

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. IPR2023-01369

U.S. Patent No. 10,755,409

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

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EXHIBIT LIST

Exhibit Number	Description
2031	Curriculum Vitae of Budi Kusnoto, D.D.S., M.S.
2032	American Association of Orthodontists, <i>2023 Economics of Orthodontics Analysis Reporting on 2022 Practice & Patient Statistics: Member Report</i> (Aug. 28, 2023)
2033	American Board of Orthodontists, <i>Ideal Photographs and Radiographs</i>
2034	American Board of Orthodontists, <i>Information for Candidates: "Orange Book"</i> (6d ed., May 2001)
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)
2039	J. Liu et al., <i>Machine Learning in Orthodontics: Challenges and Perspectives</i> , 30(10) Adv. Clin. Exp. Med. 1065 (2021)
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)

I. INTRODUCTION

1. I have been retained by counsel for 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. 10,755,409 (“the ’409 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.

II. BACKGROUND

A. Qualifications

2. My qualifications are summarized below and are presented in more detail in my professional CV (EX2031). Additionally, the following overview of my background pertains to my qualifications for providing expert testimony in this matter.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

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

- Morris R, Hoye L, Elnagar M, Atsawasuwan 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).

9. 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.”

10. 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.

11. 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

12. 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

13. 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 the Carrier Provisional (EX1006), Carrier (EX1005), and Salah (EX1008).

14. 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

15. 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

16. 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.

17. 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.

18. My specific understanding of a POSA with respect to the field of the ’409 patent is summarized below. *Infra* ¶¶26-29.

B. Date of Invention

19. 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).

20. 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.

21. I understand that neither Align nor Dr. Foroosh have disputed the priority date of July 21, 2017 for the '409 patent.

C. Prior Art

22. 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. SUMMARY OF OPINIONS

23. As of the priority date of the '409 patent, there was a standard set of orthodontic dental photographs that were captured by dental professionals during in-office patient consultations, generally using a DSLR camera setup. Specialized training and experience were required to capture these images because they needed to include all of the teeth required for the specific view and to be of sufficiently high quality for a qualitative assessment. Dental professionals relied on these images for many reasons, including to diagnose and monitor the progression of dental disease. At this time, cell phones were not typically used to acquire high quality dental photographs, and deep learning or machine learning was not in use in the acquisition of dental photographs. Dr. Foroosh has not identified any prior art that suggested

such a use of deep learning or machine learning in the acquisition of dental photographs.

24. For the reasons discussed below, the Carrier Provisional is directed to methods and apparatuses for (1) **dental professionals** to capture (2) a **standard set of dental photographs** (3) using a **mobile phone**, (4) with **real-time** guidance, (5) using contour detection performed by a computer program running on the mobile phone. It does not provide a written description of claim 1 of Carrier because the Carrier Provisional does not disclose a method for guiding patients to acquire dental photographs using a cell phone associated with the patient. Salah is directed to a method for monitoring the positioning, shape, and/or appearance of a patient's teeth using a three-dimensional ("3D") digital reference model, taking an updated two-dimensional ("2D") image of the patient's teeth, and updating the 3D reference model based on the image.

25. In my opinion, it would have been appropriate and, in fact, necessary, for a POSA to consult with a member of an interdisciplinary team with experience in dentistry or orthodontics in order to understand the teachings of the Carrier Provisional and Salah. This is because, as I discuss further below, both references concern dental imaging, they discuss technical concepts from the dental field, and they use terms that would have had a specific meaning to dental professionals.

26. It is my opinion that Dr. Foroosh has misunderstood how key features of the Carrier Provisional and Salah would be understood by a POSA. For example, a POSA would not, as Dr. Foroosh suggests, have understood the Carrier Provisional to suggest that an individual tooth should be detected by an image recognition algorithm. Additionally, to the extent Dr. Foroosh is arguing that a POSA would have been motivated to modify the Carrier Provisional or Salah to improve the accuracy of its alignment technique, I disagree because both the Carrier Provisional and Salah expressly state that the alignment during the image acquisition process need only be approximate. A POSA would have instead understood that improving the accuracy of the alignment technique would not result in an improvement in the operation of either the Carrier Provisional or Salah.

V. PERSON OF ORDINARY SKILL IN THE ART

27. I understand that Dental Monitoring has proposed that a person of ordinary skill in the art (“POSA”) as of the priority date of the ’409 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.

28. In accordance with my understanding of the relevant law (discussed above at ¶¶15-16), 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 '409 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.

29. 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, ¶70.

30. In my opinion, it would have been appropriate and, in fact, necessary, for a POSA to consult with a member of an interdisciplinary team with experience in dentistry and/or orthodontics in order to understand the teachings of the Carrier Provisional and Salah. This is because, as I discuss further below, both references concern dental imaging, they discuss technical concepts from the dental field, and they use terms that would have had a specific meaning to dental professionals.

VI. STATE OF THE ART

A. Dental Photograph Acquisition

31. Below, I discuss the state of the art with respect to standard orthodontic photographs.

32. ***The Standard Orthodontic Photographs:*** For decades prior to the '409 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:



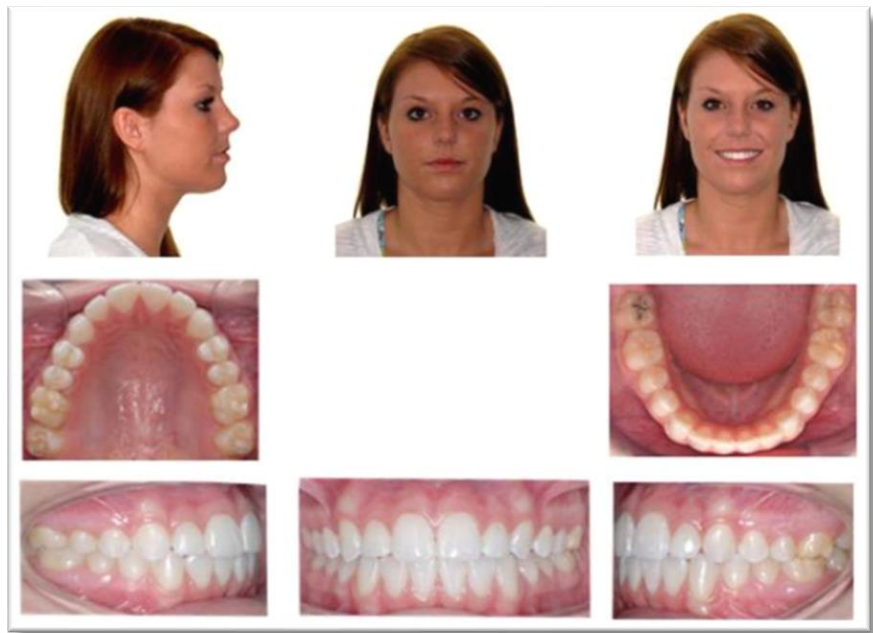
- An occlusal view of a patient's mandibular (bottom) teeth:



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).

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

34. 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).

35. ***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. *Id.*, 25¹ (discussing the “proper positioning of the

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’

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

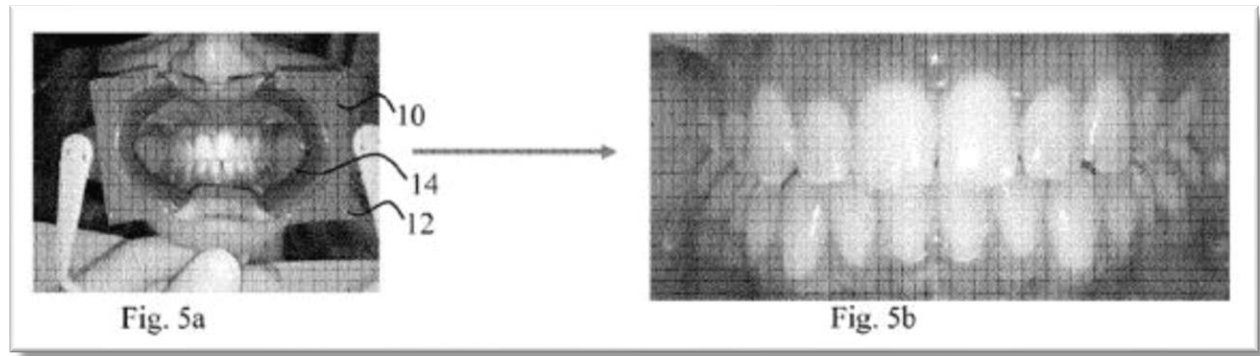
36. First, a dental professional would use cheek retractors. *Id.*, 23-24 (noting that it was recommended to use a retractor), 28 (explaining that “[i]ntra-oral photographs [*i.e.*, photographs of the teeth, gums, and oral tissue] require the proper cheek retractors”). These were lubricated, inserted 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”).

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, 25.

37. 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 and the Carrier Provisional, similar tooth retractors were available prior to the '409 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)).

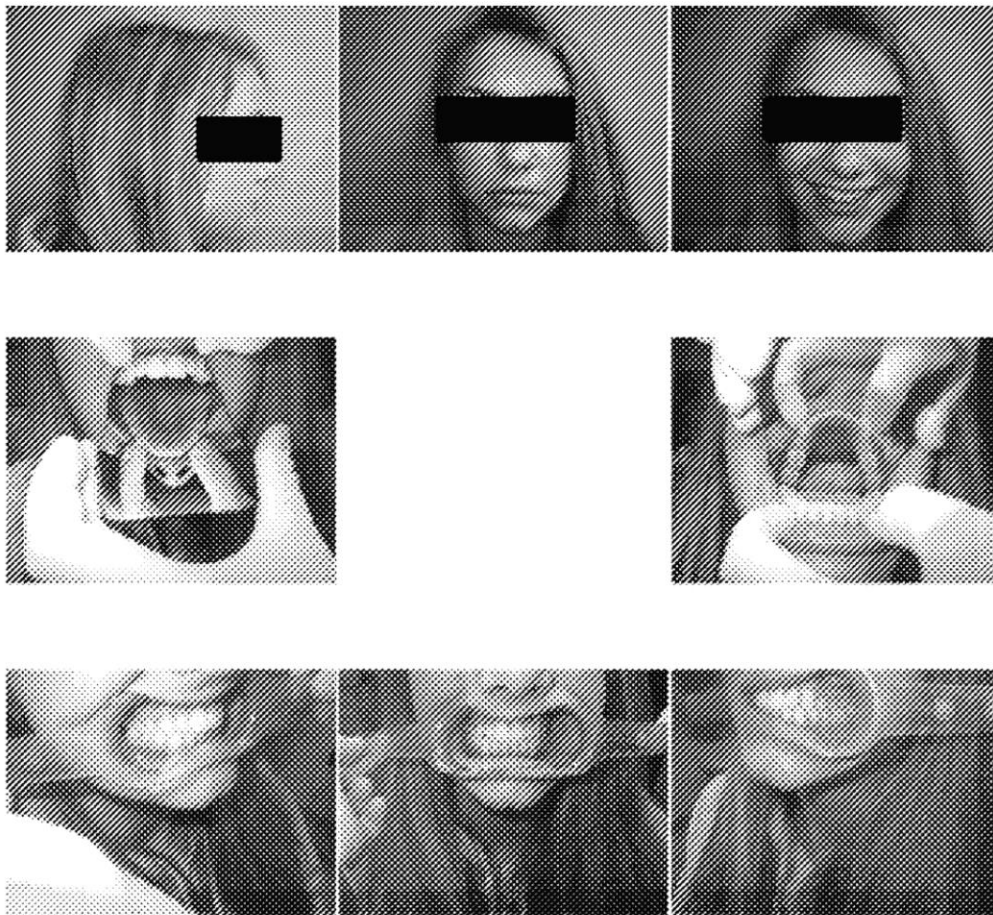


FIG. 9

EX1006 [Carrier Provisional], Fig. 9 (showing the use of dental retractors and a dental mirror).

38. 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.



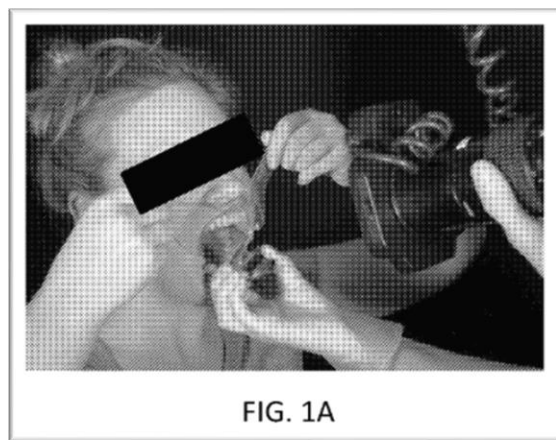
Figure 10a Camera, mirror and retractor alignment for the Upper Occlusal View



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).

39. As of 2017, the same or similar types of mirrors and techniques were used by dental professionals, although the cameras used had advanced (see further below). This is confirmed by the illustration of traditional dental photography in the Carrier Provisional reproduced below.



EX1006 [Carrier Provisional], Fig. 1A (showing the use of a mirror with a DSLR camera); *see also id.*, [0051] (“FIG. 1A shows the use of a traditional SLR camera to image a patient’s teeth. The camera is typically held by the user (*e.g.*, dentist, orthodontist, technician) and images are taken from various positions. The user must manually adjust the patient position and/or camera position.”).

40. 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. *See, e.g.*, EX1006, [0004] (“Some doctors and dental technicians may instead attempt to capture dental photos using a mobile phone. However, mobile phones typically have a wide angle camera lens. If a camera of a mobile phone is held sufficiently close to the teeth of the patient to provide an image of the teeth having a high level of

41. **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.

detail, dental photos may be blurry and have optical distortion. If the camera of the mobile phone is too far to the teeth, dental photos cannot meet the orthodontic standards.”).

42. 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)



- **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

Lateral smile left & right



- **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

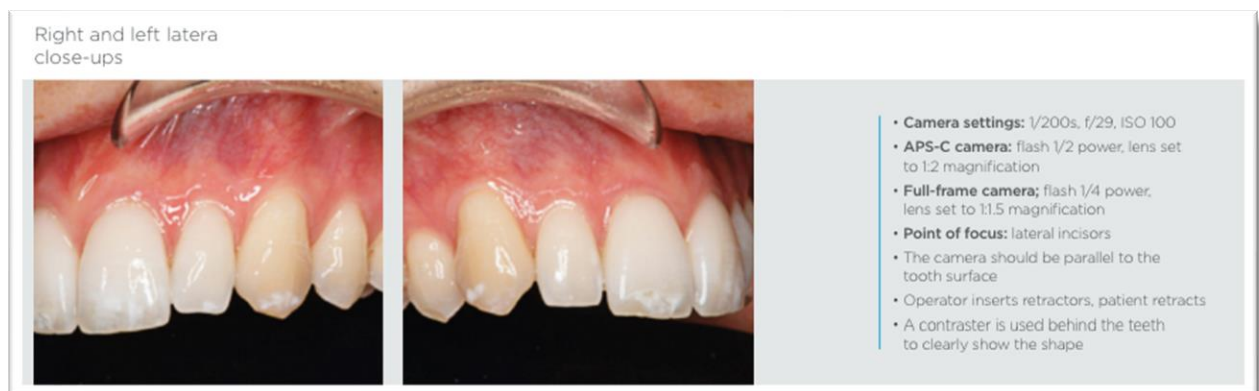
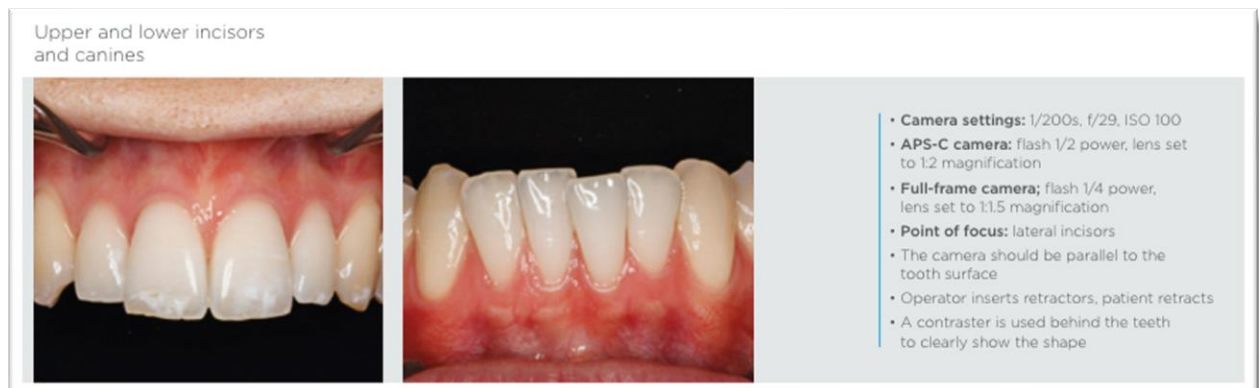
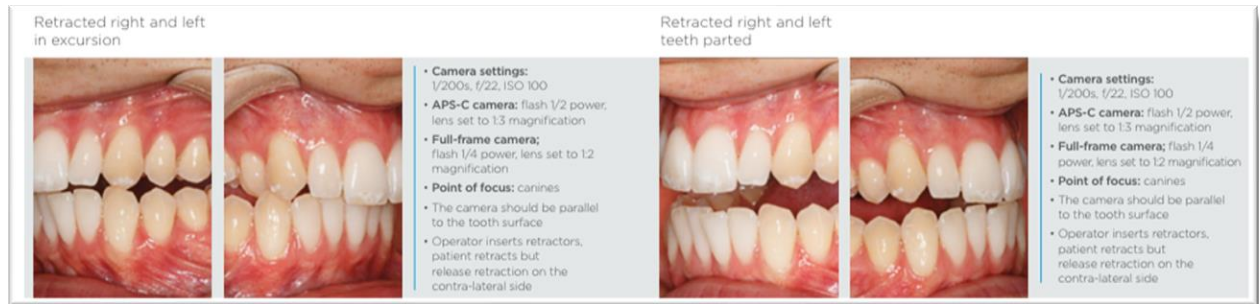


- **Camera settings:**
1/200s, f/22, ISO 100
- **APS-C camera:** flash 1/2 power; lens set to 1.3 magnification
- **Full-frame camera:**
flash 1/4 power; lens set to 1.2 magnification
- **Point of focus:** lateral incisors
- The camera should be parallel to the tooth surface
- Operator inserts retractors,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



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

43. ***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.

44. 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 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.

B. Deep Learning in Dental Photograph Acquisition

45. As of 2017, the use of deep learning or machine learning in the acquisition of dental photographs had not been accepted by the dental community. 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.

46. Nonetheless, I understand that Dr. Foroosh opines that a POSA would have been motivated to train a neural network for use in the acquisition of dental photographs using a learning base comprising more than 10,000 images of dental arches taken on a cell phone. EX1002 at, *e.g.*, ¶¶149-150. 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 dental arches or captured and labeled those photographs themselves. Dr. Foroosh has not identified any database of such images that was publicly available in 2017. *See* EX2039 [Liu] (emphasizing that, even in 2021, “[c]ompared to other medical fields, the high-quality datasets for orthodontic research [were] limited.”). Indeed, as I discussed above, cell phones were not generally used to capture dental photographs at this time.

47. A POSA would have known that capturing 10,000 or more such images would have taken considerable time. By way of illustration, the average number of patients seen by orthodontists between 2016 and 2018 was approximately 581. EX2032 [2023 Economics of Orthodontics Analysis Reporting on 2022 Practice & Patient Statistics], 22. Assuming that a dental professional captured a set of five

standard photographs from each of these patients twice a year, it would still take 1.7 years to compile 10,000 images. Based on my own experience with curating datasets of dental images, the process would have taken far longer.

48. Dental professionals are also not permitted to use patient images that are identifiable due to ethical, regulatory, and legal restrictions. 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. *See, e.g.*, EX1006 [Carrier Provisional], Figs. 9-10. 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.

49. A POSA would have understood that labeling photographs with any dental feature would normally have required a dental professional or dental training. For example, a dental professional or dental training likely would have been required to determine the identity of a tooth (molar, pre-molar, canine, incisor) or a tooth

number. Each patient's teeth are different, and each tooth can vary in size by 0.5 mm on either side (1 mm total for each tooth), leading to significant variation across an arch. Dentists spend an entire semester at dental school focused on tooth anatomy to learn to identify human teeth accurately—a skill that would be important for labeling images used to train a neural network to do the same. 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). . From my personal experience adding pixel-wise contours of teeth and annotations of tooth numbers to dental images, it would have taken an experienced dental professional approximately 20 minutes per image to conduct such labeling. Labeling a set of more than 10,000 such images would thus have taken a dental professional thousands of hours to complete. In my personal experience, projects to acquire images and apply annotations as proposed by Dr. Foroosh can be a years-long project costing millions of dollars. Even hiring trained but unlicensed dental students, for example, it could cost upwards of \$1,500,000 to capture, compile, anonymize, and label a learning base of 10,000 cell phone images of dental arches and take more than 2 years to complete.

50. For all of these reasons, in 2017, this process of obtaining a learning base for use in capturing dental photographs would have been expected to be costly and complicated.

VII. ALIGN’S REFERENCES

51. Below, I discuss how a POSA who worked as part of an interdisciplinary team with individuals having experience in dentistry and/or orthodontics would understand the teachings of the Carrier Provisional, Carrier, and Salah related to the dental field.

A. U.S. Patent Publication No. 2021/0068923 to Carrier, et al. (“Carrier”)

52. I have reviewed U.S. Patent Publication No. 2021/0068923 to Carrier, et al. (“Carrier,” EX1005). Carrier is entitled, “Methods and Apparatuses for Dental Images,” and it was filed on November 18, 2020, and published on March 11, 2021. I have also reviewed Carrier’s provisional patent application (“Carrier Provisional,” EX1006), which was filed November 4, 2016. Finally, I have reviewed EX2004, which I am informed is a redline comparison of Carrier against the Carrier Provisional, highlighting the significant information that was added to Carrier after the Carrier Provisional was filed. I have been informed that the only disclosures in Carrier that are prior art to the ’409 patent are those that are described in the Carrier Provisional. Accordingly, I have described below how a POSA, through the

appropriate consultation with an individual with dental or orthodontic experience, would have understood the Carrier Provisional.

1. The Carrier Provisional is Directed to a Method for Capturing Dental Photographs by Dental Professionals

53. The Carrier Provisional is directed to methods and apparatuses for (1) *dental professionals* to capture (2) a *standard set of dental photographs* (3) using a *mobile phone*, (4) with *real-time* guidance, (5) using contour detection performed by a computer program running on the mobile phone.

54. **First**, the Carrier Provisional is directed to dental professionals in the office, not patients. This is clear, for example, from the background section in the Carrier Provisional, which describes the standard approach to capturing dental photographs as of 2017 using a DSLR camera. EX1006, [0004], Fig. 1A-1C (“illustrat[ing] one example of traditional dental photography using a digital SLR camera”). However, DSLR cameras were expensive and could make it difficult to align the teeth. *Id.*, [0004]. The Carrier Provisional goes on to state that “[s]ome doctors and dental technicians” had “attempt[ed] to capture dental photos using a mobile phone,” but this was challenging. *Id.* On the one hand, “[i]f the camera of a mobile phone [wa]s held sufficiently close to the teeth of the patient to provide an image of the teeth having a high level of detail,” the “dental photos may be blurry and have optical distortion.” *Id.* But on the other hand, “[i]f the camera of the mobile phone [was] too far [from] the teeth,” the dental photographs could not “meet

the orthodontic standards.” *Id.* A POSA would have understood this sentence to refer to the set of standard orthodontic photographs discussed above. According to those standards, in the, *e.g.*, occlusal view of a patient’s maxillary (top) teeth (the view that is being captured in Fig. 1A of the Carrier Provisional), all the patient’s top teeth needed to be captured in the photograph. The Carrier Provisional thus teaches a POSA that, if a standard cell phone was held too far from the patient, the photographs would not contain all the teeth required to be photographed in each of the desired views.

55. The Carrier Provisional goes on to describe a method and apparatus that dental professionals could use to obtain high quality dental photographs of a patient’s teeth. *Id.*, [0006]. Specifically, the Carrier Provisional describes capturing the standard set of dental photographs that I discussed above. *Id.*, [0015] (“The predetermined view can comprise an anterior view, a buccal view an upper jaw view, or a lower jaw view. The predetermined view can comprise a set of dental images according to the orthodontic standards. For example, the method can further comprise repeating the steps of viewing, displaying, moving and capturing to capture anterior, buccal, upper jaw and lower jaw images of the patient’s teeth.”). That standard set of dental images is also shown in Figures 4A-4H, which the Carrier Provisional states, “illustrate 8 specific overlay images for the required types of photos according to the orthodontic standard.” *Id.*, [0035]. Based on my expertise

as an orthodontist, dental professionals, not their patients, acquired these standard high-quality dental photographs. In fact, this standard set includes photographs that a patient cannot (or cannot easily) take of themselves, *e.g.*, the occlusal views (shown in Figure 5A) and the external head or facial views (shown in Figures 5C and D). *Id.*, [0076]-[0077].

56. The Detailed Description of the Carrier Provisional further confirms that its methods and apparatus are for use by dental professionals. For example, in this section, the Carrier Provisional states that “[t]he camera is typically held by the user (*e.g.*, dentist, orthodontist, technician),” and the “user must manually adjust the patient position and/or camera position,” indicating that the user is someone different from the patient. *Id.*, [0051].

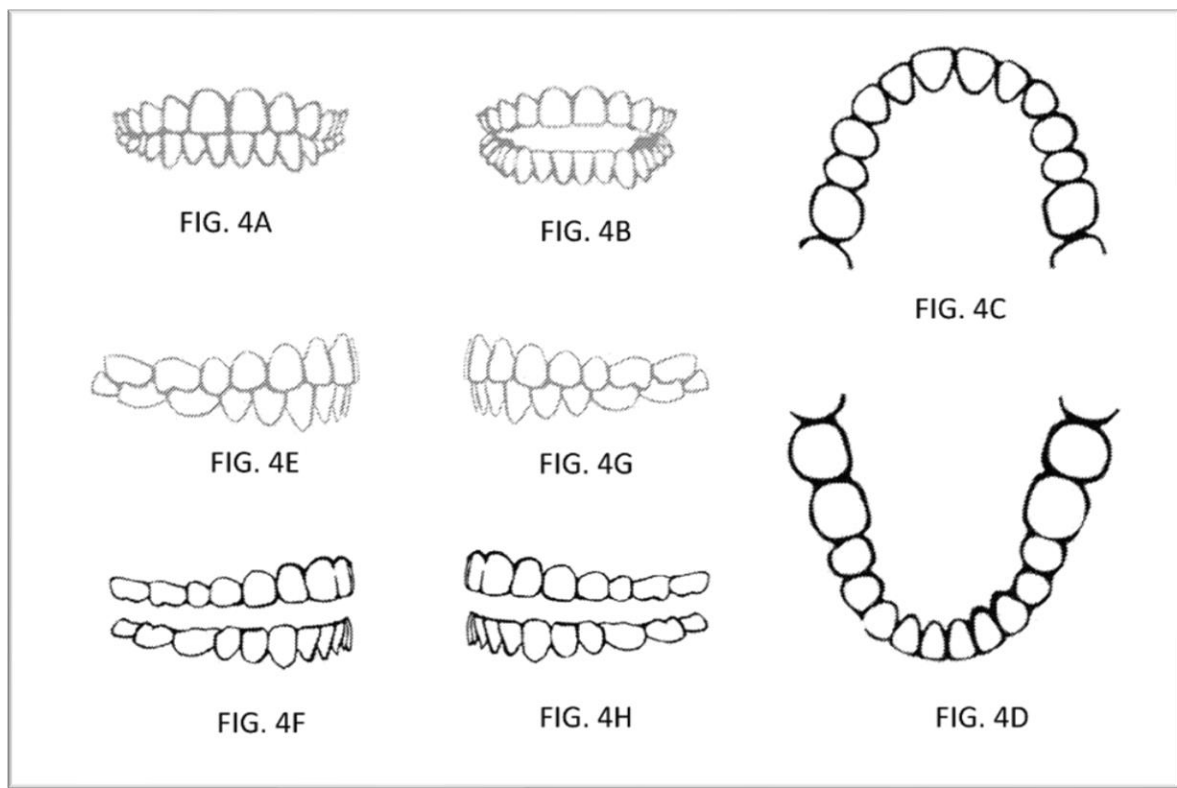
57. The Carrier Provisional further reenforces that it is directed to dental professionals by stating that “doctors can be guided to take dental photos by the on-screen overlay, saving time and effort.” *Id.*, [0056]; *see also id.*, [0057] (“The on-screen overlay with the outline of teeth can help doctors to take quality dental photos using the mobile phone.”), [0081] (“For example, if the image is too dark, or blurry, or out of focus, a warn message is shown on the screen to warn the doctors to retake the photo.”), [0095] (“Thereafter, the app may guide the doctor or clinician in taking a predetermined series of images.”).

58. The Carrier Provisional also explains that “the app may present a list of patients and/or allow patients to be added.” *Id.*, [0095]. Figure 5A similarly shows that the mobile device application interface has a “back” button indicating access to the files of other “patients” than the one selected. A POSA would have understood that a patient’s mobile device would not have access to the files of other patients. Instead, a POSA would have recognized that the example in Figure 5A is on a phone associated with the dental professional. The Carrier Provisional further states that “[u]sers can select one of the plurality overlays that best fit the teeth of the patient and be guided to match the selected overlay with the teeth of the patient.” *Id.*, [0061]. A POSA would have also understood that the dental professional, not the patient, would determine the best overlay for the patient.

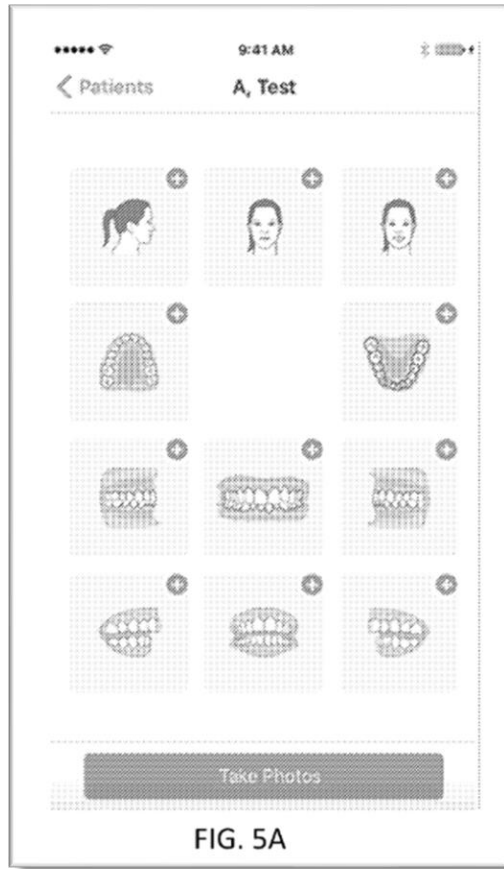
59. Furthermore, the Carrier Provisional refers to the use of retractors and dental mirrors. *Id.*, [0096]. In my experience, patients did not have access to or know how to use dental mirrors, and they also did not have a dental retractor unless they were specifically provided with one in a kit (as, *e.g.*, expressly described in Salah (EX1008, 11:13-15)). The suggestion to use dental mirrors and retractors would have further indicated to a POSA that the methods described in the Carrier Provisional were meant to be carried out by a dental professional in the office.

60. **Second**, the Carrier Provisional guides the dental professional to take the standard set of dental images that I discussed above. *Supra* ¶¶32-34. In particular,

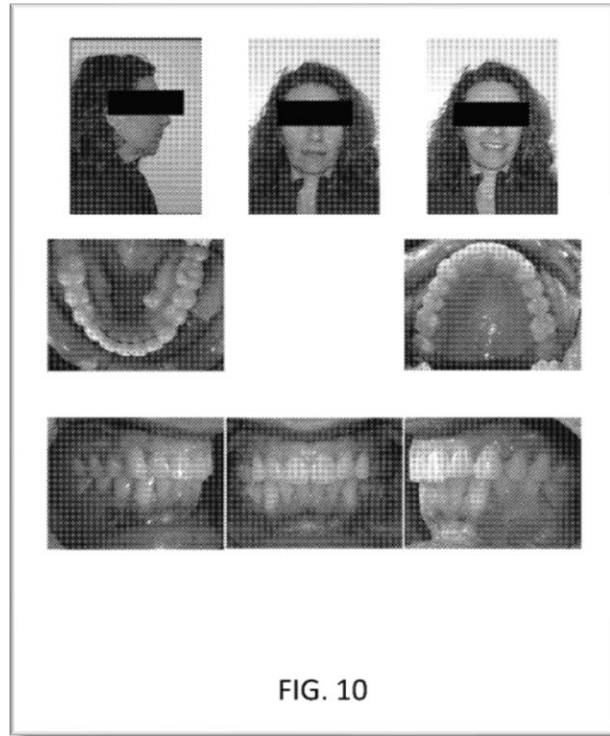
the Carrier Provisional describes capturing “an anterior view, a buccal view[,] an upper jaw view, or a lower jaw view.” EX1006, [0008], [0015]. In Figures 4A-4H, the Carrier Provisional further illustrates a set of overlays that can be used to aid in the capture of the dental photographs that correspond to “the required types of photos according to the orthodontic standard.” *Id.*, [0035].



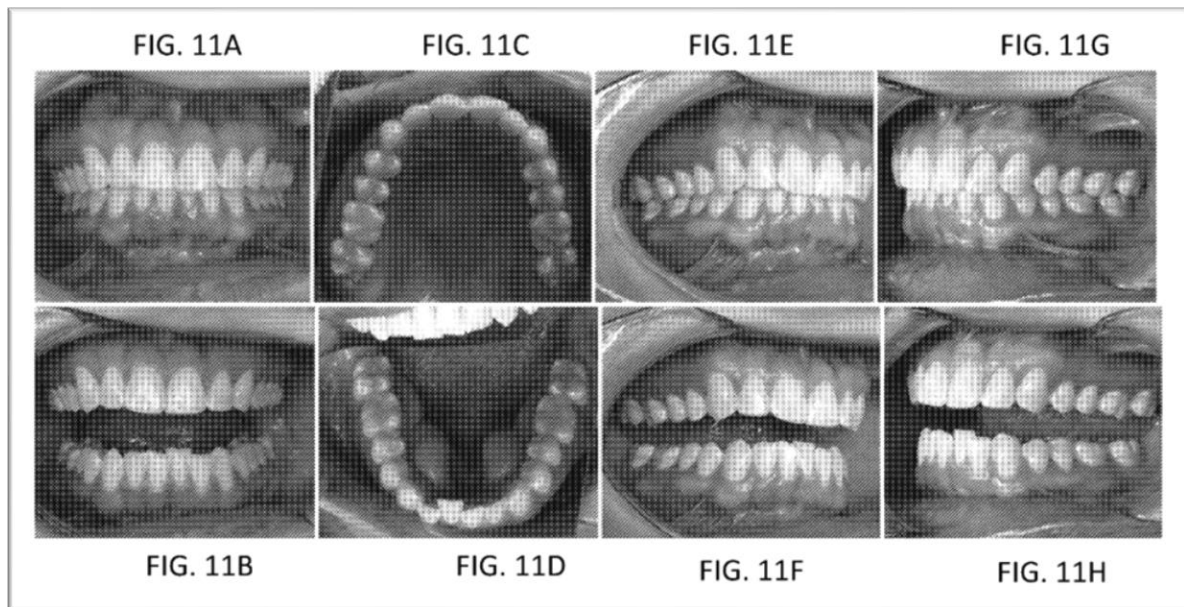
61. Figure 5A of the Carrier Provisional is “an example of a user interface to enable a user to select one of a plurality of overlays for a plurality of dental images in a plurality of predetermined views.” *Id.*, [0036]. As shown below, those overlays for the predetermined views correspond to the standard orthodontic photographs I have already described.



62. Similarly, Figure 10 shows “an example of a set of facial and dental images of a patient captured by using a mobile phone through the method disclosed [in the Carrier Provisional],” which again corresponds to the standard set of orthodontic photographs. *Id.*, [0047].



63. Figure 11 further illustrates my point by showing a standard set of orthodontic photographs captured on a mobile phone using the methods in the Carrier Provisional. *Id.*, [0048].

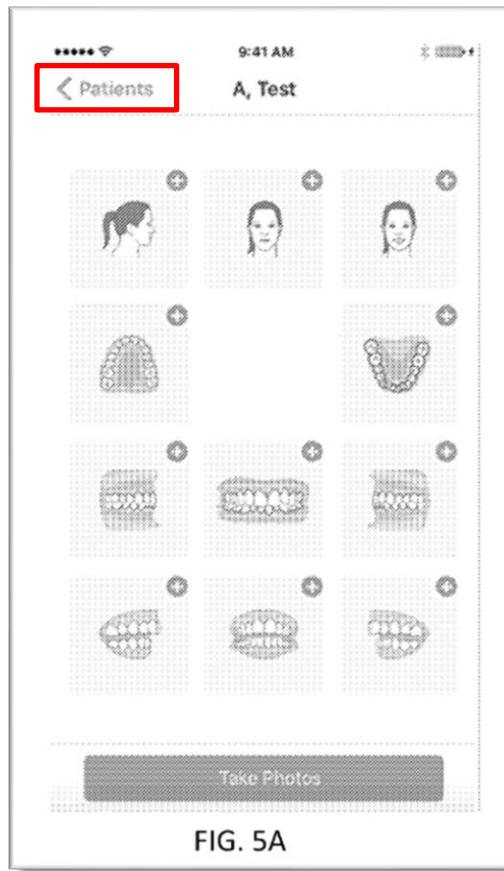


64. A POSA would have recognized that aligning the teeth with the on-screen overlays would be sufficient to ensure that the “required teeth” are on the image. *See, e.g., id.*, [0081] (“In some embodiments, the method can further comprise using image recognition algorithms to ensure that all required teeth are visible.”). With the guidance of a dentist or orthodontist, a POSA would have understood that “required” teeth in this context means the teeth that are intended to be the subject of the specific predetermined view in the photograph. Different views were (and still are) used to capture photographs of different teeth—a POSA would have known that it is not important, for example, that a sliver of a patient’s molars are or are not visible in the background of a front view. Rather, the “required teeth” for such an image are those that are visible when a photograph of the patient’s dental arch is captured from the appropriate viewpoint as determined by an “approximate” match with those teeth shown in the overlay for that predetermined view. This is illustrated in Figure 2C of the Carrier Provisional, which shows an example of an overlay on the screen “which *shows what teeth should be visible in the view.*” *Id.*, [0032] (emphasis added).

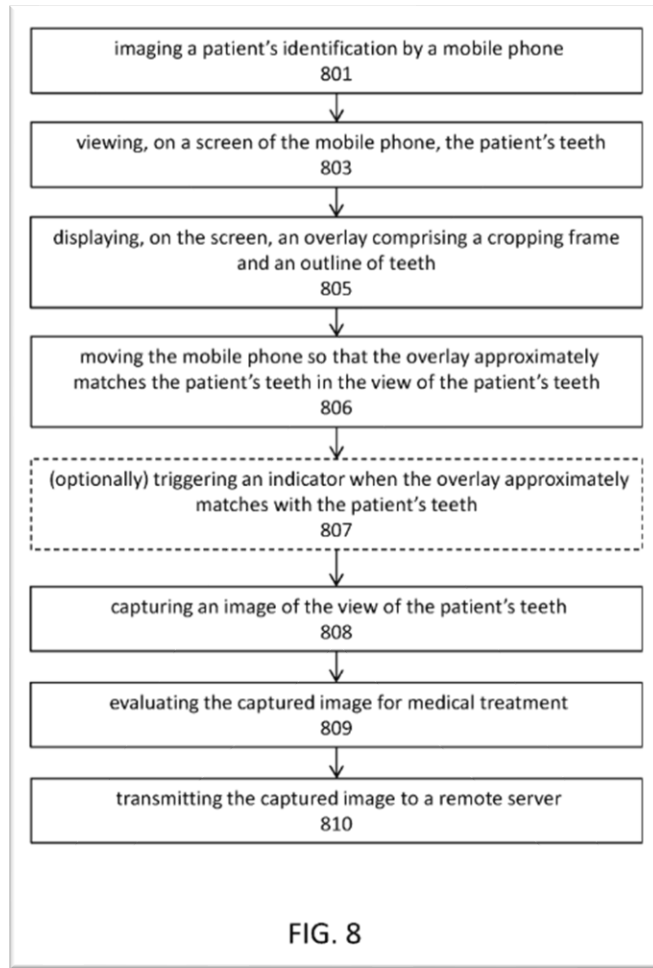
65. **Third**, the Carrier Provisional teaches dental professionals to use a mobile phone. The Carrier Provisional highlights the advantage of mobile phone cameras to acquire the standard dental photographs—*i.e.*, that they are “faster and easier to use” than traditional DSLR cameras—and it describes a method for “obtaining high

quality dental images” using such devices. *Id.*, [0004]-[0005], [0006], [0051], [0052], [0054].

66. A POSA would have recognized that the mobile phone used to acquire the photographs in the Carrier Provisional is associated with the dental professional, not the patient. For example, as I explained above, the Carrier Provisional explains that “the app may present a list of patients and/or allow patients to be added.” *Id.*, [0095]. Figure 5A also shows that the mobile phone app has a “back” button to allow access to the files of other “patients.” A POSA would have recognized that a patient’s mobile device would not have access to the files of other patients, and instead, the example in Figure 5A is on a phone associated with the dental professional.



Id., Fig. 5A (red box added). Similarly, when describing the process in Figure 8, the Carrier Provisional indicates that the “captured image” is “evaluat[ed] . . . for medical treatment” prior to “transmitting [it] to a remote server.” *Id.*, [0086], Fig. 8.



Id. A POSA would have understood that where the photograph is evaluated for medical treatment on the device, it is evaluated by the dental professional, not the patient. In my opinion, there is nothing in the Carrier Provisional that suggests that a patient's mobile phone should be used to capture the dental images.

67. **Fourth**, the Carrier Provisional provides the dental professional with real-time guidance. A POSA would have understood that real-time guidance to occur during the process of capturing the photograph, while the patient's teeth are displayed on the screen of the mobile phone. *See, e.g.,* EX1005, [0007] (“For

example, the methods described herein may include displaying, on a screen (*e.g.*, of a mobile communications device such as a smartphone, etc.), an overlay comprising an outline of teeth in a predetermined view. The overlay may be displayed atop the view from the camera, which may show[] a real-time display of from the camera.”); EX1006, [0054] (“In particular, these apparatuses and methods may include the use of an ‘overlay’ on a real-time image of the screen, providing immediate feedback on each of the desired orientations.”); EX1005 [0099] (“In particular, these apparatuses and methods may include the use of an ‘overlay’ on a real-time image of the screen, providing immediate feedback on each of the desired orientations, which may also be used to adjust the lighting and/or focus, as described herein.”).

68. The Carrier Provisional discloses the use of software running on the mobile phone to achieve this real-time feedback on the image acquisition process. EX1006, [0019] (“For example, described herein are non-transitory, computer-readable storage media storing a set of instructions capable of being executed by a processor of a mobile phone, that, when executed by the processor, cause the processor to display real-time images of the patient’s teeth on a screen of the mobile phone, display an overlay comprising an outline of teeth in a predetermined view atop the images of the patient’s teeth, trigger an indicator when the overlay approximately matches with the patient’s teeth, and enable capturing an image of the patient’s teeth when the indicator is triggered.”), [0063] (“Once the apparatus (*e.g.*,

software/application software) determines that the teeth are in alignment with the overlay, as shown in FIG. 3B, the screen may display an indicator, such as, in FIG. 3B, changing the color of the overlay from the first color to a second color (*e.g.*, green, blue, etc.) and/or automatically taking the image.”).

69. A POSA would have recognized that, in this context, the dental professional would not have benefitted from delayed guidance about camera alignment while engaging in live photo taking. For example, if the dental professional received a notification to adjust the camera position only after a delay, that guidance would not be helpful in **guiding** the dental professional (as the Carrier Provisional envisages). *See, e.g., id.*, [0053] (“In general, these method[s] and apparatuses may improve on existing technology **by guiding a user through the process of collecting relevant patient images** (*e.g.*, a predetermined set of images)”), [0054] (“the methods and apparatuses described herein may use a user’s own handheld electronics apparatus having a camera (*e.g.*, smartphone) and **adapt it so that the user’s device guides the user in taking high-quality images** (*e.g.*, at the correct aspect ratio/sizing, magnification, lighting, focus, etc.) of a predetermined sequence of orientations”), [0063] (“[A]ny of the methods and apparatuses described herein may be used to indicate (*e.g.*, by visual and/or audible and/or tactile) image that the teeth are aligned in the frame with the overlay.”) (emphases added). As the Carrier Provisional explains, Figure 3A “illustrates an example of automatic

detection of alignment in real-time with a patient's teeth and an overlay" in which "the overlay (in a first color, such as red) shows lines that illustrate the outline of teeth in a first desired predetermined view (*e.g.*, frontal), when the patient's teeth are not aligned with the overlay." *Id.*, [0063]. "Once the apparatus (*e.g.*, software/application software) determines that the teeth are in alignment with the overlay, as shown in FIG. 3B, the screen may display an indicator, such as, in FIG. 3B, changing the color of the overlay from the first color to a second color (*e.g.*, green, blue, etc.) and/or automatically taking the image." *Id.* If the guidance in the Carrier Provisional were not real time, either the dental professional and the patient would have to hold perfectly still while awaiting the guidance, or the mobile phone would no longer be in the same place when the guidance arrived. A POSA would have recognized that such a process would not be workable, as it would be very difficult for a dental professional to hold a mobile phone completely stable and for a patient to stay perfectly still. Based on my experience, a patient would also not be willing to wait a long period of time to have their teeth photographed, and such a slow process would be a waste of time and resources for the dental practice.

70. ***Fifth***, that guidance is accomplished using, for example, edge (or contour) detection image processing. The Carrier Provisional requires a predetermined overlay on the screen of a mobile phone and instructs the dental professional to move the mobile phone so that the overlay approximately matches the view of the patient's

teeth on the screen. *See id.*, [0007] (“The method can comprise viewing the patient’s teeth, for example, on a screen of a mobile phone. The method can further comprise displaying, on the screen, an overlay comprising an outline of teeth in a predetermined view, wherein the overlay is displayed atop the view of the patient’s teeth. The method can comprise moving the mobile phone relative to the patient’s teeth and triggering an indicator when the overlay approximately matches with the patient’s teeth.”); *see also* EX1005, [0008]. The Carrier Provisional discloses that the method can comprise “automatically triggering an indicator when the overlay approximately matches with the patient’s teeth,” where the indicator “can be a visual indicator, such as a change of color” or “a voice indicator.” EX1006, [0010]. This method can further comprise “estimating an indicator of the distance between an edge of the patient’s teeth at two or more regions and the outline of teeth and comparing that indicator to a threshold value.” *Id.*, [0010].

71. The Carrier Provisional contains a general reference to the use of “edge detection image processing” or “image recognition algorithms,” in the context of software or application software running on the cell phone. *Id.*, [0063] (“Once the apparatus (*e.g.*, software/application software) determines that the teeth are in alignment with the overlay, as shown in FIG. 3B, the screen may display an indicator. . . . For example, the method or apparatus may determine alignment when a threshold amount/percentage of the edges of the patient’s teeth in the image are

within a predetermined minimum distance of the overlay. . . . The edges of the teeth may be determined by any appropriate technique (*e.g.*, edge detection image processing, etc.).”), [0080]-[0081] (“In some embodiments, the method can further comprise using image recognition algorithms to ensure all required teeth are visible.”).

2. The Carrier Provisional Does Not Describe the Subject Matter of Claim 1 of Carrier

72. I have been asked to address whether the Carrier Provisional discloses the subject matter of claim 1 of Carrier. In my opinion, it does not. Claim 1 of Carrier recites the following:

1. A computer-implemented method comprising: providing a mobile application ***on a mobile device associated with a patient***, the mobile application configuring a user interface for display on the mobile device; ***guiding the patient through the user interface to take a first plurality of photos of teeth of the patient***, the first plurality of photos corresponding to a first plurality of predetermined views of the teeth, wherein guiding the patient to take the first plurality of photos comprises showing a first plurality of overlays over the teeth in accordance with the first plurality of predetermined views; ***guiding the patient through the user interface to take a second plurality of photos of the teeth***,

the second plurality of photos corresponding to a second plurality of predetermined views of their teeth, wherein guiding the patient to take the second plurality of photos comprises showing a second plurality of overlays over the teeth in accordance with the second plurality of predetermined views; and transmitting the first plurality of photos and the second plurality of photos so the first plurality of photos and the second plurality of photos can be evaluated for medical treatment.

EX1005, Claim 1 (emphasis added).

73. I note that Dr. Foroosh has only proposed the level of ordinary skill in the art with respect to the '409 patent and not with respect to Carrier. I would consider the level of skill in the art for Carrier to be similar to that for the '409 patent, and as with the '409 patent, it would be important for the POSA to have an understanding of dentistry and orthodontics because of the disclosure in Carrier and the Carrier Provisional that is specific to the dental field.

74. As I have explained above, a POSA working as part of an interdisciplinary team would understand the Carrier Provisional to describe a method in which a dental professional is guided to acquire standard dental photographs using a mobile phone associated with the dental professional. In my opinion, the Carrier Provisional does not describe a method for guiding *a patient* to acquire a set of predetermined

dental images using a mobile phone associated with the **patient**, as recited in claim 1 of Carrier.

75. Dr. Foroosh cites instances in which the Carrier Provisional uses the term “user” in a context where “user” implies “patient” but not a dental professional. EX1002, ¶¶49, 55 (citing EX1006, [0055] (indicating overlay can be derived from “user’s teeth,” referring to a patient’s and not a dentist’s teeth)). However, in other instances, “user” clearly refers to a dental professional to the exclusion of patients. For example, as discussed above, the Carrier Provisional states that Figure 5A is “an example of a user interface to enable a user to select” from overlays for predetermined views. As discussed above, the “user” selecting the views is the dental professional, particularly because this screen shows access to the images of other patients. *See also* EX1006 [Carrier Provisional], [0051] (“user must manually adjust the patient position”). Dr. Foroosh appears to imply that the term “user” is universally defined as including a “patient” throughout the Carrier Provisional, but as shown above, a POSA would have understood that this is not the case. Because it would be clear to a POSA that the term “user” is context specific in the Carrier Provisional, a POSA would not have understood the reference to a “user’s teeth” in the context of forming an overlay to redefine “user” throughout to include patients. Instead, a POSA considering the Carrier Provisional in its entirety, as described above, would have recognized that it is directed to guiding a dental professional to

capture images of their patients' teeth using the dental professional's cell phone, instead of the traditional DSLR camera.

3. Dr. Foroosh's Opinions Are Based On a Misunderstanding of the Carrier Provisional

76. As discussed above, the Carrier Provisional states that “[i]n some embodiments, the method can further comprise using image recognition algorithms to ensure all required teeth are visible.” *Id.*, [0081]. I understand that Dr. Foroosh has opined that a “POSA would understand that to ensure all required teeth are visible, each required tooth should be detected by the image recognition algorithm.” EX1002 at, *e.g.*, ¶115. I disagree that this is how a POSA, working as part of a multidisciplinary team, would have understood the Carrier Provisional.

77. The Carrier Provisional discloses a method that overcomes certain challenges with using cell phones to acquire dental photographs and provides a method and apparatus that allowed users to take clinically useful images of a patient's teeth with a mobile phone. EX1006, [0004] (disclosing that holding the mobile phone “close to the teeth” in order to get a “high level of detail” could result in “blurry” and “optical[ly] distort[ed]” dental photographs, and holding the phone “too far” from the teeth results in dental photographs that could not “meet the orthodontic standards.”). Carrier's solution—enabling users to acquire images at the correct distance and with the correct alignment—relies upon an overlay to guide the user to the approximate camera position. *Id.*, [0009] (“the overlay can comprise a

generic overlay”), [0060] (“an *approximate* visual match is needed to select the correct distance, correct angle and correct view of the patient’s teeth”), [0061], [0063] (alignment may be achieved when only 50% to 90% of outline is within 0.1 mm to 1 mm of overlay) (emphases added).

78. The Carrier Provisional nowhere suggests to a POSA that all teeth should be detected, nor does it disclose a method for detecting individual teeth. To the contrary, a POSA would have understood that the “required teeth” are established by the predetermined views that the dental professional is trying to capture and that, if the patient’s teeth are approximately aligned with the overlay, the “required teeth [will be] visible” in the photograph. This is apparent from, for example, Figures 10 and 11, which show that, using the method disclosed in the Carrier Provisional, all the teeth required for each of the predetermined views are shown in the photographs. *Id.*, [0047]-[0048].

79. The Carrier Provisional further indicates that a generic overlay (*i.e.*, an overlay that is not specific to the patient’s own teeth) can be used to capture high quality dental photographs. *Id.*, [0009] (“the overlay can comprise a *generic* overlay” (emphasis added)). As illustrated in the photos below, however, patients’ teeth are different sizes, they have different relative positions, and patients may have different numbers of teeth, for example, because certain teeth never erupted (never

emerged from the soft tissue of the gum) or have been lost (for example, due to injury or disease).



Figure 8 Right Buccal View - In Occlusion.

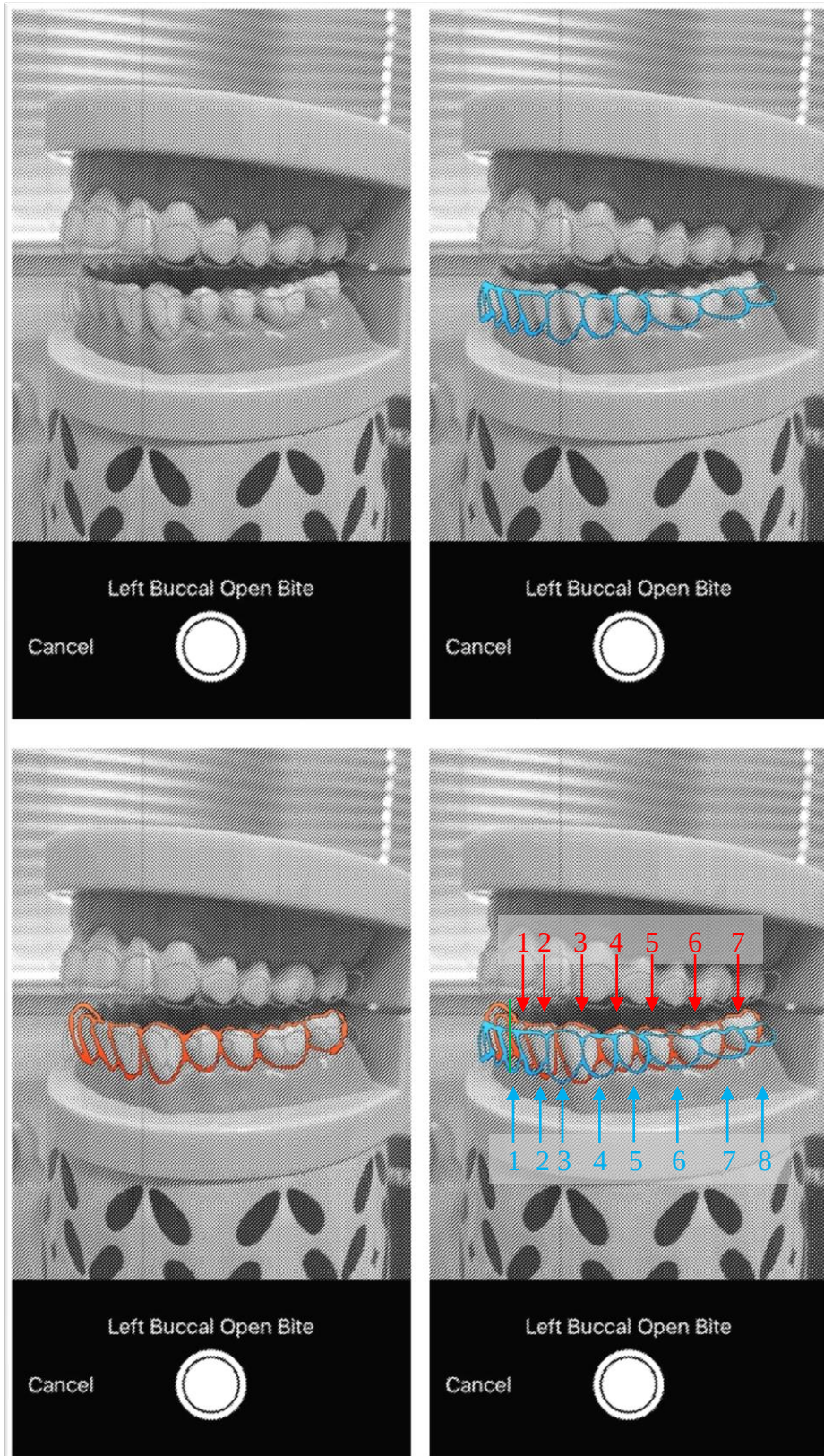


Figure 9 Left Buccal View - In Occlusion.

EX2040 [Samawi], 29 (showing a right buccal view in which there is 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 a concomitant gap in the dental arch). As such, a POSA would have recognized that it was not necessary to detect all the teeth in order to capture a specific predetermined view. Indeed, if a patient was missing a tooth, it would have been impossible to detect all the teeth ordinarily found in the applicable predetermined view. According to the Carrier Provisional, however, these differences between patients, that would have been known to a POSA, do not preclude the use of a generic overlay or the capture of the desired set of photographs using a generic overlay.

80. My opinion that the Carrier Provisional is not directed to detecting individual teeth is further confirmed by Figure 2C. The Carrier Provisional states

that the “overlay with an outline of teeth in a predetermined view can further provide information such as ***required visible teeth*** in the predetermined view.” EX1006, [0060] (emphasis added). Figure 2C is an example that “illustrates a buccal view overlay which shows what teeth should be visible in the view” and teaches that this overlay can be used to capture high quality dental photographs even though the overlay has a different number of teeth than in the dental arch. *Id.*



Id. (top-left: original; top-right: I outlined the overlay in blue; bottom-left: I outlined the modeled teeth in red; bottom-right: I labeled the modeled teeth (red), beginning with 1 on the near-side of the center line of the modeled teeth (green) and labeled the corresponding teeth on the overlay (blue) beginning with 1 on the near-side of the center line of the modeled teeth). It is apparent from this figure that the number of teeth in the overlay does not match the number of teeth on the model. Nonetheless, the Figure represents an appropriate view for a Left Buccal Open Bite image, and the overlay can be used to capture high quality dental photographs, according to the Carrier Provisional. The presence of a third molar in an overlay for this same view can be seen even more clearly in Figure 4H below (tooth annotated in red):

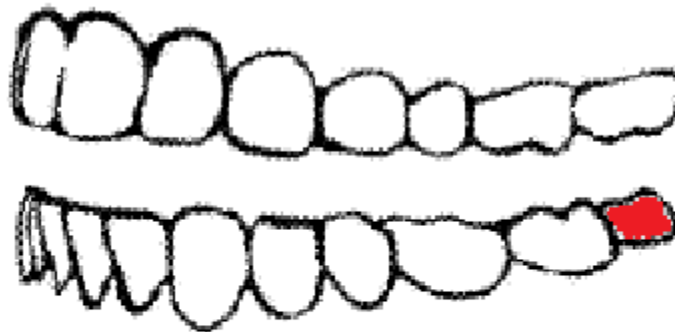


FIG. 4H

81. To the extent Dr. Foroosh is arguing that a POSA would have been motivated to modify the Carrier Provisional to improve the accuracy of its alignment

technique, I also disagree. EX1002, *e.g.*, ¶87. The Carrier Provisional teaches that a high degree of accuracy is not necessary, and instead, high quality dental photographs can be captured “when the overlay *approximately* matches with the patient’s teeth.” EX1006, [0006]-[0007]; *see, also id.*, [0060] (“an **approximate** visual match is needed to select the correct distance, correct angle and correct view of the patient’s teeth” (emphasis added)), [0061], [0063] (alignment when only 50% to 90% of outline is within 0.1 mm to 1 mm of overlay). As discussed, the Carrier Provisional further discloses that a generic overlay can be used, and that it is sufficient to achieve the goal of the Carrier Provisional (*i.e.*, the capture of standard orthodontic photographs) that the positioning of the patient’s teeth approximately matches a generic overlay.

82. A POSA would have further recognized that the Carrier Provisional describes an alternative method to the traditional techniques used to capture dental photographs in 2017, *i.e.*, using DSLR cameras. *Id.*, [0004], [0029] (explaining that Figs. 1A-1C “illustrate one example of traditional dental photography using a digital SLR camera”). As I explained above (*supra* ¶¶43-44), those traditional techniques were used to conduct qualitative (not quantitative) assessments, such as, the condition of the teeth (*i.e.*, if there is decay or restoration), the relationship between one tooth to another, the shape of each clinical crown of each tooth (*i.e.*, if there is 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 are any pathologic issues), identify malocclusion (*i.e.*, teeth that are not properly aligned) or an overjet (*i.e.*, the extent to which the top teeth protrude over the bottom teeth), and detect crowding. For these assessments, the dental professional simply requires a high-quality photograph showing each of the standard orthodontic views. A POSA would have recognized that there was no need for precision beyond aligning the teeth in the photograph to a level consistent with the traditional DSLR techniques—images that are often taken freehand without additional alignment tools. *See, e.g.*, EX1006, [0006]-[0007], [0060]-[0061], [0063].

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

83. 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. In the following paragraphs, I discuss some of the steps of the Salah process and how they would have been understood by a POSA who is part of a multi-disciplinary team that includes a dental and/or orthodontic professional.

1. Salah is Directed To A Method for Capturing Dental Photographs by Patients

84. The first step of Salah involves the creation of a detailed 3D model of the patient's teeth. Salah describes the process that was typically used in 2017, which involved making a digital 3D model from a plaster (or other physical) model or "preferably . . . using a professional device, such as a 3D scanner, preferably implemented by a healthcare professional, such as an orthodontist or orthodontic laboratory." EX1008, 19:25-20:21.

85. After the creation of the 3D model, Salah describes the acquisition of an "updated image" of the patient's dental arch. *Id.*, 23:24-33:8. Preferably, an orthodontist determines when the updated image is acquired, or the updated images is acquired after a time that is likely to correspond to a potentially significant change in tooth position. *Id.*, 24:8-20.

86. The updated image is preferably acquired with "a personal device commonly available on the market, for example a cell phone," and that the "updated image" is "preferably created by the patient himself or by one of his relatives." *Id.*, 25:14-19. Salah also indicates that it is "preferabl[e]" that "the image acquisition apparatus includes a specialized application for implementing step b)," and that "a dental retractor is used" "as shown in Figures 5a and 5c." *Id.*, 26:19-27:4, Figs. 5a, 5c. A retractor, as I discussed above, is a device that holds the patient's lips and cheeks back from the teeth, helping ensure visibility of the desired teeth. And Salah

describes an image acquisition kit that expressly includes a retractor (EX1008, 11:13-15)—a POSA would have recognized that this is because a patient would not otherwise be expected to have access to a dental retractor.

87. Salah further describes the use of the detection and acquisition kit to acquire the updated image. EX1008, 27:19-28:4. In particular, Salah teaches that “the image-acquisition apparatus includes verification means to facilitate its approximate positioning relative to the patient prior to acquisition of the updated image.” *Id.*, 27:19-20.

88. Salah identifies several exemplary means for providing guidance to the patient while they are acquiring the updated image. For example, Salah describes “written and/or voice prompts,” including ones that indicate whether the patient should take the image from the “front” or the “right,” *e.g.*, “an arrow to orient the user,” or by indicating that the photograph “is acceptable” or that the user “must take another photo.” *Id.*, 27:21-28:2.

89. Going into greater detail, Salah explains that “verification means” are used to assist with alignment of the “updated image” in relation to the view of the patient’s dental arch. *Id.*, 28:4-33:5. The “verification means” disclosed in Salah include a “reference” that appears on the viewfinder or screen of the patient’s mobile device and is ideally in a fixed position. *Id.*, 28:5-12. Salah explains that this “reference” can be, for example, a “line intended to be aligned with the general direction of the

juncture between the upper and lower teeth,” or it can represent where the patient’s facial features should be visible on the mobile phone screen. *Id.*, 28:5-12. Salah also suggests the use of “augmented reality” to display a transparent view of the patient’s teeth that was derived from the reference 3D model. *Id.*, 30:16-21. Based on my experience, a POSA would have recognized that “references” corresponding to the patient’s eyes, mouth, face, or dental arch make “it very easy for the patient” to approximately align the teeth on the screen, consistent with the teaching in Salah. *See id.*

90. Salah also discloses “registration marks,” which can be shapes, colors, letters, or numbers etc., that can be used to “guide the positioning of the image acquisition apparatus ***at the time of image acquisition***, by means of corresponding references appearing on the acquisition apparatus display.” *Id.*, 28:13-29:17, 32:27-29 (emphasis added). Those “registration marks” are illustrated in Figure 5a of Salah, where they are labelled “12.” *Id.*, 33:18-19. Such “registration marks” are also visible on the tooth retractor from Patent Owner, Dental Monitoring, from about 2018, that I had in my clinic (the four green dots).



91. Salah also teaches that the acquisition apparatus can include “a computer program comprising program code instructions for locating the mark(s) on the retractor in real time, analyzing its/their position(s) and/or dimensions, in particular the relative position(s) of several mark(s) and, as a result, providing an indication, preferably light or sound, so as to inform the user of said acquisition apparatus.” EX1008, 10:22-26.

92. Salah never suggests the use of patient’s eyes, mouth, face, or teeth for automatic alignment using a computer program. In fact, Salah says the opposite:

“Preferably, no measurements are taken on the teeth to bring the acquisition apparatus into the matching position.” *Id.*, 31:26-27. A POSA would have understood from a dental professional that this is because there is significant variation in the size and position of teeth between patients, and also that during the course of an orthodontic treatment, an individual patient’s teeth are expected to move relative to each other. *See id.*, 8:19-23 (explaining that Salah is preferably implemented during orthodontic treatment).

93. Throughout Salah, the comparison of the registration mark to the reference occurs in real-time during the acquisition of the updated image. *See, e.g., id.*, 54:12-15 (“Preferably, the acquisition apparatus is programmed so that in real time, to detect registration marks on the retractor, analyze their relative positions or dimensions and, as a result, inform the user of the device to modify the position of the acquisition apparatus in relation to the patient’s teeth.”). Salah also repeatedly confirms that the real-time analysis of the image during image acquisition runs on software on the device that is used to capture the image. *Id.*, 10:22-26 (“the first and/or second **acquisition apparatus includes a computer program** comprising program code instructions for locating the mark(s) on the retractor in real time, analyzing its/their position(s) and/or dimensions, in particular the relative position(s) of several mark(s) and, as a result, providing an indication, preferably light or sound, so as to inform the user of said acquisition apparatus” (emphasis added)). As Salah

explains, “[i]n particular, the acquisition apparatus can be a cell phone, and the program can be a specialized cell phone app.” *Id.*, 32:1-12.

94. A POSA would have recognized that this real-time feedback was important to the operation of Salah. Neither a dental professional nor a patient would patiently wait—while holding absolutely still—for delayed feedback about the position of the cell phone camera. Additionally, hand or head movements could occur during any delay in providing the feedback, as the method in Salah is preferably carried out “without the use of a mechanical stabilization device for the acquisition apparatus and/or without the use of any device other than a cell phone and/or without the use of any device other than a cell phone and/or without use of a standard calibration gauge.” *Id.*, 13:24-28. A POSA would have understood that such movements could instantly change the frame that needed to be analyzed and/or result in incorrect images being captured.

2. Dr. Foroosh’s Opinions Are Based On a Misunderstanding Of Salah

95. To the extent Dr. Foroosh is arguing that a POSA would have been motivated to modify Salah to improve the accuracy of its alignment technique, I also disagree. EX1002, *e.g.*, ¶87. Salah confirms that alignment during the image acquisition process need only be “approximate.” EX1008, 27:19-20 (“the image-acquisition apparatus includes verification means to facilitate its approximate positioning relative to the patient prior to acquisition of the updated image.”)

Further, the method for “checking the positioning and/or shape of teeth according to the invention” in Salah expressly uses “a simple image of the teeth, taken without precise pre-positioning of the teeth in relation to the image acquisition apparatus, such as a photograph taken by the patient, to accurately assess tooth displacement and/or deformation since the initial reference model was produced.” EX1008, 2:21-27; *see, also id.*, 31:12-13 (“The person creating the images also positions the image acquisition apparatus in an approximate manner.”). Regarding the capture of dental images, Salah discloses that: “image acquisition can be carried out by the patient himself or by one of their relatives, using a simple cell phone.” *Id.*, 31:5-6. “The ability to acquire images ***with limited precision*** is a ***considerable advantage***, since it makes acquisition possible anywhere and by anyone.” *Id.*, 31:23-24 (emphasis added). Thus, a POSA would have understood that Salah does not require or relate to the acquisition of highly accurate, high-quality dental images.

VIII. CONCLUSION

96. For the reasons discussed above, it is my opinion that Dr. Foroosh has misunderstood how key features of the Carrier Provisional 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 May 28, 2024, in Chicago, Illinois.



Budi Kusnoto
Dr. Budi Kusnoto