32(1), 1-14 (2019).
- Talaat S, Kaboudan A, Talaat W, Kusnoto B, Sanchez F, Elnagar MH, Bourauel C., “Improving the accuracy of publicly available search engines in recognizing and classifying dental visual assets using convolutional neural networks,” International journal of computerized dentistry, 23(3), 211-218 (2020).
- Masoud AI, Alwadei FH, Alwadei AH, Lin EY, Viana MGC, Kusnoto B, Evans CA., “Developing pediatric three-dimensional upper airway normative values using fixed and interactive thresholds,” Oral Radiol. 36(1), 89-99 (2020).
- Talaat S, Kaboudan A, Talaat W, Kusnoto B, Sanchez F, Elnagar MH, Ghoneima A., “The validity of an artificial intelligence application for assessment of orthodontic treatment need from clinical images,” Seminars in Orthodontics, 27(2), 164-171 (2021).

- Bulatova G, Kusnoto B, Viana G, Tsay TP, Avenetti DM, Sanchez F., “Assessment of automatic cephalometric landmark identification using artificial intelligence,” *Orthodontics and Craniofacial Research*, 24(S2), 37-42 (2021).
- Makki A, Elnagar MH, Sanchez F, Caplin J, Viana G, Kusnoto B., “Assessment of Handicapping Labio-Lingual Deviation index scoring methods and their effect on orthodontic treatment coverage by Medicaid,” *Journal of Public Health Dentistry* (2022).

10. Between 2019 and 2022, I was awarded research grants relating to artificial intelligence in dentistry. These projects included:

- American Association of Orthodontists Foundation – \$20,000 awarded for research at UIC: “Optimizing Orthodontic Appliances Efficiency with Remote Dental Monitoring and Artificial Intelligence Algorithms.”
- American Association of Orthodontists Foundation – \$20,000 awarded for research at UIC: “Evaluation of Anterior Open Bite Treatment. Strategies and Outcomes Using Artificial Intelligence.”
- American Association of Orthodontists Foundation – \$29,056 awarded for research at UIC: “Assessment of Automatic

Cephalometric Landmark Identification Using Artificial Intelligence Deep Learning Convolutional Neural Networks.”

11. I also have had the opportunity to work with Dental Monitoring products, including products that employ artificial intelligence and machine learning for dental treatment, aligner treatment, teledentistry, and other purposes.

12. For at least these reasons, and based on the additional education and experience set forth in my CV, I believe I am qualified to provide the opinions in this declaration.

B. Compensation

13. My hourly rate for my work on this matter is \$100. Payment of my compensation is being made in full to the Foundation for Modern Bioprogressive Orthodontics. My compensation does not depend in any way on the outcome of this matter or the particular testimony or opinions that I express.

C. Materials and Other Information Considered

14. My opinions are based on my years of education, research, and experience, as well as my investigation and study of relevant materials. In forming my opinions, I have considered the materials I identify in this declaration. In particular, in forming my opinions, I have considered the declaration of Dr. Foroosh (EX1002), as well as Kim (EX1005), Invisalign (EX1006), Salah (EX1008), and Frey (EX1009).

15. My analysis of the materials in this investigation is ongoing and I will continue to review any new material as it is provided to me. This declaration represents only those opinions I have formed to date on the issues addressed herein. I reserve the right to revise, supplement, and/or amend my opinions stated in this declaration based on new information and on my continuing analysis of the materials already provided.

III. RELEVANT LEGAL PRINCIPLES

16. I am not an attorney and offer no opinions on the law. I have relied on instructions from counsel as to the applicable legal standards to use in arriving at my opinions in this declaration. Below is my understanding regarding the relevant legal standards based on those instructions.

A. Person of Ordinary Skill in the Art

17. I understand that, in the context of a validity or patentability analysis, the person of ordinary skill in the art (“POSA”) is a hypothetical person who looks to the prior art at the time of the invention and without the benefit of hindsight. I further understand that a POSA is not only defined by the patent but also by the relevant prior art. I understand that the POSA is presumed to have knowledge of all references that are sufficiently related to one another and to the pertinent art, and to have knowledge of all art reasonably pertinent to the particular problem that the claimed invention addresses.

18. I further understand that factors that may be considered in determining the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field.

19. My specific understanding of a POSA with respect to the field of the '248 patent is summarized below. See ¶¶54-57.

B. Date of Invention

20. I understand that the priority date credited to an alleged invention is relevant to an analysis of the validity or patentability of that alleged invention at least because it determines which art is prior art to the alleged invention (for my understanding of the categories of prior art, see the “prior art” section below for more details).

21. I understand that when the date of invention is based on the filing of a patent application, the date of invention is the earliest effective filing date of a patent's claims. I understand that the earliest effective filing date of a patent's claims may predate the actual filing date of the U.S. application for that patent. For example, if an application is a continuation of an earlier application (a “parent application”), the earliest effective filing date of the claims resulting from the later application may be the filing date of the parent application if the parent application's

disclosure satisfies the enablement and written description requirements for those claims. Similarly, if a non-provisional patent application claims priority to an earlier provisional application, the earliest effective filing date of the claims resulting from the non-provisional application may be the filing date of the provisional application if the provisional application's disclosure satisfies the enablement and written description requirements for those claims.

22. I understand that neither Align nor Dr. Foroosh has disputed the priority date of July 21, 2017 for the '248 patent.

C. Prior Art

23. I understand that prior art includes items that were publicly known or that were used by others before the effective filing date of the alleged invention. Prior art also includes any printed publications, published patent applications, or patents that were published or effectively filed before the effective filing date of the alleged invention. I further understand that the prior art must be assessed from the perspective of a person of ordinary skill in the art.

IV. DENTAL PHOTOGRAPH ACQUISITION

24. Below, I discuss the state of the art with respect to standard orthodontic photographs as of 2017.

25. ***The Standard Orthodontic Photographs:*** For decades prior to the '248 patent, dental photographs captured by dental professionals during in-office patient consultations were (and continue to be) an integral part of dental care.



EX2038 [Kaplan, *Standardization for Serial Intraoral Photography*, The C.V. Mosby Co. 431 (1979)], 436 (showing the acquisition of a left buccal intraoral photograph using then-available technologies). In 2017 (and long before), there was a recognized standard set of orthodontic photographs that comprised the following specific views of a patient's teeth:

- A frontal view of a patient's teeth:



- A left buccal view of a patient's teeth:



- A right buccal view of a patient's teeth:



- An occlusal view of a patient's maxillary (top) teeth:



- An occlusal view of a patient's mandibular (bottom) teeth:



EX2033 [American Board of Orthodontics, *Ideal Photographs and Radiographs*], 5-12; EX2040 [Shadi Samawi, *Clinical Digital Photography in Orthodontics: Professional Photographic Records in Daily Practice*, 18 *Jordan Dental J.* 20 (2012) (“Samawi”)], 28-31; EX2034 [IMI National Guidelines Orthodontic Photography], 25. This set of photographs allowed the dental professional to capture all of the views necessary for maintaining proper patient records and to perform qualitative assessments of a patient's teeth for clinical purposes (discussed further below).

26. I note that, in a related district court litigation, *Dental Monitoring SAS v. Align Technology, Inc.*, 3:22-cv-07335-WHA (Dkt. 104-5), Petitioner Align's dental expert, Dr. Maureen Valley, submitted an expert report in which she confirmed that the photographs discussed above reflect a standard set of orthodontic photographs that dental professionals would capture from their patients in 2017. EX2037 [Valley Report], 4-5. In particular, Dr. Valley relied upon the American Board of Orthodontics, *Photograph Requirements*, as reflecting the standard orthodontic photographs as of July 21, 2017. *Id.*, 4-5 & n. 2.



EX2033 [American Board of Orthodontics, *Ideal Photographs and Radiographs*],

12. As shown above, the photographs Dr. Valley identified as the standard set of orthodontic photographs are the same as the ones I identified.

27. The goal of standard orthodontic photographs was to capture the view of a patient's dental arch from a specific view; they were agnostic to the details of the individualized patient's mouth and were not patient-specific views. For example, the views shown below would be the same for a patient missing a canine as for a patient missing two molars or for a patient with all of their teeth.



Figure 8 Right Buccal View - In Occlusion.



Figure 9 Left Buccal View - In Occlusion.

EX2040 [Samawi], 29 (showing the same left and right buccal views, despite the teeth in the right view comprising an ectopically erupting upper right canine, a small white crown next to the upper right central incisor that is transposed (switched places) with the upper right lateral incisor, and the left view showing teeth with none of these issues).

28. ***Capturing Standard Orthodontic Photographs:*** As I explained above, as of 2017, these standard orthodontic photographs were captured by dental professionals during in-office patient appointments. To do this, the dental professional would position the patient for each image and employ a set of tools to aid in capturing the photographs. EX2040 [Samawi], 25¹ (discussing the “proper

¹ While Samawi states that there is no “standard” set of clinical photographs “that is universally approved,” it goes on to confirm that “it [could] generally be accepted - based on many practitioners’ opinions - that a complete ‘Clinical Photographic Set’ for any orthodontic patient at any stage of treatment, that would enable the clinician to obtain maximum benefit and information, should include a minimum of nine photographs; four extra-oral, and five intraoral photographs per set”—these are the same intraoral photographs that I have described above. EX2040 [Samawi], 25.

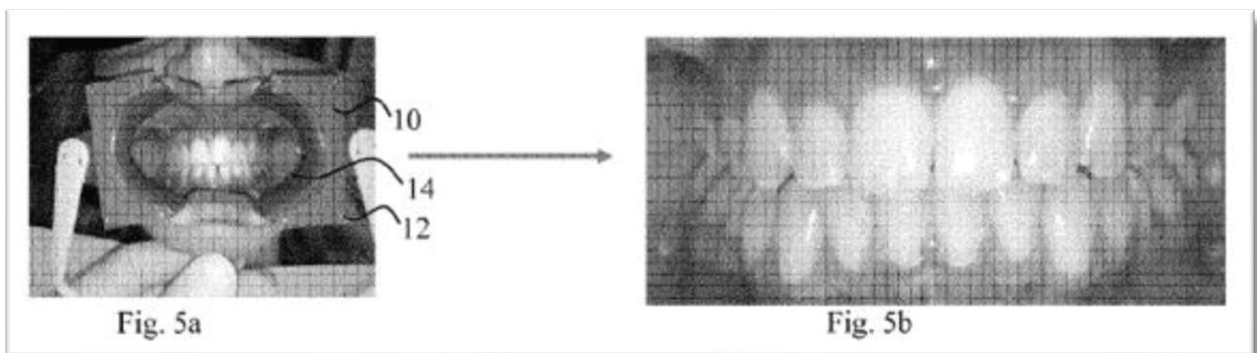
positioning of the patient and clinician”), 28-31 (discussing the proper patient positioning for each intra-oral photograph and how this was achieved by the dental professional).

29. First, a dental professional would use cheek retractors. *Id.*, 23-24 (noting that it was recommended to use a retractor), 28 (explaining that “[i]ntra-oral photographs [*i.e.*, photographs of the teeth, gums, and oral tissue] require the proper cheek retractors”). These were lubricated, inserted into the patient’s mouth, and rotated into position by the dental professional. EX2034 [IMI National Guidelines: Orthodontic Photography], 15 (“To help the retractors slide easily against the patient’s lips, either wet the retractors, by running under cold water, or ask the patient to lick their lips. . . . [P]lace the retractors on the lower lip first and then rotate them until their handles are horizontal”). The dental professional would then use the retractor to pull the patient’s lips away from the patient’s teeth to expose the required teeth while taking a photograph of each of the different views. *E.g.*, EX2040 [Samawi], 28 (describing the use of “the larger retractors from their wider ends to retract the patient’s lips sideways and outward, away from the teeth and gingivae”).

30. I have included below a photograph of a tooth retractor that I had in my clinic and that was available from Patent Owner Dental Monitoring in about 2018.



As can be seen from the figures in Salah, similar tooth retractors were available prior to the '248 patent and were used to expose the patient's teeth so that the required teeth could be photographed.



EX1008 [Salah Translation], Figs. 5A-5B (depicting a retractor (Fig. 5A) exposing a front view of teeth (Fig. 5B)).

31. As of 2017 (and long before), dental professionals would also use specialized mirrors that were inserted into the patient's mouth to allow them to capture photographs of the patient's teeth that were covered by the cheeks or lips. EX2040 [Samawi], 24 (explaining that "[m]any types of mirrors may be used for clinical photography"), 28 (explaining that "[i]ntra-oral photos require ... dental photography mirrors"). This is illustrated in the following page from the IMI national guidelines on orthodontic photography.

The Upper Occlusal View (See Figures 10a & 10b)

- A scale of 1:2 or 1:2.5 should be used, if the camera has a full frame sensor.
- Place one retractor over the upper lip and pull forward and upwards, away from the anterior teeth.
- If the patient has a large mouth and/or very fleshy lips, it may be necessary to use two retractors to hold the top lip away from the teeth (see fig. 9a).
- Place the mirror into the mouth, far enough back so that the molars can be seen.
- The mirror should be angled downwards, at 45° to the occlusal plane, with the lens axis of the camera at an angle of 45° to the mirror, in order to obtain a view that appears to be taken from 90° to the occlusal plane.
- The image from the camera should be rotated through 180° and flipped horizontally in order to provide a true image.



Figure 10a Camera, mirror and retractor alignment for the Upper Occlusal View



Figure 10b The Upper Occlusal View

EX2034 [IMI National Guidelines: Orthodontic Photography], 21 (showing insertion of a dental mirror, reflecting the maxillary teeth, to acquire one of the standard orthodontic photographs).

32. Once the patient, retractor, and mirror (if one was needed for the specific view) were in position, the dental professional in 2017 would acquire the standard set of images, typically with a DSLR camera setup. This setup usually comprised a DSLR camera, a specific type of lens, and a ring light. EX2040 [Samawi], 22 (“The ideal camera setup that is best-suited and recommended for clinical photography is a Digital Single Lens Reflex camera setup (DSLR) with a suitable Ring Flash unit.”). A DSLR camera was used to enable the acquisition of sufficiently high-quality images. A dedicated macro lens was known to provide improved close-up photographs, usually with higher definition and better focus. *Id.* (“[A] dedicated Macro lens attached to a DSLR camera provides even better close-up photos usually with higher definition and better focus, and is by far the superior choice.”). And the dedicated ring flash was used to illuminate the teeth while eliminating shadows, “which may obstruct important details.” *Id.*, 23.²

² I am aware that, prior to July 2017, some dental professionals had asked their patients to capture and send photographs of their teeth, but this was rare because of the skills and training generally required to acquire photographs with clinical utility and the challenges with using a cellphone to take dental photographs, not least because the cellphones existing as of 2017 took low quality pictures and because the patients were unable to control acquisition parameters (such as lighting, distance between the lens and teeth, etc.).

33. **Required Training:** Acquiring the standard orthodontic images required specialized training that dental professionals would begin in dental school and continue to receive throughout their careers. In the district court, Align’s dental expert Dr. Valley noted that she had to take required courses in dental photography as a dental student, resident, and in continuing medical education, and she confirmed that these courses taught the standard orthodontic photographs and their capture. EX2037 [Valley Report], 4. Dr. Valley’s testimony on this topic is consistent with my own experience. In 2017, I was the interim chair and program director of the Department of Orthodontics at UIC. I was also the clinical director and a tenured professor in the Department of Orthodontics at UIC. I recall that UIC dedicated a full semester to teaching dental image acquisition. Based on my experience, it was typical for dental schools to require dental students to learn to work with their patients; to use a variety of tools; and to master large, expensive, and complex DSLR cameras. I took these courses when I was in training, and we still teach those courses today.

34. First, a dental professional would need to learn proper patient care techniques (how to safely and professionally position the patient and place hands, retractors, and mirrors in the patient’s mouth). *E.g., id.* (“These courses taught camera and accessory (*e.g.*, cheek and lip retractor) usage, and correct dental photo composition.”). Second, the dental professional would learn to position the camera

relative to the patient and/or the mirror to capture the required view. Third, the dental professional would learn how to use the camera. For example, the dental professional would learn to adjust the camera's settings (aperture, shutter speed, ISO, and white balance) in order to capture each particular photograph with the requisite quality (including: focus, framing, and lighting). This step required a significant amount of training because each combination of camera, lens, flash, and ambient conditions could require specific adjustments. As such, camera companies provided specific guidance on how to adjust a particular camera setup to capture each dental photograph.



Retracted teeth apart & eyes (Incisal/interpupillary line relationship)	Lateral smile left & right
 • Camera settings: 1/200s, f/11, ISO 100 • APS-C camera: flash 1/2 power; lens set to distance of 1m • Full-frame camera: flash 1/4 power; lens set to distance of 0.7m • Point of focus: lateral incisor • A pair of retractors should be used	 • Camera settings: 1/200s, f/22, ISO 100 • APS-C camera: flash 1/2 power; lens set to 1:3 magnification • Full-frame camera: flash 1/4 power; lens set to 1:2 magnification • Point of focus: lateral incisor • The camera should be parallel to the tooth surface

Frontal smile anterior



- **Camera settings:** 1/200s, f/22, ISO 100.
- **APS-C camera:** flash 1/2 power, lens set to 1.3 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.2 magnification
- **Point of focus:** central incisors
- The camera should be parallel to the tooth surface

Retracted anterior in occlusion



- **Camera settings:** 1/200s, f/22, ISO 100
- **APS-C camera:** flash 1/2 power, lens set to 1.3 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.2 magnification
- **Point of focus:** lateral incisors.
- The camera should be parallel to the tooth surface
- Operator inserts retractors, patient retracts

Retracted right and left in occlusion



- **Camera settings:** 1/200s, f/22, ISO 100
- **APS-C camera:** flash 1/2 power, lens set to 1.3 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.2 magnification
- **Point of focus:** lateral incisors.
- The camera should be parallel to the tooth surface
- Operator inserts retractors, patient retracts but release retraction on the contra-lateral side

Retracted anterior teeth parted



- **Camera settings:** 1/200s, f/22, ISO 100
- **APS-C camera:** flash 1/2 power, lens set to 1.3 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.2 magnification
- **Point of focus:** lateral incisors
- The camera should be parallel to the tooth surface
- Operator inserts retractors, patient retracts

Retracted right and left in excursion



- **Camera settings:** 1/200s, f/22, ISO 100
- **APS-C camera:** flash 1/2 power, lens set to 1.3 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.2 magnification
- **Point of focus:** canines
- The camera should be parallel to the tooth surface
- Operator inserts retractors, patient retracts but release retraction on the contra-lateral side

Retracted right and left teeth parted



- **Camera settings:** 1/200s, f/22, ISO 100
- **APS-C camera:** flash 1/2 power, lens set to 1.3 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.2 magnification
- **Point of focus:** canines
- The camera should be parallel to the tooth surface
- Operator inserts retractors, patient retracts but release retraction on the contra-lateral side

Upper and lower incisors and canines



- **Camera settings:** 1/200s, f/29, ISO 100
- **APS-C camera:** flash 1/2 power, lens set to 1.2 magnification
- **Full-frame camera:** flash 1/4 power, lens set to 1.15 magnification
- **Point of focus:** lateral incisors
- The camera should be parallel to the tooth surface
- Operator inserts retractors, patient retracts
- A contrastor is used behind the teeth to clearly show the shape



EX2035 [Canon Dental Photography Guide] (explaining the specific settings for a particular camera setup).

35. ***Use of the Standard Orthodontic Photographs in Patient Care:*** This training and expertise in capturing the standard orthodontic photographs was needed to ensure that the photographs were clinically useful. In particular, the images needed to include all of the teeth required for the specific view and to be high quality for qualitative assessment.

36. Dental professionals relied on these images for many reasons, including to diagnose dental disease, monitor the progression of dental disease, determine a patient's eligibility for certain treatments, and monitor the progress of those treatments. For example, in my experience, an orthodontist might rely on the standard orthodontic photographs from a series of patient visits to monitor the condition of the teeth (*i.e.*, if there was decay or restoration), the relationship between one tooth to another, the shape of each clinical crown of each tooth (*i.e.*, if there was a broken crown or chipped incisal edges), the oral hygiene of the patient,

the healthiness of the gum, the status of the surrounding soft tissue (if there were any pathologic issues). The left and right photographs were typically used to identify the dental malocclusion (*i.e.*, teeth that were not properly aligned), classification of the case (Class I, II, and III) for molars as well as canines, and for a rough estimation of overjet (*i.e.*, the extent to which the top teeth protruded over the bottom teeth). The frontal photograph was also used to perform a rough estimate of overjet (*i.e.*, deep bite or open bite), while the upper and lower arch photographs were used to perform estimates of the amount of crowding or spacing as well as the location of each tooth and their alignment in relationship to the ideal dental arch. *E.g.*, EX2047 [Finlay] (“Diagnostically, the [buccal and anterior views] focus . . . on gingival architecture, intra-arch relationships of the teeth, some macro elements of smile design, and occlusal and incisal plane evaluation.” “Diagnostically, [occlusal views are] very beneficial in evaluating anterior restorations relative to facial anatomy, embrasures and line angles that affect reflective zones, and visual proportions of teeth when viewed from the anterior.”); EX2046 [Ahmad], 460-461 (explaining that dental images can be used for “examination, diagnosis, treatment planning,” “oral health,” “monitoring . . . pathological lesions,” “tooth movement,” and post-treatment outcomes). The standard orthodontic photographs were also important for record-keeping and to satisfy legal obligations. EX2046 [Ahmad], 459-460. A

poor-quality photograph or an incomplete photoset might not have been useful to the dental professional's qualitative determination.

V. ALIGNER TREATMENT

37. As of July 2017, use of clear aligners was an increasingly popular class of orthodontic treatment for tooth alignment. *See, e.g.*, EX2022 [Wheeler], 83-89. Aligners are a type of orthodontic appliance designed to exert gentle pressure to reposition a patient's teeth. At the time, aligners were known to be designed to progressively move teeth into positions desired by a dentist, orthodontist, or other dental professional. *See, e.g., id.* Set forth below is a summary of conventional aligner treatment as of July 2017.

A. Diagnosis

38. As of July 2017, aligner treatment generally began with a patient attending an in-person consultation with an orthodontist for an initial clinical examination to establish a proper diagnosis as to the patient's suitability for aligner treatment.³ This examination typically was conducted and obtained either by visual inspection and/or using in-office scanning technology.

³ Most aligner treatment was, and still is, provided by orthodontists. Some general practice dentists (sometimes referred to as doctors) were also trained to provide clear aligner treatment to their patients. In this declaration, I have generally referred to treatment as provided by orthodontists, but this should be understood to encompass the aligner treatment provided by any dental professional trained to provide such treatment.

39. If the orthodontist determined that the patient was a suitable candidate for aligner treatment, and if the patient chose to move forward with that treatment, the orthodontist would then conduct scans of the patient's starting dentition. These in-office scans were typically conducted on specialized machines employing various scanning technologies that generated digital three-dimensional models of a patient's dentition, and were conducted by an orthodontist or a specially trained technician. *See* EX2023 [Taneva], 147-80; *see also* EX1001, 27:26-33 ("Conventionally, at the start of an orthodontic treatment, the orthodontist determines the positioning of the teeth that he or she wants to obtain at a so-called 'set-up' instant of the treatment. The set-up may be defined by means of an imprint or from a three-dimensional scan of the teeth of the patient. The orthodontist then has manufactured, or manufactures, accordingly, an orthodontic appliance suited to this treatment.").

40. Based on these initial scans, a sequence of aligners would be designed and fabricated by one of several third-party companies, such as Petitioner. *See* EX1001, 27:35-47 ("An aligner conventionally takes the form of a removable single-piece appliance, conventionally made of a transparent polymer material, which comprises a channel conformed for several teeth of an arch, generally all the teeth of an arch, to be able to be housed therein. . . . At the start of the treatment, the shapes that the different aligners have to take at different moments of the treatment are

conventionally determined, then the set of corresponding aligners is manufactured. At predetermined instants, the patient changes the aligner.”).

B. Treatment

41. As of July 2017, aligner treatment typically involved three general categories of steps: (1) a patient wearing a series of aligners according to the treatment plan of their orthodontist; (2) an orthodontist assessing the progress of that treatment, including aligner fit, at regular intervals; and (3) an orthodontist adjusting the treatment plan as necessary.

1. Wearing the Aligners

42. Once the patient received their set of aligners, they would be required to wear their aligner until they were instructed to change from one aligner to the next to continue shifting their teeth according to the orthodontist’s treatment plan. *See id.* Orthodontists typically instructed patients to change aligners every one to two weeks. *See, e.g.,* EX2007 [Zhao], 1. The timing could, however, change depending on the nature of a patient’s dentition, their compliance with treatment protocols, and the fit of their aligners on their teeth. EX2024 [Tuncay], 263 (“Patient compliance is crucial in orthodontic treatment involving removeable appliances.”). In a clinically optimal setting, patients would be instructed to change aligners as soon as their current aligner became “passive”—that is, the patient’s dentition had shifted

sufficiently such that the current aligner was no longer applying any force to the patient's dentition.

43. As of July 2017, the most common orthodontist-prescribed interval for each aligner was one week. The typical one-week period for wearing a particular aligner was selected primarily because patients were found to be most compliant under a treatment regime with weekly aligner changes, even though one week (or seven days) might not necessarily be the clinically optimal amount of time a patient should wear each aligner. *See, e.g.*, EX2025 [Caruso], 10 (“The choice to change aligners every 7 days in an adult patient is strongly related to compliance[.]”). For instance, a patient's aligner might become passive in five days (before the one-week mark), but the patient would unnecessarily wait the few extra days to change their aligner at the one-week mark. Alternatively, if a patient exhibits slower dentition progression, they may have benefited from a longer change interval.

2. Assessing the Aligner Treatment

44. As of July 2017, effective conventional aligner treatment required frequent and regular in-person orthodontic examinations. Regular in-person examinations were necessary because aligners were changed frequently, rates of progress varied from person to person, and treatments varied in complexity depending on the specific starting and desired dentition for each patient. *See, e.g.*, EX1001, 17:39-43 (“It is desirable for each to regularly check his or her dentition,

particularly in order to check that the position of his or her teeth is not changing for the worse. In an orthodontic treatment, this change for the worse may in particular lead to the treatment being modified.”).

45. In addition, as of July 2017, conventional in-person aligner treatment examinations were performed every 10 weeks or so by an orthodontist. These in-person examinations did not involve quantitative measurements concerning aligner fit, nor did they involve making any quantitative measurements of separations between the aligner and the dental arch on a tooth-by-tooth basis.

46. Instead, conventional in-person aligner treatment examinations as of July 2017 involved two primary qualitative and subjective assessments at a patient’s examination: an assessment of alignment of teeth and an assessment of aligner fit.

47. For the first, orthodontists would visually inspect the current state of dentition (*i.e.*, the patient’s teeth) and compare that state to the anticipated dentition expected at that point in the aligner treatment. *See* EX1001, 27:55-59 (“At regular intervals, the patient goes to the orthodontist for a visual inspection, notably to check whether the displacement of the teeth conforms to the expectations and whether the aligner worn by the patient is still suited to the treatment.”). In other words, if a patient was on week 10 of their treatment, an orthodontist would make a visual comparison between the dentition observed on the patient and a visual rendering of expected dentition at week 10 for that patient. *See id.* If the actual dentition deviated

from the expected dentition, the orthodontist would examine the areas of deviation and assess what issues were causing dentition to progress differently than expected. These subjective visual inspections performed by orthodontists were susceptible to inconsistency and inaccuracy, for example, due to level of experience, length of the appointment, speed of review, number of patients seen, fatigue, etc. Reliance on periodic in-person examinations also meant that treatment issues could go undiagnosed for multiple weeks between check-ins.

48. Second, orthodontists assessed the aligner treatment. Typical issues that might be identified during the assessment included problems with aligner fit, tooth attachments, or dentition complications. *See, e.g.*, EX2026 [Glaser], 39-40, 275-76 (discussing various treatment features to be monitored at each visit); EX1006 (discussing monitoring by the orthodontist of aligner fit, dentition, and attachments). In addition, aligners might be too tight, overcorrect, or move a tooth in an unintended direction (*i.e.*, non-tracking) such that the movement would be detrimental to the patient. For example, if the aligner moves the tooth in the wrong direction, a patient could suffer from side effects such as periodontal defects (potentially severe gum complications) or fenestration of gingival recession (exposure of the tooth root due to bone loss).

49. Generally, a patient was asked to try on their current aligner, and each aligner was visually and manually examined for large gaps between the aligner and

the teeth. These gaps are referred to as aligner “unseats.” Using their hands, the orthodontist would manually examine the aligner for potential rocking (that is, movement of one part of the aligner off of a patient’s teeth when pressure is applied to another part of the aligner). A similar examination was then conducted using the next aligner in a patient’s sequence.

50. In his report, Dr. Foroosh cites to an online post by Dr. Scott Frey attempting to replicate Patent Owner’s 2017 product. EX1002, ¶¶73, 90 (citing EX1009). Dr. Frey’s post, from April 29, 2017, describes a “DIY Dental Monitoring Solution.” EX1009, 17-27. Frey teaches orthodontists to use Google forms and/or email to collect information from patients remotely (including videos of patients with and without their aligners seated), and to analyze that information for remote monitoring of orthodontic treatment. *Id.*, 18, 24, 26. Frey does not disclose any image analysis techniques, and thus a POSA would have understood Frey to suggest a visual inspection of the videos submitted by the patients.

51. I understand that Frey’s discussion of the remote evaluation of aligner fit using images recorded on a patient’s cellphone is not prior art because it comes from Dental Monitoring. In July 2017, it was not standard of care to rely on images of aligners in the service position, let alone images captured using a cellphone camera, to evaluate aligner fit. Rather, as I described above, assessing aligner fit

involved a combination of visual, in-person inspections and manual manipulation of the aligner, as described in Invisalign and also discussed above. EX1006.

3. Adjusting the Treatment Plan

52. When an orthodontist identified significant issues with dentition progression or with aligner fit at the in-person examinations, the orthodontist typically instructed patients to pause their aligner sequencing. The orthodontist would then re-image the patient's bite, which was conventionally conducted using in-office LiDAR (Light Detection and Ranging) scanning technology. Using these new scans, the orthodontist would then order a refined aligner sequence, which was intended to correct issues identified with dentition and/or aligner fit, and tell the patient to discard the old aligners. Fabrication and shipping of refined aligners typically would delay treatment by at least two, and often three, weeks. *See, e.g.,* EX1001, 27:60-67 ("If the orthodontist diagnoses an unsuitability to the treatment, he or she takes a new imprint of the teeth, or, in an equivalent manner, a new three-dimensional scan of the teeth, then orders a new series of aligners configured accordingly. It is considered that, on average, the number of aligners finally manufactured is approximately 45, instead of 20 aligners conventionally provided at the start of the treatment.").

53. Alternatively, where an orthodontist identified unseats that were not so significant as to require refined aligners, the orthodontist might prescribe "chewies,"

small rubber shapes to be chewed on in specific locations in the mouth, which could reduce unseats.

VI. PERSON OF ORDINARY SKILL IN THE ART WITH RESPECT TO THE '248 PATENT

54. I understand that Dental Monitoring has proposed that a person of ordinary skill in the art (“POSA”) as of the priority date of the '248 patent would have had a bachelor’s degree or higher in computer science, bioinformatics, or a related engineering discipline, and several years of work experience relating to the development of machine learning or artificial intelligence models or algorithms. A POSA would have also worked as part of a multi-disciplinary team, which includes individuals familiar with medical imaging, dental imaging, dentistry, and/or orthodontics.

55. In accordance with my understanding of the relevant law (discussed above at ¶¶17-19), I agree with this definition and have applied it in formulating my opinions. As a practicing orthodontist for over twenty years in July 2017, I met (or exceeded) the qualifications of a member of such a multi-disciplinary team as of the priority date of the '248 patent. In connection with my research relating to orthodontic diagnosis, treatment planning, and treatment through the use and implementation of 3D imaging technology, artificial intelligence, and machine learning, I have also worked as part of a multi-disciplinary team, which included

computer scientists and other individuals familiar with medical imaging, dental imaging, dentistry, and/or orthodontics.

56. I understand that Dr. Foroosh has opined that “a person of ordinary skill in the relevant field as of July 21, 2017 would typically have an advanced degree, such as a Masters’ Degree or Ph.D. in computer science or a related field, with at least two years of work in computer vision, image analysis, medical imaging, or related areas. A POSA could have less education but significant professional experience in one or more of these fields. A POSA could be a member of an interdisciplinary team including persons with backgrounds such as electrical engineering, computer science, optical imaging, and dentistry or orthodontics, and could call upon the knowledge of other team members as appropriate.” EX1002, ¶61.

57. The relevant field of the ’248 patent is aligner treatment. Thus, in my opinion, a POSA would have consulted with a member of an interdisciplinary team with experience in dentistry and/or orthodontics in order to understand the teachings of Kim, Invisalign and Salah, as well as Frey. This is because, as I discuss further below, those references concern technical details of orthodontic practice and/or dental imaging. Further, they discuss technical concepts from the dental field, and they use terms that would have had a specific meaning to dental professionals.

VII. ALIGN'S REFERENCES

A. The Invisalign Clinical Monitoring Guide ("Invisalign")

58. The Invisalign Clinical Monitoring Guide ("Invisalign," EX1006) describes the practice of in-person aligner treatment that was conventional as of July 2017. It was published by Petitioner "to help the Invisalign practitioner successfully monitor Invisalign treatments and address issues that may arise between receipt of Aligners from [Petitioner] to the completion of treatment." EX1006, i. "To prevent issues from occurring," Invisalign teaches orthodontists to "perform the following [certain steps] at every patient appointment." *Id.*, ii. It is clear that Invisalign is concerned with in-person treatment because it recommends that orthodontists have their "patients arrive with the previous stage Aligner and the current Aligner." *Id.* Invisalign also instructs orthodontists to perform steps in-office that could not be performed remotely or virtually, such as assessing tight contacts with floss and testing aligner retention with a dental scaler. *E.g., id.* (Instructing the orthodontist to "[e]valuate for tight contacts with unwaxed floss and relieve with finishing strips if present" at each appointment. This is something that could only be done in the office.); *id.*, 1 (Further instructing the orthodontist to use a scaler "to trim attachment flash as well as check retention." This is also something that could only be done in the office.). This is consistent with my discussion above, that during an in-office

appointment, a patient was generally asked to try on their aligner, and it was visually and manually examined.

59. Invisalign notes that a separation between the teeth and the aligner of greater than 1 mm can be considered a general aligner fit issue, but a separation less than that is a “natural deflection that should occur so the Aligner can move the tooth.” *Id.*, 1. Invisalign does not, however, disclose any method to accurately measure separation, even during an in-office appointment, nor does it disclose any method for assessing aligner fit other than visual approximation. It also does not specify whether the 1 mm threshold should be assessed at a particular location on the teeth or at multiple locations. Consistent with my experience providing aligner treatment in July 2017, a POSA would have understood Invisalign to suggest only that an orthodontist perform a qualitative visual or manual in-person approximation of the aligner fit. This method is subjective, and as noted above, it can produce inconsistent and inaccurate results due to factors including the level of experience, length of the appointment, speed of the review, number of patients seen, and fatigue. In my experience, an orthodontist in July 2017 could not reliably and consistently distinguish in-person between, for example, separations of 0.9 mm (on-track treatment) and 1.1 mm (off-track treatment) based on the visual examination taught in Invisalign. For this reason, Invisalign suggests that, in the case of a separation

that *appears* to be less than 1 mm, the orthodontist should simply continue to monitor aligner fit. *Id.*

60. Invisalign does not teach or suggest any method for remote or virtual assessment of aligner fit that could be performed in between in-office orthodontist check-ups, and I am not aware of any product that Petitioner offered in 2017 that could have been used to remotely or virtually assess aligner treatment progress. Although Invisalign includes certain photos, a POSA would have understood that these photos were simply examples of what an orthodontist might observe during an in-person appointment. *Id.*, 1. There is no suggestion in Invisalign that those images were taken remotely, for example, using a cellphone, or that such images could be used for the remote or virtual assessment of aligner treatment.

61. Dr. Foroosh relies on the below example from Invisalign, which Invisalign describes as “Aligner seating poorly, >1mm.”

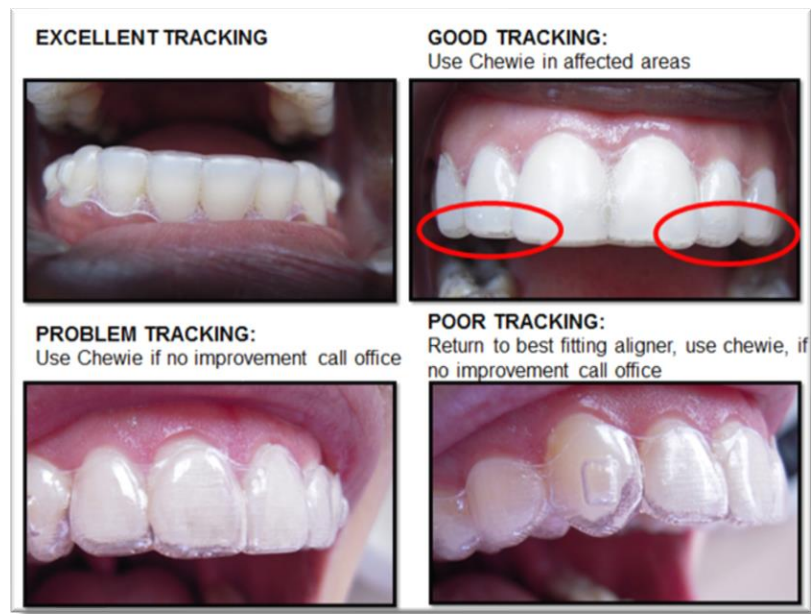


Id., 1. In my opinion, based on my experience, this is an aligner that has been partially inserted to demonstrate the gap between teeth and aligners and is not

representative of an aligner fit situation that would have been encountered by an orthodontist in 2017. When the patient inserts an aligner, they must ensure that each portion is equally and fully inserted. Thus, it was unusual to encounter an aligner as in Invisalign Figure A having approximately even separation on each tooth; in such cases, the patient could typically apply pressure to reduce the separation for all teeth. A POSA would also have recognized that most aligner unseats would have a substantially less visible gap and that an unseat would generally be detected and addressed well before reaching the extreme level of separation shown in the above image.

62. Reproduced below are images I obtained from various publicly accessible websites that better represent typical aligner fit. Although these images post-date the '248 patent, based on my nineteen years of experience as an orthodontist as of 2017, they are representative of what an orthodontist would have observed in that timeframe during in-person in-office consultations with their clear aligner patients. In the first set of images below (EX2055 [Making Sure Your Invisalign Aligners Fit Correctly], 2), the separation between the aligner and the teeth is significantly less than in the image from Invisalign. The “GOOD TRACKING” photograph on the top-right illustrates an aligner that fits relatively well, but that is still in need of some intervention (the use of chewies). Here, the small separation is difficult to detect even with these high-quality photographs and

it appears that the authors of the website thus felt it necessary to highlight the separation between the incisors and the aligner. *Id.* Even the “POOR TRACKING” photograph (bottom-right) is not as extreme as the photograph from the Invisalign reference, even though the website authors suggest replacing that aligner entirely with a different aligner. *Id.*



Id. When patients had aligner fit issues in 2017, it was most common to see poorly fitting aligners that resemble the “PROBLEM TRACKING” photograph above. However, whether a patient developed aligner fit issues in 2017 (and still today) depended on several situational factors, including the type of tooth (lateral incisors generally do not track as well, for example), the type of attachment design, the type of tooth movement desired, and patient compliance. Not all patients in 2017 developed aligner fit issues and so it was common for an orthodontist to observe an

aligner that resembled “EXCELLENT TRACKING” or “GOOD TRACKING” when the patient visited the orthodontist for an in-person appointment.

63. Similarly, the post-2017 photograph reproduced below shows separation that, based on my many years of experience, I would categorize as unseated and requiring adjustment or replacement. EX2063 [Clear aligner therapy], 1. In this image, the separation is much harder to detect from a photograph than the exaggerated example of separation shown in Invisalign. Importantly, the separation cannot be assessed with precision even though this appears to be a high-quality photograph taken with controlled lighting and acquisition conditions, and not a patient-created cellphone image.



Id. Petitioner itself appears to recognize the extreme and artificial nature of the Invisalign image relied on by Dr. Foroosh, as it depicts an aligner that does not “fit at all” with significantly smaller gaps between the aligner and the teeth.

The Aligners don't fit at all.

	ROOT CAUSES	SOLUTIONS	REFERENCES
A  <i>Aligners that do not fit properly</i>	BEGINNING TX ONLY: Check to make sure patient was given correct Aligner <i>see fig. B</i> Prevention Note 1.10	BEGINNING TX ONLY: Try next Aligner first (read imprint on Aligner); otherwise, call Customer Support for additional troubleshooting; may require new impressions and Mid-Course Correction.	

EX1006, 6.

64. In reality, there was no way to make quantitative evaluations of aligner fit from visual inspection of a digital image in 2017. For example, Invisalign's example of an "[a]ligner seating well" (reproduced below) shows a gap between the aligner and the teeth that is supposedly less than 1 mm, and is a much better example of what orthodontists typically observed during the normal course of treatment.

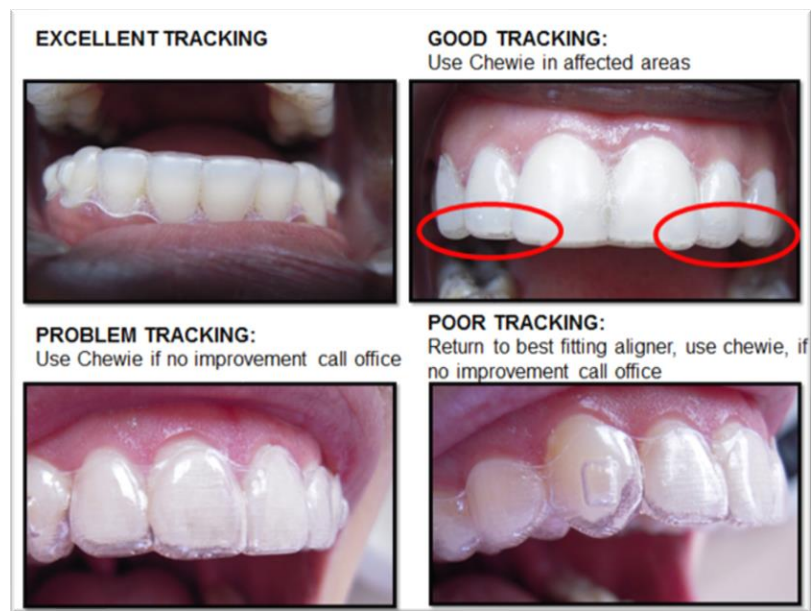


Id., 1. The visual difference in separation between that image and a typical unseated or poorly-seated aligner⁴ was not readily quantifiable, let alone to a specific 1 mm

⁴ The terms "unseated," "untracked," and "poorly seated" are synonyms that refer to aligners that are not tracking as prescribed.

threshold. From my experience, there was no method to determine a separation quantitatively, and instead, orthodontists relied on visual approximations.

65. Furthermore, as is apparent from the images reproduced below, the separation between teeth and aligner frequently varies significantly depending on the tooth observed. EX2055 [Making Sure Your Invisalign Aligners Fit Correctly], 2 (for example, the “PROBLEM TRACKING” photograph in the bottom left appears to fit better on the patient’s left side, but poorly on the patient’s right side).



Id.

66. Given the practice to perform a holistic evaluation of aligner fit, including through a visual and manual inspection, an orthodontist would have understood Invisalign to teach a general assessment of fit based on an orthodontist’s best judgment, and not a specific 1 mm cut-off between “bad” and “good” fit.

67. In my opinion, the images in Invisalign were likely captured with a DSLR camera (or even a film camera) and with controlled conditions and lighting to achieve the requisite high-quality of this image type. EX2040 [Samawi], 22 (“The ideal camera setup that is best-suited and recommended for clinical photography is a Digital Single Lens Reflex camera setup (DSLR) with a suitable Ring Flash unit.”). Indeed, Dr. Foroosh states that Invisalign was published in 2003. EX1002, ¶47. As of 2003, cellphones were not used to capture dental images because they could not be used to capture the necessary high-quality dental images. EX2056 [Apple Reinvents the Phone with iPhone], 4 (noting that the first iPhone was released in June 2007). Invisalign makes no suggestion that any image was taken using a cellphone, including by an untrained person, nor does Invisalign suggest that aligner fit should be remotely assessed from images, *e.g.*, those acquired using a cellphone.

68. Finally, a POSA would have understood the teaching in Invisalign to submit high-quality records, including photos, to refer to the need to collect in-office accurate information to design and manufacture the aligners. EX1006, iii. As I explained above, if the patient chose to move forward with aligner treatment, the orthodontist would conduct scans of the patient’s starting dentition, and based on these initial scans, a sequence of aligners would be designed and fabricated. See § V.A. Invisalign teaches that a “root cause” of fit issues is a “[d]istorted initial impression,” and therefore advises orthodontists to “[i]mprove quality of initial

records.” EX1006, 1. The PVS impressions and photos discussed in Invisalign were an alternative to such scans that could also be used to design and manufacture aligners.

69. For all of these reasons, unlike the ’248 patent, in my opinion, Invisalign does not suggest acquisition of images showing an aligner inserted on patient’s teeth for the purposes of assessing aligner treatment or any method for remote assessment of aligner fit in between in-office orthodontist check-ins. Rather, Invisalign teaches that aligner fit should be performed in-person, and it describes a method for assessing aligner fit that cannot be performed virtually or remotely. Invisalign also does not disclose any method or tool for making any quantitative measurements of separations between the aligner and the dental arch.

B. U.S. Patent Publication No. 2017/0281313 to Kim (“Kim”)

70. I have reviewed U.S. Patent Publication No. 2017/0281313 to Kim (“Kim”), which is entitled “Method and System for Providing Remote Teeth Alignment Services and Computer-readable Medium on which the Method is Recorded.” Kim is directed to the problems that could occur when a patient was not capable of frequently visiting the orthodontist by providing a way to assess “teeth alignment” remotely. EX1005, [0009], [0010]. A POSA would have understood that Kim teaches methods for a dental professional to obtain two things: information

about a patient's teeth without an aligner and information about a clear aligner on its own.

71. **First**, Kim relates to a method for a dental professional to remotely determine the alignment of teeth without an aligner as a method for evaluating the progression of treatment. *Id.*, [0008], [0010] (Disclosing a method allowing “a dentist to accurately check the state of [a patient's] teeth and determine a currently appropriate step of a clear aligner.” In other words, a dentist may “remotely and accurately diagnose the condition of the patient based on the teeth alignment information, and may remotely provide information about an accurate step of a clear aligner to be currently worn by the orthodontic patient.”). Assessing alignment of teeth refers to the evaluation of the patient's dentition to determine whether the orthodontic treatment is progressing as planned. This was a routine part of orthodontic treatment in 2017 that was carried out regardless of the specific type of orthodontic treatment (braces, aligners, retainers, etc.) that the patient was receiving.

72. In particular, Kim discusses the use of “teeth alignment report information” sent by the patient may include “a front-view teeth photo, a bottom-view low-angle teeth photo, a front-view automatically-recognized mouth gag photo, a front-view automatically-recognized face contour photo, a left-side-angle automatically-recognized mouth gag photo, a left-side-angle automatically-recognized face contour photo, a right-side-angle automatically-recognized mouth

gag photo, a right-side-angle automatically-recognized face contour photo, a collection of top, bottom, left, and right side photos surrounding a central front photo, a low-angle upper jaw photo, a high-angle lower jaw photo, and combinations thereof, which are taken using a camera of the orthodontic patient terminal.” *Id.*, [0013]. A POSA would have understood that the teeth alignment information report contains photos of the patient’s teeth without an aligner for purposes of assessing whether the treatment is progressing. As I explained above, orthodontists would visually inspect the current state of dentition (*i.e.*, the patient’s teeth) and compare that state to the anticipated dentition expected at that point in the aligner treatment in order to assess treatment progress in 2017. Clear aligners, however, mask the teeth making it difficult to perform an assessment of their position when an aligner is inserted on the patient’s teeth. A POSA would have recognized that this is why Kim discloses the use of only images of the patient’s teeth (without an aligner in place) for the purposes of assessing tooth alignment.

73. None of the disclosures in Kim as a whole or in Kim’s discussion of the teeth alignment information report would have suggested to a POSA that an aligner was on the teeth in such images. *E.g.*, *id.*, [0056] (discussing acquisition of images of the patient’s teeth, while omitting any mention of a clear aligner), [0081] (same), [0087] (same), Figs. 8-13 (depicting images of the patient’s teeth without aligners), 16 (same), 19 (same), 23 (same). Kim never purports to provide a new method of

assessing aligner fit from a photograph, let alone explains how that could be done. Kim is instead consistent with the practice at the time, *i.e.*, that images of aligners inserted on teeth were not used to remotely assess orthodontic treatment or aligner fit. And, to assess the progress of a patient’s aligner treatment, the position of the patient’s teeth was compared with their expected position at that point in the aligner treatment. *See* § V.B.

74. **Second**, Kim relates to a method for a dental professional to obtain information about an aligner on its own. For example, Kim explains that an orthodontist may obtain “clear aligner information” by checking “a photo or a video of the clear aligner currently worn by the orthodontic patient, and determine[] whether the clear aligner is normal and corresponds to an appropriate step.” *Id.*, [0066]. Unlike its use of “teeth alignment information”—which the dental professional may use to “remotely and accurately diagnose the condition of the patient”—a POSA would have understood the disclosure that “the clear aligner is normal and corresponds to an appropriate step” is about the condition of the aligner on its own. *Compare id.*, [0093], with [0066]. Namely, a POSA would have understood the language in paragraph [0066] to refer to whether the aligner on its own is the correct aligner and whether the aligner has abnormalities, such as damage.

75. None of the disclosures in Kim as a whole or in Kim’s discussion of the clear aligner information report would have suggested to a POSA assessing aligner

fit from an image of a patient wearing their aligner. Rather, a POSA would have known that aligner fit issues were often difficult to detect with the naked eye, especially when they had only just begun to emerge, and thus, in-person manual manipulation of the aligner was used to assess fit. Kim nowhere describes acquiring images or a video with an aligner inserted on patient's teeth and Kim discloses a method that uses images acquired using the patient's cellphone. EX1006, [0010], [0013], [0093]. A POSA would have recognized that images captured according to the disclosure in Kim—by an untrained person using a cellphone in 2017—would not be expected to be of high quality. Although Kim discloses a program to provide guidance to the patient on positioning their head or teeth and that can automatically recognize the patient's head or teeth (*id.*, [0014]), there is no disclosure of any guidance on how to acquire an image with an aligner inserted on teeth.

76. Additionally, an orthodontist would have understood Kim to teach that the teeth alignment information, and not the clear aligner information, be used to diagnose patients. Kim instructs that orthodontists should use the photographs of teeth in the teeth alignment information report to assess alignment such that “an orthodontist may obtain accurate teeth alignment information using a device, *e.g.*, a smartphone, of an orthodontic patient, [and] may remotely and accurately diagnose the condition of the patient based on the teeth alignment information.” *Id.*, [0093]; *see also id.*, [0010] (“The present invention provides a method and system for

providing remote teeth alignment services, by which an orthodontist may ... remotely and accurately diagnose the condition of the patient based on the teeth alignment information”); [0085] (“the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal”), [0087] (“the orthodontist may remotely provide accurate diagnosis by checking [the various photos] capable of showing the teeth alignment state of the orthodontic patient”); [0063] (“the orthodontist accurately determines a current teeth alignment state . . . and advises, for example, an appropriate step of a clear aligner to be currently worn by the orthodontic patient.”). A POSA would not have understood Kim to suggest assessing aligner fit from a photograph. Assessing aligner fit is different from assessing teeth alignment. As I explained above, assessing alignment of teeth refers to the evaluation of the patient’s dentition to determine whether the orthodontic treatment is progressing as planned. Assessing aligner fit refers to an evaluation of the aligner to ensure that it was thermoformed to the appropriate shape to exert sufficient pressure on the patient’s teeth to move them into the desired position. In 2017, assessing aligner fit typically involved a combination of visual and manual inspections performed by an orthodontist during in-person appointments.

77. Kim also instructs orthodontists to order new aligners from the manufacturer using the teeth alignment information, and not the clear aligner information. *Id.*, [0067] (“The clear aligner manufacturing program 70 may be a

program for transmitting the clear aligner manufacturing information to the clear aligner manufacturer terminal 30 ***upon determining that an additional or modified clear aligner is needed, based on the teeth alignment report information***) (emphases added); *see also id.*, [0020] (“the method may further include (g) transmitting the clear aligner manufacturing information to the clear aligner manufacturer terminal upon determining that an additional or modified clear aligner is needed, based on the teeth alignment report information using the clear aligner manufacturing program”); [0010] (“the teeth alignment information may be easily used by the orthodontist by providing the teeth alignment information in the form of report information and classifying the teeth alignment information based on time, [and] teeth alignment may be precisely performed in a customized manner by providing manufacturing information to a clear aligner manufacturer when an additional or modified clear aligner is necessary”). This is consistent with the general practice at the time to use images of patient’s teeth, not aligner images, to design and manufacture clear aligners.

78. Lastly, Kim instructs orthodontists to perform at most a visual inspection of the teeth alignment information and/or clear aligner information, and does not disclose any image analysis techniques other than that visual inspection.

79. For all of these reasons, unlike the ’248 patent, in my opinion, Kim does not suggest acquisition of images showing an aligner inserted on patient’s teeth for

the purposes of assessing aligner treatment or any method for remote assessment of aligner fit. Kim also does not disclose any method or tool for making any automatic or quantitative assessment of separations between the aligner and the dental arch.

C. PCT Publication No. WO2016066651 to Salah et al. (“Salah”)

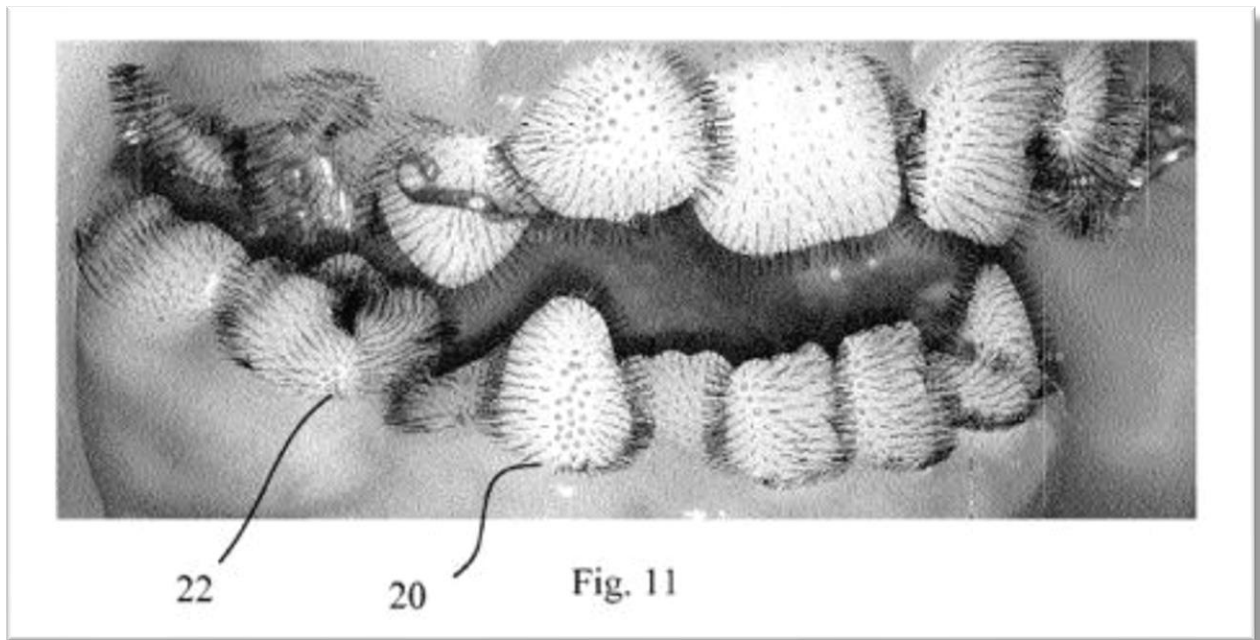
80. I have reviewed PCT Publication No. WO2016066651 to Salah et al. (“Salah”), which is entitled, “Method for Monitoring Dentition.” Salah is directed to taking an updated two-dimensional (“2D”) image of a patient’s teeth, comparing that image to a three-dimensional (“3D”) digital reference model, and thereby monitoring the positioning, shape, and/or appearance of a patient’s teeth. EX1008, 1:1-2:19.

81. A POSA would not have understood Salah to disclose a method for assessing aligner fit nor found any reason to do so in the text of Salah. Salah is about tracking the movement of teeth, not the apparatus moving them. In other words, Salah merely teaches a method for monitoring the movement of a patient’s teeth over time as a result of orthodontic treatment. *Id.*, Abstract (describing “a method for monitoring the positioning and/or shape and/or appearance of a patient’s **teeth**”) (emphasis added); *see also id.*, 1:12-22 (describing the importance of assessing the results of orthodontic treatment, not the fit of a dental appliance), 8:19-25 (“In particular, the method can be used during orthodontic treatment, especially to monitor progress,” and “[t]he procedure can also be used after orthodontic treatment,

to check that the positioning of the teeth is not changing unfavorably”); 46:15-24 (describing “remotely monitor[ing] the progress of an orthodontic *treatment*”) (emphasis added).

82. As I explained above, assessing aligner fit is different from assessing teeth alignment. Assessing alignment of teeth refers to the evaluation of the patient’s dentition to determine whether the orthodontic treatment is progressing as planned. Assessing aligner fit refers to an evaluation of the aligner to ensure that it was thermoformed to the appropriate shape to exert sufficient pressure on the patient’s teeth to move them into the desired position. Salah is only concerned with assessing the position of teeth over time, it does not teach or suggest assessing aligner fit from an image or disclose a way to conduct such an assessment.

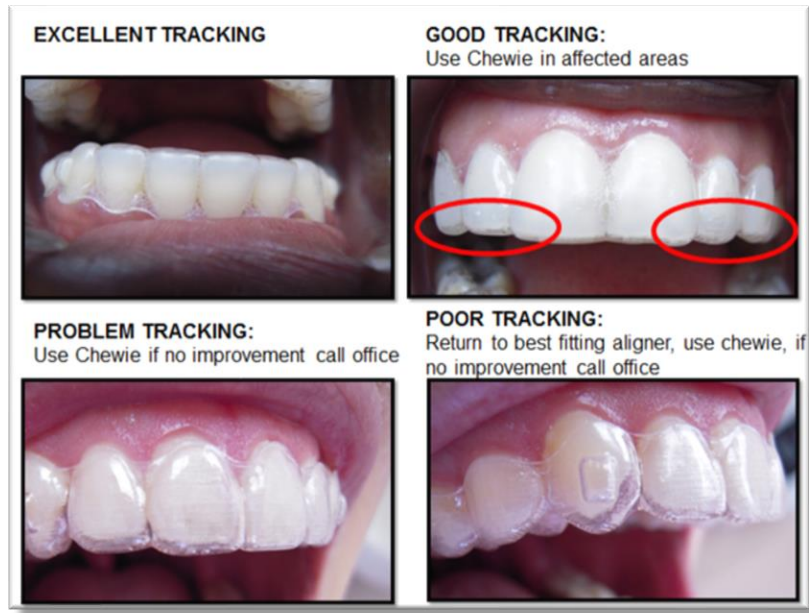
83. In fact, the only indication in Salah of an interaction between a device and teeth is a single figure showing teeth with a bonded expander anchored to the patient’s teeth.



Id., Fig. 11 (showing a bonded expander—not a clear aligner—anchored to the depicted teeth). Dr. Foroosh mistakes this as a broad disclosure of acquiring images with an orthodontic appliance. EX1002, ¶89 (“Salah similarly teaches acquiring dental images with a cellphone, including of teeth fitted with orthodontic appliances.”). But a POSA in 2017 would not have understood Salah in this way. The device shown in Figure 11 of Salah is a bonded expander. A POSA would have understood that bonded expanders, like the one in Figure 11, could not be removed by the patient before taking a picture and thus, Salah teaches that its assessment of tooth movement can be used despite a device affixed to the teeth. *Id.*, 64:29-32 (“[A]s shown in figure 11, vectors (black dashes 20) of equal length, perpendicular to the 30 faces of the reference model, **can be** projected onto the reference image. Circles 22 represent these vectors when viewed along their length. The reference

map is thus formed by these black lines 20 and circles 22.’”) (emphases added), 19:18 (“figure 11 shows a reference map prepared to show reflection information,” despite the presence of a device), 64:7-8 (“figure 11 shows a reference map superimposed on the acquired image, relating to reflection information (discriminant information)”). Salah does not suggest that the device itself is evaluated or that this evaluation of reflection information could be performed with an aligner in place.

84. Finally, while Salah does show an image with a device, it never discusses images with removable clear aligners, nor the unique challenges that imaging and analyzing clear aligners would have posed to orthodontists, let alone lay persons. The image processing of Salah is used to “detect high contrast regions,” whereas a clear aligner has very low contrast with the patient’s teeth. *E.g., id.*, 34:5-36:14. For example, as shown in the image below, both the teeth and the aligner appear as light colored. In particular, the edges of the aligner (which appear more white than translucent) are nearly the same color as the teeth. In the case of the “EXCELLENT TRACKING” and “GOOD TRACKING” photographs, the teeth and aligners are (by design) nearly-indistinguishable from a photograph alone because they are intended to visually blend with the teeth.



EX2055 [Making Sure Your Invisalign Aligners Fit Correctly], 2. Thus, nothing in Salah would have guided a POSA to acquire an image of teeth with a clear aligner, let alone evaluate such an image, particularly to measure aligner fit.

VIII. DEEP LEARNING IN DENTAL PHOTOGRAPHY

85. As explained above, in July 2017, orthodontists did not rely on images of aligners in the service position, let alone images captured using a cellphone camera, to evaluate aligner fit.

86. The use of deep learning or machine learning in the acquisition and/or analysis of dental photographs had not been accepted by the dental community as of July 2017. As Align’s dental expert, Dr. Valley, has previously opined, “the dental and orthodontic field” is “a very conservative field,” and “[i]t takes a while before new methods become mainstream.” EX2036 [Valley Dep. Tr. IPR-2019-000132],

50:3-5, 50:19-24 (“Again, as I mentioned, even if the technology was out there -- and I’m -- I don’t know what technology was out there or I can’t opine on that today. I wasn’t asked to. But it takes a while for a conservative group of people -- that is, those in the dental art -- to take in new technologies.”). This is because our decisions to adopt new technologies impact patient outcomes. As a field, we were thus very cautious to change how we did things.

87. Nonetheless, I understand that Dr. Foroosh opines that a POSA would have been motivated to train a neural network for use in the analysis of aligner fit using a learning base comprising “far more than 1000 images” including “over 10,000 images” aligners in the service position taken on a cellphone. EX1002 at, *e.g.*, ¶¶122-23. I disagree. A POSA would have believed that obtaining such a learning base would require a tremendous undertaking in 2017. As an initial matter, a POSA would have needed to obtain 10,000 or more labelled cellphone photographs of aligners in the service position or captured and labeled those photographs themselves. EX2054 [Foroosh Tr.], 154:3-156:10. Dr. Foroosh has not identified any database of such images that was publicly available in 2017. *See* EX2010 [Liu], 1072 (emphasizing that, even in 2021, “[c]ompared to other medical fields, the high-quality datasets for orthodontic research [were] limited.”). Indeed, cellphones were not generally used to capture **any** dental photographs at this time, let alone photographs of aligners in the service position.

88. Dental professionals are also not permitted to use patient images that are identifiable due to ethical, regulatory, and legal restrictions, such as HIPAA. Thus, the images would have needed to be anonymized, which can take a significant amount of time (up to about 30 minutes) per image. This process involves redacting identifiable features of a patient's face, removing patient identifying information and metadata, and assigning unique and random identifiers to the image. Having recently been involved in projects that required anonymization of dental images, I know that the cost of anonymization can exceed \$100,000 per practice for datasets that are smaller than the 10,000 at issue here. A POSA also would have known that there may be yet further costs and barriers, such as consultations with an attorney to ensure that the redacted images comply with the applicable legal and regulatory requirements. If these costs were cleared, a dental professional would still need to label the images.

89. A POSA would have understood that labeling photographs with any dental feature would normally have required a dental professional or dental training. For example, as described above, it is challenging to visually identify with precision the gap between tooth and aligner edge, and a POSA would have recognized the need for a dental professional who has significant experience evaluating aligner fit to annotate the photographs so that they are sufficiently accurate to train the deep learning device. Therefore, a POSA would have believed that it could have cost

hundreds of dollars per hour for a dental professional to undertake the labeling. *See, e.g.,* EX2032 [2023 Economics of Orthodontics Analysis Reporting on 2022 Practice & Patient Statistics], 17 (explaining that roughly half of orthodontists earn over \$300,000 per year).

90. For all of these reasons, in 2017, this process of obtaining a learning base for use in evaluating aligner fit would have been expected to be costly and complicated.

IX. CONCLUSION

91. For the reasons discussed above, it is my opinion that Dr. Foroosh has misunderstood how key features of Invisalign, Kim, and Salah would have been understood by a POSA.

I, Budi Kusnoto, do hereby declare and state, 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, under Section 1001 of Title 18 of the United States Code.

I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct.

Executed July 12, 2024, in Chicago, Illinois.

/ BUDI KUSNOTO /
Dr. Budi Kusnoto