

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. IPR2024-00110

U.S. Patent No. 11,109,945

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

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EXHIBIT LIST

Exhibit Number	Description
2002	Declaration of John T. Mongan, M.D., Ph.D., dated February 20, 2024
2007	May 7, 2020 Press Release of Petitioner, Align Technology, Inc.
2008	U.S. Pat. Pub. 2017/0325689 (Dental Monitoring's English Language Translation of the International Patent Application published as Salah (PCT Publication No. WO2016066651))
2029	Updated Curriculum Vitae of John T. Mongan, M.D., Ph.D.
2048 ¹	Deposition Transcript of Dr. Hassan Foroosh, Ph.D., in IPR2023-01369 (May 17, 2024)
2053	Declaration of Nathaniel E Frank-White
2054	Deposition Transcript of Dr. Hassan Foroosh, Ph.D., in IPR2024-00110 and IPR2024-00052 (June 28, 2024)
2064	Provisional Patent Application No. 62/417,985 to Carrier et al.

¹ Patent Owner is not yet in receipt of the witness's signature or the officer's certification and will coordinate with Petitioner to file an updated exhibit once complete. 42.53(f)(5)-(6).

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. 11,109,945 (“the ’945 patent”) (EX1001) and on matters relating to the patentability of the challenged claims of that patent, as well as to respond to the opinions of Dr. Hassan Foroosh (EX1002). The following is my written declaration on these issues.

II. SUMMARY OF OPINIONS

2. In summary, my opinions are as follows:

- The ’945 patent discloses and claims a novel method for evaluating the shape of an orthodontic aligner using an image of an aligner in a service position. Kim, Invisalign, and Salah fail to disclose or render obvious that method, and there would have been no motivation to combine the references as proposed to arrive at the claimed methods.
- Dr. Foroosh misreads each of Kim, Invisalign, and Salah, none of which disclose or provide a reason to capture images of a patient’s teeth with aligners in a service position, let alone for the purpose of evaluating such an image to determine the shape of the aligner. Moreover, neither Kim nor Invisalign disclose any computer-implemented image analysis.

- Salah does not suggest that aligner shape could be assessed from an image, and in fact discloses that its contour detection techniques rely on high contrast to achieve a quality analysis. Salah describes low contrast contours as “unreliable” and teaches away from their use. I understand from consulting with Dr. Kusnoto that an aligner would visually blend with teeth and not provide high contrast.
- Kim, Invisalign, and Salah fail to disclose or render obvious a method of determining and comparing interior and exterior tooth outlines for each of a plurality of teeth, in which the interior tooth outline represents the free end of a tooth and the exterior tooth outline represents the interior surface of the aligner. Neither Kim nor Invisalign discloses any computer-implemented image analysis, and Salah discloses only the determination of generic contours.
- Salah—the only reference on which Dr. Foroosh relies for image analysis—relates to a method of monitoring tooth movement over time, and it does not need to use or suggest using image processing to detect the contours of aligners. Salah also does not need to recognize or suggest recognizing which detected contours correspond to teeth as opposed to something else, like an aligner as is necessary to practice the claimed methods.

- Given the disparate teachings of Kim, Invisalign, and Salah, a POSA would not have been motivated to pursue a brand-new method that involves evaluating the shape of an aligner from simple cellphone images when the references relate to entirely different methods having different purposes and the art teaches away from the claimed methods.

III. BACKGROUND

A. Education and Industry Experience

3. My qualifications are summarized below and are presented in more detail in my updated professional CV (EX2029).

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

5. 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.

6. 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.

7. 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 fourth 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.

8. 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.

9. 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. I have recently been promoted to full professor, effective July 1, 2024. 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.

10. 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.

11. 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 20 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.

12. 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

co-chair of the Imaging Artificial Intelligence Oversight Committee and a member of its sister committee, the Artificial Intelligence Governance Oversight Committee, both of which review artificial intelligence prior to clinical deployment to ensure safety and efficacy.

13. 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.

14. 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 applications of artificial intelligence to radiology and medical imaging.

15. I have authored over 59 peer-reviewed journal articles, 24 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.

16. 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.

17. Finally, as noted above, I am currently named as an inventor or co-inventor on three issued U.S. patents related to computers and software.

18. 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

19. I am being compensated at my customary 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

20. 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.

21. In particular, in forming my opinions, I have considered the Petition (Paper 2) and the declaration of Dr. Foroosh (EX1002), and the exhibits cited therein.

22. 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.

IV. UNDERSTANDING OF THE LAW

23. 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

24. 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. I further understand that factors that may be considered in determining the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. My specific understanding of a POSA with respect to the field of the ’945 patent in particular is summarized below.

B. Date of Invention

25. 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).

26. 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

27. 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. I further understand that the prior art must be assessed from the perspective of a person of ordinary skill in the art.

D. Claim Construction

28. 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.

29. 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.

30. 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.

31. 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

32. 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 '945 patent issued was filed after March 16, 2013.

33. 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 '945 patent claims are unpatentable by a preponderance of the evidence.

F. Obviousness

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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 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.

V. THE '945 PATENT

A. The Effective Filing Date of the '945 Patent

45. The '945 patent was filed as U.S. Application No. 16/001,049 on June 6, 2018, claiming priority to French Patent Application No. FR1755187, June 9, 2017. I understand that Petitioner has not challenged the entitlement of the '945 patent to this priority date. Pet. 10; EX1002, ¶26.

B. Person of Ordinary Skill in the Art

46. In my opinion, a person of ordinary skill in the relevant field as of June 9, 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 image analysis techniques 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.

47. Dr. Foroosh contends that “a person of ordinary skill in the relevant field as of June 9, 2017, would typically have an advanced degree, such as a Masters' Degree or Ph.D. in computer science or a related field, with at least two years of work in computer vision, image analysis, medical imaging, or related areas. A POSA could have less education but significant professional experience in one or more of these fields. A POSA could be a member of an interdisciplinary team including persons with backgrounds such as electrical engineering, computer science, optical imaging, and dentistry or orthodontics, and could call upon the knowledge of other team members as appropriate.” EX1002, ¶51.

48. In my declaration in support of Patent Owner's Preliminary Response, I adopted Dr. Foroosh's definition of a POSA. EX2002, ¶48. My opinions are not materially different under either definition. While in my opinion a POSA *would* be

part of a multidisciplinary team, and Dr. Foroosh’s definition provides that a POSA only *could* be part of such a team, Dr. Foroosh’s definition still recognizes that a POSA could consult with individuals having experience in dentistry and/or orthodontics *as appropriate*.²

49. As Dr. Foroosh recognizes, Kim, Invisalign, and Salah relate to dental and/or orthodontic treatment, and Kim and Salah discuss dental imaging, and in several respects these references are directed to and/or assume the knowledge of dental professionals. EX1002, ¶¶56-58, 62; *see also infra* §§VI.A-C, VII-VIII. Invisalign targets orthodontic and/or dental professionals directly. As Dr. Derakhshan alleges in her declaration, she “provided orthodontists and dentists” with Invisalign as “part of [her] duties at Align” to “provide[] instruction to orthodontists and dentists to certify them in the use of ... Invisalign clear plastic aligners.” EX1011, 1-2. As such, it is my opinion that it would be “appropriate” for a POSA to consult with individuals having experience in dentistry and/or orthodontics to understand the teachings of Kim, Invisalign, and Salah. Accordingly, I have consulted with Dr. Budi Kusnoto, D.D.S., M.S. regarding the dental and/or orthodontic aspects of Kim, Invisalign, and Salah in forming my opinions herein, including as specifically noted throughout my report.

² All emphasis is added unless noted otherwise.

C. Background on Aligner Treatment

50. I have reviewed the description of aligner treatment in the '945 patent. EX1001, 1:16-56. According to the '945 patent, aligners are one type of orthodontic device designed to exert gentle pressure and thereby reposition a patient's teeth. *Id.*, 1:23-31. The '945 patent further explains that as of June 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.*, 1:16-22. 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.*, 1:21-36. 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.*, 1:35-36. At that time, effective aligner treatment required frequent in-person orthodontic examinations to determine whether treatment was on track. *Id.*, 1:42-45. This reliance on periodic in-person examinations meant that treatment issues could go undiagnosed for multiple weeks between check-ins. *Id.*, 1:53-59. 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.*, 1:46-52. As a result, the '945 patent states that aligner treatment was often delayed and prolonged. *Id.*, 1:49-59.

D. Introduction to the '945 Patent

51. The '945 patent relates to new and improved methods of “evaluating the shape of an orthodontic aligner” for purposes of aligner treatment. *See, e.g.*, EX1001, 1:65-66, 2:24-27 (“[A] method according to the invention makes it considerably easier to evaluate the suitability of the aligner for the treatment, while at the same time making this evaluation particularly reliable.”), Abstract, 13:59-60. “According to the invention, the shape of the aligner is evaluated by comparing an outline of this aligner, in its service position, with an outline of the teeth wearing it.” *Id.*, 6:7-9.

52. In particular, the '945 patent discloses a method comprising “acquisition of at least one two-dimensional image of the teeth of [a] patient, referred to as ‘updated image’, under actual acquisition conditions.” *Id.*, 2:1-3. “[A]t least one updated image referred to as ‘aligner image’, at least partially representing the aligner in a service position in which it is worn by said teeth.” *Id.*, 2:4-6. And “at least one updated image referred to as ‘dentition image’, identical to or different from the aligner image, representing said teeth.” *Id.*, 2:7-9.

53. “In one embodiment, the dentition image is the aligner image.” *Id.*, 6:15-16. In those circumstances, it is possible not only to see the aligner outline but

also to see the dentition outline through the aligner, and a “single image therefore makes it possible to compare aligner and dentition outlines.” *Id.*, 6:15-20. This avoids the need for a readjustment step. *Id.*, 6:20-21.

54. “In another embodiment, the dentition image is an image of the teeth in the absence of the orthodontic aligner, referred to as the ‘bare dentition image’.” *Id.*, 6:22-24. “[I]f the dentition image is different from the aligner image,” the ’945 patent discloses “conversion of the dentition image so that it represents said teeth (represented on the dentition image) as seen under the acquisition conditions used during the acquisition of the aligner image.” *Id.*, 2:10-14.

55. The ’945 patent further discloses “determination, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively.” *Id.*, 2:15-19. The ’945 patent states that a “tooth outline” is understood to mean a line displaying the shape of a free end of a tooth on an image. *Id.*, 5:8-9. “[S]uch a line may delimit the free end of this tooth,” in which case the “tooth outline is then qualified as an ‘interior tooth outline.’” *Id.*, 5:10-13. “Such a line may also delimit part of the aligner,” and “is then qualified as an ‘exterior tooth outline.’” *Id.*, 5:14-15. As the bottom of the tray of an aligner substantially complements the free ends of the teeth, “in an image depicting the

bottom of the tray, the tray-bottom outline defines a set of exterior tooth outlines.”
Id., 5:15-20.

56. The ’945 patent invention further comprises “comparison of the interior and exterior tooth outlines, followed by determination of at least one score according to said comparison.” *Id.*, 2:20-22. The comparison step is performed “preferably in accordance with one of the two particular embodiments ... corresponding respectively to FIGS. 7 and 8” of the ’945 patent. *Id.*, 11:35-38.

57. For example, “for each of a plurality of teeth for which interior and exterior tooth outlines have been determined,” “a distance d between the interior and exterior tooth outlines of each of said teeth is determined.” *Id.*, 11:40-43. This “may for example be the mean distance or the maximum distance between the pixels of said outlines corresponding to one and the same point on the tooth.” *Id.*, 11:45-47. “[A] distance threshold S_d is determined, preferably using the distances [already] determined.” *Id.*, 11:51-52. Preferably, the distance threshold “is substantially equal to the smallest of the distances [already] determined.” *Id.*, 11:53-55. Next, the “distance score” is determined, for each of the teeth, “as a function of the distance d between the interior and exterior tooth outlines and of the distance threshold.” *Id.*, 11:63-67. “The higher the distance score, the greater the separation of the tooth concerned from the tray.” *Id.*, 12:4-5.

58. As another example, as set forth in Figure 8, “at least one score known as the ‘offset score’, is determined, for each pair of teeth of [a consecutive] triplet, as a function of the difference in offset with a tooth adjacent to said tooth and of the offset-difference threshold.” *Id.*, 13:7-10. “In particular, the difference in offset of the first tooth with the second tooth may be compared against the offset-difference threshold.” *Id.*, 13:11-13. “The offset-difference threshold may notably be subtracted from the offset difference of the first tooth with respect to the second tooth in order to determine a score for the offset between the first and second teeth.” *Id.*, 13:13-17. “This offset score indicates, for example if it is positive, that one or each of the first and second teeth is liable to be separated from the bottom of the tray.” *Id.*, 13:17-20. The ’945 patent explains that “[i]n general, when a first offset score for first and second teeth indicates the separation of one of these two teeth, a second offset score is determined for the second tooth and a third tooth adjacent to the second tooth. If the second offset score is lower than the first offset score, it is probable that it is the first tooth that has separated from the bottom of the tray. If not, it is probably the second tooth that has separated.” *Id.*, 13:28-34.

59. According to the ’945 patent, preferably, “an evaluation method according to the invention also has one or more of the ... optional features,” including “comparison of the score against an acceptability threshold and the emission of information according to the result of the comparison.” *Id.*, 2:32-38.

60. Finally, in one embodiment, the invention disclosed in the '945 patent “is used to establish a diagnosis and/or to modify the treatment, particularly to recommend a change in aligner and/or to determine the characteristics of a future aligner for the patient.” *Id.*, 13:44-47. The invention in the '945 patent further provides “a method of adapting an orthodontic treatment, in which method an evaluation method according to the invention is implemented and then, according to the result of said evaluation, a new aligner is manufactured.” *Id.*, 3:36-40.

E. Prosecution of the '945 Patent

61. I have reviewed the prosecution history of the '945 patent. The '945 patent issued on September 7, 2021 and claims priority to French Application No. 1755187, filed June 9, 2017.

62. I understand from the prosecution history that the 16/001,049 Application was rejected once before it was granted. Specifically, the Examiner issued one office action (December 30, 2020), which objected that claim 1 lacked clarity regarding what was comparing the interior and exterior tooth outlines and what reference parameter was used to make that comparison. EX1004, 187. The Examiner further rejected claims 1-10 as indefinite because they did not clearly disclose what was determined and which determining steps (or logic or algorithm) were used to arrive at the final output result. *Id.*, 188. Finally, the Examiner rejected claims 1, 2, 4, and 6 as obvious over Greenberg (U.S. Pat. Pub. 2014/0120488) in

view of Wen (U.S. Pat. Pub. 2017/0100214), while recognizing that claims 3, 5, 7, 8, 9, and 10 were otherwise allowable. *Id.*, 189-195.

63. Patent Owner responded on March 25, 2021 and amended claim 1 by adding that the determination is made “by means of image processing software” and that the comparison is made “so as to determine” a score. *Id.*, 238. I note that when responding to the indefiniteness rejection, Patent Owner observed that “[a]s set forth within the subject application,” “[a POSA] knows how to process an image in order to isolate an outline,” including an interior or exterior tooth outline. *Id.*, 241-42. Patent Owner here confirmed that, with the benefit of the teaching in the specification, a POSA would have been able to practice the invention claimed in the ’945 patent. Patent Owner did not, in my opinion, admit that the prior art taught or suggested making a determination of interior or exterior tooth outlines using an aligner image. Additionally, Patent Owner pointed out that Greenberg and Wen relate to the determination of an aligner’s shape and its subsequent creation, rather than an evaluation from an image of the suitability of an already formed aligner on the patient’s teeth. *Id.*, 242-44.

64. On May 5, 2021, the Examiner issued a Notice of Allowance. *Id.*, 249-59. The Examiner explained that Greenberg teaches the design and subsequent manufacture of an aligner based on a CT scan. *Id.*, 255-56. Wen teaches a scanned model of the patient’s dentition that is used to develop a treatment plan and the

subsequent manufacture of aligners. *Id.*, 256. Another reference, Kitching (U.S. Pat. No. 8,562,338), teaches tracking a patient's progress through an orthodontic treatment by comparing a digital representation of where the patient's teeth are to where they should be. *Id.*

65. However, the Examiner explained that the prior art did not, alone or in combination, teach that “if the dentition image is different from the aligner image, conversion of the dentition image so that it represents said teeth as seen under the acquisition conditions used during the acquisition of the aligner image in step 1);” “determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively;” or a “comparison of the interior and exterior tooth outlines so as to determine at least one score according to said comparison.” *Id.*, 254-55. Thus, I understand that the Examiner allowed claims 1-10. *Id.*, 249-59.

VI. OVERVIEW OF THE ASSERTED ART

A. Kim

66. U.S. Patent Publication No. 2017/0281313 to Kim is entitled “Method and System for Providing Remote Teeth Alignment Services and Computer-readable Medium on which the Method is Recorded.” EX1005 [Kim]. Kim was filed on

April 5, 2016, and was published after the '945 patent priority date, on October 5, 2017. *Id.*

67. As Kim explains, as of 2016, “[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.” *Id.*, [0008]. Thus, Kim is directed to the problems that could occur when a patient was not capable of frequently visiting the orthodontist by providing a way to assess “teeth alignment” remotely. *Id.*, [0009], [0010].

68. Kim thus relates to a method for remotely determining the alignment of teeth by “providing remote teeth alignment services” to assess whether treatment is progressing correctly, and not for evaluating aligner fit. *Id.*, [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 teaches only photographs taken by the patient, using the “orthodontic patient terminal.” *E.g., id.*, [0013], [0041], [0056], [0058], Fig. 6. Kim is also clear that the orthodontic patient terminal is a personal electronic device of the patient, such as “a personal computer, a mobile device, a personal digital assistant (PDA), a smart pad, a laptop computer, a smart camera, a smart camcorder, an electronic book, a smart scanner, or the like.” *Id.*,

[0042]. Thus, Kim does not disclose that photographs should be taken by a trained professional, using correct lighting and camera equipment. Kim asserts that, on the basis of the teeth alignment information, the orthodontist may “remotely and accurately diagnose the condition of the patient based on the teeth alignment information, and may remotely provide information about an accurate step of a clear aligner to be currently worn by the orthodontic patient.” *Id.*, [0010].

69. 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.*, [0013]; *see also id.*, [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). These are all images of the patient’s teeth taken without an aligner in the service position. While

Kim discloses the use of programs to “display[] a virtual face contour line on a screen” to guide camera positioning and automatically capture photographs, it does not disclose doing so while the patient wears their aligner in a service position. *Id.*, [0014].

70. I understand from Dr. Kusnoto that, as of 2017, assessing the fit of an aligner and assessing the alignment of teeth were two different analyses. At that time, assessing the fit of an aligner involved checking that the aligner provided adequate and effective pressure on the patient’s teeth to bring about the desired movement of the teeth. During an in-person appointment, this typically involved a combination of visual and manual inspections that were performed by the dental professional. By contrast, assessing the alignment of the patient’s teeth in 2017 involved an overall evaluation of the patient’s dentition to determine whether the orthodontic treatment was progressing as planned. Such an assessment of teeth alignment was based on tooth positions, and it was a standard part of orthodontic treatment in 2017 that was not specific to the type of treatment (braces, aligners, retainers, etc.). I further understand from Dr. Kusnoto that clear aligners can mask the teeth, which would make it difficult to analyze teeth positions from an image in which an aligner is worn by the patient. Thus, a POSA would not have been motivated to use an aligner image to determine *teeth alignment*.

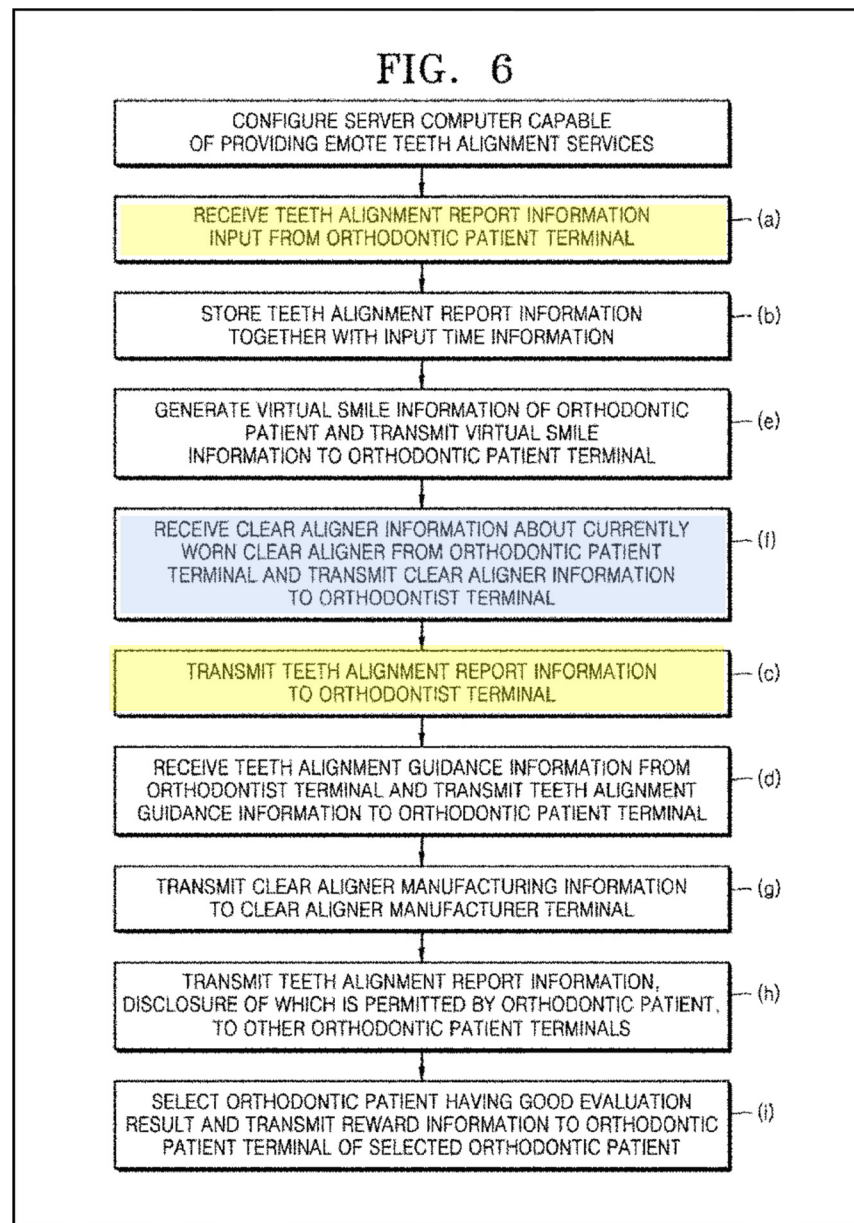
71. Dr. Foroosh nonetheless opines that “Kim teaches acquiring an aligner and dentition image (i.e., an image depicting an aligner worn on a patient’s teeth).” EX1002, ¶71. In support of this opinion, he relies on Paragraph [0066] of Kim, which states as follows:

The *clear aligner information transmission program* 69 may be a program *for receiving the clear aligner information about a currently worn clear aligner* from the orthodontic patient terminal 10, storing the clear aligner information, and transmitting the clear aligner information to the orthodontist terminal 20 in such a manner that the orthodontist checks a photo or a video of the clear aligner currently worn by the orthodontic patient, and determines whether the clear aligner is normal and corresponds to an appropriate step.

EX1005, [0066]. For the reasons discussed below, I disagree with Dr. Foroosh, and 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 two-dimensional image” including an “‘aligner image,’ at least partially representing the aligner in a service position in which it is worn by said teeth,” as required by all challenged claims.

72. Kim draws a clear distinction between the “clear aligner information” referred to Paragraph [0066] and “teeth alignment information.” For example, in Figure 6 of Kim (shown below), in different steps of the methods of Kim, the server “receive[s] teeth alignment report information input from orthodontic patient terminal” and separately “receive[s] clear aligner information about currently worn clear aligner from orthodontic patient terminal.” EX1005, Fig. 6 (steps (a) and (f), highlighted below). Likewise, Kim discloses that “teeth alignment report

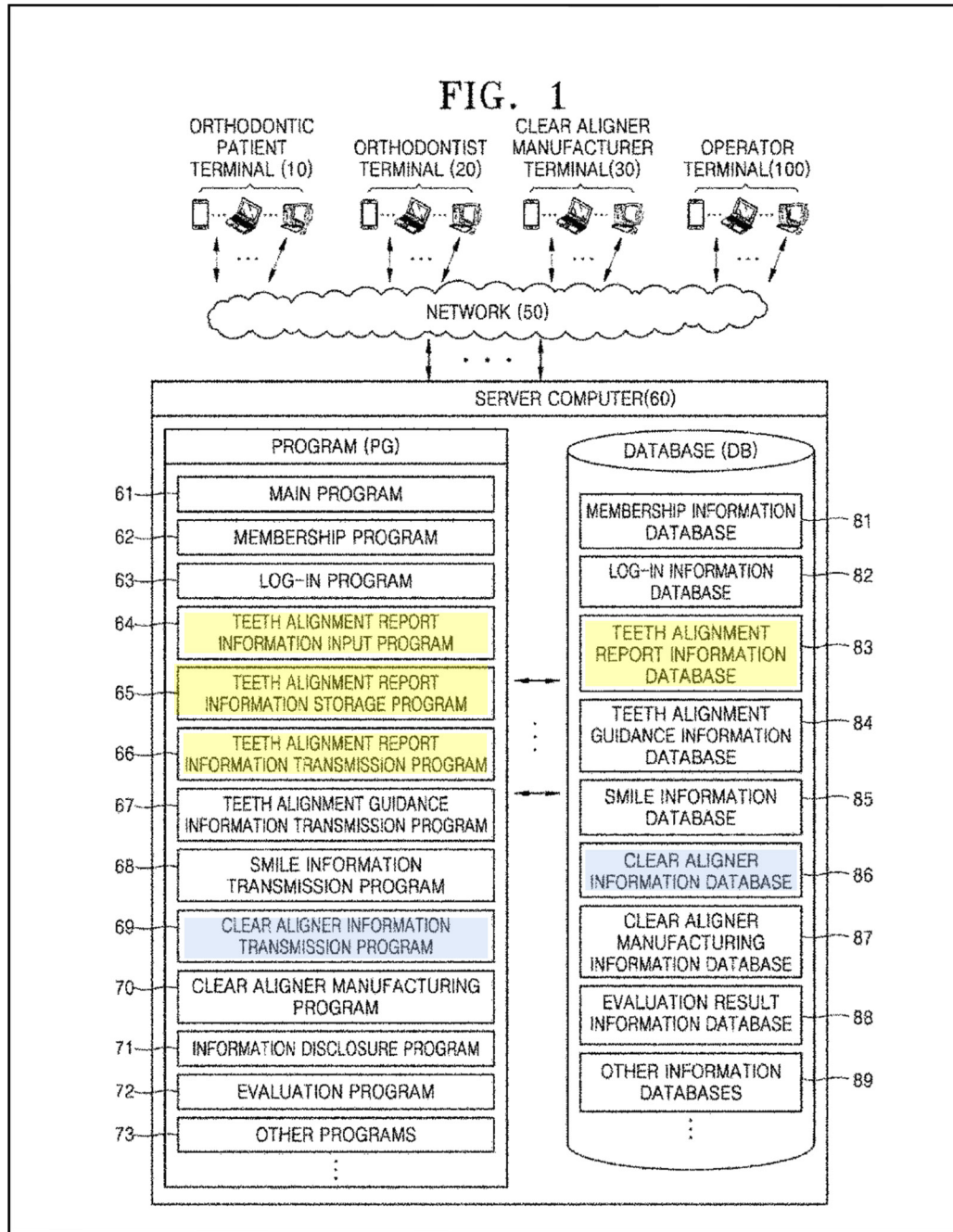
information” and “clear aligner information” are transmitted separately to the orthodontist terminal. *Id.*, Fig. 6 (steps (c) and (f), highlighted below).



73. Kim further explains that the teeth alignment information is collected by patients and transmitted to orthodontists using a “teeth alignment report information input program” and “teeth alignment report information transmission

program.” *Id.*, [0055], [0060], Fig. 2 (illustrating teeth alignment report information input program), Fig. 3 (illustrating teeth alignment report information transmission program). That teeth alignment information is stored in a “teeth alignment report information database.” *Id.*, [0073]. By contrast, the *clear aligner information* is maintained in a “clear aligner information database” and transmitted to orthodontists “using the clear aligner information transmission program.” *Id.*, [0073]-[0074].

74. The fact that teeth alignment information and clear aligner information is collected, transmitted, and stored separately is plain from Figure 1 of Kim (shown with highlighting below):



75. As explained above, the “teeth alignment report information” sent by the patient may include photographs of the patient’s teeth. *Id.*, [0013]; *see also id.*, [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). However, Kim never suggests that the "teeth alignment report" includes information about the aligner, let alone a photograph of the aligner in a service position. *Id.*, [0013], [0056], [0081], [0087]. The sample illustrations of the teeth alignment report likewise do not show the aligners. *E.g., id.*, Figs. 8-13, 19; *id.*, [0083] (describing Figure 13 as the teeth alignment report information checked and transmitted by the patient), [0085] (describing Figure 19 as the teeth alignment report information transmitted to the orthodontist).

76. According to Kim, the teeth alignment information, not the clear aligner information, is used by the orthodontist to diagnose patients and provide aligner advice based on the position of the teeth, not the aligner fit itself. *Id.*, [0010] ("The present invention provides a method and system for providing remote teeth alignment services, by which an orthodontist may ... remotely and accurately diagnose the condition of the patient ***based on the teeth alignment information***"); *see also id.*, [0085] ("the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal"), [0087] ("the orthodontist may remotely provide accurate diagnosis by checking [the various photos] capable of showing the teeth alignment state of the orthodontic patient"); *see also id.*, [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.”). In fact, Kim discloses that, according to its “embodiments of the present invention, an orthodontist may obtain accurate teeth alignment information using a device, e.g., a smartphone, of an orthodontic patient, may remotely and accurately diagnose the condition of the patient *based on the teeth alignment information.*” *Id.*, [0093]. There is no suggestion in Kim to use the clear aligner information for diagnosis or to monitor tooth positions.

77. Kim similarly discloses that the “clear aligner manufacturing program” may transmit clear aligner manufacturing information to the clear aligner manufacturer terminal “upon determining that an additional or modified clear aligner is needed, based on the *teeth alignment report information.*” *Id.*, [0067]; *see also id.*, [0020] (same), [0090] (same). I understand that, at deposition, Dr. Foroosh agreed that Kim discloses diagnosis, treatment, and manufacturing based on the teeth alignment information. EX2054, 13:11-19 (“Q. And Kim generally relates to diagnosing and treating patients based on those patient-created photographs in what Kim calls a ‘teeth alignment report’; right? A. Yes. Q. And Kim also discloses that new aligners can be manufactured based on that teeth alignment report? A. Yes.”).

78. I understand from Dr. Kusnoto that an orthodontist would have thus understood Kim to instruct orthodontists to look at the teeth alignment information report—containing photos of the patients’ teeth without an aligner—for purposes of

assessing how the treatment is progressing. I further understand from Dr. Kusnoto that aligners can make it difficult to see the exact tooth positions. Thus, a POSA would not have been motivated to use aligner images to assess teeth alignment. I further understand that, in 2017, the position of the teeth (e.g., as captured in images or models) was used to design and manufacture aligners, and that the progress of treatment was evaluated by assessing tooth alignment. Thus, I understand that using images of teeth alone, as in Kim, would have been consistent with these purposes.

79. By contrast, the clear aligner information received by the orthodontist can include information about “a **currently worn** clear aligner” (EX1005, [0018]) and the orthodontist can transmit clear aligner information about “a clear aligner **to be worn** in a current step among a clear aligner set” (*id.*, [0016]). Kim discloses that the former may, but need not, include “a photo or a video of the clear aligner currently worn.” *Id.*, [0066]. A POSA would have understood this language to refer to a photo or video of the aligner itself. That is because, in Kim, collecting and transmitting “clear aligner information” about the aligner itself is entirely separate from collecting and transmitting information about the patient’s teeth. The clear aligner information of Kim is also not used for diagnosis, but instead to “determine[] whether the clear aligner is normal and corresponds to an appropriate step,” that is, whether the aligner appears to be in working condition and the patient is using the right aligner for their current step of treatment. *Id.*, [0066].

80. To the extent Dr. Foroosh suggests that the phrase “currently worn” aligner suggests that the aligner is being worn at the time the patient takes a photograph, a POSA would not have understood the “currently worn” aligner to be worn at the exact moment of the photograph, but instead during the patient’s current phase of treatment. Kim uses the phrase “currently worn” to refer to the aligner that the patient is wearing or should be wearing during the current step in their treatment, and not when taking photographs. *E.g., id.*, [0041] (“the orthodontic patient terminal 10 may be a device of an orthodontic patient who desires to remotely receive information ***about an accurate step of a clear aligner to be currently worn*** by the orthodontic patient”); [0063] (“The teeth alignment guidance information transmission program 67 may be a program for receiving the teeth alignment report information and then transmitting the teeth alignment guidance information received from the orthodontist terminal 20, to the orthodontic patient terminal 10 in such a manner that the orthodontist accurately determines a current teeth alignment state of the orthodontist ***and advises, for example, an appropriate step of a clear aligner to be currently worn*** by the orthodontic patient.”); [0093] (“an orthodontist may obtain accurate teeth alignment information using a device, e.g., a smartphone, of an orthodontic patient, may remotely and accurately diagnose the condition of the patient based on the teeth alignment information, and ***may remotely provide information about an accurate step of a clear aligner to be currently worn by the***”

orthodontic patient, thereby greatly reducing a diagnosis time and cost of the orthodontic patient and the orthodontist”); *see also id.*, [0051] (describing “a clear aligner information transmission program 69 for receiving a clear aligner information about a currently worn clear aligner from the orthodontic patient terminal 10, storing the clear aligner information, and transmitting the clear aligner information to the orthodontist terminal 20”).

81. Kim never claims to provide a novel way to assess aligner fit from a photograph, nor explains how that could be done. A POSA further would have understood that images captured by a patient using a cellphone, according to Kim, were unlikely to be of high quality. For example, holding the phone “close to the teeth” to get a “high level of detail,” could result in “blurry” images and “optical distortion.” EX2064, [0004]. But holding the phone “too far” from the teeth, resulted in a different problem—photos that “cannot meet the orthodontic standards.” EX2064, [0004]. This is significant because I understand from Dr. Kusnoto that aligner fit issues can be difficult to detect, especially when they are just emerging. Although Kim discloses a program to provide guidance to the patient on positioning their head or teeth (*id.*, [0014]), there is no disclosure of any guidance on how to acquire an image with an aligner seated on teeth. This confirms that Kim is not directed to assessing aligner fit from an image of a patient wearing their aligner.

82. Finally, Dr. Foroosh further states that “Kim also teaches that automatic recognition of contours of a patient’s face and teeth may be employed as part of the imaging process.” EX1002, ¶56 (citing EX1005, [0014] (“As one example, Kim teaches providing a ‘teeth contour automatic recognition photographing program for displaying a virtual teeth line on the screen of the orthodontic patient terminal and automatically recognizing and taking a photo of teeth of the orthodontic patient shown on the screen.’”)). This disclosure relates to the acquisition of images, not to the review of the acquired images. Kim does not suggest the use of contour detection in the review of any images of the patient’s dental arch. In fact, Kim does not suggest any non-human analysis of orthodontic treatment from the acquired images. *See, e.g.,* EX1005, [0085] (“Then, as illustrated in FIG. 19, the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal 20.”).

83. In particular, Kim does not disclose the claim limitations: “determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively;” or “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.”

B. Invisalign

84. 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, i. Invisalign teaches that, “[t]o prevent issues from occurring,” dental professionals should “perform” certain steps “*at every patient appointment.*” *Id.*, ii. 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.*

85. Unlike the challenged claims of the ’945 patent, Invisalign discloses only a method for assessing aligner fit that is performed in-person, during in-office orthodontist check-ups. Invisalign does not suggest that aligner treatment progress can be remotely assessed from an image of a patient wearing their aligner in a service position. In fact, I understand that, until 2020, Petitioner did not offer any product for remotely assessing aligner treatment progress. EX2007.

86. I further understand from Dr. Kusnoto that a POSA would have understood Invisalign to instruct orthodontists to perform certain steps at each appointment that *could not* be performed remotely. These include, for example, Invisalign’s instruction that: “At each appointment ... [e]valuate for tight contacts with unwaxed floss and relieve with finishing strips if present.” Ex. 1006, ii.

Invisalign also instructs orthodontists to use a scaler “to trim attachment flash as well as check retention.” *Id.*, 1. I understand from Dr. Kusnoto that manipulating and evaluating aligner fit using a scaler cannot be performed remotely.

87. 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, 1. However, I understand from Dr. Kusnoto that the specific image from Invisalign on which Dr. Foroosh relies (Figure “A,” reproduced below) is an extreme example of an unseated aligner that is not engaged with the patient’s teeth. I further understand from Dr. Kusnoto that Figure A does not accurately reflect the spaces between the aligner and the teeth that would typically have been observed during aligner treatment in 2017 and that the spaces were generally much less perceptible than shown in Figure A below. According to Dr. Kusnoto, Invisalign’s image of “Aligner seating well” (Figure “B,” reproduced below) is a far better representation of what orthodontists had to evaluate during the normal course of aligner treatment. EX1006, 1.



88. Additionally, Invisalign makes no suggestion that any image was taken using a cellphone, nor that images should or could be acquired using a cellphone to assess aligner treatment. A POSA would have understood that the images in Invisalign were taken with a more sophisticated camera, such as a DSLR, and in-office with bright and controlled lighting, as I understand Dr. Foroosh has also acknowledged. EX2054, 134:10-135:24 (When asked how he “know[s] that the photograph in Invisalign is a digital photograph?,” responding “I just assume that in modern days, even in dentist office I’ve been, they are using SLR cameras. Those are all digital.”; “I was referring to SLR type of cameras that, you know, dentists use in offices as opposed to, let’s say, camera on our cell phones. I’ve seen that they’re all digital cameras.”).

89. I also understand from Dr. Kusnoto that specialized training and equipment, e.g., cheek retractors, dental mirrors, and a DSLR camera, were required to acquire high quality dental images and that in 2017, it was rare for dental practitioners to use cellphones to acquire images of their patients. EX2007 (Petitioner’s CEO, Joe Hogan, stating that “[e]arly on [in the 2020 COVID-19 pandemic], many doctors *began* using video calls, texts, and patient-submitted photos through a variety of platforms to help monitor patient progress, reduce in-office appointments, and ensure continuity of patient care during treatment.”). A POSA would have expected that images acquired on a cellphone would be lower resolution and lower quality than a DSLR camera, especially if they were acquired by a non-trained professional as envisaged by Kim and Salah. *Supra* §VI.A; *infra* §VI.C.

90. 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.” EX1006, 1. 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 measuring a separation, 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.*

91. Invisalign discusses only the collection of images for the purposes of aligner design and manufacture, *i.e.*, before the aligners exist. Contrary to Dr. Foroosh's suggestion, there is nothing in Invisalign that indicated that such images should be taken with a cellphone. *See* EX1002, ¶74. As discussed above, the '945 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 V.C. As these images were taken before the aligners were manufactured, they could not have included images of a patient wearing an aligner in a service position.

92. For the above reasons, I disagree with Dr. Foroosh that Invisalign describes acquiring "photographs of the teeth of the patient wearing the aligners." EX1002, ¶45. Unlike the '945 patent challenged claims, Invisalign does not suggest acquisition of images showing the aligner in a service position for the purposes of assessing aligner treatment.

93. Finally, Invisalign does not disclose analysis of any image, let alone non-human analysis satisfying the claim limitations: “determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively;” or “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.”

C. Salah

94. PCT Publication No. WO2016066651 to Salah *et al.* (“Salah”) is entitled “Method for Monitoring Dentition.” EX1008. While Salah names five inventors (*id.*), four of whom match the inventors listed on the ’945 patent, as discussed further below, it is my opinion that Salah is directed to an invention that is different from the ’945 patent.

95. 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. *Id.*, 1:1-2:19; *see also* EX2002, ¶¶83-89. In other words, Salah is directed to assessing teeth alignment, which I understand from Dr. Kusnoto is distinct from assessing aligner fit or the shape of an aligner in a service position. I understand that Dr. Foroosh similarly

confirmed that “Salah is not talking about clear aligners; so obviously could not talk about how it fits -- how a clear aligner fits or seating on the teeth.” EX2054, 117:1-4.

96. In summary, the invention in Salah “provides a method for monitoring the position and/or shape of a patient’s teeth” comprising the following steps:

- a) creation of a 3D digital reference model of at least part of an arch called an “initial reference model” and, preferably, using the initial reference, defining a 3D digital reference model of each tooth called the “tooth model”;
- b) acquisition of at least one 2D image of the patient’s arches called an “updated image”, under actual acquisition conditions;
- c) analysis of each updated image and production of an updated map relating to discriminant information;
- d) optionally, determination of gross virtual acquisition conditions approximating the real acquisition conditions for each updated image;
- e) searching for a final reference model corresponding to the positioning and/or shape of the teeth at the time of acquisition of the updated image, preferably using a metaheuristic method, and
- f) for each tooth model, comparison of the positions or shapes of the tooth model in the initial reference model and in the final reference

model so as to determine the deformation and/or displacement of teeth between the steps a) and b).

EX1008, 1:25-2:19.

97. Salah states that its invention provides a method to “accurately assess tooth displacement and/or deformation since the initial reference model was produced” based on “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.” *Id.*, 2:21-26; *see also id.*, 31:4-7 (“A kit according to the invention advantageously enables image acquisition without the need for a specialist person, in particular an orthodontist. In particular, image acquisition can be carried out by the patient himself or by one of their relatives, using a simple cellphone, anywhere, and especially outside a medical, dental or orthodontic practice.”). I have discussed each of the steps in Salah in further detail below.

1. Step a) – formation of a 3D model

98. First, in what Salah refers to as “step a),” a detailed 3D model of the patient’s teeth is formed using physical modeling (*e.g.*, “plaster model”) or “preferably ... using a professional device, such as a 3D scanner, preferably implemented by a healthcare professional, such as an orthodontist or orthodontic laboratory.” *Id.*, 19:25-20:21. This 3D model is processed to determine the orientation of the arches in relation to each other and to create models of individual

teeth (“tooth model”). *Id.*, 20:22-23:27, Figs. 3-4. These models can be stored “in a centralized database” but are “preferably” transferred to “the personal device” that will be used for image acquisition such as “the patient’s cell phone.” *Id.*, 23:9-19.

99. Salah’s accuracy depends on starting with this detailed 3D model, as it becomes the reference for further analyses of the patient’s teeth over time. By having a detailed reference model, Salah provides a point of comparison for later-taken, lower-quality images. Salah does not disclose that low quality images are useful in the absence of a detailed reference model. In other words, Salah teaches that a detailed and high-quality 3D model is a necessary starting point, and does not disclose any means of starting with patient-created photographs to achieve detailed measurements about their teeth from those photographs alone.

2. Step b) – acquisition of an “updated image”

100. Next, in what Salah refers to as “step b),” an “updated image” of the patient’s dental arch is acquired. *Id.*, 23:24-33:8. In the first section, titled “Acquisition,” Salah teaches that the “updated image” is acquired at some time interval after the model was created in step a), including preferably at times that are determined by an orthodontist or that are likely to correspond to a potentially significant change in tooth position. *Id.*, 23:28-24:20.

101. The next section titled “Image acquisition apparatus” describes the equipment used to acquire the “updated image.” *Id.*, 25:13-27:13. Salah teaches

that “[p]referably, the image acquisition apparatus is a personal device commonly available on the market, for example a cell phone” and that the “updated image” is “preferably created by the patient himself or by one of his relatives.” *Id.*, 25:14-19. I note that a cellphone is the only image acquisition apparatus disclosed in Salah that Dr. Foroosh relies on for his combination. EX1002, ¶¶49, 83. Salah also indicates that it is “preferabl[e]” that “the image acquisition apparatus includes a specialized application for implementing step b)” and that “a dental retractor is used ... as shown in Figures 5a and 5c.” EX1008, 26:19-27:4, Figs. 5a, 5c.

3. Step c) – analysis of the “updated image”

102. Next, in what Salah refers to as “step c),” each “updated image is analyzed to produce ... an updated map relating to at least one piece of discriminant information,” which Salah defines as “characteristic information that can be extracted from an image (‘image feature’)” such as “contour information” or “[b]rightness information.” *Id.*, 33:9-10, 18:11-17. As a preliminary step the “updated image” may be cropped to focus on the patient’s dental arch, as shown in Figures 5b and 5d. *Id.*, 33:14-34:2, Figs. 5a-d. This cropping “is facilitated by registration marks on the updated image,” which Salah describes as taking the form of “asymmetrical shape[s],” colors that stand out against the color of the retractor, and/or shapes and colors that make them individually identifiable. *Id.*, 33:16-26. It is the registration marks, and not any image analysis to identify the patient’s dental

arch, that makes “it possible to identify the area of the updated image containing ... the teeth and gums.” *Id.*, 33:27-34:1.

103. From the updated image, an updated map presenting discriminant information is then obtained. *Id.*, 34:5-36:16. Salah indicates that “[d]iscriminant information is preferably chosen from the group consisting of contour information, color information, density information, a distance information, brightness information, saturation information, reflection information and combinations of these.” *Id.*, 34:8-10. An example of an “updated tooth contour map” is depicted in Figure 6b. *Id.*, 34:7, Fig. 6b. Salah does not disclose the use of semantic segmentation or object recognition to generate or analyze the updated image.

104. Salah identifies eighteen “preferred methods” and eighteen methods that are “not preferred” but “can also be used,” for determining “discriminant information.” *Id.*, 34:15-36:14. Discriminant information includes, but is not limited to, contours. The preferred methods include long-established contour detection techniques, such as the Canny algorithm, which Salah specifically identifies as associated with determining contours. *Id.*, 34:15-16 (disclosing “well-known and preferred methods” including “applying a Canny filter, in particular to search for contours using Canny’s algorithm”). The non-preferred methods also include techniques that can be used in the process of determining and refining contours. *Id.*, 36:14. “Deep learning” is expressly identified at the bottom of the list

of methods that are “not preferred.” *Id.* As Dr. Foroosh agreed in his deposition, Salah is not teaching “deep learning” as a preferred method for determining any discriminant information, including contours, and has expressly identified more than a dozen other techniques that are “preferred” by comparison. EX2048 [Foroosh Tr.], 199:11-200:4.

105. Nowhere does Salah indicate that the contour map for the “updated image” would reflect identification of contours associated with individual identified teeth. To the contrary, the contour example in the definition of “discriminant information” contemplates that contour values are stored at the pixel level (0 and 1 indicating whether a pixel is part of a contour or not) and Salah does not mention any other potential values. EX1008, 18:14-15. Figure 6b is a simple contour map (*id.*, Fig. 6b), and while individual teeth may be identifiable in the contour map, there is no indication in Salah that they are identified during the analysis or annotated or otherwise marked on or associated with the “updated image.”

106. Salah’s reference to the disfavored approach of “deep learning” would not have suggested to a POSA using such a technique to identify which contours are associated with individual teeth, i.e., semantic contours. This is not necessary for the purposes of Salah.

107. As a result, Salah does not disclose the claim limitations: “determination, by means of image processing software, for each of a plurality of

teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively;” or “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.” EX1001, 14:9-17.

108. In his deposition, Dr. Foroosh suggested that Salah Figure 11 reflects the determination of semantic contours or semantic segmentation because the annotation of dashes 20 and circles 22 on the updated image coincide with the patient’s teeth. *E.g.*, EX2054, 98:10-99-6 (“If you look at it, it’s only restricted to teeth ... that’s because ... obviously they have segmented out certain portions of the jaw[.]”); *id.*, 105:4-21 (“That discriminant information of reflection is restricted to teeth and appliances in teeth, and that indicates to a POSA that a segmentation has taken place. In other words, when Salah is disclosing a teaching that used contour detection algorithm to perform that segmentation, it clearly says that the ... extraction of discriminant information ...[is] using [that] contour detection and edge detection.”). In other words, Dr. Foroosh appears to suggest that an image segmentation algorithm (e.g., deep learning) was used to recognize teeth in the updated image and identify a contour bounding them. Dr. Foroosh misunderstands Salah, which discloses no such thing.

109. In Figure 11, a “reference map” of lines 20 and circles 22 from the computerized 3D reference model is “superimposed on the acquired image.” EX1008, 64:6-8. Those lines 20 and circles 22 represent “vectors” pointing in a direction “perpendicular to the faces [of the teeth] in the reference model.” *Id.*, 64:29-32. The lines 20 and circles 22 are not determined from any information in the acquired image—they come directly from the 3D reference model. *Id.* While this “reference map” almost perfectly overlaps with the patient’s teeth in the acquired image, that is not because the patient’s teeth were identified and segmented/contoured in the acquired image. Rather, the “reference map” directly overlaps with the patient’s teeth in Figure 11 because the location of the patient’s teeth are known in the reference model. *See, e.g., id.*, Fig. 4d. In other words, a POSA would have understood that Salah teaches pulling from the 3D reference model only those vectors associated with the faces of the patient’s teeth and “project[ing them] onto the reference image.” *Id.*, 64:29-32. As explained below, the “reference image” (from the 3D model) and the “acquired image” (from the patient) are aligned to reflect the same “acquisition conditions,” including the same perspective. Thus, the location of the patient’s teeth in the reference image coincides with the location of the patient’s teeth in the acquired image. If the reference map of the patient’s teeth from the reference image (lines 20 and circles 22) is superimposed on the acquired image, the map will necessarily coincide with the

location of the patient's teeth, even though the acquired image was never analyzed to determine their contours. In fact, Salah does not disclose that any contours were determined in this embodiment at all—the embodiment described in connection with Figure 11 only discusses the use of “discriminant information” “relating to reflection information” rather than contours, as discussed elsewhere. *Id.*, 64:6-66:8.

110. Furthermore, the superimposition depicted in Figure 11 is not part of the process disclosed in Salah for aligning the acquired image with the reference image. A POSA would have understood it is a demonstrative figure that illustrates this embodiment of Salah, in which the brightest spots in the image (“those areas of the acquired image which have a brightness above a quality threshold”) can be expected to coincide with those areas of the teeth with surfaces directly facing the camera (represented by circles 22 in the reference image). *Id.*, 64:13-65:14. As Salah describes, the process of aligning the reference image to the acquired image involves comparing the location of those circles 22 (the “reference map”) with the location of the brightest spots in the image (the “acquired map”)—not with the acquired image itself. *Id.* Thus, not only would a POSA have understood that Salah does not teach the semantic segmentation of teeth in the acquired image, a POSA would also have understood that Salah does not teach creating the superimposed image depicted in Figure 11 as part of the image analysis.

111. Dr. Foroosh is thus incorrect that Salah discloses the determination of semantic contours, either in connection with Figure 11 or in any other instance.

4. Steps d) to f) – updating the 3D model

112. In the subsequent steps, Salah describes how this discriminant information from the “updated image” is ultimately used to update the 3D model to reflect any changes to the patient’s dental arch since the 3D model was originally formed or last updated. *Id.*, 36:17-47:24. In order to compare the “updated image”—a 2D photo—with the computerized 3D model, a corresponding “virtual” 2D image called a “reference image” is generated using computer algorithms to simulate what a photograph of the 3D “reference model” *would* look like if it could be photographed in the real world. *E.g., id.*, 40:7-12 (“The image acquisition apparatus is then virtually configured under the virtual acquisition conditions to be tested, in order to acquire a reference image of the reference model under these virtual acquisition conditions to be tested. The reference image thus corresponds to the image that the image acquisition apparatus would have taken if it had been positioned, relative to the reference model to be tested, and optionally calibrated in the virtual acquisition conditions to be tested.”).

113. If the “reference image” is generated to simulate conditions closely analogous to those used to capture the “updated image”—conditions referred to as “*virtual* acquisition conditions”—it can be compared directly to the initial reference

model, and their differences should reflect how the patient's teeth have changed (*i.e.*, moved or deformed) since the time of the initial reference model. *E.g., id.*, 46:10-14 (“The final reference model corresponds substantially to the updated image. By comparing step f), it is possible to observe the differences between tooth positioning in step a) (initial reference model) and during acquisition of the updated image (step b)). In this way, it is possible to accurately determine the movements of individual teeth between these two stages.”). Notably, Salah discloses tracking orthodontic treatment only by analyzing tooth movements; it does not suggest assessing aligner fit.

114. To obtain a virtual “reference image” of the virtual 3D “reference model” that can be directly compared to the “updated image,” Salah first teaches determining “virtual acquisition conditions” that most closely reflect the actual acquisition conditions used to obtain the “updated image.” Salah defines “acquisition conditions” as “specify[ing] the position and orientation in space of an image acquisition apparatus relative to the patient’s teeth or a model of the patient’s teeth, and preferably the calibration of this image acquisition apparatus.” *Id.*, 17:11-13. “Calibration” is defined as consisting of “all the calibration parameter values,” which are parameters “intrinsic to the acquisition apparatus” and “which affect[] the acquired image” such as “the depth of field,” “[e]xposure time,” “[f]ocal length,” and “[s]ensitivity.” *Id.*, 17:14-22. As an example, Salah depicts virtual images

acquired at two different focal lengths in Figures 12a and 12b. *Id.*, 42:16-17, Fig. 12.

115. Optional “step d)” takes advantage of the presence of the “registration marks” in the “updated image” to approximate the acquisition conditions by evaluating their apparent alignment, orientation, size, and/or spacing. *Id.*, 36:17-38:9. The **known** orientation and geometry of the “registration marks” can be used to determine the positioning of the acquisition device relative to the patient’s teeth. *Id.* An example of the use of “registration marks” to determine orientation and distance is depicted in Figure 7. The size, distance, and orientation of the “registration marks” can be used to determine the angle and distance from which the photograph of the exemplary cube was acquired. *Id.*, 36:26-37:2.; Fig. 7. Such marks, when applied to the retractor (labeled as “12” in Figure 5a), can facilitate a similar determination with respect to the patient’s teeth. *Id.* The “registration marks” can also be used to evaluate focal length, exposure time, sensitivity, and depth of field. *Id.*, 38:19-39:2. The use of the “registration marks” for this determination “advantageously limits the number of tests on virtual acquisition conditions” in the subsequent processing and therefore “speeds up step e) **considerably.**” *Id.*, 36:19-20. Some acquisition conditions such as “gyroscopic data,” can also be obtained directly from the acquisition device. *Id.*, 38:10-11.

116. In “step e),” the virtual acquisition conditions are determined, including by using the estimated conditions from “step d)” as a starting point, and the reference model is updated to reflect changes in the patient’s teeth. Salah describes an iterative process of comparing discriminant information such as contours between the reference images and updated image, including as the reference model is deformed to match the position and shape of the patient’s teeth as depicted in the updated image. *Id.*, 39:21-46:8.

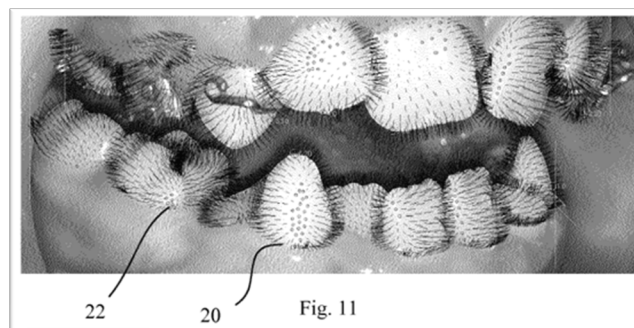
117. Finally, in “step f),” the final reference model can be compared with the initial reference model “to observe the differences between tooth positioning” and “accurately determine the movements of individual teeth between ... two stages.” *Id.*, 46:9-14. Salah does not disclose the comparison of any edges or contours within an “updated image.” A POSA would have understood that the “accura[cy]” of Salah’s method depends on having started with a precise 3D scan of the patient’s teeth, as described in “step a).”

118. It is my opinion that, as is apparent from the above description of Salah, the method for monitoring tooth displacement in Salah is distinct from the method for assessing the shape of an orthodontic aligner in the ’945 patent. Salah does not use images showing an aligner in a service position, and it nowhere suggests assessing aligner fit for treatment, as required by all the challenged claims.

119. In addition, Salah's discussion of contours as "discriminant information" would not have suggested to a POSA that contours of individual teeth should be separately determined from the "updated image." Only the full contour of all teeth collectively needs to be obtained to determine the differences in outline between the reference image and the updated image. *See id.*

5. Salah's Alleged "Orthodontic Appliance"

120. Dr. Foroosh also relies on Salah as disclosing images of "teeth of a patient using orthodontic appliances." EX1002, ¶73. For this teaching, Dr. Foroosh points exclusively to Figure 11 of Salah (shown below), in which the patient is wearing a bonded expander on the upper teeth during imaging. *Id.*



121. As a preliminary matter, Salah does not disclose assessing the *distance* between the bonded expander shown in Figure 11 and the tooth, or any feature of the bonded expander. I also understand from Dr. Kusnoto that, unlike an aligner, this bonded expander on the upper teeth could not be readily removed by the patient. A POSA would have understood that the bonded expander on the upper teeth was included for that reason, not because it was desirable to acquire an image of the

bonded expander on the upper teeth. Salah would not have taught a POSA to acquire image of any removable device, such as an aligner.

122. Additionally, Salah's contour detection techniques are reliant on distinguishing between highly contrasting areas. For example, to assess tooth positions, Salah teaches that "[i]n the case of a contour, for example, contrast analysis provides more or less reliable information: an area of high contrast can be assimilated to an area corresponding to a contour with a high probability, and the quality of the points of this area will be high. On the other hand, a low-contrast area, such as a blurred zone, can be assimilated to an area corresponding to a contour with a low probability, and the quality of the points of this area will be low." EX1008, 60:17-22. Salah thus recommends processing the reference image to retain only the outlines identified with a high probability. EX2008 [U.S. Pat. Pub. Salah], [0533]; EX1008, 61:2-4. That is because, if the "quality threshold is low, the discriminant information retained will be abundant, but unreliable" and this "will then lead to the retention of 'false' contour points, i.e. points which, will be mistakenly considered as belonging to the contour of teeth and gums." *Id.* Salah thus teaches that it is preferred that "the quality threshold is high in order to retain only highly reliable discriminating test information." *Id.* In other words, Salah teaches that high contrast is *required* to achieve a quality analysis. A POSA would have understood that an aligner would not provide a high contrast with the patient's teeth or mouth because

aligners visually blend with the teeth. Thus, a POSA would have understood Salah to teach away from using contour detection with aligner images as the methodology would need to be altered to detect areas of low contrast instead.

VII. CLAIM CONSTRUCTION

123. Dr. Foroosh proposes constructions of the claim terms “aligner and dentition images” and “interior and exterior tooth outlines.” Ex. 1002, ¶¶54-55. The constructions of these terms do not change my opinions set forth herein, and accordingly, I have applied Dr. Foroosh’s proposed constructions.

124. I discuss below my construction of the term “shape of an orthodontic aligner” and “for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth,” which are not explicitly construed by Dr. Foroosh.

A. “shape of an orthodontic aligner”

125. The term “shape of an orthodontic aligner” appears in the preamble to claim 1 of the ’945 patent. I am informed by counsel that whether a claim preamble is a substantive limitation is determined based on the overall form of the claim and the invention as described in the specification and in the prosecution history. I understand that a preamble is limiting when it is necessary to understand the subject matter encompassed by the claim, when it provides an antecedent basis to terms used in the body of the claim, when it presents the essence or a fundamental characteristic

of the invention, when patentability depends on the limitations stated in the preamble, or when the preamble recites structure underscored as important by the patentee. By contrast, a preamble is less likely to be limiting where it merely gives a name or describes a use or purpose of the invention.

126. I understand that it is Dental Monitoring's position that, in the event that the preamble is limiting, the "shape of an orthodontic aligner" should be construed to mean "the shape of the aligner relative to the shape of the teeth of the patient." In my opinion, this construction is consistent with the specification of the '945 patent, and I agree with this construction. For example, the '945 patent relates to a method of "evaluating the shape of an orthodontic aligner" for purposes of aligner treatment. *See, e.g.*, EX1001, claim 1; *see also id.*, Abstract, 1:65-67.

127. The '945 patent further explains that the shape of the aligner is assessed relative to the patient's teeth so as to determine its suitability for treatment. EX1001, 5:1-7 ("The interior surface of the aligner is referred to as the 'tray' 12. The shape of the tray is determined to fix the aligner on the teeth, but also according to a target positioning desired for the teeth. More specifically, the shape is determined in such a way that, when the aligner is in its service position, it applies forces that tend to move the treated teeth toward their target positioning."). A POSA would have understood that, as set forth in the '945 patent, the "shape of an orthodontic aligner" can be assessed by "comparing an outline of this aligner, in its service position, with

an outline of the teeth wearing it.” EX1001, 6:7-9; *see also id.*, 11:42-47 (“In step i), a distance *d* between the interior and exterior tooth outlines of each of said teeth is determined (FIG. 7). The distance between the interior 14 and exterior 18 tooth outlines of a tooth may for example be the mean distance or the maximum distance between the pixels of said outlines corresponding to one and the same point on the tooth.”). The ’945 patent thus teaches that the “shape” of the aligner is evaluated by comparing the outline of the teeth and the outline of the aligner.

128. Dr. Foroosh opines that the preamble is satisfied by alleged prior disclosure of a method of “assessing the fit of the aligner” that involved “determining a distance between the teeth and the aligner when worn by the patient.” EX1002, ¶68. Dr. Foroosh thus appears to understand that the preamble, if limiting, should be construed to refer to a method of assessing “the shape of the aligner relative to the shape of the teeth of the patient,” *i.e.*, aligner fit.

B. “for each of a plurality of teeth ... interior and exterior tooth outlines representing the outline of the free end of said tooth”

129. It is my opinion that the phrase “for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth,” which is recited in claim 1, should be construed as requiring the use of image processing software to determine “for each of multiple teeth, an interior tooth outline representing the

outline of the free end of each of the multiple teeth and an exterior tooth outline representing the corresponding part of the aligner.”

130. The claimed methods of the '945 patent require not only the use of image processing software to determine contours, but also that the contour belongs to a tooth or an aligner, and that the interior and exterior tooth outlines correspond to the same tooth. This is apparent from the working of the claim, which requires “**determination**, by means of image processing software, for **each of a plurality of teeth** represented on the dentition and aligner images, **of interior and exterior tooth outlines** representing the outline of the free end of **said tooth** on the dentition and aligner images.”

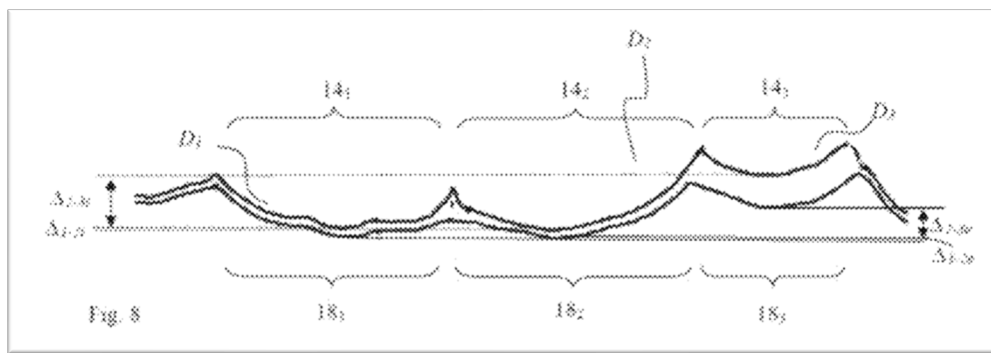
131. This construction is also evident from other limitations in claim 1 and the dependent claims. For instance, Step 4) of claim 1 recites “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.” EX1001, cl. 1. As the specification explains, the comparison step is performed “preferably in accordance with one of the two particular embodiments ... corresponding respectively to FIGS. 7 and 8” of the '945 patent. *Id.*, 11:35-38. For example, “for each of a plurality of teeth for which interior and exterior tooth outlines have been determined,” “a distance *d* between the interior and exterior tooth outlines **of each of said teeth is determined.**” *Id.*, 11:40-43. This “may for example be the mean distance or the maximum distance between the pixels

of said outlines *corresponding to one and the same point on the tooth.*” *Id.*, 11:45-47. As another example, as set forth in Figure 8, “at least one score known as the ‘offset score’, is determined, for *each pair of teeth of [a consecutive] triplet*, as a function of the difference in offset with a tooth adjacent to said tooth and of the offset-difference threshold.” *Id.*, 13:7-10. “In particular, the difference in offset of *the first tooth with the second tooth* may be compared against the offset-difference threshold.” *Id.*, 13:11-13. In other words, the comparison must be between interior and exterior tooth outlines corresponding to the free end *of the same tooth*.

132. Claim 5 further recites: “determination of a distance score dependent on the distance between the interior and exterior teeth outlines.” *Id.*, cl. 5. Again, it is clear from the ’945 patent that the distance score is the distance between a tooth and the portion of the aligner corresponding to that tooth (*i.e.*, the interior tooth outline and corresponding exterior tooth outline). *Id.*, 12:1-5 (“For preference, the distance score for a tooth is equal to $S(d, S_d)$ namely the difference between the distance between the interior and exterior tooth outlines *for this tooth* and the distance threshold. The higher the distance score, the greater the separation *of the tooth concerned* from the tray.”).

133. This interpretation is further supported by the specification, which explains that the method determines an interior tooth outline and its “*corresponding*” exterior tooth outline, meaning the outline of the aligner region

associated with the particular tooth. *Id.*, 5:33-40 (“When a tooth is positioned in the tray ... its interior tooth outline substantially coincides with the *corresponding* exterior tooth outline ... or is offset and substantially parallel to the *corresponding* exterior tooth outline”). This concept is illustrated in Figure 8 of the ’945 patent, reproduced below:



Id., Figure 8. As shown in Figure 8, the method identifies individual interior tooth outlines pertaining to teeth (14₁, 14₂, and 14₃) and corresponding individual exterior tooth outlines pertaining to regions of the aligner (18₁, 18₂, and 18₃) for multiple teeth (D₁, D₂, and D₃). *See also id.*, 12:16-19, 13:5-27.

134. As discussed further below (*infra*, §VIII.C), Dr. Foroosh is thus incorrect that this claim element can be satisfied by using image processing software to determine generic contours, without identifying that the contour belongs to a tooth or an aligner, and that the interior and exterior tooth outlines correspond to the same tooth.

VIII. THE ’945 PATENT WOULD NOT HAVE BEEN OBVIOUS IN VIEW OF KIM, INVISALIGN, AND SALAH

135. For the reasons set forth below, I disagree with Dr. Foroosh that the challenged claims of the '945 patent would have been obvious in view of Kim, Invisalign, and Salah.

136. The '945 patent claims a novel method of evaluating the shape of an orthodontic aligner using an aligner image showing the aligner in a service position. Dr. Foroosh misreads each of Kim, Invisalign, and Salah, none of which disclose or provide a reason to capture images of a patient's teeth with aligners in a service position, let alone for the purpose of evaluating such an image to determine the shape of an orthodontic aligner. Kim, Invisalign, and Salah fail to disclose or render obvious a method of determining and comparing interior and exterior tooth outlines for a plurality of teeth, in which the interior tooth outline represents the free end of a tooth and the exterior tooth outline represents the interior surface of the aligner.

137. In reaching these opinions, I have relied on my discussion in each of the preceding sections as further explained below.

A. Dr. Foroosh's Proposed Combination

138. Dr. Foroosh's combination relies on all three of Kim, Invisalign, and Salah. I understand that Petitioner identifies Kim as the primary reference and Invisalign and Salah as secondary references. Paper 2, 13, 17. However, Dr. Foroosh does not appear to adopt that distinction. My opinion does not change regardless of which reference is identified as the primary reference.

139. Dr. Foroosh's analysis begins with Kim. EX1002, ¶56. According to Dr. Foroosh, "Kim discloses methods for providing remote tooth alignment services, including evaluation of a clear aligner to be worn by a patient and determination of, for example, 'when a new or modified clear aligner is necessary.'" *Id.* (quoting EX1005, Abstract, [0010], [0042]). Dr. Foroosh further states that "Kim also teaches that automatic recognition of contours of a patient's face and teeth may be employed as part of the imaging process," pointing to Kim's disclosure of displaying a virtual tooth line on-screen during photo capture. EX1002, ¶56 (citing EX1005, [0014]). Dr. Foroosh does not suggest that this aspect of Kim would have motivated a POSA to assess the fit of an aligner by determining contours. I agree that Kim would not have provided such a motivation because this teaching concerns the acquisition of images of the patient's teeth, without an aligner in place. As discussed above, Kim does not suggest any non-human analysis of orthodontic treatment from the acquired images. Instead, Kim is concerned with the assessment of teeth alignment using images of a patient's teeth without aligners present; this is a different assessment from aligner fit or the shape of an aligner.

140. Dr. Foroosh then points to the clear aligner information transmission program of Kim, as "operat[ing] to provide orthodontists with images of aligners worn by the patient that may be usefully analyzed by the orthodontist," and that this review "reduce[s] diagnosis time and cost" as well as "enhanc[ing] accuracy."

EX1002, ¶57 (citing EX1005, [0008]-[0010], [0066], [0072]). As explained above, however, the clear aligner information transmission program of Kim involves only photographs of the aligners *on their own*. See *supra*, §VI.A. It is the “teeth alignment information”—referring to information about the patient’s teeth without an aligner in place—that is used for diagnosis and to determine whether new aligners need to be ordered, not the “clear aligner information,” which refers to information about the aligner on its own. *Id.* Accordingly, the alleged benefits of Kim come from the capture and review of images of the teeth, not the aligner on the patient’s teeth. Thus, it is my opinion that Dr. Foroosh’s motivation to combine the references is based on an incorrect understanding of Kim. Moreover, Dr. Foroosh does not articulate *any* other motivation for combining Kim with the other references beside his mistaken reading of Kim.

141. Dr. Foroosh next alleges that “Invisalign corroborates Kim’s teachings regarding imaging an aligner in a service position on teeth.” EX1002, ¶58. As explained above, Kim nowhere discloses photographing or otherwise imaging an aligner seated on a patient’s teeth. Nonetheless, Dr. Foroosh goes onto allege that Invisalign teaches “assessments that can be used to determine whether the clear aligner is normal and corresponds to an appropriate step,” including “that if an aligner is well seated, there will be a distance of less than 1 mm between the end of the teeth and the surface of the aligner.” *Id.* Dr. Foroosh points to one image of a

poorly-seated aligner in Invisalign to demonstrate that the resulting gap of more than 1 mm “is plainly visible on the photograph.” *Id.* But Invisalign is concerned with an analysis that is performed in-person, it instructs orthodontists to perform certain steps at each appointment that could not be performed remotely, and I understand from Dr. Kusnoto that the image on which Dr. Foroosh relies is not representative of the typical aligner fit observed by dental practitioners at the time. *See supra*, §VI.B.

142. Dr. Foroosh then asserts that “[i]n view of Kim’s disclosure of orthodontic checking of a photo or video of an aligner currently worn by the patient and Invisalign’s teachings of how to evaluate aligner fit, illustrated by an image of an aligner worn on a patient’s teeth, a POSA would have had reason to analyze images of the teeth of a patient wearing an aligner in a service position to evaluate whether the aligner fits appropriately.” EX1002, ¶59. As noted above, Dr. Foroosh’s opinion is based on a misunderstanding of Kim’s and Invisalign’s disclosures—neither Kim nor Invisalign suggests evaluating aligner fit from an image of a patient wearing an aligner. *See supra*, §§VI.A., VI.B. Dr. Foroosh is thus incorrect that the combination of Kim and Invisalign “would be applying known methods for orthodontic evaluation of aligner fit.”

143. Dr. Foroosh concludes that a POSA would thus have reason to evaluate images for aligner fit, and thus separation, including because Kim teaches that

remote treatment results in enhanced accuracy and more efficient results. EX1002, ¶59 (citing EX1005, [0010], [0072]). But again, those alleged benefits of Kim stem from the capture and review of images of the teeth, not the aligner on the patient's teeth. *See supra*, §VI.A.

144. Dr. Foroosh next points to the reference Frey³ (EX1009) as “confirm[ing]” “that POSAs were motivated” to use images of aligners for orthodontic evaluation. EX1002, ¶60. Frey describes a “DIY” method of implementing Dental Monitoring's software and does not relate at all to using a computer for image analysis. EX1009, 17-27. Frey does not disclose determining and comparing interior and exterior tooth outlines using image analysis software. Instead, Frey suggests obtaining a video which the orthodontist would then remotely visually inspect.

145. As none of Kim, Invisalign, Salah, or Frey disclose determining the width of gaps between teeth and aligners from a photograph, Dr. Foroosh pivots to argue that “[a] POSA would have known how to determine the width of such gaps using image processing software.” EX1002, ¶61. Dr. Foroosh argues that Salah provides useful disclosure by teaching the determination of the edges of objects in

³ I understand that Frey is not prior art because it reflects a disclosure by the inventors of the '945 patent, but whether Frey is prior art does not change my opinions.

cellphone pictures of teeth to track teeth during orthodontic treatment. *Id.* He further opines that, “[l]ike Kim, Salah teaches application of computer image analysis to dental images for orthodontic treatment purposes.” *Id.* I disagree that Dr. Foroosh has identified a motivation for a POSA to determine the width of such gaps using image processing software and also that Kim discloses any “computer image analysis” for orthodontic treatment purposes. *See supra*, §VI.A. And unlike the ’945 patent, both Kim and Salah teach a POSA to use teeth positions, not aligner fit, to assess orthodontic treatment progress. *See supra*, §§VI.A., VI.C.

146. Dr. Foroosh next says “Salah teaches that images may be analyzed to ‘measure the effectiveness of orthodontic treatment,’” and “that analysis of acquired images may include determining contours of objects in an image, including by using image processing software for contour or edge detection.” EX1002, ¶62. As detailed above, Salah does not suggest detecting the contour of a low-contrast aligner seated on teeth. *Supra*, §VI.C. To the contrary, Salah teaches away from using low contrast contours, as would be presented by an aligner on the patient’s teeth, calling them “unreliable” and teaching that they should be filtered out. *Id.*

147. Nonetheless, Dr. Foroosh asserts that Invisalign provides the motivation to use Salah for the purpose of assessing aligner fit by “teach[ing] that the gap between the surfaces of teeth and an aligner should be below a threshold value (1 mm) when fitting well,” and that this “align[s] with Kim’s teaching to assess

whether an aligner was ‘normal and corresponds to an appropriate step.’” *Id.*, ¶63. But Invisalign teaches only approximating aligner fit during in-person appointments that includes techniques that cannot readily be performed remotely. Furthermore, Invisalign cannot “align” with Kim as Dr. Foroosh contends, because Dr. Foroosh is incorrect in saying that Kim teaches photographing a seated aligner.

B. Kim, Invisalign, and Salah Fail to Disclose Or Render Obvious the Claimed Method of Evaluating the Shape of an Orthodontic Aligner Using An Aligner Image, and There Is No Motivation To Combine the References as Proposed

148. The challenged claims of the ’945 patent recite a method of evaluating the shape of an orthodontic aligner using an image of an aligner in a service position, including such an image captured on a cellphone.⁴ As an initial matter, none of Dr. Foroosh’s references individually disclose this technique: Kim and Salah do not disclose images taken of an aligner in a service position, and Invisalign does not disclose doing so either with a cellphone or for the purposes of evaluating the shape of an aligner. *See supra*, §§V.A-C. Even taken together, Dr. Foroosh’s combination

⁴ While the challenged claims do not require image acquisition using a cellphone, Dr. Foroosh does not suggest that a POSA would have been motivated to use any other acquisition device to capture an image. *E.g.*, EX1002, ¶¶ 56-57, 60-61, 68, 71-74, 83.

of references fails to teach or render obvious acquisition of aligner images for use in a method of assessing aligner fit.

149. First, Dr. Foroosh's motivation to combine Invisalign and Kim is premised on the incorrect assertion that Kim teaches the use of photographs of seated aligners in remote treatment. EX1002, ¶58 ("Invisalign corroborates Kim's teachings regarding imaging an aligner in a service position on teeth, showing how such an aligner may be assessed to determine if it fits appropriately."); ¶59 ("In view of Kim's disclosure of orthodontic checking of a photo or video of an aligner currently worn by the patient and Invisalign's teachings of how to evaluate aligner fit, illustrated by an image of an aligner worn on a patient's teeth, a POSA would have had reason to analyze images of the teeth of a patient wearing an aligner in a service position to evaluate whether the aligner fits appropriately."). As explained above, however, Kim is concerned with assessing teeth alignment, not the distinct process of assessing the shape of an aligner in a service position. To assess the alignment of teeth, Kim teaches the acquisition of images of the patient's teeth without aligners. The "clear aligner information transmission program" of Kim relates to photographs of aligners *on their own*. *Supra* §VI.A; EX1005, [0066], Figs. 1 and 6. There is no suggestion in Kim that these photographs of aligners should be used for diagnostic or treatment purposes; rather, Kim instructs that the photographs of patients' teeth that comprise the separate teeth alignment information

report should be used for those purposes. EX1005, [0085] (“the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal”), [0087] (“the orthodontist may remotely provide accurate diagnosis by checking [the various photos] capable of showing the teeth alignment state of the orthodontic patient”); *see also id.*, [0063], [0093]. Thus, the methods of Kim do not disclose the use (or usefulness) of photographs showing seated aligners or suggest that such photographs would be useful to an orthodontists’ remote or virtual evaluation of a patient’s treatment.

150. Second, Dr. Foroosh is incorrect that “Invisalign confirms that analyzing a two-dimensional image of an aligner in a service position as well as the patient’s teeth (such as a photo or video taken by a cellphone, as taught by Kim) can produce measurements useful for orthodontic assessment.” EX1002, ¶72. Invisalign discusses the collection of patient images only for the purposes of aligner design and manufacture, *i.e.*, before the aligners exist, and there is nothing in Invisalign that indicates that such images could be taken with a cellphone. Rather, a POSA would have understood that such dental photographs would have been taken with a more sophisticated camera, such as a DSLR, and in-office with bright and controlled lighting by a trained dental professional. I understand from Dr. Kusnoto that, in 2017, in-office photographs taken by a trained dental professional with a

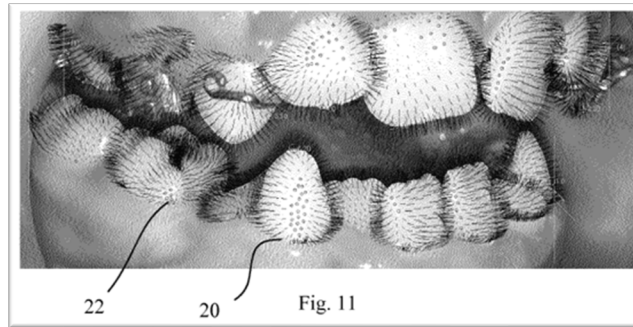
professional-grade camera were of significantly higher quality than patient-created photographs using a cellphone would have been.

151. Further, while Invisalign notes that a separation of greater than 1 mm between the tooth and the aligner is indicative of a fit issue, Invisalign nowhere suggests that aligner fit can be assessed simply by looking at an aligner image. Instead, Invisalign sets out various steps that should be performed in person to evaluate aligner fit. EX1006, ii (“At each appointment ... [e]valuate for tight contacts with unwaxed floss and relieve with finishing strips if present.”). Indeed, I understand from Dr. Kusnoto that, to assess aligner fit, an orthodontist would visually and manually examine the aligner, using their hands to check for rocking (movement of one part of the aligner off of a patient’s teeth when pressure is applied). I further understand from Dr. Kusnoto that, when an aligner is properly seated, even if there are fit issues, they are difficult to diagnose solely by visual inspection by a dental professional. For example, I understand from Dr. Kusnoto that even a trained orthodontist cannot reliably tell if an aligner is within 1 mm of the tooth without further manipulation, such as using a tooth scaler or other tool to evaluate fit and provide scale. *See also* Ex. 1006, 1 (Invisalign describing the use of a scaler to “check retention”). Moreover, based on my review of Invisalign as confirmed by Dr. Kusnoto, Invisalign does not disclose any methods for measuring whether an aligner is within 1 mm of the tooth, apart from visual approximation. A

POSA would have understood that this is because, in 2017, orthodontists did not quantitatively assess aligner fit and did not measure the distance between an aligner and the teeth.

152. For these reasons, upon review of Invisalign, a POSA would not have been motivated to modify the approach in Kim so as to capture aligner images and measure the distance between tooth and aligner from a cellphone image captured by an untrained person. Nothing in the combination of Kim and Invisalign suggests that the in-person approximation, combined with in-person visual and manual inspection and manipulation of the aligner, could be successfully replaced with computer-implemented analyses of patient-initiated photographs captured using a cellphone, or would have motivated a POSA to do so.

153. Combining Salah with Invisalign and/or Kim also would not have motivated a POSA to acquire images showing an aligner in a service position for use in a method of evaluating the shape of an aligner. While Salah includes one image that includes a device, I understand from Dr. Kusnoto that a POSA would have recognized that Figure 11 shows a bonded expander on the upper teeth that could not be removed by the patient prior to taking the photograph—and not a clear aligner, which could have been readily removed before taking the picture. EX1008, Fig. 11 (shown below).



154. Further, Salah assesses tooth positions, it does not provide any methodology to measure aligner fit or suggest that it could be assessed from an image. To the contrary, Salah teaches that “[i]n the case of a contour, for example, contrast analysis provides more or less reliable information: an area of high contrast can be assimilated to an area corresponding to a contour with a high probability, and the quality of the points of this area will be high. On the other hand, a low-contrast area, such as a blurred zone, can be assimilated to an area corresponding to a contour with a low probability, and the quality of the points of this area will be low.” EX1008, 60:17-22. Salah further recommends filtering and retaining only the outlines identified with a high probability, calling those identified with a low probability “unreliable”. EX1008, 61:2-4. In other words, Salah teaches that high contrast is *required* to achieve a quality analysis. I further understand from Dr. Kusnoto, that a clear aligner does not present a high contrast with teeth or the mouth. Thus, Salah teaches away from using contour detection with images involving a clear aligner.

155. Finally, Dr. Foroosh opines that Frey “confirms that acquiring digital photographs of patient’s teeth, including patient-acquired cellphone images of teeth of patients wearing aligners in a service position, was known to be a useful practice for assessment of a patient’s orthodontic treatment status.” EX1002, ¶74. I understand from Dr. Kusnoto that this is not correct. It was rare to use dental images captured by patients in 2017 and there would have been many challenges with acquiring images in this way for the purposes of assessing aligner fit. Consistent with that understanding, Frey only suggests remotely obtaining a video that the orthodontist would then visually inspect.

156. I note that Dr. Frey published another post on his blog approximately two weeks earlier evaluating Dental Monitoring’s “GoLive” product, which was “designed for Invisalign patients” and which involved taking “photos ... with aligners in place” to advise the patient whether to “advance to the next aligner.” EX2053, 6. Dr. Frey states that “DM GoLive is an interesting concept, but weekly photo submissions add additional compliance burdens on patients and in my view would be counterproductive to treatment,” further noting that “[t]he patients compliant enough to complete these weekly evaluations aren’t the ones need[ing] a service to help titrate their aligner wear effectively.” Id., 7. Dr. Frey also noted the “additional costs” as a discouraging factor. Thus, contrary to Dr. Foroosh’s suggestion, Dr. Frey’s blog confirms that there was no motivation to acquire images

of a patient's dental arch with aligners in a service position to assess aligner fit, and indeed, Frey teaches away from doing so.

157. In conclusion, each of the challenged claims recites “[a] method for evaluating the shape of an orthodontic aligner worn by the patient” that requires “acquisition of at least one two-dimensional image” including an “‘aligner image,’ at least partially representing the aligner in a service position in which it is worn by said teeth.” None of Dr. Foroosh's references taken alone or together disclose or render obvious the acquisition of aligner images for use in a method of assessing aligner fit.

C. Kim, Invisalign, and Salah Fail to Disclose Or Render Obvious the Claimed Evaluation of Interior and Exterior Tooth Outlines

158. Even if they were motivated to combine Kim, Invisalign, and Salah as Dr. Foroosh proposes—and they would not have been—a POSA would not have achieved a method of “evaluating the shape of an orthodontic aligner” that includes “determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively” and “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison,” as each of the challenged claims requires. *See* EX1001, steps 1(3) and 1(4) of claim 1.

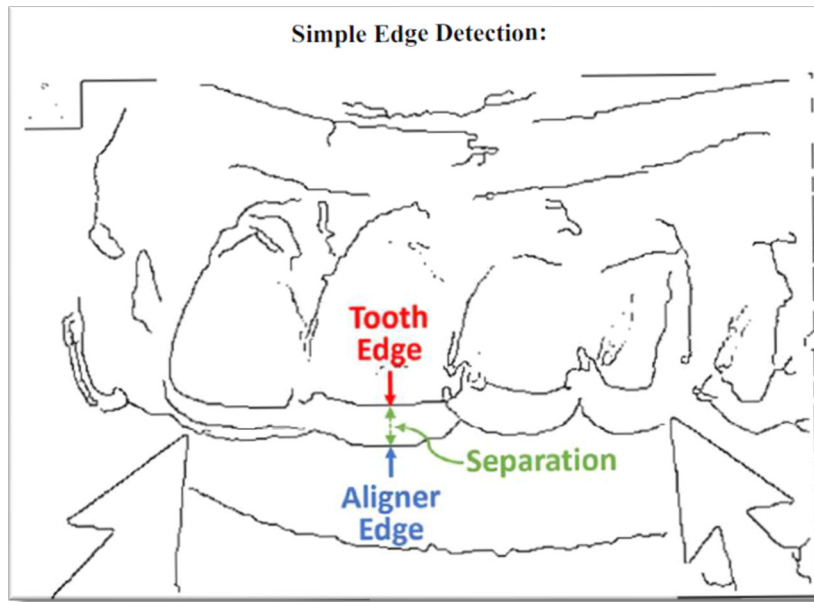
159. Dr. Foroosh limits his analysis to claimed embodiments in which the dentition and aligner images are the same two-dimensional image, and also adopts the construction that the interior tooth outline is the free end of the teeth and the exterior tooth outline is the surface of the aligner. EX1002, ¶80. As such, I have also only considered this embodiment as well. For the reasons discussed below, Kim, Invisalign, and Salah, taken together, do not suggest determining interior and exterior tooth outlines for each of a plurality of teeth from a single image, and then comparing them to determine a “score,” as claimed.

160. According to Dr. Foroosh, Salah teaches analysis of “contours of objects depicted in the [dental] images.” EX1002, ¶81. While Salah discloses a contour map of detected tooth edges showing the outline of teeth in Figure 6b, Salah nowhere suggests the use of image processing to detect aligners, let alone determining exterior tooth outlines representing the outline of the free end of said tooth on the aligner images. Salah instead discloses a method of monitoring tooth movements that updates a 3D reference model with an updated 2D image of a patient’s teeth *without aligners* to identify a final 3D reference model. The final 3D model thus corresponds to the position of the teeth in the updated 2D image, and is compared with the initial 3D reference model in order to determine tooth displacement for any type of orthodontic or dental treatment, independent of whether that treatment includes aligners. *Supra*, §VI.A; EX1008, 46:9-14, 1:1-2:27. Salah

thus discloses an entirely different approach to the challenged claims—one that monitors tooth positions, and not the shape of an aligner as in the '945 patent. During prosecution, the Examiner agreed that methods of monitoring tooth movement are distinct from the claimed methods that require “determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively.” EX1004, 254-59.

161. Furthermore, although Salah discloses contour detection, it does not disclose recognizing which detected contours correspond to teeth as opposed to something else, like an aligner as required by the claims. Rather, Salah discloses only the detection of generic contours. Salah similarly does not disclose recognizing that the contours belonging to the tooth or the aligner correspond to the same tooth. That sort of image analysis is simply not necessary to practice the methods of Salah.

162. These shortfalls in applying Salah are illustrated by Dr. Foroosh himself, who took Figure A of Invisalign and applied the Canny edge detection taught as a “preferred” method in Salah. EX1002, ¶83. The result is an image that shows lines corresponding to edges, but does not say what the edges relate to. *Id.* Dr. Foroosh had to manually identify and label the “Tooth Edge”, “Aligner Edge,” and “Separation” in his resulting image below:



EX1002, ¶83; EX2054, 179:25-180:23 (“Canny edge detection ... wouldn’t be able to say which edge is a tooth edge or any other edge.”). However, as confirmed by the prosecution of the ’945 patent, the claims require determination and analysis of the interior and exterior tooth outlines “by means of image processing software” “so as to determine” a score. EX1004, 238. In my opinion, Dr. Foroosh manually applying annotations to an image does not qualify as analysis “by means of image processing software.”

163. As a result, even if a POSA did rely on Salah as proposed by Dr. Foroosh, it would not have resulted in a method to distinguish the edge of a tooth from the edge of an aligner in order to “determine[e], by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end

of said tooth on the dentition and aligner images, respectively,” as recited in claim 1. For the same reasons, it does not disclose “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison” as required by all challenged claims, or “determination of a distance score dependent on the distance between the interior and exterior teeth outlines, and the distance threshold,” as recited in claim 5.

164. Salah discloses one example of a reference map generated for an image with a bonded expander (EX1008, Fig. 11), but, as detailed above, that device is not an aligner. And the discriminant information used to generate this map was reflection information, not contour information. *Id.*, 64:7-8. Regarding contour information, Salah teaches that image processing can be used to “detect high contrast regions and determine contours.” *Id.*, 34:13-14. However, “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.” EX1008, 60:17-24. That is because, if the “quality threshold is low, the discriminant information retained will be abundant, but unreliable” and this “will then lead to the retention of ‘false’ contour points, i.e. points which, will be mistakenly considered as belonging to the contour of teeth and gums.” *Id.*, 60:25-61:4. Salah thus teaches that it is preferred that “the quality threshold is high in order to retain only highly reliable

discriminating test information.” *Id.*, 61:2-4. Salah therefore recommends processing the reference image by filtering out data to retain only the outlines identified with a high probability. *Id.* However, a clear aligner would not provide the required strong contrast. *Supra*, §VII.C. I understand from Dr. Kusnoto that a POSA would have understood that clear aligners in a service position present a low contrast with teeth because they would visually blend with the teeth. Thus, Salah teaches away from the methods claimed in the ’945 patent.

165. In sum, because Salah discloses a different method for assessing tooth positions, and does not disclose analysis of photographs showing an aligner in a service position in a patient’s mouth, “[a]pplying the image processing approach taught by Salah to use image processing software to detect contours in an image representing a patient’s teeth with an aligner” would not “result in detection of the edges of the depicted objects (teeth, aligner portions, etc.)” as Dr. Foroosh says. EX1002, ¶83. Furthermore, Dr. Foroosh points to no teaching or motivation in the other ground references or elsewhere that could fix this deficiency.

166. Kim discloses only that the orthodontist conducts some unspecified visual review of images of the patient’s teeth without aligners or images of the aligners alone. *See, e.g.*, EX1005, [0085] (“Then, as illustrated in FIG. 19, the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal.”), [0066] (teeth alignment report information

is transmitted “in such a manner that the orthodontist checks a photo or a video”). Invisalign also does not disclose analysis of an aligner image by *any* means, let alone with image processing software, or determination of interior and exterior tooth outlines. Rather, Invisalign discloses a visual approximation performed in-person by a dental practitioner. EX1006, ii (dental professionals should have “*patients arrive* with the previous stage Aligner and the current Aligner” so the dental professional can evaluate any treatment concerns that may arise). I also understand from Dr. Kusnoto that Invisalign does not provide any method to measure separation with precision, and that is because, in 2017, orthodontists did not quantitatively assess aligner fit or measure the distance between an aligner and the teeth. Thus, it is my opinion that Invisalign does not suggest evaluation of the shape of an aligner based on an aligner images using image processing software. And as set forth above, Salah would have taught a POSA that, given the lack of strong contrast, it could not.

167. Even if a POSA did somehow decide to use the image analysis of Salah on the images of Invisalign or Kim, it would not result in “determine[ing] ... *for each of a plurality of teeth* represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively,” as required by each challenged claim. That is, none of the references discloses that aligner fit should be evaluated based on a comparison between the aligner and teeth *at multiple positions*. Dr.

Foroosh points to Salah and Invisalign for this teaching (EX1002, ¶¶102-104) but neither instructs a POSA to evaluate aligner fit at multiple positions from an aligner image. Salah concerns the movement of teeth using generic contours only, and Invisalign does not specify whether its 1 mm threshold should be detected at one location or several. Instead, Dr. Foroosh exclusively relies on what an orthodontic practitioner would have checked for during an in-office visit based on a single photograph of Invisalign and says that the two red arrows pointing to teeth in this photograph instruct orthodontists to assess aligner fit at two or more positions. EX1002, ¶¶103 (noting two arrows in Figure A of Invisalign, and concluding “[i]n light of this disclosure, a POSA would have understood that the distance measurements disclosed by Invisalign applied to a plurality of teeth and the corresponding aligner surfaces for each tooth, not just a single tooth”). However, I have consulted with Dr. Kusnoto and understand from him that Invisalign would not have instructed a POSA to measure for 1 mm distances at multiple locations. Rather, Dr. Kusnoto informed me that Invisalign instructs orthodontists to perform a holistic analysis of teeth alignment and aligner fit, consistent with the standard of care in 2017.

168. Moreover, given the disparate teachings and shortfalls of Kim, Invisalign, and Salah, a POSA would not have been motivated to pursue a brand-new method that involves evaluating the shape of an orthodontic aligner from simple

cellphone images. That is, none of the references individually disclose such a method and, in fact, they each relate to different methods having different purposes—in the case of Kim, remotely monitoring tooth alignment and not aligner fit; in the case of Invisalign, treating patients in-person with aligners; and in the case of Salah, monitoring tooth alignment and not aligner fit over time. *Supra*, §VI.A-C. As a result, Dr. Foroosh’s combination involves reconfiguring the references to create a novel analysis method that none suggests or indicates would be successful. The methods claimed in the ’945 patent are thus not a mere improvement in efficiency or scale—the ’945 patent relates to a new paradigm for assessment of aligner fit using image processing software.

169. For the reasons above, Petitioner’s references fail to disclose or render obvious “determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively” in Step 1(3) of claim 1.

170. Furthermore, because the combination does not disclose Step 1(3), Petitioner’s references also fail to disclose “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison” as recited in Step 1(4). Further with respect to the claimed “score” of Step 1(4), Dr. Foroosh points to Kim’s teaching of determining “whether the clear aligner is normal

and corresponds to an appropriate step,” and says that the measurement of separation in Invisalign would be used “[a]s part of this assessment.” EX1002, ¶87 (citing EX1005, ¶66; EX1006, 1). As detailed above, Dr. Foroosh is incorrect. This cited portion of Kim does not relate to assessing aligner fit or images showing an aligner seated on teeth, and describes only assessing whether the aligner is in working condition and the patient is using the right aligner for their current step of treatment. *Supra* §VI.A. Thus, a POSA would not have understood the separation described in Invisalign to be a parameter relevant to whether a clear aligner is “normal and corresponds to an appropriate step” in Kim. *See id.*

IX. CONCLUSION

171. For the foregoing reasons, it is my opinion that Dr. Foroosh has failed to establish that any of the challenged claims would have been obvious to a POSA in June 2017 in view of Kim, Invisalign, and Salah.

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.

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

Executed July 12, 2024, in San Francisco, California.

/ John Mongan /

Dr. John Mongan