

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. JOHN MONGAN IN SUPPORT OF PATENT
OWNER'S PRELIMINARY RESPONSE**

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EXHIBIT LIST

Exhibit Number	Description
2002	Declaration of John Mongan, dated December 7, 2023
2003	Curriculum Vitae of John T. Mongan, MD, PhD
2004	Redline of Carrier against the Carrier Provisional
2005	GeForce GTX TITAN X Specifications
2006	<i>Andri et al., YodaNN: An Architecture for Ultralow Power Binary-Weight CNN Acceleration</i>
2007	<i>Shrestha and Dang, Deep Learning-Based Real-Time Auto Classification of Smartphone Measured Bridge Vibration Data</i>
2008	<i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 59, Order Denying Second Motion to Dismiss (N.D. Cal., July 19, 2023)
2009	<i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Defendant's Patent Local Rule 3-3 and 3-4 Initial Invalidity Contentions and Disclosures (N.D. Cal., September 11, 2023)
2010	<i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 86, Align's Notice of Pending <i>Inter Partes</i> Review Petition (N.D. Cal., October 5, 2023)
2011	<i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 92, Order Re Updated Patent Showdown Deadlines (N.D. Cal., October 26, 2023)
2012	<i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 56, Patent Showdown Scheduling Order (N.D. Cal., July 14, 2023)

I. SCOPE OF ENGAGEMENT

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 the state of the art for the technology described in U.S. Patent No. 10,755,409 (“the ’409 Patent”) (EX1001) and on matters relating to the patentability of the claims of that patent. The following is my written declaration on these issues.

II. BACKGROUND

A. Education and Industry Experience

2. My qualifications are summarized below and are presented in more detail in my professional CV, which is attached as Appendix A to this declaration.

3. Additionally, the following overview of my background pertains to my qualifications for providing expert testimony in this matter.

4. I have worked as a professor in the field of radiology for nine years, and have been involved with various aspects of informatics including machine learning, deep learning, and neural networks for the duration of my career.

5. I received a B.S. from Stanford University (1999) in Chemistry, graduating with honors and distinction. I then received a Ph.D. (2006) in bioinformatics and an M.D. (2008) from the University of California San Diego.

6. From 1995 to 2000, I worked part time as a programmer in the software testing development department of Autodesk, Inc. My work there led to three issued U.S. patents on which I am named as an inventor or co-inventor. I am the lead author of *Programming Interviews Exposed*, currently in its 4th edition. This book has sold over 100,000 copies across all editions and has been translated and republished in China (Simplified Chinese), South Korea (Korean), India (English), Russia (Russian), and Poland (Polish). During my PhD, I created and contributed to several molecular simulation software applications, including AMBER, on which I am a named contributor for versions 8 through 10, and Interactive Essential Dynamics.

7. My post-graduate medical training included an internship in Internal Medicine at Kaiser Oakland Medical Center from 2008 to 2009, a residency in Diagnostic Radiology at University of California San Francisco from 2009 to 2013, and a fellowship in Ultrasound and Abdominal Imaging, also at University of California San Francisco from 2013 to 2014.

8. Since 2014, I have worked as a professor in the Department of Radiology and Biomedical Imaging at University of California San Francisco, initially at the assistant professor level until my promotion to associate professor in 2019. In this role, I practice abdominal radiology, including reading X-rays, CT, Ultrasound, and MRI studies; and performing image-guided biopsies and intra-operative image guidance. I train residents and fellows in radiology, incorporating

them into my clinical work, as well as delivering formal lectures on a wide range of topics with a particular focus on artificial intelligence, informatics, and physics. I also conduct grant and industry-supported research, with a focus on artificial intelligence and informatics.

9. I hold two medical board certifications: Diagnostic Radiology from the American Board of Radiology and Clinical Informatics from the American Board of Preventive Medicine. In 2022, I became a Fellow of the Society of Abdominal Radiology.

10. Since 2014, I have held leadership roles in Informatics within the Department of Radiology and Biomedical Imaging, as Associate Chair of Informatics, Vice Chair of Informatics, and Associate Chair of Translational Informatics. In these roles, I have overseen the development of a shared departmental infrastructure for AI research and translational deployment, supervised an Imaging Information Technology (IT) group of approximately 15 people responsible for the clinical computer systems used for imaging, and supervised the Scientific Computing Services IT group that manages the shared research compute infrastructure for the department.

11. I hold several university-wide leadership roles in IT and artificial intelligence, including serving since 2022 as the Chair of the IT Governance Committee on Research Technology, which provides guidance for University

investment in and use of computational infrastructure for research, and serving as a member of the Artificial Intelligence Governance Committee, which reviews artificial intelligence for clinical deployment to ensure safety and efficacy.

12. I have leadership roles in artificial intelligence and informatics in national professional societies. I have been a member since 2018 and chair since 2020 of the Artificial Intelligence Committee of the Radiological Society of North America (RSNA). The RSNA is one of the largest radiology professional societies in the world, with over 54,000 members. Under my leadership, the Artificial Intelligence Committee has hosted artificial intelligence competitions on the Kaggle website every year. Several of these competitions have drawn approximately 1000 teams to compete. The committee also advises the RSNA board on AI position statements, endorsement of multi-society AI-related manuscripts, and the development of the AI Certificate education program. I have also served on the Society of Abdominal Radiology Artificial Intelligence Emerging Technology Committee since 2020.

13. Since 2018, I have been an Associate Editor and Editorial Board Member of the peer-reviewed journal *Radiology: Artificial Intelligence* (impact factor 9.8), which focuses on application of artificial intelligence to radiology and medical imaging.

14. I have authored over 50 peer-reviewed journal articles, 17 of which are related to artificial intelligence and machine learning, and I have given over 130 lectures, including invited plenary lectures on artificial intelligence for the German Röntgen Congress and the Colombian Congress of Radiology.

15. I have completed multiple successful research projects involving development of artificial intelligence for radiology. A highlight of my research work was development of an artificial intelligence model for detection of pneumothorax. This work was published in *Public Library of Science: Medicine* (impact factor 11.6) and licensed to General Electric (GE) for incorporation into their Critical Care Suite. I worked with GE to achieve FDA clearance for the model, and it is currently commercially available on GE X-ray machines. I am the site primary investigator for a pending National Institutes of Health R01 grant that will support development of artificial intelligence for risk stratification of colorectal cancer patients for treatment planning.

16. I am currently named as an inventor or co-inventor on three issued U.S. patents related to computers and software.

17. 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

18. I am being compensated at a rate of \$800 per hour. My opinions are objective, and compensation for my services is not contingent on my opinions or the outcome of this proceeding.

C. Materials and Other Information Considered

19. 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 and those listed in the Petition's Attachment B.

20. In particular, in forming my opinions, I have considered the Petition and the declaration of Dr. Foroosh (EX1002). While I do not address every argument or reference discussed in the Petition or by Dr. Foroosh, that should not be taken as indicating that I agree with Petition or Dr. Foroosh on those arguments or references. Rather, I understand that, if the proceedings are instituted, I will have an opportunity to submit a declaration responding to additional arguments and references. I may rely upon the materials I identify in this declaration and those listed in the Petition's Attachment B and/or additional materials to respond to additional arguments raised by the Petitioner and Dr. Foroosh. I may also consider additional documents and information in forming any necessary additional opinions, including documents that may not yet have been provided to me or that I have not yet identified for myself.

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

III. UNDERSTANDING OF THE LAW

22. 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

23. 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 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 arts reasonably pertinent to the particular problem that the claimed invention addresses. My specific understanding of a POSA with respect to the field of the ’409 Patent in particular is summarized below.

B. Date of Invention

24. 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).

25. 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.

C. Prior Art

26. 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. However, I understand that prior art does not include a public disclosure, publication, or patent that describes the inventor's own work if it was disclosed less than one year before the date of invention.

D. Claim Construction

27. I understand that claim construction is a matter of law and that claim terms are interpreted as a POSA would have understood them at the time of the invention, in view of the patent and evidence related thereto.

28. I understand that there are two types of claims: independent claims and dependent claims. I understand that an independent claim stands alone and includes only the limitations it recites. I further understand that a dependent claim, on the other hand, is a claim that depends on another claim, and that dependent claims include all of the limitations recited in the dependent claim as well as any limitations included in the claim(s) on which it depends.

29. I understand that, to determine the meaning of claim terms, one should first consider the intrinsic evidence, which includes the claim language itself, the

patent specification, and the patent's prosecution and any post-issuance history before the Patent Office. For example, the patent specification may show that the inventor used words or terms in a manner inconsistent with their plain and ordinary meaning. Specifically, I understand that where the specification reveals a special definition given to a claim term by the inventor that differs from the meaning it would otherwise possess, the inventor's lexicography governs. I understand that the prosecution history of the patent may also provide guidance in construing a claim term. For example, the prosecution history may show that the patent applicant might have limited the scope of some or all of the claims during prosecution, either affirmatively or by implication.

30. I understand that if the intrinsic evidence is not conclusive regarding the meaning of a particular claim term, extrinsic evidence may also be used to determine its meaning. I understand that extrinsic evidence may be used, for example, to help determine what a POSA at the time of the invention would have understood the claim term to mean. Extrinsic evidence may include, for example, dictionaries, technical treatises, journals, articles, or expert testimony.

E. Patentability

31. I understand that on March 16, 2013, the America Invents Act (AIA) went into effect, changing American patent laws and rules as applied to patents filed

on or after March 16, 2013. I understand that the application from which the '409 Patent was filed after March 16, 2013.

32. I understand that generally the party challenging the validity or patentability of an issued U.S. patent bears the burden of proof to demonstrate that such patent is invalid or unpatentable. I understand that in this proceeding, Petitioner has the burden to show that the '409 Patent claims are unpatentable by a preponderance of the evidence.

F. Obviousness

33. I understand that a claim is invalid or unpatentable for obviousness if the differences between the invention and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the subject matter pertains.

34. I understand that obviousness is ultimately a question of law based on a determination of a number of factual issues. Those factual issues relate to: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention as a whole, (3) the level of ordinary skill in the art at the time the invention was made, and (4) secondary considerations reflecting indicia of nonobviousness of the subject matter sought to be patented, as discussed further below.

35. I understand that the obviousness inquiry takes place at the time of the invention. Therefore, care must be taken to avoid the impermissible use of hindsight in an obviousness analysis. I understand that it is improper to use the invention as a plan or template for hindsight reconstruction of elements of the prior art to piece together the claimed invention.

36. It is my further understanding that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was known independently in the prior art. There must be an apparent reason why it would have been obvious to modify the prior art to arrive at the claimed invention with a reasonable expectation of success of doing so. I understand that to avoid impermissibly applying hindsight, one insight into the obviousness determination is whether there is a teaching, suggestion, or motivation in the prior art that would lead a POSA to combine the elements.

37. I also understand, however, that a person of ordinary skill in the art is also a person of ordinary creativity, and not an automaton. Thus, I understand that the ordinary creativity of a skilled artisan may provide a motivation to combine references. I understand that common sense may also provide a motivation to combine references. I understand that the obviousness analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, but instead can take account of the “ordinary innovation” and experimentation that does

no more than yield predictable results, which are inferences and creative steps that a person of ordinary skill in the art would employ.

38. I further understand that the patent challenger bears the burden to show that a person of ordinary skill in the relevant field had a reason and ability to combine the elements in the manner claimed and a reasonable expectation of success in doing so when asserting obviousness in view of a combination of references.

39. I further understand that where a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. Similarly, I understand that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious. That is, the claimed improvement must be more than the predictable use of prior art elements according to their established functions.

40. I further understand that if a technique has been used to improve one device, and a POSA would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

41. I further understand that a reference may be said to “teach away” from the invention when a POSA, upon reading the reference, would be discouraged from

following the path set out in the invention, or would be led in a direction divergent from the path that was taken by the patentee. For example, a reference teaches away if (1) a combination would produce a seemingly inoperative device, or (2) the reference leaves the impression that the product would not have the desired property. However, mere expression of a general preference for one alternative, even if over another alternative, does not teach away if it does not criticize, discredit, or otherwise discourage investigation into the claimed invention.

42. I further understand that a reference qualifies as prior art for an obviousness determination where that reference is analogous to the claimed invention. I understand that art is analogous to the claimed invention where it is either (1) from the same field of endeavor, regardless of the problem addressed or (2) even if not from the same field, is still reasonably pertinent to the particular problem with which the inventor is involved. I understand that a field is analogous to the claimed invention where a POSA would reasonably be expected to look to that field for a solution to the problem at hand. I understand that a reference is reasonably pertinent if it is one which, because of its subject matter, logically would have commended itself to an inventor's attention in considering his problem.

43. I also understand that the following are examples of rationales that may support a conclusion of obviousness:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known technique to improve similar devices/products in the same way;
- Applying a known technique to a known device/product ready for improvement to yield predictable results;
- “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavour may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention with a reasonable expectation of success.

G. Secondary Considerations Relevant to Nonobviousness

44. I understand that factors commonly known as “secondary considerations” may weigh against finding claims obvious. I understand that, for

such secondary considerations to be accorded substantial weight, a nexus or causal connection must exist between the evidence and the merits of the claimed invention itself. I understand that, where the offered secondary consideration actually results from something other than what is both claimed and inventive in the claim, there is no nexus to the merits of the claimed invention. I further understand that such secondary considerations are not determinative, and that one may conclude that a patent claim is obvious even in the face of considerable evidence of secondary considerations. For example, such secondary considerations must be considered in light of all other factors and evidence that support obviousness.

45. I understand that secondary considerations may include:

- *Third Party Recognition*: I understand that evidence of praise of the invention by persons skilled in the art can be considered as an indication of nonobviousness where there is a nexus between the claimed invention and the praise. I understand that for there to be a nexus, the praise by persons skilled in the art must be due to what is both claimed and inventive in the claim. I understand that, at the very least, a nexus requires that any products that are praised fall within the subject matter of each claim.
- *Commercial Success*: I understand that evidence of commercial success of the invention can be considered as an indication of nonobviousness if there is a nexus between the claimed invention and the commercial success. I

understand that for there to be a nexus, the commercial success must be due to what is both claimed and inventive in the claim. For commercial success based on sales, in particular, I understand that the sales must be a direct result of the unique characteristics of the claimed invention.

- *Licensing*: I understand that evidence of commercial success can also take the form of licenses for the claimed invention, but that such evidence likewise requires a nexus with the claimed invention. For example, I understand that the mere fact of licensing, without more, is generally not a strong indication of nonobviousness if it cannot also be shown that the licensees did so out of respect for the patent rather than to avoid litigation expense.
- *Failure of Others*: I understand that evidence that others tried but failed to solve the problem solved by the claimed invention can be considered as an indication of nonobviousness. However, like the other factors, this failure of other must have a nexus to what is both claimed and inventive in the claim.
- *Long-Felt But Unsolved Need*: I understand that evidence that a claimed invention solved longstanding problems or fulfilled a long-felt need in an industry can be considered as an indication of nonobviousness. But I understand again that any such evidence must be considered in light of all other factors and evidence that support obviousness.

- *Unexpected and Superior Results*: I understand that where a claimed invention results in unexpected results that provide improved properties that are greater than would have been predicted, those unexpected results may indicate that the claimed invention yielded more than predictable results. I understand that when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art. I understand that any such evidence must be considered in light of all other factors and evidence relevant to obviousness.
- *Initial Skepticism and Rapid Replacement of Prior Art Technology*: I understand that evidence that a claimed invention faced initial skepticism from those of ordinary skill in the art, and that despite the initial skepticism, over time the claimed invention was widely adopted and praised, this evidence can be an indication of non-obviousness. As elsewhere, I understand that any such evidence must be considered in light of all other factors and evidence that support obviousness. As with other secondary considerations, it must be shown that the skepticism—and the eventual adoption and praise—result from what is both claimed and inventive in the claim.
- *Copying*: I understand that evidence of copying of the patented invention may be an indication of non-obviousness, but that any such evidence must be considered in light of all other factors and evidence that support obviousness.

I further understand that not every competing product that arguably falls within the scope of a patent is evidence of copying; otherwise, every infringement suit would automatically confirm the nonobviousness of the patent. I understand that copying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product.

IV. THE '409 PATENT

A. The Effective Filing Date of the '409 Patent

46. The '409 Patent was filed as U.S. Application No. 16/031,201 on July 10, 2018, claiming priority to French Patent Application No. 1756947, July 21, 2017. I understand that Petitioner has not challenged the entitlement of the '409 Patent to this priority date. Pet. 13; EX1002 ¶26.

B. Person of Ordinary Skill in the Art

47. In my opinion, a person of ordinary skill in the relevant field as of July 21, 2017 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 would have included individuals familiar with medical imaging, dental imaging, dentistry, and/or orthodontics.

48. I understand that Petitioner has contended 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.

49. In my opinion these definitions are not materially different, and to the extent they are different, my opinions contained herein are not impacted by any such differences.

C. Introduction to the '409 Patent

50. The claims of the '409 Patent are directed to inventions relating to dental treatment. The claims addressed an "ongoing need for a method simplifying the analysis of" dentition, aligner, and other related images used to provide dental treatment to patients, *e.g.*, orthodontic treatment using aligners. *See, e.g.*, '409

Patent, 1:16–19, 3:60–63, 4:21–27. The claims solved that need by, for instance, providing new and improved methods that employ a deep learning device to acquire and analyze such images in a manner that is “particularly reliable” for dental treatment. *See, e.g., id.*, 18:56–61, 28:44–48. Through the use of the deep learning device, “the invention advantageously makes it possible to immediately recognize the content of the analysis image.” *See, e.g., id.*, 1:59–62.

51. The deep learning devices employed in the claims of the ’409 Patent are specifically trained for the purpose of acquiring and analyzing images for dental treatment. *See, e.g.*, ’409 Patent, 3:13–17. As the patent explains, for example, the “invention provides a method that is particularly effective for creating a learning base” that may be used to train the deep learning device to perform the analysis and make an accurate assessment, which is vital to effective dental treatment. *See, e.g., id.*, 13:62–63.

52. In addition to these technological improvements, the claims of the ’409 Patent also provide a new and improved method of “embedded monitoring” for the acquisition of dentition, aligner, and other related images such that the process meets certain acquisition conditions—which ultimately is necessary for effective dental treatment. *See, e.g.*, ’409 Patent, 23:46–24:8, 25:13–20. For instance, by specifically determining whether the quality or another characteristic of an acquired image (*e.g.*, “opening of the mouth” or “wearing of a dental appliance”) meets a particular

“setpoint” for such an image, requiring adjustments if that “setpoint” is not met, and “guid[ing]” a patient to make the correct adjustments, the claims of the ’409 Patent “considerably speed up the execution” of this method “while making this assessment particularly reliable.” *Id.*, 27:16–22, 28:44–48, 32:13–33. The claims of the ’409 Patent therefore provide yet another specific technological advance in remotely acquiring (including by a patient without medical training) and analyzing dentition, aligner, and other related images for the purposes of dental treatment.

V. OVERVIEW OF THE ASSERTED ART

A. The Asserted Art

1. Salah

53. PCT Publication No. WO2016066651 to Salah et al. (“Salah”) is entitled “Method for Monitoring Dentition.” Salah names five inventors, four matching the inventors listed on the ’409 Patent. Salah teaches 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 image of the patient’s teeth, and comparing the updated image to the reference model. EX1008, 1:1–2:19.

54. The method for “checking the positioning and/or shape of teeth according to the invention” in Salah 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. Salah’s disclosed invention concerns comparing those simple 2D images to a 3D model to update the 3D model. EX1008, 1:12–24. The purpose of Salah’s disclosed invention is not an improved method for acquiring dental images, as is claimed by the ’409 Patent.

55. Regarding the capture of dental images, Salah discloses: “The person creating the images also positions the image acquisition apparatus in an approximate manner,” and “[p]referably, no measurements are taken on the teeth to bring the acquisition apparatus into the matching position.” EX1008, 31:12–13, 31:26–27. “In particular, image acquisition can be carried out by the patient himself or by one of their relatives, using a simple cell phone.” EX1008, 31:6–7. “The ability to acquire images with limited precision is a considerable advantage, since it makes acquisition possible anywhere and by anyone.” EX1008, 31:23–24. Accordingly, Salah does not require or relate to the acquisition of highly accurate, high-quality dental images, as is claimed by the ’409 Patent.

56. The goal of the image acquisition method disclosed in Salah is to provide real-time guidance during actual image acquisition. *See, e.g.*, EX1008, 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.”). To do so, Salah discloses a method that uses reference marks that are “preferably ‘immobile’ on the screen.” EX1008, 28:11–12; *see generally id.*, 28:4–30:15 (describing the use of reference marks for image acquisition).

57. Salah repeatedly states that the software to perform the real-time analysis of the image during image acquisition runs on the image acquisition device itself. EX1008, 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”), 11:13–22 (“an image acquisition apparatus comprising ... a computer program comprising program code instructions for simultaneously displaying an image on said screen and a reference, said reference being in a position such that, when the registration mark corresponds to the reference on the display, the acquisition apparatus complies with target acquisition conditions”), 16:13–21 (“a personal device, in particular a cell phone or tablet, in which such a program is loaded”), 30:22–31:2, 54:12–15, and claims 4 and 7. Indeed, Salah states that “[i]n

particular, the acquisition apparatus can be a cell phone, and the program can be a specialized cell phone app.” EX1008, 32:1–12.

58. In contrast with the ’409 Patent, Salah does not disclose the use of a deep learning device trained by means of a learning base during the image acquisition process. Instead, Salah mentions deep learning only once as a non-preferred method in a list of 38 methods for *post*-acquisition updating of the 3D image. EX1008, 34:15–36:14.

2. Carrier

59. U.S. Patent Publication No. 2021/0068923 to Carrier, et al. (“Carrier,” EX1005) is entitled “Methods and Apparatuses for Dental Images.” Carrier was filed on November 18, 2020, and published on March 11, 2021. Carrier claims priority to (a) Application No. 16/827,594 (EX1010), filed March 23, 2020, (b) Application No. 15/803,718 (EX1011), filed November 3, 2017, and (c) Provisional Patent Application No. 62/417,985 (“Carrier Provisional,” EX1006), filed November 4, 2016.

60. There are significant and relevant differences between Carrier and the Carrier Provisional. EX2004 (highlighting the significant differences and added subject matter between these disclosures).

61. For example, Carrier includes disclosure relating to a method for guiding a patient through a user interface on a mobile device to a take a first and

second plurality of photos of their own teeth for transmission to a dental professional for evaluation. EX1005, ¶19. In contrast, the Carrier Provisional only discloses a method for dental professionals, as opposed to the patient themselves, to use a mobile phone to capture “high quality dental images.” *See, e.g.*, EX1006, ¶6; *see also id.*, ¶57 (“The on-screen overlay with the outline of teeth can help doctors to take quality dental photos using the mobile phone.”).

62. It is my opinion that the Carrier Provisional is directed to a fundamentally different invention from that claimed in claim 1 of Carrier. More specifically, as noted above, the Carrier Provisional is directed to methods and apparatuses for dental professionals to capture dental images, whereas claim 1 of Carrier requires “guiding the patient through the user interface to take a [first or second] plurality of photos of teeth of the patient.” *See, e.g.*, EX1006, ¶4 (“Some doctors and dental technicians may instead attempt to capture dental photos using a mobile phone”), ¶51 (“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.”), ¶56 (“Therefore, doctors can be guided to take dental photos by the on-screen overlay, saving time and effort.”), ¶57 (“The on-screen overlay with the outline of teeth can help doctors to take quality dental photos using the mobile phone.”), ¶81 (“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.”), ¶95 (“Thereafter, the app may guide the doctor or clinician in taking a predetermined series of images.”).

63. I have reviewed Dr. Foroosh’s cited evidence that the “guiding the patient” limitations in claim 1 of Carrier are supported by the Carrier Provisional, namely, ¶¶36, 61, 73-75, 85, Figs. 4A-5A, 8, 10 of the Carrier Provisional. EX1002, 30-31. It is my opinion that, when read as a whole, these disclosures do not describe guiding a **patient** to capture dental images in sufficient detail that a POSA could reasonably conclude that the Carrier Provisional inventors had possession of such an invention. Instead, these disclosures, and the Carrier Provisional viewed as a whole, concern guiding a dental professional how to capture dental images of a patient.

64. The fact that the invention claimed in claim 1 of Carrier is not adequately supported by the Carrier Provisional is also made evident by the substantial additions to the specification of Carrier. *See, e.g.*, EX1005, ¶¶41, 52-54, 95, 97, 135, 154-56 179-81, *see also* EX2004. These disclosures added to Carrier are significant additions because they relate to a patient capturing their own dental images in order to allow for remote screening outside of the supervision of a dental professional. These disclosures are also notably absent from the dental professional driven approach in the Carrier Provisional.

65. Regarding the capture of dental images, Carrier and the Carrier Provisional both require a predetermined overlay on the screen of a mobile telecommunication device and moving the mobile telecommunications device so that the overlay approximately matches the view of the patient's teeth on the screen. *See, e.g.*, EX1006, ¶6 (“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, ¶8. The method in Carrier and the Carrier Provisional is expressly designed for mobile phones (or traditional handheld consumer electronics, such as smartphones, smartwatches, pads, and tablets) to be used to capture images “instead of using expensive and bulky SLR cameras.” *See, e.g.*, EX1006, ¶¶51, 52, 54; *see also* EX1005, ¶4.

66. Like Salah, the method disclosed in Carrier and the Carrier Provisional concerns real-time guidance during actual image acquisition. *See, e.g.*, EX1005, ¶7 (“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 showing a real-time display of from the camera.”), ¶54 (“In particular, these apparatus 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.”); EX1006, *e.g.*, ¶99 (“ 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.”).

67. Also, like Salah, Carrier and the Carrier Provisional disclose the use of software running on a mobile phone. EX1006, ¶19 (“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 then indicator is triggered.”), ¶63 (“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.”), ¶87 (“Various embodiments of the disclosure further disclose a non-transitory, computer-readable storage medium storing a set of instructions capable of being executed by a processor of a mobile telecommunications device...”), ¶87 (“For example, the non-transitory, computer-readable storage medium, wherein the set of instructions, when executed by the processor, can further cause the processor to estimate an indicator of the distance between an edge of the patient’s teeth in the view of the patient’s teeth...”); EX1005, ¶¶20, 108, 155, 156.

68. While Carrier expressly mentions the use of “machine learning,” all such disclosure concerning “machine learning” was added after the priority date of the ’409 Patent. EX2004. The Carrier Provisional contains only 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 image acquisition apparatus. EX1006, ¶63 (“Once the apparatus (e.g., software/application software executing on the apparatus) determines that the teeth are in approximately aligned with (e.g., approximately match) 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.).”), ¶¶80–81(“Any of these methods and apparatuses may further include reviewing the captured image on the mobile telecommunications device to confirm image quality and/or automatically accept/reject the image(s).”). It is my opinion that, given this context, a POSA would not have understood the Carrier Provisional to refer to or suggest a neural network of the type disclosed in Maninis. Maninis discloses a much more complex architecture than is necessary to perform the method disclosed by the Carrier Provisional, and as discussed below, the Maninis neural network architecture is not suited to operate on the mobile devices used in the Carrier Provisional.

3. Maninis

69. Kevis-Kokitsi Maninis et al.’s article entitled “Convolutional Oriented Boundaries: From Image Segmentation to High-Level Tasks” (“Maninis,” EX1007), discloses an approach to perceptual grouping via boundary detection using two different convolutional neural network (“CNN”) architectures. EX1007, 13.

70. Maninis is an academic paper. It makes no mention of the use of its neural network architecture for any medical application, including for dental or aligner images. Maninis also does not disclose that its neural network architecture can be used during image acquisition. Dr. Foroosh does not identify any reason why a POSA would have been aware specifically of Maninis, and I am not aware of any such reason.

71. Additionally, Maninis does not disclose that its neural network architecture would be suitable for use on a mobile device. In my opinion, it would not have been because the GPU used in Maninis is a processor designed for computationally intensive applications on a desktop computer. EX2005.

72. As of July 2017, it was known to POSA that the Maninis neural network models were too computationally expensive and resource draining to run on even the most optimized mobile devices, and they were not suitable for real-time object recognition on devices with power limitations. *See, e.g.*, EX2006 (“Convolutional neural networks (CNNs) have revolutionized the world of computer vision over the last few years, pushing image classification beyond human accuracy. The computational effort of today’s CNNs requires power-hungry parallel processors or GP-GPUs. Recent developments in CNN accelerators for system-on-chip integration have reduced energy consumption significantly. Unfortunately, even these highly optimized devices are above the power envelope imposed by mobile and deeply embedded applications.”); EX2007 (confirming, after the ’409 Patent priority date, that “[s]uch costly computation complexity makes the deployment of CNN models unaffordable for common PCs and mobile devices”).

VI. A POSA WOULD NOT HAVE BEEN MOTIVATED TO COMBINE MANINIS WITH SALAH AND/OR CARRIER

73. It is my opinion that neither Carrier¹ nor Salah discloses any problem or shortcoming with its image acquisition method that a POSA would have been motivated to try to address by combining one or both of the references with Maninis. In fact, Carrier's method was specifically designed to use "traditional handheld consumer electronics," such as smartphones, and avoid the use of "expensive and bulky" equipment like SLR cameras. EX1006, ¶¶51, 52, 54. Carrier also discloses that its methodology already achieves the desired high quality dental images. EX1006, ¶6. Similarly, Salah expressly states that a benefit of its invention is that it requires only simple images of a patient's teeth that can be acquired on a cell phone. EX1008, 2:22-27. Salah further teaches a POSA that its invention "does not require precise positioning of the image acquisition apparatus relative to the teeth." EX1008, 27:15-16. Accordingly, Maninis does not provide any specific functionalities that a POSA would have believed were missing from or required by the image acquisition methods of Salah or Carrier.

74. It is my opinion that none of the alleged prior art cited by Petitioner and Dr. Foroosh suggests the use of a deep learning device for guiding any type of image acquisition, including for acquisition of dental and aligner images. The broad

¹ In Sections VI and VII, my discussion of Carrier is limited to the teachings of Carrier that are supported by the Carrier Provisional.

references to “edge detection image processing” and “image recognition algorithms” in Carrier would not have motivated a POSA to specifically select a deep learning device for the purposes of Carrier’s image acquisition method that was designed to run on a mobile phone, particularly when no prior art cited by Petitioner and Dr. Foroosh suggest such use. It is also my opinion that Salah’s reference to deep learning also would not have motivated a POSA to combine the image acquisition method in Salah (and/or Carrier) with Maninis. This is because Salah mentions deep learning only once as a non-preferred option in a list of almost 40 potential methods that relate to post-image acquisition updating of a tooth contour map, and it does not suggest that deep learning can be used in guiding image acquisition. EX1008, 34:5-36:14.

75. As discussed above, the Maninis neural network architecture was computationally intensive and therefore, expensive and time-consuming to develop. *See* EX2007 (confirming, after the ’409 Patent priority date, that “[s]uch costly computation complexity makes the deployment of CNN models unaffordable for common PCs and mobile devices”). A POSA also would have known that the specific deep learning architecture of Maninis was not suited for use on mobile devices, such as smartphones, or for real-time object recognition on mobile devices. For this reason, a POSA would not have believed that the Maninis neural network would be compatible with the image acquisition methods in Carrier and Salah that

were designed to provide real time guidance and run on a mobile device, and a POSA would not have been motivated to combine Maninis with Carrier and/or Salah.

76. For the above reasons, it is my opinion that a POSA would not have been motivated to combine Salah or Carrier with Maninis, which was neither suited for use on a mobile device nor providing real-time object recognition.

VII. A POSA WOULD NOT HAVE HAD A REASONABLE EXPECTATION OF SUCCESS IN COMBINING MANINIS WITH SALAH AND/OR CARRIER

77. As discussed above, none of the references relied on by Dr. Foroosh, *i.e.*, Carrier, Salah and Maninis, discloses the use of a deep learning device for any type of image acquisition, including acquisition of dental and aligner images. Salah and Carrier expressly disclose the use of traditional image processing software running on the image acquisition device, such as a cell phone, to provide real-time guidance during image acquisition. *See, e.g.*, EX1005, ¶7 (“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.”); EX1008, 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 discloses the use of deep learning but like Maninis, this was only in the context of image analysis *post*-acquisition. EX1008, 34:5-36:14.

78. As discussed above, it is my opinion that a POSA would have known that the specific neural network architecture disclosed by Maninis requires “power-hungry parallel processors or GP-GPUs” and was not suitable for real-time object recognition on devices with power limitations e.g., smartphones. *See* EX2006.

79. Accordingly, it is my opinion that a POSA would not have a reasonable expectation of successfully combining Carrier and/or Salah with Maninis.

VIII. SUBSTANTIALLY THE SAME ART WAS PREVIOUSLY PRESENTED TO THE OFFICE

80. It is my opinion that the art asserted in the Petition and relied on by Dr. Foroosh is duplicative of the art considered by the Examiner during prosecution of the application that led to the '409 Patent.

81. Salah is cited extensively in the specification of the '409 Patent and listed as a reference considered by the Examiner. *See* '409 Patent at Page 2; 2:43; 3:10; 7:11; 7:21; 7:33; 7:53; 8:56; 9:37; 10:49; 17:65; 18:16; 19; 36; 20:53; 22:12; 24:2; 23:45; 23:50; 23:61; 25:21; 27:19; 27:27; *see also, e.g.,* EX1004, 71, 436, 571, 1018, 1027.

82. As discussed above, Carrier, like Salah, requires the use of an overlay or reference marks to guide capture of a dental image, and simply compares the new

image against that reference. It is my opinion that Carrier is duplicative of Salah, which was considered by the Examiner.

83. To the extent Carrier is not duplicative of Salah, however, other references considered by the Examiner disclose any missing elements. For example, similar to Carrier, U.S. Patent Application 2018/0168780 (“Kopelman”) describes acquiring 2D images with guidance from overlays projected over the teeth. *See* EX1004, 833. The only material difference between the approach disclosed in Kopelman and that described in Carrier is that Kopelman describes using dedicated augmented reality (“AR”) hardware (*i.e.*, a headset). *See* EX1004, 833. As discussed above, however, Salah was before the Examiner and discloses the use of a cell phone to capture dental images. Accordingly, it is my opinion that the arguments presented with respect to Salah and Carrier are duplicative of those already considered by the Examiner in Salah and/or Kopelman.

84. With respect to Maninis, the specification of the ’409 Patent discloses exemplary neural networks, a type of deep learning device, that perform image classification and object detection and classification (*e.g.*, Faster R-CNN). *See, e.g.*, ’409 Patent, 16:15-43. The neural network described in Maninis is also capable of performing these tasks. The only material difference between Maninis and neural networks like Faster R-CNN is that the Maninis neural network can generate a hierarchical organization of detected contours and regions. Those capabilities are,

however, not discussed or cited by Dr. Foroosh. Accordingly, with respect to the capabilities that are relied on with respect to the '409 Patent, nothing additional is disclosed by Maninis that was not already disclosed in the specification. In addition, I note that multiple other references related to neural networks were before the Examiner detailed on Page 2 of the '409 Patent, including at least: "Annual International Conference on the Theory and Applications of Cryptographic Techniques, Eurocrypt 2018", vol. 7477, 17 September 2012, ISBN: 978-3-642-17318-9, Kelwin Fernandez et al: "Teeth/Palate and Interdental Segmentation Using Artificial Neural Networks", Sep. 17, 2012 (Sep. 17, 2012), Artificial Neural Networks in Pattern Recognition, Springer Berlin Heidelberg, Berlin, Heidelberg, pp. 175-185, XP047017215, ISBN: 978-3-642-33211-1"; Miki Yuma et al: "Tooth labeling in cone-beam CT using deep convolutional neural network for forensic identification", Progress in Biomedical Optics and Imaging, SPIE-International Society for Optical Engineering, Bellingham, WA, US, vol. 10134, Mar. 3, 2017 (Mar. 3, 2017), pp. 101343E-101343E, XP060086665, ISSN: 1605-7422, DOI: 10.1117/12.2254332, ISBN: 978-1-5106-0027-0; Miki Yuma et al: "classification of teeth in cone-beam CT using deep convolutional neural network" Computers in Biology and Medicine, New York, NY, US, vol. 80, Nov. 12, 2016 (Nov. 12, 2016), pp. 24-29; Miki Yum, et. al: "Tooth labeling in cone-beam CT using deep convolutional neural network for forensic identification", Progress in Biomedical

Optics and Imaging , vol. 10134, 3 March 2017 (2017-03-03),; Young-Jun YU: “Machine Learning for Dental Image Analysis”, 29 November 2016 (2016-11-29), XP055430578.

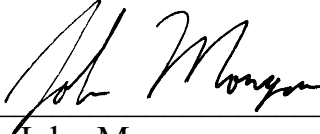
85. Accordingly, it is my opinion that for the same reasons the claims of the '409 Patent were not obvious in light of the deep learning models like Faster R-CNN, they remain nonobvious in light of Maninis.

IX. CONCLUSION

86. For the foregoing reasons, it is my opinion that a POSA would not have been motivated to combine Salah and/or Carrier with Maninis; a POSA would not have a reasonable expectation of success in combining Salah and/or Carrier with Maninis; and the art presented by Petitioner is duplicative of the art considered by the Examiner.

I, John Mongan, 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.

Executed December 6, 2023, in San Francisco, CA.



Dr. John Mongan