

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALIGN TECHNOLOGY, INC.,

Petitioner,

v.

DENTAL MONITORING SAS,

Patent Owner.

Case No. IPR2024-00052

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

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

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EXHIBIT LIST

Exhibit Number	Description
2003	Curriculum Vitae of John T. Mongan, M.D., Ph.D.
2008	May 7, 2020 Press Release of Petitioner, Align Technology, Inc.
2009	U.S. Pat. Pub. 2017/0325689 (Dental Monitoring's English Language Translation of the International Patent Application published as Salah (PCT Publication No. WO2016066651))
2010	J. Liu et al., Machine learning in orthodontics: Challenges and perspectives, 30(10) Advances in Clinical and Experimental Medicine 1065
2017	The PASCAL-Context Dataset (June 13, 2017 version available at https://web.archive.org/web/20170613074321/https://cs.stanford.edu/~roozbeh/pascal-context/)
2018	The PASCAL VOC 2010 Dataset (July 7, 2017 version available at https://web.archive.org/web/20170707024736/http://host.robots.ox.ac.uk/pascal/VOC/voc2010/#data)
2019	The Berkeley Segmentation Data Set (BSDS 500) (July 22, 2016 version available at https://web.archive.org/web/20160722194737/http://www.eecs.berkeley.edu/Research/Projects/CS/vision/grouping/resources.html)
2020	The PASCAL VOC 2012 Segmentation dataset (July 13, 2017 version available at https://web.archive.org/web/20170713000522/http://host.robots.ox.ac.uk/pascal/VOC/voc2012/#data)
2021	The NYUD v2 Datasets (July 13, 2017 version available at https://web.archive.org/web/20170705142032/https://cs.nyu.edu/~silberman/datasets/nyu_depth_v2.html)

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. 11,049,248 (“the ’248 Patent”) (EX1001) and on certain matters relating to the patentability of the claims of that patent.

II. BACKGROUND

A. Education and Industry Experience

2. My qualifications are summarized below and are presented in more detail in my professional CV (EX2003), 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 Ph.D., 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 the University of California San Francisco from 2009 to 2013, and a fellowship in Ultrasound and Abdominal Imaging, also at the 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 the 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 the 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 the development of artificial intelligence for radiology. A highlight of my research work was the 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 the 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, those listed in the Petition, and the exhibits thereto.

20. In particular, in forming my opinions, I have considered the Petition (Paper 2) 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 the 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, its attachments, 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 art reasonably pertinent to the particular problem that the claimed invention

addresses. My specific understanding of a POSA with respect to the field of the '248 Patent 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 '248 Patent issued 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 '248 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 POSA.

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 POSA 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 POSA would employ.

38. I further understand that the patent challenger bears the burden to show that a POSA 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 person of ordinary skill in the art 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 a 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 endeavor 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 '248 PATENT

A. The Effective Filing Date of the '248 Patent

46. The '248 Patent was filed as U.S. Application No. 16/030,137 on July 9, 2018, claiming priority to French Patent Application No. FR1756956, July 21, 2017. I understand that Petitioner has not challenged the entitlement of the '248 Patent to this priority date. Pet. 12; EX1002 ¶ 26.

B. Person of Ordinary Skill in the Art

47. In my opinion, a POSA 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 contends that a POSA as of July 21, 2017 would typically have an advanced degree, such as a Master's 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 would not be impacted by

any such differences. Regardless, for the purposes of this declaration, I have been asked to use Petitioner's definition of a POSA.

C. Background on Aligner Treatment

50. I have reviewed the description of aligner treatment in the '248 Patent. EX1001 at 4:52–62, 17:39–53, 27:26–47, 27:55–67, 28:1–6. According to the '248 Patent, aligners are one type of orthodontic device designed to exert gentle pressure and thereby reposition a patient's teeth. *Id.* at 4:52–62. The '248 Patent further explains that as of July 2017, aligner treatment generally began with a patient attending an in-person consultation with an orthodontist or other dental professional who would conduct scans of the patient's starting dentition and determine the desired final positioning. *Id.* at 27:26–30. Based on these initial scans, a sequence of aligners would be designed and fabricated by one of several third-party companies, such as Petitioner. *Id.* at 27:31–46. Once the patient received their aligners, the patient would wear one aligner for a predetermined interval of time and then change to the next aligner to continue shifting their teeth according to the treatment plan. *Id.* at 27:46–47. At that time, effective aligner treatment required frequent in-person orthodontic examinations to determine whether treatment was on track. *Id.* at 17:39–49, 27:55–59. This reliance on periodic in-person examinations meant that treatment issues could go undiagnosed for multiple weeks between check-ins. *Id.* at 17:48–53, 28:1–6. When an orthodontist did identify significant issues with the patient's

progress at an in-person examination, the patient's teeth would have to be rescanned, a new series of aligners manufactured and the old ones discarded. *Id.* at 27:60–67. As a result, the '248 Patent states that aligner treatment was often delayed and prolonged. *Id.* at 27:66–67.

D. The Invention of the '248 Patent

1. Overview

51. The '248 Patent relates to new and improved methods of “assessing the shape of an orthodontic aligner” for purposes of aligner treatment. *See, e.g., id.* at 32:6–23, *see also, e.g., id.* at 28:34–38 (describing the invention as “considerably simplify[ing] the assessment of the good suitability of the aligner to the treatment, while making the assessment particularly reliable”); *see also id.* at 30:60–62 (“The suitability of the aligner can be assessed in the context of an orthodontic treatment (separation [*i.e.*, space between the aligner and the teeth] compatible or not with the orthodontic treatment).”).

52. In particular, the '248 Patent discloses a method comprising “acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, called ‘analysis image.’” *Id.* at 28:13–15. This step can be “performed at the moment when the assessment of the shape of an aligner is desired, for example more than 1 week after the start of the treatment with the aligner.” *Id.* at 30:27–30. The analysis image can be captured

remotely, for example, on a patient's cellphone. *Id.* at 15:30–35; *see also, e.g., id.* at 19:41–44, 25:60–63.

53. The “analysis image” is then analyzed by a specific “deep learning device,” preferably a neural network, that was trained on a specific dataset, a “learning base.” *Id.* at 1:39–43; *see also, e.g., id.* at 1:66–2:1, 16:5–6, 24:3–5. The ’248 Patent describes “training” as a process where, “[b]y presenting, as input for the deep learning device, historical images (images+descriptions), the deep learning device progressively learns to recognize patterns on an image.” *Id.* at 16:38–41; *see also id.* at 16:46–48 (“Through its training in the step 2), the deep learning device is capable of analyzing the analysis image and of recognizing said patterns therein.”). A deep learning device “trained by means of a learning base” is thus a deep learning device that has undergone the process of training using a collection of images and corresponding attribute values for those images. *See id.* The ’248 Patent further discloses a “detailed analysis method” and a “global analysis method” using the deep learning device. *E.g., id.* at 1:29–3:18 (detailed), 3:19–4:39 (global).

54. In the detailed analysis method, the “analysis image” is analyzed by the deep learning device “so as to determine a value for at least one tooth attribute of an ‘analysis tooth zone’ representing, at least partially, a tooth on said analysis image.” *Id.* at 32:15–19. The tooth attribute relates “to a separation between the tooth represented by the analysis tooth zone, and the aligner represented on the analysis

image.” *Id.* at Abstract, 28:21–24, 32:19–21. The tooth attribute value thus “provides an information item relating to the shape of the aligner relative to the shape of the teeth of the patient.” *Id.* at 30:42–44. It “can be a measurement of the separation, for example a measurement of the maximum separation, or of the mean separation for the tooth represented by the historical tooth zone.” *Id.* at 30:45–48. Alternatively, the tooth attribute value can be, e.g., a tooth number, a tooth type, and a tooth shape parameter. *Id.* at 7:64–8:7, 28:48–61, 30:42–54.

55. The deep learning device is trained by means of a learning base comprising, for example, more than 1000 images of dental arches, or “historical images,” each historical image representing an aligner worn by a “historical” patient. *Id.* at 34:23–31; *see also, e.g., id.* at 15:65–16:4, 16:37–43. Each “historical image” comprises “one or more zones each representing a tooth, or ‘historical tooth zones’ to each of which, for at least one tooth attribute relating to a separation between the tooth represented by the historical tooth zone considered, and the aligner represented, a tooth attribute value is assigned.” *Id.* at 34:23–31; *see also, e.g., id.* at 1:33–38.

56. In one embodiment of the detailed analysis method, the deep learning device analyzes the analysis image—the image of the patient’s dental arch with an aligner in the service position—to determine “at least one probability relating to” “the presence, in a location of said analysis image, of an analysis tooth zone; and the

attribute value of the tooth represented on that said analysis tooth zone.” *Id.* at 34:34–40. As a function of that probability, an amplitude of the separation between the patient’s teeth and the aligner is determined. *Id.* at 34:41–42.

57. The analysis may also be performed globally, without identification of the individual situation of each of the teeth represented. *E.g., id.* at 3:19–4:39. In this global analysis method, the analysis image is analyzed by a specially trained “deep learning device” so as to determine a value for an image attribute relating to a separation between at least one tooth and the aligner. *E.g., id.* at Abstract, 29:31–53. The image attribute relates to the image as a whole and includes the maximal separation, the mean separation, and the overall acceptability of the separation between the teeth and the aligner. *Id.* at 28:48–61; *see also id.* at 31:20–29 (“For example, the value of the image attribute may be ‘globally acceptable’ or ‘globally unacceptable’. The value of the image attribute can also, for example, be a measurement of the separation, for example a measurement of the maximum separation, or of the mean separation between the teeth represented on the analysis image and the aligner.”).

58. Preferably, an “assessment of the suitability of the aligner” is made as a function of the tooth or image attribute value. *E.g., id.* at Fig. 9, 28:29–31, 32:26–27, 34:60–61. For example, a search may be “conducted to see if the separation of the aligner with at least one tooth exceeds an acceptability threshold” and, if so, the

patient's aligner is replaced by a better-suited one. *Id.* at 30:56–59. As a function of the suitability assessment, an information message may be sent to the patient and/or the orthodontist. *Id.* at 32:35–36; *see also, e.g., id.* at 26:35–27:3. “The orthodontist can then use this information, possibly in combination with additional information, for example the age of the patient or the duration for which the aligner has been worn, to establish a diagnosis and, if necessary, decide on a suitable treatment.” *Id.* at 31:7–11.

2. The Challenged Claims

59. I understand that Petitioner challenges claims 1-2, 4, 7-8, and 13-16 of the '248 Patent (“the Challenged Claims”).

60. Relevant to my opinions explained in this declaration, independent claim 1 of the '248 Patent, requires that “more than 1 week after the start of the treatment with the aligner,” there is an “acquisition of at least one image” with a “cellphone” that “at least partially represent[s] the aligner” in the “service position in which it is worn by a patient.” *Id.* at 32:6–23. The claim further requires that the image is “a photograph, or an image extracted from a film.” *Id.* The analysis image is then analyzed “by means of a deep learning device, trained by means of a learning base,” “so as to determine a value for at least one tooth attribute of an ‘analysis tooth zone’ representing, at least partially a tooth” on the image. *Id.* The “tooth attribute

relat[es] to a separation between the tooth represented by the analysis tooth zone”
“and the aligner.” *Id.*

61. Claim 2, which depends from independent claim 1, requires an
“assessment of the suitability of the aligner as a function of the value of” the “tooth
attribute.” *Id.* at 32:24–27.

62. Claim 4, which depends from dependent claim 2, requires sending “an
information message as a function of” the assessment of claim 2. *Id.* at 32:33–36.

63. Claim 7, which depends from independent claim 1, requires the
“creation of a learning base comprising more than 1000 images of dental arches,”
each image “representing an aligner worn by a ‘historical’ patient and comprising
one or more zones each representing a tooth,” “to each of which, for at least one
tooth attribute relating to a separation between the tooth represented by the historical
tooth zone” and the aligner, “a tooth attribute value is assigned.” *Id.* at 32:45–67.
The claim further requires “training of at least one deep learning device, by means
of the learning base.” *Id.* It also requires “submission of the analysis image to the
deep learning device” for the deep learning device to determine at least one
probability relating to: (1) “the presence, in a location of said analysis image, of an
analysis tooth zone” and (2) “the attribute value of the tooth represented on said
analysis tooth zone.” *Id.* Finally, the claim requires a “determination, as a function

of said probability, of the presence of a separation of the aligner and of the tooth represented by said analysis tooth zone.” *Id.*

64. Claim 8, which depends from independent claim 1, requires the “creation of a learning base comprising more than 1000 images of dental arches,” each “image comprising an attribute value for at least one image attribute,” “the image attribute relating to a separation between the tooth or teeth and the aligner.” *Id.* at 33:1–15. The claim further requires “training of at least one deep learning device, by means of the learning base.” *Id.* The claim also requires “submission of the analysis image to the deep learning device for it to determine” “at least one probability relating to said image attribute value.” *Id.*

65. Claim 13, which depends from independent claim 1, requires that “the deep learning device is a neural network.” *Id.* at 34:19–20

66. Claim 14, which depends from independent claim 1, requires the “creation of a learning base comprising more than 1000 images of dental arches,” each image “representing an aligner worn by a ‘historical’ patient and comprising one or more zones each representing a tooth.” *Id.* at 34:21–42. Further, to each zone, “for at least one tooth attribute relating to a separation between the tooth represented by the historical tooth zone considered, and the aligner represented, a tooth attribute value is assigned.” *Id.* In addition, the claim requires “training of at least one deep learning device, by means of the learning base.” *Id.* The claim also

requires “submission of the analysis image to the deep learning device for it to determine at least one probability relating to: the presence, in a location of said analysis image, of an analysis tooth zone” and “the attribute value of the tooth represented on said analysis tooth zone.” *Id.* Finally, the claim requires a “determination, as a function of said probability, of an amplitude of said separation.” *Id.*

67. Independent claim 15 requires “more than 1 week after the start of the treatment with the aligner,” the “acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient.” *Id.* at 34:43–57. The claim further requires that the analysis image is “a photograph, or an image extracted from a film.” *Id.* In addition, the claim requires “analysis of the analysis image by means of a deep learning device, trained by means of a learning base, so as to determine a value for an image attribute of the analysis image.” *Id.* That “image attribute relat[es] to a separation between at least one tooth represented on the analysis image” and the aligner. *Id.*

68. Claim 16, which depends from claim 15, requires “assessment of the suitability of the aligner as a function of the value of said image attribute.” *Id.* at 34:58–61.

E. Prosecution History

69. I have reviewed the prosecution history of the '248 Patent. The '248 Patent issued on June 29, 2021 and claims priority to French application No. 1756956, filed on July 21, 2017.

70. I understand from the prosecution history that the 16/030,137 Application was rejected three times before it was ultimately granted. In a Non-Final Rejection (February 27, 2020), the Examiner rejected claims 1–4 under 35 U.S.C. § 102 as anticipated by Matov (U.S. Pat. Pub. No. 2013/0230818). EX1004 at 811–18. Claims 5–6 and 9 were rejected for obviousness under § 103 over Matov in view of Kuo. *Id.* at 818–22. Similarly, claims 10–12 were rejected under § 103 over Matov in view of Borovinskih (U.S. Pat. Pub. No. 2017/0049311). *Id.* at 822–24. Claims 7 and 8 were objected to as depending on rejected claims, but were otherwise found allowable. *Id.* at 824.

71. Patent Owner responded (May 27, 2020) by amending the claims and explaining that Matov did not render the application anticipated or, in combination with other prior art, obvious. *Id.* at 839–50. Patent Owner noted that “Matov does not disclose the acquisition of an image at least partially representing the aligner, and even less in a service position,” as required by claim 1. *Id.* at 842. And “[t]he aim of Matov is to determine the shape and the positioning of a dental appliance by determining the movement between an initial position of a tooth and a target position

of said tooth” using X-ray images and images to provide information about tooth roots. *Id.* at 843–44. Patent Owner also pointed out that Matov did “not disclose the submission of an image to a deep learning device,” and any discussion of neural networks was not linked to the images, let alone to determining tooth or image attributes. *Id.* at 844.

72. In a Final Rejection (June 19, 2020), the Examiner rejected claims 1–6 and 9–14 under §§ 102 (anticipation) and 103 (obviousness) based again on Matov alone or in combination with Kuo (adding a learning base of more than 1000 images) and Borovinskih (adding a cellphone). *Id.* at 851–72. Patent Owner responded (September 4, 2020), *id.* at 891–99, by amending the claims to require that the method occur during aligner treatment, *i.e.*, more than one week after its start. *Id.* at 893. Patent Owner further distinguished Matov on the grounds that Matov was directed to the design and selection of an aligner, not to determining the fit of an existing aligner, and Matov did not disclose acquisition of an image with an aligner during treatment. *Id.* Patent Owner further argued that Matov did not disclose submitting any image—let alone one with an aligner—to a deep learning device. *Id.*

73. In a Non-Final Rejection (September 28, 2020), *id.* at 902–27, the Examiner again rejected claims 1–6 and 9–16 on the grounds that an image “acquired more than 1 week after the start of treatment with the aligner” was described in Wen (U.S. Pat. Pub. No. 2017/0300207). *Id.* at 908–09. Thus, the Examiner rejected the

claims under § 103 for obviousness over Matov in view of Wen (adding acquisition of an image during treatment), Kuo (adding a learning base of more than 1000 images), and Borovinskih (adding a cellphone). *Id.* at 911–26.

74. Patent Owner responded (December 28, 2020) noting again that Matov is directed to designing an aligner *before* its manufacture, thus precluding the patient from wearing an aligner in an image. *Id.* at 940–51. Patent Owner also observed that Matov never suggests the submission of an image with an aligner (or any image) to a deep learning device to determine a value for a tooth attribute relating to a separation between the tooth and the aligner. *Id.* With respect to Wen, Patent Owner argued that it neither describes the acquisition of an image with an aligner as it is directed to simulating tooth movement, nor determining a tooth attribute relating to separation. *Id.* at 950.

75. Following this argument and a telephonic interview, the Examiner issued a Notice of Allowance (February 22, 2021). *Id.* at 954–69. The Examiner accepted Patent Owner’s December 28, 2020, arguments. *Id.* at 960–61. In doing so, the Examiner acknowledged that “neither Matov nor Wen teach or suggest, among other things, more than 1 week after the start of the treatment with the aligner, acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, and [a] tooth attribute relating to a separation between the tooth represented by the analysis tooth zone, and the aligner

represented on the analysis image, [or that] a cellphone is used to acquire the analysis image.” *Id.* (cleaned up).

V. OVERVIEW OF THE ASSERTED ART

A. U.S. Patent Publication No. 2017/0281313 to Kim et al. (“Kim”)

76. I have reviewed U.S. Patent Publication No. 2017/0281313 (“Kim,” EX1005). Kim is entitled “Method and System for Providing Remote Teeth Alignment Services and Computer-readable Medium on which the Method is Recorded.” Kim was filed on April 5, 2016, and was published after the ’248 Patent priority date, on October 5, 2017. Consistent with the ’248 Patent, Kim discloses that “[u]sing the [then] conventional clear-aligner treatment method, an orthodontic patient should regularly visit a dental clinic for a long period of time to allow a dentist to accurately check the state of his/her teeth and determine a currently appropriate step of a clear aligner.” EX1005 at [0008].

77. Kim related to a method for determining the alignment of teeth to assess whether treatment is progressing correctly and not for evaluating aligner fit. *Id.* at [0010] (disclosing “a method and system for providing remote teeth alignment services”). That method involves an orthodontic patient sending the orthodontist “teeth alignment information using a device, e.g., a smartphone.” *Id.* Kim asserts that the orthodontist may then “remotely and accurately diagnose the condition of the patient based on the teeth alignment information, and may remotely provide

information about an accurate step of a clear aligner to be currently worn by the orthodontic patient.” *Id.*

78. Specifically, “[t]he teeth alignment report information” sent by the patient may include “a front-view teeth photo, a bottom-view low-angle teeth photo, a front-view automatically-recognized mouth gag photo, a front-view automatically-recognized face contour photo, a left-side-angle automatically-recognized mouth gag photo, a left-side-angle automatically-recognized face contour photo, a right-side-angle automatically-recognized mouth gag photo, a right-side-angle automatically-recognized face contour photo, a collection of top, bottom, left, and right side photos surrounding a central front photo, a low-angle upper jaw photo, a high-angle lower jaw photo, and combinations thereof, which are taken using a camera of the orthodontic patient terminal.” *Id.* at [0013]; *see also* [0056] (discussing acquisition of images of the patient’s teeth, not the aligner as worn by the patient), [0081] (same), [0087] (same), Figs. 8–13 (showing only images of the patient’s teeth without aligners), 16 (same), 19 (same), 23 (same).

79. It is my opinion that Kim does not relate to a method for assessing the fit of an aligner and it does not disclose “acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient,” as required by all Challenged Claims. While Kim states that “the orthodontist checks a photo or a video of the clear aligner currently worn,” *id.* at

[0066], a POSA would not understand this to refer to an image of the patient wearing the aligner. Rather, a POSA would understand this language to refer to a photo or video of the aligner that would be used to determine whether the aligner is the correct aligner and whether the aligner has abnormalities, such as damage. This is because Kim nowhere describes acquiring images or a video with an aligner being worn by a patient and Kim instead discloses that the patient sends “clear aligner information about a currently worn clear aligner” to the orthodontist. *E.g., id.* The images and/or video of the aligner are transmitted “in such a manner that the orthodontist checks a photo or a video” and “determines whether the clear aligner is normal and corresponds to an appropriate step.” *Id.*

80. In my opinion, Kim discloses that the orthodontist provides aligner advice based on the position of the teeth, not the aligner fit itself. *Id.* at [0063] (“the orthodontist accurately determines a current teeth alignment state . . . and advises, for example, an appropriate step of a clear aligner to be currently worn by the orthodontic patient.”). Kim does not suggest determining a value for a tooth or image attribute relating to the separation between the teeth and the aligner, and it does not suggest any non-human analysis of the images. *See, e.g., id.* at [0085] (“Then, as illustrated in FIG. 19, the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal 20.”).

81. Finally, Kim does not disclose analysis of any image by a deep learning device trained by means of a learning base.

B. Invisalign Clinical Monitoring Guide (“Invisalign”)

82. I have reviewed the Invisalign Clinical Monitoring Guide (“Invisalign,” EX1006). I understand that Invisalign was published by Petitioner “to help the Invisalign practitioner successfully monitor Invisalign treatments and address issues that may arise between receipt of Aligners from [Petitioner] to the completion of treatment.” EX1006 at i. Invisalign teaches that, “[t]o prevent issues from occurring,” dental professionals should “perform” certain steps “*at every patient appointment.*” *Id.* at ii (emphasis added). For example, Invisalign discloses that dental professionals should have the “*patient arrive* with the previous stage Aligner and the current Aligner” so the dental professional can evaluate any treatment concerns that may arise. *Id.* (emphasis added).

83. Unlike the Challenged Claims of the ’248 Patent, Invisalign does not disclose any method for remotely assessing aligner fit that can be performed in between in-office orthodontist check-ups. I understand that, until 2020, Petitioner did not offer any product for virtually assessing aligner treatment progress. EX2008.

84. Invisalign includes only exemplary images of what a dental practitioner might see during an in-person appointment when the aligner does not fit properly. EX1006 at 1. Invisalign makes no suggestion that any image was taken remotely

using a cellphone, nor that images should be remotely acquired using a cellphone to assess aligner treatment.

85. Invisalign does indicate that a separation between the teeth and the aligner of greater than 1 mm reflects a general aligner fit issue, whereas a discrepancy less than 1 mm is a “natural deflection that should occur so the Aligner can move the tooth.” *Id.* But Invisalign does not disclose any method to assess the separation, other than a visual in-person approximation, and it does not provide any method and/or tool for accurate measurement, even in person. A POSA would not have been able to make any measurement from the images in Invisalign without the ability to determine the scale of the image. This is significant because, for example, if a patient held their phone six inches from their mouth, the gap would appear to be a different size than if they held their phone a foot from their mouth. Thus, Invisalign suggests that, in the case of a separation that appears to be less than 1 mm, the dental professional should simply continue to monitor aligner fit. *See id.*

86. Invisalign further discusses only the collection of images for the purposes of aligner design and manufacture. As discussed above, the '248 Patent discloses that conventional aligner treatment generally began with a patient attending an in-person consultation with an orthodontist or other dental professional who would conduct scans (or collect an impression and/or photos) of the patient's starting dentition, which were used to design and fabricate the clear aligners. *See*

Section IV.C. Unlike the '248 Patent Challenged Claims, Invisalign does not suggest acquisition of images showing the aligner in the service position in which it is worn by the patient for the purposes of assessing aligner treatment.

87. Finally, Invisalign does not disclose analysis of any image by means of a deep learning device trained by means of a learning base.

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

88. I have reviewed PCT Publication No. WO2016066651 to Salah et al. (“Salah”). Salah is entitled “Method for Monitoring Dentition.” Salah names five inventors, with four matching the inventors listed on the '248 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 two-dimensional (“2D”) image of the patient’s teeth, and comparing the updated image to the reference model. EX1008 at 1:1–2:19.

89. The method for “checking the positioning and/or shape of teeth according to the invention,” *id.* at 2:21–22, in Salah starts with the creation of a 3D “initial reference model” of the patient’s dental arch. *Id.* at 1:28–32. After some period of time, an “updated image” is acquired, which may be “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.” *Id.* at 2:21–27. The “initial reference model” is then modified until a new reference model is obtained that corresponds to the updated image, known as a “final reference model.” *Id.* at 39:13–15.

90. This modification process involves generating a succession of “to-be-tested” reference models, preferably by a metaheuristic procedure. *Id.* at 39:16–20. Each model is then used to generate a reference image under virtual acquisition conditions that correspond to the actual acquisition conditions, *i.e.*, the actual position and orientation of the acquisition apparatus when the updated image was captured. *Id.* at 39:21–27. The reference image thus reflects the image that the image acquisition apparatus would have taken of the “to-be-tested” reference model. *Id.* at 40:7–12. If the reference image and the analysis image are superimposable, the “to-be-tested” reference model accurately reflects the updated position of the patient’s teeth. *Id.* at 40:13–15. If they are not, additional reference models are generated and tested until a match, that is, a final reference model, is found. *Id.* at 44:24–26.

91. In order to compare the images, discriminant information is extracted from each of them. *Id.* at 40:19–20. Salah discloses multiple different types of discriminant information that can be used: contour information, color information, density information, a distance information, brightness information, saturation information, reflection information, and combinations of these. *Id.* at 34:8–10. This

discriminant information is preferably obtained by one of eighteen well-known and preferred methods. *Id.* at 34:15–35:11. Salah also identifies eighteen other ***non-preferred*** methods for extracting discriminant information, the last of which is deep learning. *Id.* at 35:12–36:14.

92. Once a final reference model is obtained, it can be compared with the initial reference model in order to determine tooth displacement between acquisition of the initial reference model and the updated image. *Id.* at 46:9–14.

93. It is my opinion that, as is apparent from the above description of Salah, the method for monitoring tooth displacement in Salah is wholly distinct from the method for assessing aligner fit in the '248 Patent. Salah does not use images showing an aligner in the service position, and it nowhere suggests determining a value for a tooth or image attribute related to the separation between the aligner and the patient's teeth, nor assessing aligner fit for treatment, as required by all the Challenged Claims.

94. Salah is cited throughout the '248 Patent, and was disclosed in an Information Disclosure Statement ("IDS") by Patent Owner during prosecution. EX1001 at References Cited, 2:43, 3:10, 7:11, 7:16, 7:24, 7:41, 8:46, 9:29, 14:41, 17:58, 19:27, 20:43, 22:2, 23:34, 23:39, 23:51, 23:58, 25:9–10, 27:7, 27:15; EX1004 at 80.

D. “Convolutional Oriented Boundaries: From Image Segmentation to High-Level Tasks” (“Maninis”)

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

96. In order to train the neural networks, Maninis used various labeled datasets, all of which were standard datasets that were used for academic research and were publicly available for download as of July 2017. *See* EX1007 at 6; EX2017 (June 13, 2017) (an additional set of annotations or attributes for the PASCAL VOC 2010 dataset. EX2018 (July 7, 2017)); EX2019 (July 22, 2016); EX2020 (July 13, 2017); EX2021 (July 13, 2017).

97. Maninis is an academic paper. It makes no mention of the use of its deep learning architecture for any medical application, let alone specifically for aligner treatment or determining a value for at least one tooth or image attribute relating to a separation between the tooth and the aligner.

VI. A POSA WOULD NOT HAVE BEEN MOTIVATED TO COMBINE KIM, INVISALIGN, SALAH, AND MANINIS

98. In my opinion, a POSA would not have been motivated to combine Kim, Salah, Invisalign, and Maninis.

99. First, a POSA would not have been motivated to combine Kim or Salah with Invisalign. Kim and Salah disclose a fundamentally different approach from Invisalign, and there is nothing in the prior art that suggests their methods could be combined. Kim and Salah relate to *remote* monitoring of *teeth positions* using images of the patient's teeth captured *without aligners* in place. EX1005 at [0010]; EX1008 at 2:21–27. By contrast, Invisalign describes an assessment performed *in person* when the patient visits the orthodontist's office. EX1006 at ii (recommending that dental professionals should “perform” certain steps “*at every patient appointment*” (emphasis added)). Invisalign does not disclose any way to *remotely* monitor aligner fit using images *with or without aligners* in place. A POSA would not have been motivated to combine Invisalign's visual in-person approximation with the remote assessments in Kim or Salah because neither Invisalign, nor any of the cited prior art, suggests that aligner fit can be *remotely* assessed from an aligner image or describes how that could be done. Indeed, determining whether the separation between the aligner and teeth was greater or less than 1 mm would not have been possible without a method for determining the scale of the image—a method described nowhere in the Petitioner's references.¹

¹ Petitioner and Dr. Foroosh point to a further reference, Frey, in support of the motivation to use images of aligners. But Frey also does not provide a motivation
(Cont'd on next page)

100. Second, a POSA would not have been motivated to combine Kim, Salah, and/or Invisalign with Maninis. Maninis nowhere mentions the use of its deep learning architecture for any medical application, let alone specifically for dental or aligner images. The only reference that Petitioner and Dr. Foroosh cite from the dental arts that mentions deep learning is Salah. But Salah would not have motivated a POSA to specifically select deep learning for contour detection or combine the prior art from the dental field with an unrelated reference, like Maninis. Salah mentions deep learning only once, and even then, as the last, non-preferred option in a list of almost 40 potential methods for determining discriminate information. EX1008 at 35:12–36:14, 34:5–36:14. Salah further discloses multiple different types of discriminant information that could be used to update 3D dental

here as it states that videos work better than individual photos. EX1009 at 19. Frey also does not explain how to implement a remote aligner fit assessment, and instead calls out the benefit of remote monitoring to address other issues: “loose/broken appliances, wire pokes, and other patient concerns so that [the orthodontist’s] team can schedule repair *appointments* more effectively,” and “[r]educ[e] appointments when using appliances that do not require doctor activation (Invisalign, *elastic bite correction, jack screw expanders, habit appliances*, etc.).” *Id.* at 26 (emphasis added).

arch models: “contour information, color information, density information, a distance information, brightness information, saturation information, reflection information and combinations of these.” *Id.* at 34:8–10. A POSA would have had no reason to combine Salah and Maninis because that combination merely provides a specific non-preferred deep learning architecture for the analysis of tooth positions disclosed in Salah. A POSA similarly would have had no reason to combine Maninis with Kim or Invisalign because the cited art contains no suggestion that a deep learning architecture as in Maninis could or should be combined with Kim’s analysis of teeth positions or the Invisalign in-person approximations.

101. For the reasons above, it is my opinion that Petitioner’s purported motivation to combine is not supported by the unrelated and incompatible references it cites or the motivations of a POSA in July 2017.

VII. A POSA WOULD NOT HAVE UNDERSTOOD PETITIONER’S REFERENCES TO DISCLOSE ACQUISITION OF AN ANALYSIS IMAGE

102. It is my opinion that even if a POSA were motivated to combine the references, none discloses acquisition of an image of an aligner, as worn by a patient, during aligner treatment.

103. All of the Challenged Claims require: “more than 1 week after the start of the treatment with the aligner, acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, called

‘analysis image’, the analysis image being a photograph, or an image extracted from a film,” and all but two of those claims further require that the image be acquired with a “cellphone.”

104. Kim discloses only the acquisition of images of a patient’s teeth and not an aligner image. Specifically, “[t]he teeth alignment report information” sent by the patient may include “a front-view *teeth* photo, a bottom-view low-angle *teeth* photo, a front-view automatically-recognized mouth gag photo, a front-view automatically-recognized face contour photo, a left-side-angle automatically-recognized mouth gag photo, a left-side-angle automatically-recognized face contour photo, a right-side-angle automatically-recognized mouth gag photo, a right-side-angle automatically-recognized face contour photo, a collection of top, bottom, left, and right side photos surrounding a central front photo, a low-angle upper jaw photo, a high-angle lower jaw photo, and combinations thereof, which are taken using a camera of the orthodontic patient terminal.” EX1005 at [0013] (emphasis added); *see also* [0056] (discussing acquisition of images of the patient’s teeth, not the aligner as worn by the patient), [0081] (same), [0087] (same), Figs. 8–13 (showing only images of the patient’s teeth without aligners), 16 (same), 19 (same), 23 (same).

105. Invisalign does not disclose acquisition of an analysis image at least partially representing the aligner in a service position during aligner treatment.

Instead, Invisalign describes aligner issues for which dental practitioners should visually check during in-person, in-office appointments. EX1006 at i–ii. To the extent that Invisalign teaches any image capture, that image capture is done for the purposes of creating aligners, not assessing the fit of those aligners in a patient’s mouth. *Id.* at iii, 4, 6, 9 (discussing the importance of initial photos and impressions to designing or redesigning aligners to avoid aligner fit problems). During prosecution, Patent Owner explained, and the Examiner agreed, that methods for designing aligners are distinct from the Challenged Claims. EX1004 at 893, 940–51, 960–61.

106. Salah also does not disclose acquisition of an analysis image at least partially representing the aligner in a service position. While Petitioner alleges that Salah discloses an example of an image showing an intraoral appliance (Pet. at 30), that intraoral appliance is not an aligner. *See* EX1008 at Fig. 11. Moreover, Salah concerns the use of an updated 2D image of a patient’s teeth *without aligners* to identify a final 3D reference model that corresponds to the position of the teeth in the updated 2D image, and compares that final 3D model with the initial 3D reference model to determine tooth displacement with any type of orthodontic and dental treatment, independent of the type of appliance. EX1008 at 1:1–2:19. This is a fundamentally different approach from the Challenged Claims, and nothing in Salah suggests that aligner images could be acquired for assessing aligner treatment.

107. Finally, Maninis does not disclose acquisition of an analysis image at least partially representing the aligner in a service position. Maninis has nothing to do with image acquisition, let alone dental or aligner treatment. *See* EX1007.

108. Accordingly, it is my opinion that Petitioner's references fail to disclose acquisition of an aligner image for purposes of aligner treatment assessment.

VIII. A POSA WOULD NOT HAVE UNDERSTOOD PETITIONER'S REFERENCES TO DISCLOSE ANALYSIS WITH A DEEP LEARNING DEVICE SO AS TO DETERMINE AN ATTRIBUTE VALUE RELATING TO A SEPARATION BETWEEN THE TOOTH AND THE ALIGNER

109. It is further my opinion that, even if a POSA were motivated to combine Petitioner's references, that combination does not disclose nor render obvious the requirement: "analysis of the analysis image by means of a deep learning device, trained by means of a learning base, so as to determine a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner," as required by all Challenged Claims.

110. As an initial matter, I note that Petitioner and Dr. Foroosh improperly combine unrelated disclosures from Salah. *See* Pet. at 34–35 (citing EX1008 at 55:21–56:7 (relating to a method for checking the appearance of teeth (*id.* at 52:6)), 34:5–14 (relating to a method for controlling tooth positioning (*id.* at 19:22)), and Fig. 11 (relating to a method using reflection information (*id.* at 64:7–8))); EX1002 at ¶¶ 93–96 (same).

111. Furthermore, while Salah discloses a contour map of detected tooth edges showing the outline of teeth in Fig. 6b, Salah nowhere suggests the use of image processing generally—or deep learning specifically—to detect aligners, let alone a value for a tooth or image attribute relating to a separation between the tooth and the aligner. Instead, Salah discloses a method of monitoring tooth movements that uses an updated 2D image of a patient’s teeth *without aligners* to identify a final 3D reference model that corresponds to the position of the teeth in the updated 2D image, which final 3D reference model is then compared with the initial 3D reference model in order to determine tooth displacement. EX1008 at 46:9–14, 1:1–2:22. Salah thus discloses an entirely different approach to the Challenged Claims—one that monitors tooth positions, and not aligner fit as in the ’248 Patent. During prosecution, Patent Owner explained, and the Examiner agreed, that methods of monitoring tooth movement are distinct from the claimed methods that require determination of “a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner.” EX1004 at 947–51, 960–61.

112. Petitioner and Dr. Foroosh allege that Salah discloses an example of a reference map generated for an image with an intraoral appliance. Pet. at 35 (citing EX1008 at Fig. 11). That intraoral appliance, however, is not an aligner. See EX1008 at Fig. 11. And the discriminant information used to generate this map was reflection information, not contour information. *Id.* at 64:7–8. With respect to

contour information, Salah teaches that image processing can be used to “detect high contrast regions and determine contours.” EX1008 at 34:13–14. But the inventors’ own translation of Salah goes on to explain, “in the example of an outline, the analysis of the contrast provides, for example, more or less reliable information.” EX2009 at [0531]; EX1008 at 60:17–24. “[A] zone of strong contrast can be likened to a zone corresponding to an outline with a high probability,” whereas “a zone of weak contrast, for example a blurred zone, can be likened to a zone corresponding to an outline with a low probability.” EX2009 at [0531]; EX1008 at 60:17–24. Salah thus recommends processing the reference image to retain only the outlines identified with a high probability. EX2009 at [0533]; EX1008 at 61:2–4. But aligners are generally transparent and do not represent any strong contrast with a patient’s teeth or the inside of the patient’s mouth. EX1001 at 27:35–43 (“An aligner conventionally takes the form of a removeable single-piece appliance, conventionally made of a transparent polymer material...”). Accordingly, in my opinion, a POSA would not have understood Salah to teach or suggest analysis of an *aligner* image by means of a deep learning device so as to determine a value for a tooth or image attribute relating to a separation between the tooth and the aligner.

113. Maninis similarly makes no mention of the use of its deep learning architecture for any medical application, let alone specifically for aligner treatment or determining a value for a tooth or image attribute relating to a separation between

the tooth and the aligner. As noted above, adding Maninis to Salah merely provides a specific non-preferred deep learning architecture for the analysis of tooth positions disclosed in Salah. The combination does not disclose or suggest the fundamentally different use of a deep learning device recited in the Challenged Claims of the '248 Patent, *i.e.*, for “analysis of the analysis image . . . so as to determine a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner.”

114. Kim discloses only that the orthodontist conducts some unspecified analysis of images of a patient’s teeth without aligners. *See, e.g.*, EX1005 at [0085] (“Then, as illustrated in FIG. 19, the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal.”), [0063–0066] (“teeth alignment report information” is transmitted “in such a manner that the orthodontist checks a photo or a video”). Kim does not disclose analysis with a deep learning device, or determining a tooth or image attribute value relating to a separation between the tooth and the aligner.

115. Finally, Invisalign also does not disclose analysis of an aligner image by means of a deep learning device so as to determine a tooth or image attribute value relating to a separation between the tooth and the aligner. Rather, Invisalign discloses a visual approximation performed in person by a dental practitioner. EX1006 at ii (dental professionals should have “*patient arrive* with the previous

stage Aligner and the current Aligner” so the dental professional can evaluate any treatment concerns that may arise). Invisalign does not suggest that such an approach could be applied to the analysis of aligner images using a deep learning device. And as set forth above, Salah would have taught a POSA that, given the lack of contrast, it could not.

IX. A POSA WOULD NOT HAVE HAD A REASONABLE EXPECTATION OF SUCCESS IN COMBINING KIM, INVISALIGN, SALAH, AND MANINIS

116. It is further my opinion that a POSA would not have had a reasonable expectation of success in combining Kim, Invisalign, Salah, and/or Maninis.

117. As noted above, Maninis does not disclose analysis of any dental images. Such an analysis is described only in Salah, and even then, the analysis method is fundamentally different—comparing the position of the same discriminant information on different images. A POSA would not have had a reasonable expectation of success because Salah discloses that “a zone of weak contrast,” such as between the aligner and the teeth, can only be “likened to a zone corresponding to an outline with a low probability.” EX2009 at [0531]; EX1008 at 60:17–24. And Salah recommends processing the reference image to retain only the outlines identified with a high probability. EX2009 at [0533] ; EX1008 at 61:2–4.

118. Additionally, neither Petitioner, nor Dr. Foroosh, identify any prior art teaching what constitutes an *appropriately* annotated training set, for example, the

number and nature of the images, or the labels to apply, in order to train a deep learning device for the specific dental application claimed in the '248 Patent Challenged Claims. While Dr. Foroosh relies on Maninis (EX1002 at ¶ 102), Maninis used only standard, pre-labelled datasets that were available for download for academic research into neural networks. See ¶¶ 96–97 above. Maninis does not teach a POSA how to design a dataset to train a deep learning base, as required by the '248 Patent, including the images to use or the labels to apply. Indeed, even years after the priority date of the '248 Patent, the art recognized that, “[c]ompared to other medical fields, the high-quality datasets for orthodontic research [we]re limited.” EX2010 at 1072.

119. Dr. Foroosh further relies on an analysis he performed using a “Canny edge detection technique.” EX1002 at ¶ 103. This analysis appears to be improperly guided by hindsight in an effort to show that a POSA *could* have performed the methods recited in the '248 Patent Challenged Claims using the methods disclosed in Salah. It does not, however, demonstrate that a POSA *would* have been motivated to perform the claimed methods with a reasonable expectation of success without knowledge of the '248 Patent. Regardless, Canny edge detection does not involve deep learning, and unlike deep learning, it is one of the “well-known and *preferred* methods” for image processing disclosed in Salah. EX1008 at 34:15–16. In my opinion, even if a POSA were able to detect contours using Canny edge detection,

that is not enough to reasonably expect success with a deep learning device in the methods of the Challenged Claims. All of those Challenged Claims require determination of “a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner.” In his example, Dr. Foroosh “added [the] simple annotations indication the locations of the tooth edge of a tooth and the edge of a corresponding part of the aligner, as well as showing the separation between the two.” EX1002 at ¶ 103. He does not show that a POSA would have reasonably expected success in determining the claimed attribute values with a different, *non-preferred* methodology listed in Salah.

120. Accordingly, it is my opinion that Petitioner has failed to show that a POSA would have had a reasonable expectation of success in combining references as proposed in the Petition.

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

121. 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 '248 Patent.

122. Salah is cited extensively in the specification of the '248 Patent, and was disclosed in an Information Disclosure Statement (“IDS”) by Patent Owner during prosecution. EX1001 at References Cited, 2:43, 3:10, 7:11, 7:16, 7: 24, 7:41,

8:46, 9:29, 14:41, 17:58, 19:27, 20:43, 22:2, 23:34, 23:39, 23:51, 23:58, 25:9–10, 27:7, 27:15; EX1004 at 80.

123. Petitioner and Dr. Foroosh cite Kim in part for the same reasons as Salah. Pet. at, e.g., 24, 29–30; EX1002 at ¶¶ 74, 87, 89. Thus, Kim is duplicative of Salah in those respects. Petitioner and Dr. Foroosh also cite Kim, as well as Invisalign, for the alleged disclosure of the element of determining aligner separation that is missing from Salah and Maninis. Pet. at 20–22; EX1002 at ¶ 71. But the '248 Patent itself discusses the state of the art, stating that “[a]t regular intervals, the patient goes to the orthodontist for a visual inspection, notably to check . . . whether the aligner worn by the patient is still suited to the treatment.” EX1001 at 27:55–59. It is my opinion that for the same reasons the claims of the '248 Patent were not obvious over orthodontist’s practice of in-person checks to see if aligners were still suitable for treatment, they remain nonobvious in light of Kim and Invisalign.

124. With respect to Maninis, the specification of the '248 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.*, EX1001 at 16:10–35. 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. Dr. Foroosh does not

discuss how this capability is relevant to performing the steps of the claims or how it would get a POSA closer to the Challenged Claims than the exemplary deep learning architectures already disclosed in the '248 Patent specification. Accordingly, with respect to the capabilities that are relied on in relation to the '248 Patent, nothing additional is disclosed by Maninis that was not already disclosed in the specification.

125. In addition, as is apparent from the face of the '248 Patent, the Examiner had before him numerous other references related to neural networks, including at least: Kelvvin 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 Berling Heidelberg, Berlin, Heidelberg, pp. 175–85, 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; and Young-Jun YU: “Machine Learning for Dental Image Analysis”, 29 November 2016 (2016-11-29), XP055430578.

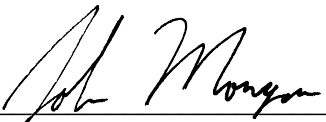
126. It is my opinion that, for the same reasons the claims of the '248 Patent were not obvious in light of the deep learning models like Faster R-CNN, they remain nonobvious in light of Maninis.

XI. CONCLUSION

127. For the foregoing reasons, it is my opinion that a POSA would not have been motivated to combine Kim, Salah, Invisalign, and/or Maninis; none of Kim, Salah, Invisalign, or Maninis disclose acquisition of the claimed analysis image for aligner treatment assessment; none of Kim, Salah, Invisalign, or Maninis disclose analysis with a deep learning device so as to determine an attribute value relating to a separation between the tooth and the aligner; a POSA would not have a reasonable expectation of success in combining Kim, Salah, Invisalign, and/or 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 January 30, 2024, in San Francisco, California.



Dr. John Mongan