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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
Patent No. 11,109,945

**PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 11,109,945**

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LISTING OF CHALLENGED CLAIMS

1. A method for evaluating the shape of an orthodontic aligner worn by a patient, said method comprising the following steps:

1) acquisition of at least one two-dimensional image of teeth of said patient, referred to as “updated image”, under actual acquisition conditions;

at 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; and at least one updated image referred to as “dentition image”, identical to or different from the aligner image, representing said teeth,

2) 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);

3) 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;

4) comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.

2. The method as claimed in claim 1, comprising, after step 4), the following step:

5) comparison of the score against an acceptability threshold and the emission of information according to the result of the comparison.

4. The method as claimed in claim 1, in which the dentition and aligner images are the same image.

5. The method as claimed in claim 1, in which step 4) comprises the following steps:

for each of a plurality of teeth for which the interior and exterior tooth outlines have been determined;

- i) determination of a distance between the interior and exterior tooth outlines;
- ii) determination of a distance threshold, preferably using the distances determined in the immediately preceding step;
- iii) for each of said teeth, determination of a distance score dependent on
 - the distance between the interior and exterior teeth outlines, and
 - the distance threshold.

6. The method as claimed in claim 5, in which the distances are measured in pixels.

Align Technology, Inc., (“Petitioner” or “Align”) requests review of United States Patent No. 11,109,945 to Philippe Salah et al. (“the ’945 patent,” EX1001), currently assigned to Dental Monitoring SAS (“Patent Owner”). This petition demonstrates by a preponderance of the evidence that claims 1-2 and 4-6 of the ’945 patent are unpatentable as obvious.

I. INTRODUCTION

The ’945 patent purports to have invented a method for analyzing the shape of orthodontic aligners. However, the claims of the ’945 patent merely recite the use of generic image processing software to perform long-known methods of assessment of orthodontic appliances.

The sole independent claim of the ’945 patent recites steps of acquiring one or more images of the teeth of patients, including an image of the patient wearing orthodontic aligners in a service position. Image processing software is used to produce outlines of “interior and exterior tooth outlines” (outlines of teeth and aligners), and the outlines are compared to produce a score. The independent claim does not indicate what comparisons are involved in producing the score, but a dependent claim indicates that distance between the interior and exterior outlines may be used to determine the score. The claims optionally include a step of converting an image of teeth to match conditions of an image including an aligner, but this step is not required.

The prior art, including published applications from the inventors of the '945 patent, already taught acquiring images of patients' teeth and aligners and determining outlines of dental images using image processing software. Further, scoring an aligner's fit based on its separation from the patient's teeth when worn—corresponding to a measurement between the teeth's and aligner's outlines—was long established in the published prior art as a way to assess aligner fit.

Claims 1-2 and 4-6 of the '945 patent should thus be found unpatentable and cancelled.

A. Background

This petition is supported by the Declaration of Dr. Hassan Foroosh, a Professor in the Department of Computer Science at the University of Central Florida. EX1002, ¶¶1-16; EX1003. As Dr. Foroosh explains and as addressed in further detail below, the involved claims would not have been considered new or non-obvious to a person of ordinary skill in the art ("POSA") at the relevant time.

The '945 patent describes methods involving image processing and analysis, with specific focus on analysis of orthodontic images. The brief background described below provides a concise overview of some important elements of image processing that are relevant to understanding what a POSA would have known in these areas at the time of filing of the '945 patent. EX1002, ¶¶27-35.

1. Image analysis and computer vision

Image analysis is often described as the process of extracting information from images that may be subsequently used to perform certain tasks. EX1002, ¶28. Developing methods and computer algorithms to provide such capability has been the subject of study in computer vision in the past few decades. However, it was not until after the early years of last decade, with major breakthroughs in machine learning techniques, including deep learning, that computers managed to also outperform humans in vision tasks. EX1015, 1-2, 8; EX1002, ¶29. Hardware developments made it possible for deep learning networks to be trained in an end-to-end manner and on much larger training sets, involving tens of thousands to millions of images. EX1002, ¶29.

Computer vision, in simple terms, is the science of making computers see. Vision tasks can be divided into three levels: low-level, mid-level, and high-level tasks. EX1016, 1538-39, 1541; EX1002 ¶30. Accordingly, computer vision algorithms were traditionally developed to handle low-level, mid-level, and high-level vision problems. Low-level computer vision methods process images at pixel-level (e.g., quantization, encoding, image restoration, image enhancement); mid-level computer vision methods produce feature-level representations of images (e.g., color features, edge features, 3D geometric features); and high-level computer vision aims to understand image contents and contextual relationships

(e.g., object classification, localization, and instance recognition). EX1002, ¶¶30-31. Boundary-based representations, such as edges and contours defining separation between regions in images, are common mid-level features. *Id.*

The development of machine learning techniques such as deep learning led to a new class of computer vision methods that learn features from data, as well as taking advantage of high-level labels to learn better features, while still relying also on low-level image properties to extract features. These allow a device to receive raw image data and directly learn to accomplish a vision task. EX1002, ¶32.

2. Edge detection and contour detection

Edges, contours, boundaries, and discontinuities refer to similar concepts involving a representation of a discontinuity in an image. Edges and contours have been used for various computer vision, from high-level (e.g., classification, object recognition, annotation) to low-level (e.g., registration, alignment) tasks. EX1002, ¶33.

Due to the key role of edges in computer vision, researchers developed machine-learning based methods for edge and contour detection, including methods employing deep learning. EX1017, 1-2; EX1002, ¶34; *see also* EX1007, Abstract (applying deep-learning methods). Whereas traditional edge and contour detectors used binary labels (1 and 0) for edge locations, the development of machine learning tools permitted image processing software to assign multiple

labels in the contour image. EX1017, 5-9; EX1007, 8, 9-12; *see* EX1008, 18:14-17 (1 or 0 used to denote edges); EX1002, ¶34. Each contour is labeled based on high-level labels (e.g., class, instance, etc.), which may be learned from training data. EX1017, 4; EX1007, 11-12. Thus, POSAs knew that, in addition to using traditional image processing techniques, image processing software could incorporate machine-learning methods to aid in categorization of different objects in an image into specific classes. EX1002, ¶35. These types of contours or boundaries are sometimes referred to as “category-specific” or “semantic.” *Id.*; EX1017, 9; EX1007, 11. Thus, it was known that image processing software trained to look for features based on a training set with high-level labels could return features (e.g., edges) specific to those labels. For instance, a machine trained to look for the contours of different types of teeth in intraoral images would detect edges as well as label edges and the regions they define based on which type of tooth they belong to. EX1002, ¶35.

B. Cited Art

1. Kim

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

April 5, 2016, and published on October 5, 2017. Kim is prior art to the '945 patent under 35 U.S.C. §102(a)(2).

Kim teaches methods and systems to provide “remote teeth alignment services.” EX1005, Abstract. Kim teaches methods by which an orthodontist can be provided “accurate teeth alignment information using a device, e.g., a smartphone, of an orthodontic patient,” including information allowing the orthodontist to “diagnose the condition of the patient based on the teeth alignment information” transmitted as well as to “remotely provide information about an accurate step of a clear aligner to be currently worn by the orthodontic patient.” EX1005, ¶10. Kim refers to the patient’s smartphone as an “orthodontic patient terminal,” though Kim notes that a variety of other patient devices, such as other mobile devices, laptop computers, smart cameras or camcorders, and similar devices may also be used. EX1005, ¶¶41-42; EX1002, ¶¶41-42.

As part of Kim’s methods, teeth alignment information is obtained by taking a variety of photographs of the patient’s teeth from different angles. EX1005, ¶¶55-56. Additionally, Kim teaches that the patient’s smartphone can send “clear aligner information about a currently worn clear aligner” to the orthodontist. EX1005, ¶66. This information is transmitted “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.” *Id.*; EX1002, ¶43.

2. Invisalign

The Invisalign Clinical Monitoring Guide (“Invisalign,” EX1006) was published in 2003 through multiple channels including being available for download from Align’s Online Clinical Education Center, invisaligncec.com, as archived by the Internet Archive on September 26, 2003. EX1006, i; EX1011; EX1002, ¶44. Invisalign is prior art to the ’945 patent under 35 U.S.C. §102(a)(1).

Invisalign teaches methods for monitoring progress of orthodontic treatment when using clear plastic aligners manufactured by Align Technology, Inc. EX1006, i. The guide deals with monitoring of treatment progress in patients after aligners have been received and are being worn by the patient. *Id.* Invisalign identifies key considerations for effective use of aligners, and describes the need to use high-quality records, including both dental impressions and photographs of the teeth of the patient wearing the aligners. EX1006, ii-iv; EX1002, ¶45.

Invisalign also provides specific examples of measurements to perform to track whether aligners are properly treating patients and discusses what those measurements indicate about whether the aligner is appropriate in terms of fit, seating, and other properties. *See, e.g.*, EX1006, 1-2. In one example, Invisalign illustrates how poor aligner seating may be assessed, illustrating how a digital

photograph of an aligner on a patient's teeth can depict a poor fit by showing a gap of over 1 mm between teeth and aligner. *See* EX1006, 1; EX1002, ¶46.

3. Salah

PCT Publication No. WO2016066651 to Salah et al. ("Salah") is entitled "Method for Monitoring Dentition." Salah names five inventors, including all four inventors listed on the '945 patent; however, Salah was published on May 6, 2016, more than 1 year before the earliest claimed priority date of the '945 patent. Salah is prior art under 35 U.S.C. §102(a)(1). As Salah was published in French (EX1012), a certified translation has been submitted as EX1008.

Salah discloses methods for monitoring patients' teeth, such as during orthodontic treatment. EX1008, Abstract, 1:12-22, 8:10-18. Salah teaches methods of obtaining 2D images of patient teeth, comparing those teeth to a 3D model, and using those comparisons to update the model and measure treatment progress. EX1008, 1:26-2:19, 46:15-19, Fig. 1. Salah's analysis can include using contour detection on an acquired image to determine edges of intraoral structures such as teeth. EX1008, 34:11-14, 36:14. These 2D images may be obtained by a patient or relative using a device such as a cell phone. EX1008, 2:21-27, 31:4-7. EX1002, ¶¶47-49.

C. The '945 Patent

The '945 patent is entitled “Method of Evaluating an Orthodontic Aligner.” EX1001, Title. The '945 patent describes acquiring 2D images of patients' teeth and aligners, which may either be depicted in separate images or together in a single image. EX1001, Abstract, 2:4-9, 2:57-58 (“alternatively, said dentition and aligner images are one and the same image”). The '945 patent uses the term “updated image” to refer to any such image taken of the teeth. EX1001, 5:47-49. Claim 1, the only independent claim, recites acquiring one or more such images, including an aligner image “at least partially representing the aligner in a service position in which it is worn” by the patient's teeth and a dentition image representing the teeth, which may either be the same image or a different one. EX1001, 13:59-14:16. For the latter such case, where the two images are different, the dentition image is converted to represent the teeth “as seen under the acquisition conditions used during the acquisition of the aligner image.” *Id.* Image processing software is then used to determine outlines of the teeth and aligner (referred to as interior and exterior tooth outlines, respectively). *Id.* Finally, the interior and exterior tooth outlines are compared to determine a score. *Id.*; EX1002, ¶¶36-37.

Dependent claim 5 provides further detail about how the outlines may be related to a score: a distance between the interior and exterior outlines is

determined for each tooth, and a threshold is determined, with a difference score determined based on comparison of each tooth's distance to the threshold.

EX1001, 14:40-53. The threshold may be determined based on the measured distances; however, this is indicated to only be preferred, not required by the claim. *Id.*; see also *id.*, 11:51-12:5 (discussing some options for determining scores based on thresholds that optionally depend on measured distance); EX1002, ¶39.

As to the remaining challenged claims, none adds anything beyond steps conventionally known in the art. EX1002, ¶¶38, 40. Dependent claim 2 recites comparing the score of claim 1 against an acceptability threshold and emission of information according to the comparison's result. EX1001, 14:18-22. Dependent claim 4 recites that the aligner and dentition images are the same image. EX1001, 14:38-39. Dependent claim 6 recites measuring the distances recited in claim 5 in pixels. EX1001, 14:54-55.

D. Prosecution History

The '945 patent was filed as U.S. Application No. 16/001,049 ("the '049 application") on June 6, 2018, claiming priority to French Patent Application No. 1755187, filed June 9, 2017.

In the only office action, original claims 1-2, 4, and 6 were rejected as anticipated by U.S. Patent Publication No. 2014/0120488 to Greenberg et al. in view of U.S. Patent Publication No. 2017/0100214 to Wen et al. EX1004, 189-95.

The claims were also objected to and rejected under §112(b), with the examiner noting that it was not clear what was detecting the recited outlines, what logic or algorithm was used, and what the recited comparison involved. EX1004, 187-88. The Examiner issued no art rejection for any of claims 3, 5, and 7-10. EX1004, 196.

Patent Owner responded by amending claim 1 to recite the determination of interior and exterior tooth outlines was performed “by means of image processing software,” and that the comparison of outlines was done so as to determine a score. EX1004, 238-40. Patent Owner also reemphasized the ’945 patent’s admission that determining and comparing interior and exterior tooth outlines was known in the art, stating “a person skilled in the art knows how to process an image in order to isolate an outline of interior tooth representing the outline of the free end of said tooth on the dentition images from said dentition images and how to determine an outline of exterior tooth representing the outline of the free end of said tooth on the aligner images, by means of image processing software,” and further conceded that a “person of ordinary skill in the art knows how to compare a first outline with a second outline.” EX1004, 241-42.

Patent Owner also confirmed that the interior and exterior tooth outlines are simply lines delimiting the free end of a tooth and part of an aligner on an image, respectively. EX1004, 242. Lastly, Patent Owner argued that the cited prior art

references dealt only with imaging of teeth prior to creating aligners, meaning that applying their teachings would make the recited images impossible to acquire. EX1004, 243-44 (“Therefore, the aligner does not exist yet in the method of WEN and thus an image of an aligner worn by the patient cannot be acquired.” (emphasis original)). Moreover, Patent Owner emphasized that the cited art failed to teach performing any analysis of an aligner, teaching instead to only analyze the patient’s teeth, which Patent Owner suggested could be a teaching away. EX1004, 242-43. Finally, Patent Owner argued that as a result, Greenberg and Wen failed to meet the limitations relating to imaging and generating outlines for aligners. EX1004, 244.

The Examiner responded by allowing the application. EX1004, 253-55. The Examiner did not endorse Patent Owner’s teaching away argument, instead noting that the cited art did not teach or suggest steps 2-4 of claim 1, which the Examiner indicated by underlining the claim elements as a whole. *Id.* The Examiner also noted that the closest remaining prior art reference of which he was aware, U.S. Patent No. 8,562,338 to Kitching et al., also failed to teach any of the underlined limitations. EX1004, 255-58.

E. Level of Skill in the Art

As Dr. Foroosh explains, a person of ordinary skill in the art (POSA) by June 9, 2017, would typically have an advanced degree, such as a Masters’ Degree

or Ph.D. in computer science, computer engineering, electrical engineering, 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. *See* EX1002, ¶¶50-51.

II. STATEMENT OF THE PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED

Align requests review of claims 1-2 and 4-6 of the '945 patent under 35 U.S.C. §311 and AIA §6. The grounds for relief are as follows:

Ground	Claims	Description
1	1-2, 4-6	Unpatentable under 35 U.S.C. §103 as obvious over Kim in view of Invisalign and Salah

III. CLAIM CONSTRUCTION

Claim terms should be given their ordinary and customary meaning as would be understood by a POSA in light of the specification. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). Unless otherwise stated, this petition applies the ordinary and customary meaning of the claim terms. The following terms warrant discussion.

A. aligner and dentition images

Claim 1 recites “at least one updated image referred to as an ‘aligner image,’ at least partially representing the aligner in a service position in which it is worn by said teeth; and at least one updated image referred to as ‘dentition image,’ identical to or different from the aligner image, representing said teeth.” The second element of claim 1 begins “if the dentition image is different from the aligner image,” and claim 4 recites that “the dentition and aligner images are the same image.” Read together, these limitations indicate that the dentition and aligner images may be the same image, which would be an image depicting both an aligner and a patient’s teeth. EX1002, ¶¶52-54. When considering such embodiments encompassed by claim 1, the second element of claim 1 may be ignored, since the aligner and dentition images are not different. *See, e.g., Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1297-98 (Fed. Cir. 2009) (claim covering multiple alternatives obvious if prior art teaches even one alternative).

B. interior and exterior tooth outlines

Claim 1 of the ’945 patent recites determining “interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively.” The specification indicates that “a line may delimit the free end of [a] tooth,” in which case it is an “interior tooth outline.” EX1001, 5:10-13. The specification also indicates that “a line may also delimit part of the

aligner,” in which case it is an “exterior tooth outline.” EX1001, 5:14-20. Patent Owner urged the same interpretation during prosecution, stating that “the interior tooth outline qualifies a line which delimits the free end of a tooth on an image and the exterior tooth outline qualifies a line which delimits part of the aligner on an image.” EX1004, 242. In light of this description, an “interior tooth outline” refers to a line delimiting a free end of a tooth, and an “exterior tooth outline” refers to a line delimiting a part of an aligner. EX1002, ¶¶55.

C. determination, by means of image processing software

The third step of claim 1 recites “determination, by means of image processing software ... of interior and exterior tooth outlines...” As noted below in §V, all claims based on the ’945 patent have been dismissed from Patent Owner’s pending district court action against Align. If the claims of the ’945 patent were to be asserted in the future, Align would expect to raise a defense that this is a means-plus-function limitation for which the specification does not provide sufficient structure to discern the claim’s full metes and bounds. Even if the Board agrees, that does not preclude an analysis that the claims fail to distinguish from the prior art.

However, regardless of whether this step is construed as a means-plus-function limitation, neither the claim language nor the relevant disclosure in the specification distinguishes over the prior art, as explained below for claim 1.

Indeed, the specification admits that “[a] person skilled in the art knows how to process an image in order to isolate an outline” (EX1001, 10:22-27), and Patent Owner conceded during prosecution that “a person of ordinary skill in the art knows how to determine an outline of interior tooth representing the free end of said tooth on the dentition images from said dentition images and how to determine an outline of exterior tooth representing the outline of the free end of said tooth on the aligner images, by means of image processing software” (EX1004, 241-42). Further, the ’945 patent identifies generic image processing applications that the patent admits existed in the prior art and meet the recited limitation, including the software described by PCT/EP2015/074900, another International Application by the same inventors as Salah, and provides a list of software methods for detecting the recited outlines that substantially matches a list provided by Salah. EX1001, 10:28-11:34. *Compare id.*, to EX1008, 34:15-36:14. The ’945 patent also cites to Salah (PCT/EP2015/074896) when discussing “analysis of the dentition image” to produce discriminating information, including “outline information.” EX1001, 7:26-62; *see also id.*, (“All the features of steps c) to e) described in PCT/EP2015/074896 are applicable....Image processing makes it possible to extract and quantify the discriminating information....The discriminating information is preferably chosen from the group consisting of outline information....”).

For the purposes of this petition, Petitioner identifies the recited function as determining interior and exterior tooth outlines and the structure to encompass image processing software, such as any of the examples identified at EX1001, 10:28-11:34, including using any of the methods disclosed by Salah.

IV. CLAIMS 1-2 AND 4-6 ARE UNPATENTABLE AS OBVIOUS UNDER 35 U.S.C. §103 OVER KIM, INVISALIGN, AND SALAH

A. Overview of Ground and Rationale to Combine with Reasonable Expectation of Success

As discussed in detail below, Kim in view of Invisalign and Salah renders claims 1-2 and 4-6 obvious.

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.” EX1005, Abstract, ¶10. These services involve the use of an “orthodontic patient terminal,” such as a patient’s cellphone. EX1005, Abstract, ¶¶1, 10, 42. To facilitate these services, photographic or video images may be transmitted to an orthodontist to provide information about teeth alignment and the patient’s clear aligner. EX1005, ¶12. Kim also teaches that automatic recognition of contours of a patient’s face and teeth may be employed as part of the imaging process. EX1005, ¶14. In one example, an “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, ¶66. Kim teaches that its techniques provide reduced diagnosis time and cost relative to traditional in-office visits, as well as providing for enhanced accuracy. *See* EX1005, ¶¶8-10, 72; EX1002, ¶¶56-57.

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. Moreover, to the extent Patent Owner may argue Kim does not sufficiently describe the aligner currently worn and imaged is in a service position on the patient’s teeth, taking such an image would have been readily apparent in view of Invisalign’s teachings. Invisalign teaches how to “successfully monitor Invisalign treatments and address issues that may arise between receipt of Aligners from Align to the completion of treatment.” EX1006, i. The first criterion identified by Invisalign addresses “General fit issues,” specifying 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. EX1006, 1. This is illustrated in a digital photograph, where a poorly-seated aligner worn by a patient in a service position is shown, with arrows indicating that the aligner surfaces corresponding to teeth have a separation of greater than 1 mm from the ends of the teeth. *See id.* The resulting gap is plainly visible on the photograph as a space

between the contour defining the occlusal end of the teeth and the matching contour defining the occlusal surface of the clear aligner, as reproduced below:



EX1006, 1. Thus, Invisalign teaches that orthodontic assessment of an aligner may include assessing the separation between the edges of the aligner and the patient's teeth when the aligner is worn, as may be seen in a digital photograph showing the patient's teeth as well as the clear aligner being worn in a service position on the patient's teeth. EX1002, ¶58.

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 fit appropriately.

This combination would be applying known methods for orthodontic evaluation of aligner fit based upon the appearance of the aligner worn on the patient's teeth, as taught by Invisalign, in order to analyze a photo or video of the aligner worn by the patient, as taught by Kim, predictably providing feedback regarding tooth-aligner separation to aid an orthodontist regarding whether the clear aligner is normal and corresponds to an appropriate step of treatment. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). As Kim indicates, employing such techniques would serve goals including enhancing accuracy, reducing the time and cost of treatment, and facilitating remote assessment. *See* EX1005, ¶¶8-10, 72. A POSA also would have understood that the type of image analysis suggested by Kim and Invisalign could be readily applied on images or videos showing a clear orthodontic aligner being worn on the teeth of a patient. EX1002, ¶59.

Not only are these types of images of aligners on teeth expressly depicted in Invisalign (*see* EX1006, 1), but the fact that POSAs were motivated to use such images for orthodontic evaluation was confirmed in publications by practicing orthodontists. For example, Dr. Scott Frey published a step-by-step guide on the Ortho Cosmos website explaining how to conduct a simple remote orthodontic

monitoring system allowing orthodontists to analyze orthodontic patients' teeth and aligners over the internet. EX1009, 17-27; *see* EX1010. As explained in the guide, patients would be shown example photos or videos to show exactly what images they should capture, including one video "with teeth apart and aligners in." EX1009, 19. Patients would then record and transmit such videos with their smartphone, providing orthodontists with video images sufficient to conduct typical orthodontic treatment evaluations. *See* EX1009, 20-27. Thus, published descriptions show that photographs or videos of the teeth of patients wearing aligners, including images taken with cellphones, were known to be useful to analyze for orthodontic assessment purposes. EX1002, ¶60.

A POSA would have known how to determine the width of such gaps using image processing software. Like Kim, Salah teaches application of computer image analysis to dental images for orthodontic treatment purposes. For example, Salah discloses methods useful for monitoring patient's dentitions, including by acquiring images of the patient's teeth at various times during orthodontic treatment. EX1008, Abstract, 8:19-28. The images are acquired by an acquisition apparatus such as a mobile phone. EX1008, 13:24-28, 31:4-9. Further paralleling Kim, Salah teaches that images may be analyzed to "measure the effectiveness of orthodontic treatment," including by "remotely monitor[ing] the progress of an orthodontic treatment." EX1008, 46:15-24. Salah discloses that analysis of

acquired images may include determining contours of objects in an image, including by using image processing software for edge detection. EX1008, 34:5-36:14; EX1002, ¶61.

The '945 patent and Patent Owner's statements during prosecution confirm that it was known to POSAs to use image processing techniques, such as those disclosed by Salah, to detect interior and exterior tooth outlines in images of the teeth of patients wearing an aligner. *See* EX1001, 10:22-27; EX1004, 241-42; *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (An "obviousness 'analysis *requires* an assessment of the "...background knowledge possessed by a person having ordinary skill in the art."") (emphasis and alteration in original) (quoting *Dow Jones & Co. v. Abilene Ltd.*, 606 F.3d 1338, 1349, 1353 (Fed. Cir. 2010)).

Further, it would have been obvious to measure the distance between the ends of the patient's teeth and the corresponding edges of the aligner, as taught by Invisalign, using the edge detection image processing techniques taught by Salah to detect the contours of each object in an image depicting the patient wearing the aligner on the patient's teeth, and to thereby identify the size of the gap between the aligner and the teeth. A POSA would have had reason to use Salah's techniques for contour detection to detect the edges of teeth and aligners, as Invisalign teaches that the gap between the surfaces of teeth and an aligner should be below a

threshold value (1 mm), and as Dr. Foroosh explains, a POSA would have understood that the width of a gap between two objects in a photograph is equivalent to the distance between the two contours defining the objects' edges. In the case of an image of an aligner on teeth, the distances to measure would be the distances from the contour defining the end of the teeth to the contour defining the surface of the clear plastic aligner. EX1002, ¶¶61-63.

The resulting combination would use each reference's teachings to perform substantially the same function as they provide alone, applying Salah's contour detection to detect edges of teeth and aligners to produce a measurement of distance between these surfaces, as taught by Invisalign, to assess whether the imaged aligner fits appropriately for the current step in patient treatment, as taught by Kim. POSAs would thus have had a reasonable expectation of success, as the combination would be one of complementary techniques, applied in understood ways, to produce a predictable outcome. *See KSR*, 550 U.S. at 417 (“[W]hen 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.”) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976)); EX1002, ¶¶63-64.

The discussion of claims 1-2 and 4-6 below provides further detail regarding POSAs' rationale to combine Kim, Invisalign, and Salah with a reasonable expectation of success. EX1002, ¶65.

B. Claim 1

Kim, Invisalign, and Salah teach each element of claim 1, as discussed below. EX1002, ¶¶66-88.

1. Preamble

1. A method for evaluating the shape of an orthodontic aligner worn by a patient, said method comprising the following steps:

To the extent the preamble is limiting, Kim and Invisalign teach such a method. Kim teaches evaluating an aligner by reviewing an image of the aligner currently worn by the patient, to determine whether the aligner is normal and appropriate. EX1005, ¶66. Invisalign teaches that evaluating a currently-worn clear aligner includes assessing the fit of the aligner, and that this assessment involves determining a distance between the teeth and the aligner when worn by the patient, as depicted in two-dimensional photographs showing good and poor aligner seating. EX1006, 1. Kim and Invisalign also teach that the evaluation can determine that an aligner does not fit appropriately (e.g., because the aligner may have been formed using a distorted impression of teeth). *Id.*; EX1005, ¶¶66-67; EX1002, ¶¶67-69.

2. Step 1(1)

1) acquisition of at least one two-dimensional image of teeth of said patient, referred to as “updated image”, under actual acquisition conditions; at 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; and at least one updated image referred to as “dentition image”, identical to or different from the aligner image, representing said teeth,

Step 1(1) requires acquiring “at least one” two-dimensional image of teeth, and in particular may be satisfied by acquiring only a single image that represents both an aligner worn by a patient’s teeth and the patient’s teeth themselves. *See supra* §III.A. Step 1(1) would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶70.

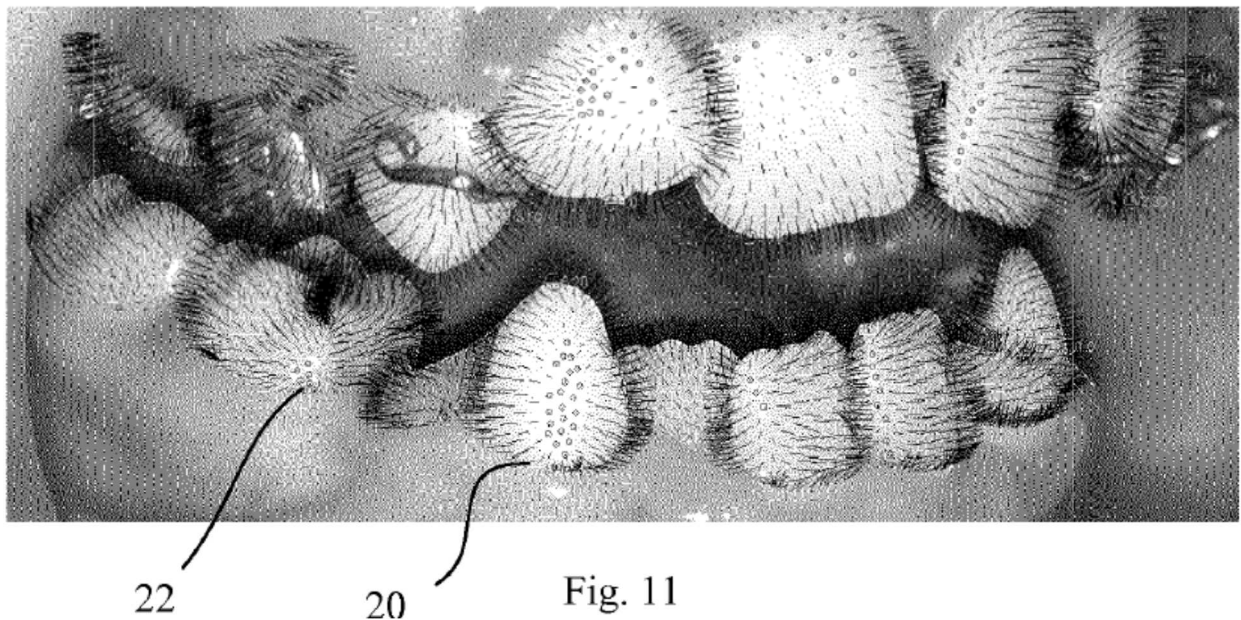
Kim teaches that a patient’s smartphone or similar device may be used to acquire orthodontic treatment information. This can include “using a camera” of the device to acquire photographs “showing a teeth alignment state of the orthodontic patient.” EX1005, ¶¶55-56. This can further include aligner information, and in particular may include “receiving the clear aligner information about a currently worn clear aligner,” enabling the orthodontist to “check[] a photo or a video of the clear aligner currently worn by the orthodontic patient,” and in particular to “determine[] whether the clear aligner is normal and corresponds to an

appropriate step” EX1005, ¶66. Thus, Kim teaches, or at a minimum suggests, acquiring an aligner and dentition image as recited in step 1(1); EX1002, ¶71.

Invisalign confirms that analyzing a two-dimensional image representing a patient’s aligner in a service position as well as the patient’s teeth (e.g., a photo or video taken by a cellphone, consistent with the teachings of Kim) can produce measurements useful for orthodontic assessment. Invisalign teaches that a large gap between a tooth and an aligner (e.g., more than 1 mm) indicates poor fit. EX1006, 1. Invisalign further illustrates that such a gap is visually distinguishable in a digital photograph of a patient’s teeth that at least partially represents an aligner worn in a service position on the teeth. *See id.* Accordingly, Invisalign provides a reason to acquire a two-dimensional image of the patient’s teeth with an aligner being worn in a service position: by assessing the gap visible between aligner and teeth, Invisalign teaches that it can be determined whether an aligner fits correctly (e.g., is normal and corresponds to an appropriate step), or whether it is seated or fit poorly. EX1002, ¶72.

Salah similarly teaches acquiring two-dimensional dental images, including of teeth fitted with orthodontic appliances. For example, Salah teaches that a user (such as a patient or relative) may acquire images of a patient’s teeth using an image acquisition apparatus such as a cellphone with a camera. EX1008, 27:11-13, 31:4-7. Salah expressly describes that such acquired images can include an

“updated image.” EX1008, 2:1-2 (“acquisition of at least one two-dimensional image of the patient's arches, the so-called ‘updated image,’ under actual acquisition conditions”). Salah also teaches that the image of the teeth may include an orthodontic appliance; for example, Fig. 11 (below) depicts a reference map generated from an image of teeth of a patient wearing an orthodontic appliance. EX1008, 64:7-12, Fig. 11 (showing teeth with orthodontic wires visible).



EX1008, Fig. 11. Thus, Salah also teaches acquiring images of a patient's teeth, including teeth of a patient using orthodontic appliances. EX1002, ¶73.

Acquiring a two-dimensional image depicting teeth wearing an aligner is also consistent with published methods of orthodontic practice. For example, a step-by-step guide for remote orthodontic monitoring published prior to the '945 patent's earliest claimed priority date described how to instruct patients to acquire

images for use in assessment of orthodontic treatment status, including taking images of “teeth apart and aligners out,” “biting down with aligners removed,” and “with teeth apart and aligners in.” EX1009, 19. This confirms that acquiring digital photographs of patient’s teeth, including patient-acquired cellphone images of teeth with aligners in a service position, was known to be a useful practice for assessment of a patient’s orthodontic treatment status. EX1002, ¶¶74-75.

Accordingly, Kim, Invisalign, and Salah teach step 1(1).

3. Step 1(2)

2) 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);

Step 1(2) only applies “if the dentition image is different from the aligner image.” As discussed above in §III.A, claim 1 does not require that the dentition and aligner images are different—it also encompasses embodiments in which the aligner and dentition images are a single, identical image. Indeed, such an embodiment is expressly recited in dependent claim 4. Step 1(2) applies no limitation to embodiments for which the “aligner image” and the “dentition image” refer to the same image. It is a “long-established rule” that claims “broad enough to read on obvious subject matter are unpatentable,” regardless of whether other encompassed embodiments are obvious. *Muniauction, Inc. v. Thomson Corp.*, 532

F.3d 1318, 1328 n.4 (Fed. Cir. 2008) (quoting *In re Lintner*, 458 F.2d 1013, 1016 (C.C.P.A. 1972)); *see also Fresenius*, 582 F.3d at 1297-98 (claim covering multiple alternatives obvious if prior art teaches even one alternative); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300 (Fed. Cir. 2007) (obviousness of embodiment corresponding to dependent claim dispositive of obviousness for broader independent claim). For the embodiment discussed above for step 1(1), step 1(2) is satisfied because the dentition and aligner images are not different, rendering the remainder of step 1(2) inapplicable. EX1002, ¶¶76-77.

4. Step 1(3)

3) 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;

As noted above, claim 1 encompasses an embodiment where the aligner and dentition images constitute only a single image representing a dentition and an aligner. For such an embodiment, step 1(3) is satisfied by determining “interior and exterior tooth outlines” for a plurality of teeth in that single image. As further discussed in §III.B, the recited “interior and exterior tooth outlines” correspond to lines delimiting the ends of teeth and a part of an aligner, respectively. In other words, step 1(3) is satisfied by detecting edges lines representing the free end of a

tooth and of a corresponding edge of an aligner in an image depicting both. Kim, Invisalign, and Salah teach step 1(3). EX1002, ¶¶78-80.

Salah teaches that dental images may be analyzed to detect “discriminant information,” which can include contours of objects depicted in the images, including teeth and other intraoral objects, such as gums. EX1008, 34:5-14, 55:21-56:7. A contour map of detected tooth edges showing the resulting outlines of teeth is shown in Fig. 6b, reproduced below.

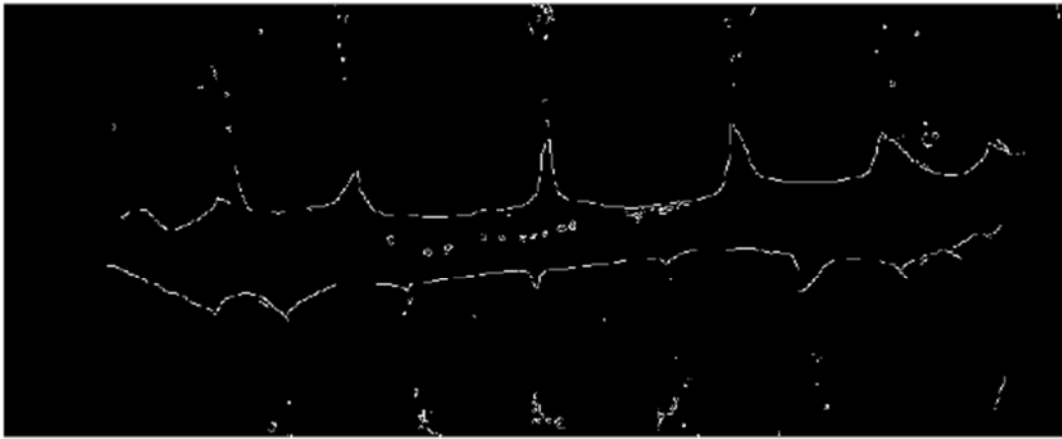


Fig. 6b

EX1008, 34:5-14, Fig. 6b. This includes outlines of the free ends of each of a plurality of teeth. *See* EX1008, 23:4-8, 34:6-7, Figs. 6a-6b. This discriminant information can be used to generate a “reference map representing the discriminant information,” and Salah provides an example of such a map generated for an image depicting teeth of a patient with an intraoral appliance. EX1008, 40:19-21, 64:7-8; *see id.*, Fig. 11; EX1002, ¶81.

Salah expressly discloses that the contours it describes may be detected using “image processing software,” which “can be used, for example, to detect high contrast regions and determine contours.” EX1008, 34:11-14. Salah further describes a list of such software, including both preferred options and other options that can also be used. EX1008, 34:15-36:14. Notably, the ’945 patent concedes that it was known to POSAs how to use image processing software to detect outlines and provides a list of generic image processing methods for outline determination that almost completely matches Salah’s list. EX1002, ¶82. *Compare* EX1001, 10:22-11:34, *with* EX1008, 34:11-36:14.

As Dr. Foroosh explains, by using image processing software to detect contours in an image representing a patient’s teeth with an aligner worn in a service position on the teeth, the edges of the objects depicted would be detected. EX1002, ¶¶83-84. This would include detecting both edges delineating the occlusal ends of each of a plurality of depicted teeth and edges delineating the tooth-shaped surfaces of the aligner corresponding to each tooth, which would constitute the recited interior and exterior tooth outlines. *Id.* For example, in the image reproduced below, Invisalign includes two arrows pointing at the aligner surfaces for different teeth, indicating that distance from the aligner should be evaluated for each of a plurality of teeth.



EX1006, 1. As Dr. Foroosh explains, just as the contours of the free ends of each tooth and the corresponding parts of the aligner are visible to the naked eye, the application of contour detection to two-dimensional images (such as the cellphone images of Kim and Salah) would identify similar contours as outlines of the free ends of the teeth and aligner. EX1002, ¶83.

Indeed, during prosecution, Patent Owner admitted that detecting outlines of teeth and aligners in dentition and aligner images was known in the art. *See* EX1004, 241-42; *supra* §I.D.

As explained above in §IV.A, a POSA would have been motivated in view of Kim and Invisalign to apply Salah's contour-detection techniques to detect edges of teeth and aligners depicted in images of patient's teeth so that the

assessment of gap between aligner and teeth could be made, as taught by Invisalign. For example, because the detected edges of the aligner and teeth correspond to the edges of the physical objects depicted, a POSA would have understood that measuring the distance between the outlines of the teeth and the aligner as detected by Salah's image processing software would allow determination of the gap between each tooth and the corresponding part of the aligner. EX1002, ¶84.

Accordingly, Kim, Invisalign, and Salah teach step 1(3). EX1002, ¶85.

5. Step 1(4)

4) comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.

Kim in view of Invisalign and Salah teaches step 1(4).

As discussed above for step 1(1), Kim teaches checking “a photo or a video of the clear aligner currently worn by the orthodontic patient” to determine “whether the clear aligner is normal and corresponds to an appropriate step.” EX1005, ¶66. As part of this assessment, a POSA would have applied the teachings of Invisalign to assess the distance between the patient's teeth and the aligner. *See* EX1006, 1; *supra* §IV.B.2. And as discussed for step 1(3), this assessment would involve measuring a distance between an outline of each tooth and the corresponding outline for the aligner, using the image processing software

of Salah to detect each outline via contour detection. *See* EX1008, 34:11-36:14; *supra* §IV.B.4. The result of this comparison would produce at least one score. As one example, the at least one score would be one or more values indicating the distance from each tooth to the aligner. This score could be a direct measurement of the image (e.g., in terms of pixels), or it could be converted to metric measurements (such as millimeters). As another option, the score could be a value comparing the distance of one or more teeth from the aligner to a threshold as taught by Invisalign; for example, the score could indicate that the aligner fit well if the distance threshold was not exceeded and did not fit well if the distance threshold was exceeded. *See* EX1006, 1 (aligners not seating well if distance exceeds 1 mm); EX1002, ¶¶86-87; *see also* EX1008, Fig. 1, 40:22-41:18 (making analogous use of scores and thresholds when performing image analysis). A POSA would have found each of these options to be natural choices, alone or in combination, for generating scores to assess aligner fit based on the teachings of Kim, Invisalign, and Salah. Thus, Kim, Invisalign, and Salah teach step 1(4).

Accordingly, claim 1 would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶¶66-88.

C. Claim 2

Claim 2 depends from claim 1 and further recites that the method comprises “after step 4), the following step: 5) comparison of the score against an

acceptability threshold and the emission of information according to the result of the comparison.” Kim, Invisalign, and Salah teach this step. EX1002, ¶89.

As discussed for claim 1, Invisalign uses a threshold to assess aligner acceptability. For example, Invisalign teaches that when an aligner worn on a patient’s teeth has a tooth-aligner gap of less than 1 mm, “this is natural deflection that should occur so the Aligner can move the tooth,” whereas if the gap is greater than 1 mm, this means that the “Aligners are not seating well.” EX1006, 1. In view of this teaching, a POSA would have been motivated to compare a score as discussed above for claim 1 (e.g., a score reflecting a separation between teeth and aligner, as determined by assessing separation by the contours detected using Salah’s image processing software) against an acceptability threshold as taught by Invisalign (e.g., 1 mm), determining that where the threshold is exceeded, the aligner is not seated well on the teeth. EX1002, ¶90.

This assessment would be consistent with Kim’s teaching to “check[] a photo or a video of the clear aligner currently worn by the orthodontic patient, and determine[] whether the clear aligner is normal and corresponds to an appropriate step.” EX1005, ¶65. For example, if applying Invisalign’s threshold assessment indicated that one or more teeth had excessive gaps, that would be an indication that the aligner was not normal or did not correspond to an appropriate step. EX1002, ¶91; *see* EX1006, 1 (evaluation may indicate aligner has “excessive

flash” or results from a “distorted impression” (meaning it was not normal)), 6 (lack of fit may indicate incorrect aligners or need for mid-course correction (meaning the aligner did not correspond to an appropriate step)).

As discussed below, a POSA would also have found it obvious to emit information according to the result of the comparison recited in claim 2 (i.e., a comparison of the aligner’s distance from teeth to the threshold), both as a matter of common sense and based on the specific teachings of the prior art. EX1002, ¶¶92-93. Broadly speaking, it would have been common sense to send a message indicating that the aligner was or was not suitable based on the assessment, because of the readily apparent benefit of making the patient (or treating orthodontist) aware of the assessment. *Id.*

Emitting such information would be consistent with the teachings of Kim and Invisalign. As one option, the comparison could be used to provide guidance to a patient about wearing the aligner. Invisalign teaches that poor fit (indicated by a tooth-aligner separation greater than 1 mm) may be due to “non-compliance,” i.e., the “patient not wearing Aligners long enough for [a] tooth to move.” EX1006, 1. In this case, the guide teaches that the patient should be told to extend weartime of the aligner, and that orthodontists should emphasize to the patient “never to dispose of their Aligners and instruct them that the Aligners should be fitting well at the end of the 2-week period.” *Id.* Emitting information (e.g., sending a

message) reflecting this instruction would constitute the emission of information recited in claim 2. EX1002, ¶94.

For example, this information could be emitted in a message sent to the patient's mobile device. This option is taught by Kim, which teaches that a "teeth alignment guidance information transmission program" can send information from the orthodontist to the patient's mobile device that "advises, for example, an appropriate step of a clear aligner to be currently worn by the orthodontic patient." EX1005, ¶63; *see also id.*, ¶64 ("[T]he teeth alignment guidance information may include at least one of a clear aligner information about a clear aligner to be worn in a current step among a clear aligner set, a wearing time information about a wearing time of the clear aligner, a replacement information about replacement of a part of or the whole clear aligner set, a clear aligner state information about the state of the clear aligner, a clear aligner usage guidance information...."); EX1002, ¶95.

Accordingly, claim 2 would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶96.

D. Claim 4

Claim 4 depends from claim 1 and further recites that "the dentition and aligner images are the same image." The discussion above for claim 1 adopted a mapping in which the dentition and aligner images are the same image. *See supra*

§§III.A, IV.B.2. Thus, claim 4 would have been obvious over Kim, Invisalign, and Salah for the same reasons as discussed above for claim 1. *See supra* §IV.B; EX1002, ¶¶97-98.

E. Claim 5

Claim 5 depends from claim 1 and further recites that step 4 comprises the following steps:

for each of a plurality of teeth for which the interior and exterior tooth outlines have been determined;

i) determination of a distance between the interior and exterior tooth outlines;

ii) determination of a distance threshold, preferably using the distances determined in the immediately preceding step;

iii) for each of said teeth, determination of a distance score dependent on

the distance between the interior and exterior teeth outlines, and the distance threshold.

As discussed below, Kim, Invisalign, and Salah teach each of these elements. EX1002, ¶¶99-100.

The first element of claim 5 is a preface to the remaining three elements, indicating that they should be performed “for each of a plurality of teeth for which the interior and exterior tooth outlines have been determined.” A POSA would have been motivated to perform the steps of claim 5 for a plurality of teeth for

which interior and exterior outlines would be determined. Salah, for example, teaches determining outlines for a plurality of objects, including teeth. EX1008, 23:4-8 (using detected gingival margins to delimit teeth and “determine which parts of the initial reference model correspond to which teeth”), 34:6-7 (“For example, figure 6b is an updated tooth contour map obtained from the updated image of figure 6a.”), Figs. 6a (showing multiple teeth), 6b (showing contours of multiple teeth). An example of Salah’s contours detected for multiple teeth is shown below in Fig. 6b:

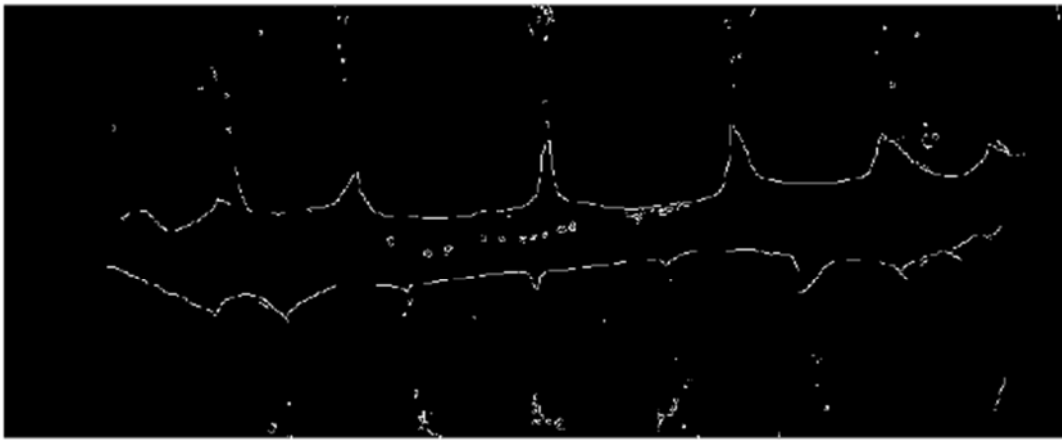


Fig. 6b

EX1008, Fig. 6b; EX1002, ¶¶101-02.

Invisalign similarly provides reason to determine distances for each tooth for which interior and exterior outlines have been determined. For example, when indicating an assessment that an aligner is seated poorly, Invisalign includes arrows pointing at multiple teeth, as shown in the figure reproduced below:



EX1006, 1. Invisalign also urges that practitioners should “be tooth/teeth specific” when indicating necessary adjustments, and it includes a section handling “tooth-specific movements.” EX1006, iv, v (table of contents), 2 (cross-referencing to sections handling tooth-specific issues such as incomplete extrusions and unintended intrusions). In 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. EX1002, ¶103.

Thus, based on the teachings of Salah and Invisalign, a POSA would have concluded that outlines of multiple teeth and their corresponding parts of the

aligner should be detected and that a distance assessment should be made for each such tooth. EX1002, ¶104.

1. Step 5(i)

Step 5(i) recites “determination of a distance between the interior and exterior tooth outlines.” This would have been obvious in view of Kim, Invisalign, and Salah as discussed above for claim 1. *See supra* §IV.B.4. For example, Salah teaches how to detect such outlines, and Invisalign motivates the detection of outlines to determine distances between teeth and aligners, to judge whether the aligners are seated and fitting well, which would inform Kim’s teaching to assess whether an appliance is normal and corresponds to an appropriate step of treatment. *Id.*; EX1002, ¶105; *see* EX1005, ¶66; EX1006, 1; EX1008, 34:11-14, 34:11-36:14.

2. Step 5(ii)

Step 5(ii) recites “determination of a distance threshold, preferably using the distances determined in the immediately preceding step.” While this step mentions that the determination may use the distances determined in step 5(i), it does not indicate that this is required, but merely a preferred example falling within the scope of the claim. Thus, the claim also encompasses determining a distance threshold in other ways, including ways that do not necessarily use the distances determined in step 5(i). *See also* EX1001, 11:51-12:5 (indicating that use of the

distances to determine the threshold is one preferred option, but not that they must be used); EX1002, ¶106.

Invisalign teaches determination of a distance threshold. For example, Invisalign teaches using a distance threshold corresponding to a 1 mm gap between teeth and aligner, with distances under 1 mm indicating acceptable fit and distances over 1 mm indicating poor fit or poor seating. EX1006, 1. Applying such a distance threshold to detected tooth and aligner outlines in the context of Kim and Salah would be straightforward. EX1002, ¶107. For example, a threshold value (e.g., 1 mm) could be stored in memory and retrieved computationally to apply the threshold to a measured value of distance for each tooth. *See, e.g.*, EX1008, 16:14-19 (storing code executable by computing device), 34:34:15-36:14 (using thresholds as part of image processing, including, for example, “applying a threshold to apply a fixed threshold to each element of a vector”); EX1002, ¶107.

To the extent determination of a distance threshold is interpreted to require more than reading and applying a stored distance value, it would also have been obvious to adapt the threshold taught by Invisalign to the particular images analyzed in view of Kim and Salah. For example, as Dr. Foroosh explains, to apply a 1 mm threshold to a distance within an image, it would have been routine to determine an appropriate distance scale to convert measurements made on the image itself (e.g., in pixels, *see* EX1008, 18:6-7 (“An image is made up of

pixels.”)) to metric units. EX1002, ¶108; *see also infra* §IV.F (discussing this aspect in the context of claim 6). This determination could be based on objects in the image; for example, using the known size of teeth (e.g., based on known typical sizes or a reference model as taught by Salah, *see* EX1008, 20:15-21) or using registration marks with known separation, as taught by Salah. *See* EX1008, 38:7-9; EX1002, ¶108; *infra* §IV.F. Scaling images to determine the size of objects based on other imaged objects of known size would have been routine to the POSA. EX1002, ¶108; EX1014, 125 (teaching that a “scale factor can be determined from one known reference length”); *see also id.*, 142-43 (using edge detection to identify lines for measurement). Adapting a threshold in metric units, such as millimeters, into units of distance in an image (e.g., pixel distance) would constitute determination of a distance threshold as recited in step 5(ii). EX1002, ¶¶108-09; *see also* EX1008, 34:34:15-36:14 (“applying an adaptive threshold to a vector” a known option for image analysis).

3. Step 5(iii)

Step 5(iii) recites “for each of said teeth, determination of a distance score dependent on the distance between the interior and exterior teeth outlines, and the distance threshold.” Kim, Invisalign, and Salah teach this element. EX1002, ¶110.

As discussed above, Invisalign teaches that discrepancies of more than 1 mm between teeth and the aligner indicates that the aligner is not seating well. *Supra*

§§I.B.2, IV.A, IV.B.5, IV.C. And as further discussed above, a POSA would have applied Invisalign’s teachings to each of the recited teeth, in order to determine whether each of the patient’s teeth were appropriately fit by the aligner. *Supra* §IV.B.4-5. This would be consistent with Kim’s teaching to determine whether the aligner was normal and corresponded to an appropriate step. EX1005, ¶65; EX1002, ¶111. Applying this teaching to interior and exterior tooth outlines detected with Salah’s image processing software (*see* EX1008, 34:11-36:14) would be achieved by determining scores dependent on both the distance between those outlines and the distance threshold for each tooth. EX1002, ¶112. For example, the distance score for each tooth would correspond to a poor fit for distances exceeding the threshold and acceptable fit for distances below the threshold. *Id.*

Thus, Kim, Invisalign, and Salah teach step 5(iii).

Accordingly, claim 5 would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶113.

F. Claim 6

Claim 6 depends from claim 5 and further recites that “the distances are measured in pixels.” Claim 6 would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶114.

As discussed above for claims 1 and 5, a POSA would have been motivated in view of Kim, Invisalign, and Salah to analyze digital images of patients’ teeth

with an aligner worn in a service position to determine gaps between the aligner and teeth by detecting contours with image processing software, then measuring distances between the resulting tooth and aligner outlines. *Supra* §§IV.A, IV.B.5, IV.C, IV.E.1. A POSA would have understood that the digital images would be composed of pixels. EX1002, ¶115. Salah expressly recognizes as much, disclosing:

By “image” we mean a two-dimensional picture, such as a photograph.

An image is made up of pixels.

EX1008, 18:6-7. Salah also teaches that its contour maps are maps over pixels, noting that “contour information may be equal to 1 or 0, depending on whether a pixel belongs to a contour.” EX1008, 18:14-17; *see also id.*, 34:22-24 (identifying image processing steps based on areas measured in pixels and interpolation based on a pixel environment); EX1002, ¶115.

Since the digital images being analyzed would be made up of pixels, and the contours detected within those images would be defined in terms of pixels, a POSA would naturally have measured distances between the contours within the images in pixels. EX1002, ¶116. Nor would a POSA have had any difficulty applying thresholds as taught by Invisalign using image measurements based on pixels. *Id.* For example, it was well known how distances measured directly on images (e.g., in pixels) could be converted to distances measured in other units

such as millimeters when analyzing the sizes of objects in an image. *Id.*; EX1014, 125 (“scale factor can be determined from one known reference length”), Figs. 1, 5, 8, 10, 12-14 (showing various distance measurements via scaling and geometric transform). As one option, a known width (like the typical size of a tooth, or the known width of the patient’s tooth, based on a model as taught by Salah) would permit a conversion of units using simple geometry. EX1002, ¶117; *see, e.g.*, EX1008, 20:15-21 (initial reference model providing geometric tooth information accurate to 1/10 mm scale); EX1014, Abstract, 123-25 (teaching geometric assessment to measure distances in images). Further, Salah teaches that registration marks with known size and spacing can be included in the images, and these too would provide a straightforward calibration basis to convert between image measurements in pixels and metric measurements in units of distance (e.g., millimeters). *See* EX1008, 38:7-9; EX1002, ¶117. Accordingly, a POSA would have found it routine to measure distances in pixels when applying Invisalign’s teachings regarding tooth-aligner distances as measured based on contours of digital images as taught by Kim and Salah. EX1002, ¶117.

Accordingly, claim 6 would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶118.

For the foregoing reasons, claims 1-2 and 4-6 would have been obvious over Kim, Invisalign, and Salah. EX1002, ¶119.

V. DISCRETIONARY DENIAL IS NOT WARRANTED

This petition does not implicate the Board's discretion according to *Fintiv*. *Apple Inc., v. Fintiv, Inc.*, IPR2020-00019, Paper 11. *See generally* Memorandum on Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022) (*Fintiv* Memo). Patent Owner filed its district court complaint in the Northern District of California on November 18, 2022, asserting three patents including the '945 patent. However, on October 12, 2023, the court adopted a joint stipulation dismissing all allegations related to the '945 patent. EX1013. Thus, there are no currently pending court proceedings regarding the '945 patent. Accordingly, there is no basis for discretionary denial under *Fintiv*.

This petition also does not implicate §325(d). The petition presents new art and argument, as neither Kim nor Invisalign was disclosed or considered during examination. Salah was cited in the specification of the '945 patent (*see, e.g.*, EX1001, 7:6-42, 9:7-8 (referring to PCT/EP2015/074896 or WO2016066651), but Salah was never disclosed in an IDS nor was an English translation ever provided. *See generally* EX1004. Nor are the references relied on in the petition cumulative to the references applied during examination, as the discussion of claim 1 shows that the prior art relied on herein discloses the elements indicated as missing by the Examiner (i.e., steps 2-4 of claim 1, *see* EX1004, 254-58) from the cited

Greenberg, Wen, and Kitching references. Finally, the discussion in the ground above explains in detail why the claims of the '945 patent were obvious over the prior art, confirming that their allowance constituted material error. *See supra* §IV.

VI. GROUNDS FOR STANDING

Align certifies that, under 37 C.F.R. §42.104(a), the '945 patent is available for *inter partes* review, and Align is not barred or estopped from requesting *inter partes* review of the '945 patent on the grounds identified.

VII. CONCLUSION

For the reasons set forth above, claims 1-2 and 4-6 of the '945 patent are unpatentable. Align therefore requests that an *inter partes* review of these claims be instituted.

Respectfully submitted,

Dated: October 31, 2023

/Matthew A. Argenti/
Matthew A. Argenti, Lead Counsel
Reg. No. 61,836

VIII. MANDATORY NOTICES UNDER 37 C.F.R. §42.8

Real Party-in-Interest (37 C.F.R. §42.8(b)(1)): Align Technology, Inc. is the real party-in-interest.

Related Matters (37 C.F.R. §42.8(b)(2)): Patent Owner had asserted the '945 patent against Petitioner in the United States District Court in the Northern District of California (3-22-cv-07335); however, the district court adopted a voluntary dismissal of all allegations related to the '945 patent on October 12, 2023.

Lead and Back-Up Counsel (37 C.F.R. §42.8(b)(3))

Lead Counsel: Matthew A. Argenti (Reg. No. 61,836)

Back-Up Counsel: Michael T. Rosato (Reg. No. 52,182); Patrick M. Medley (Reg. No. 74,735)

Service Information – 37 C.F.R. §42.8(b)(4). Petitioner hereby consents to electronic service.

Email: margenti@wsgr.com; mrosato@wsgr.com; pmedley@wsgr.com

Post: Wilson Sonsini Goodrich & Rosati, 650 Page Mill Rd., Palo Alto, CA 94304

Tel.: 650-354-4154

Fax: 650-493-6811

IX. PAYMENT OF FEES UNDER 37 C.F.R. §§42.15(A) AND 42.103

The required fees are submitted herewith. If any additional fees are due at any time during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 23-2415.

X. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 11,395 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a).

Dated: October 31, 2023

/Matthew A. Argenti/
Matthew A. Argenti, Lead Counsel
Reg. No. 61,836

XI. APPENDIX – LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,109,945 to Salah et al.
1002	Declaration of Dr. Hassan Foroosh
1003	Curriculum Vitae of Hassan Foroosh, Ph.D.
1004	U.S. Patent Application No. 16/001,049 File History
1005	U.S. Patent Pub. No. 2017/0281313 to Taewon Kim
1006	Align Technology, Invisalign Clinical Monitoring Guide (2003) (archived September 26, 2003, at http://web.archive.org/web/20030926024959/http://www.invisaligncec.com:80/consistent/pdfs/ICMG_Final.pdf)
1007	Maninis et al., “Convolutional Oriented Boundaries: From Image Segmentation to High-Level Tasks,” <i>arXiv.org</i> (Apr. 28, 2017)
1008	Translation of PCT Pub. No. WO 2016066651 to Salah et al.
1009	Scott Frey, Blog – The Ortho Cosmos, (archived May 4, 2017 at http://web.archive.org/web/20170504155213/http://theorthocosmos.com:80/blog)
1010	Declaration of Nathaniel E. Frank-Wright
1011	Declaration of Mitra Derakhshan
1012	PCT Pub. No. WO 2016066651 to Salah et al.
1013	Joint Stipulation and Order of Voluntary Dismissal Without Prejudice (Dkt. No. 90), <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , No. 3-22-cv-07335-WHA (N.D. Cal.)
1014	Criminisi et al., “Single View Metrology,” <i>International Journal of Computer Vision</i> 40(2) (2000)

1015	Krizhevsky et al., “ImageNet Classification with Deep Convolutional Neural Networks,” <i>Advances in Neural Information Processing Systems</i> 25 (2012)
1016	Patrick Cavanaugh, “Visual Cognition” <i>Vision Research</i> 51 (2011)
1017	Prasad et al., “Learning Class-specific Edges for Object Detection and Segmentation,” <i>Computer Vision, Graphics and Image Processing: 5th Indian Conference, ICVGIP 2006</i> (2006)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105(a), this is to certify that I caused to be served a true and correct copy of the foregoing Petition for Inter Partes Review of U.S. Patent No. 11,109,945 (and accompanying Exhibits 1001-1017) by overnight courier (Federal Express or UPS), on this 31st day of October 2023, on the Patent Owner at the correspondence address of the Patent Owner as follows:

Cooper Legal Group LLC
1388 Ridge Road, Unit 1
Hinckley, OH 44233

Dated: October 31, 2023

/Matthew A. Argenti/
Matthew A. Argenti, Lead Counsel
Reg. No. 61,836