

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

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit Number	Description
2002	Declaration of John T. Mongan, M.D., Ph.D., dated February 20, 2024
2003	Curriculum Vitae of John T. Mongan, M.D., Ph.D.
2004	Declaration of Budi Kusnoto, D.D.S., M.S., dated February 20, 2024
2005	Curriculum Vitae of Budi Kusnoto, D.D.S., M.S.
2006	Rui Zhao et al., Changing Clear Aligners Every 10 Days or 14 Days? A Randomised Controlled Trial, 39(1) Australasian Orthodontic J. 1 (2023)
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))
2009	Timothy T. Wheeler, Orthodontic Clear Aligner Treatment, 23(1) Seminars in Orthodontics 83 (2017)
2010	Emilia Taneva, Budi Kusnoto, Carla A. Evans, Chapter 9: 3D Scanning, Imaging, and Printing in Orthodontics, Issues in Contemporary Orthodontics (Farid Bourzgui 2015)
2011	Orhan Tuncay et al., Effectiveness of a Compliance Indicator for Clear Aligners, 43(4) J. Clin. Orthod. 263 (2009)
2012	Silvia Caruso, Sara Caruso, et al., A Knowledge-Based Algorithm for Automatic Monitoring of Orthodontic Treatment: The Dental Monitoring System. Two Cases, 21(5) Sensors (Basel) 1856 (2021)
2013	Barry J. Glaser, "The Insider's Guide to Invisalign Treatment," (3L Publishing, 2017)

I. Introduction

Patent Owner, Dental Monitoring SAS, respectfully requests that the Board decline to institute *inter partes* review of U.S. Patent No. 11,109,945 (“the ’945 Patent”) because Petitioner, Align Technology, Inc., has not shown that there is a “reasonable likelihood” that Petitioner would prevail as to at least one of claims 1–2 and 4–6 of the ’945 Patent (“the Challenged Claims”).

The ’945 Patent relates to new and improved methods for evaluating the shape of an orthodontic aligner using image processing software to analyze images of an aligner as worn by a patient. EX1001 at 13:59–60. In this Preliminary Response, Patent Owner explains that Petitioner has not—and cannot—meet its burden to show why a person of ordinary skill in the art (“POSA”) would have made the asserted prior art combination. Instead, Petitioner relies on impermissible hindsight to combine fundamentally different approaches to monitoring the progress of orthodontic treatment. Contrary to Petitioner’s assertions, however, a POSA would not have been motivated to combine Invisalign’s visual *in-person approximation* with the remote assessments in Kim or Salah because neither Invisalign, nor any of the cited prior art, suggests that the shape of an aligner can be assessed *remotely* from an aligner image or describes how that could be done. Indeed, without a method for determining the scale of an image—a method described nowhere in the

Petitioner's references—a POSA would not have been able to determine the separation between the aligner and teeth in that image.

Petitioner has similarly failed to meet its burden to show that the prior art discloses all elements of the Challenged Claims. Petitioner's Kim and Salah references disclose an approach to remote orthodontic treatment that monitors tooth positions, not the shape of an aligner as in the '945 Patent, and they rely on images of a patient's teeth *without aligners*. To the extent that Invisalign teaches any image capture, that image capture is done for the purposes of creating aligners, i.e., before the aligners are even made. Thus, the asserted prior art neither discloses acquisition of an aligner image for the purposes of evaluating the shape of an aligner, nor “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 required by all Challenged Claims.

A POSA also would not have had a reasonable expectation of success in achieving the claimed invention by combining references as proposed in the Petition. Petitioner relies heavily on Salah, but Salah nowhere suggests the use of image processing software to detect aligners, let alone interior and exterior tooth outlines on an aligner image. To the contrary, Salah discloses that “a zone of weak contrast,” such as between the aligner and the teeth, can only be “likened to a zone

corresponding to an outline with a low probability,” and preferably should not be used for any analysis.

Finally, the Board should exercise its discretion to decline to institute because Petitioner has not met its burden of showing that the same or substantially the same art and arguments were not already considered and appropriately rejected by the Examiner with respect to the '945 Patent.

II. Aligner Treatment

Aligners are one type of orthodontic device designed to exert gentle pressure and thereby reposition a patient's teeth. EX1001 at 1:23–31; EX2002, ¶49; EX2004, ¶¶16, 20. As of June 2017, aligner treatment generally began with a patient attending an in-person consultation with an orthodontist or other dental professional to establish a proper diagnosis as to the patient's suitability for aligner treatment. This examination typically was conducted either by visual inspection and/or using in-office scanning technology. EX1001 at 1:16–22; EX2002, ¶49; EX2004, ¶17. If the orthodontist determined that the patient was suitable for aligner treatment, and if the patient chose to move forward with that treatment, the orthodontist would then conduct scans of the patient's starting dentition. EX1001 at 1:16–22; EX2002, ¶49; EX2004, ¶18. These in-office scans were typically conducted on specialized machines employing various scanning technologies that generated digital three-

dimensional models of a patient's dentition, and were conducted by a dental professional or a specially trained technician. EX2004, ¶18; EX2010 at 147–80.

Based on these initial scans, a sequence of aligners would be designed and fabricated by one of several third-party companies, such as Petitioner. EX1001 at 1:21–36; EX2002, ¶49; EX2004, ¶18. 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. EX1001 at 1:35–36; EX2002, ¶49; EX2004, ¶20. In 2017, effective aligner treatment required frequent in-person orthodontic examinations to determine whether treatment was on track. EX1001 at 1:42–45; EX2002, ¶49; EX2004, ¶22. These in-person examinations did not involve quantitative assessments of aligner fit, nor did they involve making any quantitative measurements of separations between the aligner and the dental arch on a tooth-by-tooth basis. EX2004, ¶23.

Instead, as explained by Dr. Kusnoto—a practicing clinician, researcher, and academic in orthodontics for twenty-five years—conventional aligner treatment examinations as of June 2017 involved two primary qualitative and subjective assessments. EX2004, ¶24. First, orthodontists would visually inspect the current state of dentition and compare that state to the anticipated dentition for that point in the aligner treatment. *Id.*; EX1001 at 1:42–45 (“At regular intervals, the patient goes to the orthodontist for a visual inspection, notably to check whether the movement

of the teeth meets expectations and whether the aligner being worn by the patient is still suitable for treatment.”). Second, orthodontists assessed the aligner treatment for problems with, e.g., aligner fit, tooth attachments, or dentition complications. EX2004, ¶25; EX2013 at 39–40, 275–76; EX1006 at passim. Generally, a patient would be asked to try on their current aligner, and each aligner was visually and manually examined for large gaps between the aligner and the teeth. EX2004, ¶26. Using their hands, the orthodontist would manually examine the aligner for potential rocking (that is, movement of one part of the aligner off of a patient’s teeth when pressure is applied to another part of the aligner). *Id.* A similar examination was then conducted using the next aligner in a patient’s sequence. *Id.*

These subjective visual inspections performed by orthodontists were susceptible to inconsistency and inaccuracy, for example, due to level of experience, length of the appointment, speed of review, number of patients seen, fatigue, etc. EX2004, ¶24. Reliance on periodic in-person examinations also meant that treatment issues could go undiagnosed for multiple weeks between check-ins. EX1001 1:53–59; EX2002, ¶49; EX2004, ¶27. 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 remaining aligners from the previous series discarded. EX1001 at 1:46–52;

EX2002, ¶49; EX2004, ¶27. As a result, aligner treatment was often delayed and prolonged. *Id.* at 1:49–59; EX2002, ¶49; EX2004, ¶27.

III. The '945 Patent

A. The '945 Patent Invention

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 at 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.”), 13:59–60, Abstract; EX2002, ¶50. “According to the invention, the shape of the aligner is evaluated by comparing an outline of th[e] aligner, in its service position, with an outline of the teeth wearing it.” EX1001 at 6:7–9; EX2002, ¶50.

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.” EX1001 at 2:1–3; EX2002, ¶51. “[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.” EX1001 at 2:4–6; EX2002, ¶51. And “at least one updated image referred to as ‘dentition image’,

identical to or different from the aligner image, representing said teeth.” EX1001 at 2:7–9; EX2002, ¶51.

“In one embodiment, the dentition image is the aligner image.” EX1001 at 6:15–16; EX2002, ¶52. 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.” EX1001 at 6:15–20; EX2002, ¶52. This avoids the need for a readjustment step. EX1001 at 6:20–21; EX2002, ¶52.

“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’.” EX1001 at 6:22–24; EX2002, ¶53. “[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.” EX1001 at 2:10–14; EX2002, ¶53.

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.” EX1001 at 2:15–19; EX2002, ¶54. 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. EX1001 at 5:8–9; EX2002, ¶54. “[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.’” EX1001 at 5:10–12; EX2002, ¶54. “Such a line may also delimit part of the aligner,” and “is then qualified as an ‘exterior tooth outline.’” EX1001 at 5:14–15; EX2002, ¶54. As the bottom of the tray of an aligner substantially compliments 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.” EX1001 at 5:15–20; EX2002, ¶54.

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.” EX1001 at 2:20–22; EX2002, ¶55. 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. EX1001 at 11:35–38; EX2002, ¶55.

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.” EX1001 at 11:40–43; EX2002, ¶56. 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.” EX1001 at 11:45–47; EX2002, ¶56. “[A] distance threshold S_d is determined, preferably using the distances [already] determined.” EX1001 at 11:51–52; EX2002, ¶56. Preferably, the distance threshold “is substantially equal to the smallest of the distances [already] determined.” EX1001 at 11:53–55; EX2002, ¶56. 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.” EX1001 at 11:63–67; EX2002, ¶56. “The higher the distance score, the greater the separation of the tooth concerned from the tray.” EX1001 at 12:4–5; EX2002, ¶56.

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.” EX1001 at 13:7–10; EX2002, ¶57. “In particular, the difference in offset of the first tooth with the second tooth may be compared against the offset-difference threshold.” EX1001 at 13:11–13; EX2002, ¶57. “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.” EX1001 at 13:13–17; EX2002, ¶57. “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.” EX1001 at 13:18–20; EX2002, ¶57. 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.” EX1001 at 13:28–34; EX2002, ¶57.

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.” EX1001 at 2:32–38; EX2002, ¶58.

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.” EX1001 at 13:44–47; EX2002, ¶59. 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.” EX1001 at 3:36–40; EX2002, ¶59.

B. The Challenged Claims

The Challenged Claims recite “[a] method for evaluating the shape of an orthodontic aligner worn by a patient.” EX1001 at 13:59–60; EX2002, ¶61. This method requires “acquisition of at least one two-dimensional image of teeth of said patient, referred to as [an] ‘updated image’, under actual acquisition conditions.” EX1001 at 13:62–64; EX2002, ¶61. The Challenged Claims further require “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’ ... representing said teeth.” EX1001 at 13:65–14:3; EX2002, ¶61.

With the exception of claim 4, the Challenged Claims allow the dentition image to be “identical to or different from the aligner image,” but if they are different, the dentition image is converted “so that it represents said teeth as seen under the acquisition conditions used during the acquisition of the aligner image.” EX1001 at 14:2–8; EX2002, ¶62. Claim 4, which depends from claim 1, requires that “the dentition and aligner images are the same image.” EX1001 at 38–39; EX2002, ¶62.

The Challenged Claims further require “for each of a plurality of teeth represented on the dentition and aligner images” a “determination, by means of image processing software,” “of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively.” EX1001 at 14:9–14; EX2002, ¶63.

In addition, the Challenged Claims require a “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.” EX1001 at 14:15–17; EX2002, ¶64. Claim 5, which depends from claim 1, specifically requires that this comparison, “for each of a plurality of teeth for which the interior and exterior tooth outlines have been determined,” involves three steps. EX1001 at 14:40–43; EX2002, ¶64. One, there must be a “determination of a distance between the interior and exterior tooth outlines.” EX1001 at 14:44–45; EX2002, ¶64. Two, there must be a “determination of a distance threshold, preferably using the distances determined in the immediately preceding step.” EX1001 at 14:46–48; EX2002, ¶64. Three, there must be a “determination of a distance score dependent on the distance between the interior and exterior teeth outlines, and the distance threshold” “for each of said teeth.” EX1001 at 14:49–53; EX2002, ¶64. Claim 6, which depends from claim 5, further

requires that the distances in claim 5 be “measured in pixels.” EX1001 at 14:55; EX2002, ¶64.

Finally, claim 2, which depends from claim 1, requires a “comparison of the score,” that results from the comparison of the interior and exterior tooth outlines, “against an acceptability threshold and the emission of information according to the result of the comparison.” EX1001 at 14:20–22; EX2002, ¶65.

IV. Prosecution History

The '945 Patent issued on September 7, 2021 and claims priority to French Application No. 1755187, filed June 9, 2017. EX1001; EX2002, ¶66. Petitioner has not challenged, and cannot now challenge, the entitlement of the '945 Patent to this priority date. *See MaxLite, Inc. v Jiaxing Super Lighting Elec. Appliance Co.*, IPR2020-00208, Paper 10 (PTAB June 24, 2020) (holding that a petitioner must raise the issue of whether the challenged patent is entitled to an effective filing date in its petition by “identifying, specifically, the features, claims, and ancestral applications allegedly lacking written description support for the claims based on the identified features”).

During prosecution, the Examiner issued one office action (December 30, 2020). EX1004 at 185–197; EX2002, ¶67. The Examiner 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 at 187; EX2002, ¶67. The Examiner further rejected claims 1-10 under 35 U.S.C. § 112(b) 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. EX1004 at 188; EX2002, ¶67. The Examiner also rejected claims 1, 2, 4, and 6 under 35 U.S.C. § 103 as obvious over Greenberg (U.S. Pat. Pub. 2014/0120488) over Wen (U.S. Pat. Pub. 2017/0100214), while recognizing that claims 3, 5, 7, 8, 9, and 10 were otherwise allowable. EX1004 at 189–195; EX2002, ¶67.

Patent Owner responded on March 25, 2021, amending 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. EX1004 at 238; EX2002, ¶68. With respect to the rejection under 35 U.S.C. § 112, 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. EX1004 at 241–242; EX2002, ¶68. In other words, Patent Owner 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. Contrary to Petitioner’s assertions (Pet. 11), Patent Owner never admitted 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 and worn aligner. EX1004 at 242–44; EX2002, ¶68.

On May 5, 2021, the Examiner issued a Notice of Allowance. EX1004 at 249–59; EX2002, ¶69. The Examiner explained that Greenberg teaches the design and subsequent manufacture of an aligner based on a CT scan. EX1004 at 255–56; EX2002, ¶69. Wen teaches a scanned model of the patient's dentition that is used to develop a treatment plan and the subsequent manufacture of aligners. EX1004 at 256; EX2002, ¶69. 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. EX1004 at 256; EX2002, ¶69.

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.” EX1004 at 254–55; EX2002, ¶70. Thus, the Examiner allowed claims 1-10. EX1004 at 249–59; EX2002, ¶70.

V. Claim Constructions and POSA Definition

Patent Owner does not respond here to Petitioner’s proposed claim constructions (Pet. Section III) because, even under Petitioner’s proposals, the Board should deny institution. For the purposes of this Preliminary Response, Patent Owner also does not contest Petitioner’s definition of a POSA (Pet. Section I.E.). This Preliminary Response should not be interpreted as an agreement with Petitioner’s proposals, and Patent Owner reserves the right to offer competing constructions and definition, if institution is granted.

VI. Overview of References

A. U.S. Patent Publication No. 2017/0281313 to Kim et al. (“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.” EX1005, ¶76; EX2002, ¶71. Kim was filed on April 5, 2016, and was published after the ’945 Patent priority date, on October 5, 2017. EX1005; EX2002, ¶71. Consistent with the ’945 Patent and Dr. Kusnoto’s declaration, Kim discloses that “[u]sing the [then-]conventional clear-aligner treatment method, an orthodontic patient should

regularly visit a dental clinic for a long period of time to allow a dentist to accurately check the state of his/her teeth and determine a currently appropriate step of a clear aligner.” EX1005 at [0008]; EX2002, ¶71; EX2004, ¶22–27.

Kim discloses “a method and system for providing remote teeth alignment services.” EX1005 at [0010]; EX2002, ¶72. That method involves an orthodontic patient sending the orthodontist “teeth alignment information using a device, e.g., a smartphone.” EX1005 at [0010]; EX2002, ¶72. Kim asserts that the orthodontist may then “remotely and accurately diagnose the condition of the patient based on the teeth alignment information, and may remotely provide information about an accurate step of a clear aligner to be currently worn by the orthodontic patient.” EX1005 at [0010]; EX2002, ¶72.

Specifically, “[t]he teeth alignment report information” sent by the patient may include “a front-view teeth photo, a bottom-view low-angle teeth photo, a front-view automatically-recognized mouth gag photo, a front-view automatically-recognized face contour photo, a left-side-angle automatically-recognized mouth gag photo, a left-side-angle automatically-recognized face contour photo, a right-side-angle automatically-recognized mouth gag photo, a right-side-angle automatically-recognized face contour photo, a collection of top, bottom, left, and right side photos surrounding a central front photo, a low-angle upper jaw photo, a high-angle lower jaw photo, and combinations thereof, which are taken using a

camera of the orthodontic patient terminal.” EX1005 at [0013]; *see also id.* at [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); EX2002, ¶73.

Kim does not disclose “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,” as required by all Challenged Claims. EX2002, ¶74. Petitioner appears to recognize as much. Pet. at 18 (admitting that “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”).

While Kim states that “the orthodontist checks a photo or a video of the clear aligner currently worn,” EX1005 at [0066], a POSA would not have understood this to refer to an image of the patient wearing the aligner. EX2002, ¶74. Instead, a POSA would have understood this language to refer to a photo or video of the aligner that would be used to determine whether the aligner is the correct aligner and whether the aligner has abnormalities, such as damage. *Id.* This is because Kim nowhere describes acquiring images or a video with an aligner being worn by a

patient or a method or tool to evaluate such images, and instead, Kim discloses that the patient sends “clear aligner information about a currently worn clear aligner” and images of their teeth to the orthodontist for the purposes of assessing tooth alignment. *E.g.*, EX1005 at [0010], [0066]; EX2002, ¶74. The images or a video of the aligner are then transmitted “in such a manner that the orthodontist checks a photo or a video” and “determines whether the clear aligner is normal and corresponds to an appropriate step.” *E.g.*, EX1005 at [0010], [0066]; EX2002, ¶74.

Kim discloses that the orthodontist provides aligner advice based on the position of the teeth, not the aligner fit itself. EX1005 at [0063] (“the orthodontist accurately determines a current ***teeth alignment*** state . . .” (emphasis added)); EX2002, ¶75. Kim also does not suggest any non-human analysis of the images. *See, e.g.*, EX1005 at [0085] (“Then, as illustrated in FIG. 19, the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal 20.”); EX2002, ¶76. Thus, Kim does not disclose “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,” as

required by the Challenged Claims. EX2002, ¶76. Petitioner does not contend otherwise.

B. Invisalign Clinical Monitoring Guide (“Invisalign”)

The Invisalign Clinical Monitoring Guide (“Invisalign,” EX1006) was published by Petitioner “to help the Invisalign practitioner successfully monitor Invisalign treatments and address issues that may arise between receipt of Aligners from [Petitioner] to the completion of treatment.” EX1006 at i; EX2002, ¶77; EX2004, ¶29. Invisalign teaches that, “[t]o prevent issues from occurring,” Petitioner recommends that dental professionals “perform the [certain steps] *at every patient appointment.*” EX1006 at ii (emphasis added); EX2002, ¶77; EX2004, ¶29. For example, Invisalign discloses that 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. EX1006 at ii (emphasis added); EX2002, ¶77; EX2004, ¶29.

Unlike the Challenged Claims of the ’945 Patent, Invisalign does not disclose or suggest any method for “evaluating the shape of an orthodontic aligner” using an aligner image that could be performed in between in-office orthodontist check-ups. EX2002, ¶78; EX2004, ¶31. This is not surprising because, until 2020, Petitioner did not offer any product to virtually assess aligner treatment progress. EX2007; EX2002, ¶78; EX2004, ¶31.

Petitioner alleges that “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.” Pet. 7 (citing EX1006 at 1–2). To the contrary, as Dr. Kusnoto explains, Invisalign includes only exemplary images of what a dental practitioner might see during an in-person appointment when the aligner does not fit properly. EX1006 at 1; EX2002, ¶78; EX2004, ¶31. Invisalign makes no suggestion that any image should be acquired for “evaluating the shape of an orthodontic aligner.” EX2002, ¶78; EX2004, ¶31.

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 at 1; EX2002, ¶79; EX2004, ¶30. But Invisalign does not disclose any method to assess the separation, other than a visual in-person approximation, and does not provide any method and/or tool for accurate measurement of such a separation, even in-office. EX2002, ¶79; EX2004, ¶30. As Dr. Kusnoto explains, subjective visual inspections are susceptible to inconsistency and inaccuracy due to factors including the level of experience, length of the appointment, speed of the review, number of patients seen, and fatigue. EX2004, ¶30.

Citing Dr. Foroosh, Petitioner further alleges that Invisalign illustrates how a digital photograph of an aligner on a patient's teeth can depict a gap of over 1 mm between teeth and aligner. Pet. at 7–8 (citing EX1002, ¶46). But Petitioner's Dr. Foroosh is *not* an expert in dentistry or orthodontics, nor does he claim to have consulted with such an expert before rendering his opinions. In stark contrast to Dr. Foroosh, Dr. Kusnoto is a tenured Professor of Orthodontics and runs a private orthodontic clinic. EX2004, ¶6. In his declaration, Dr. Kusnoto explains that, in June 2017, a dental professional could not reliably and consistently distinguish in person between, for example, separations of 0.9 mm (on-track treatment) and 1.1 mm (off-track treatment). EX2004, ¶30. And as Dr. Mongan explains, a POSA would not have been able to make any measurements from the images in Invisalign without the ability to determine the scale of the image. EX2002, ¶80. 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. EX2002, ¶80. 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. EX1006 at 1; EX2002, ¶80; EX2004, ¶30.

Petitioner further asserts that Invisalign “describes the need to use high-quality records, including both dental impressions and photographs of the teeth of the patient wearing the aligners.” Pet. at 7 (citing EX1006 at ii–iv). That is incorrect.

Invisalign discusses only the collection of images for the purposes of aligner design and manufacture. EX2002, ¶81; EX2004, ¶32. As discussed above, and in detail by Dr. Kusnoto, 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 II; EX2004, ¶¶18, 32. Invisalign does not disclose “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,” as required by all Challenged Claims. EX2002, ¶81; EX2004, ¶33.

Finally, Invisalign does not disclose “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,” as required by the Challenged Claims. EX2002, ¶82. Petitioner does not contend otherwise.

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

PCT Publication No. WO2016066651 to Salah et al. (“Salah”) is entitled “Method for Monitoring Dentition.” EX1008. Salah names five inventors, with four matching the inventors listed on the ’945 Patent. EX2002, ¶83. Salah teaches a method for monitoring the positioning, shape, and/or appearance of a patient’s teeth using a three-dimensional (“3D”) digital reference model, taking an updated two-dimensional (“2D”) image of the patient’s teeth, and comparing the updated image to the reference model. EX1008 at 1:1–2:19; EX2002, ¶83.

Salah’s method for “checking the positioning and/or shape of teeth according to the invention,” EX1008 at 2:21–22, starts with the creation of a 3D “initial reference model” of the patient’s dental arch. EX1008 at 1:28–32; EX2002, ¶84. After some period of time, an “updated image” is acquired, which may be “a simple image of the teeth, taken without precise pre-positioning of the teeth in relation to the image acquisition apparatus, such as a photograph taken by the patient, to accurately assess tooth displacement and/or deformation since the initial reference model was produced.” EX1008 at 2:21–27; EX2002, ¶84. The “initial reference model” is then modified until a new reference model is obtained that corresponds to the updated image, known as a “final reference model.” EX1008 at 39:13–15; EX2002, ¶84.

This process involves generating a succession of “to-be-tested” reference models, preferably by a metaheuristic procedure. EX1008 at 39:16–20; EX2002, ¶85. Each model is then used to generate a reference image under virtual acquisition conditions that correspond to the actual acquisition conditions, i.e., the actual position and orientation of the acquisition apparatus when the updated image was captured. EX1008 at 39:21–27; EX2002, ¶85. The reference image thus reflects the image that the image acquisition apparatus would have taken of the “to-be-tested” reference model. EX1008 at 40:7–12; EX2002, ¶85. If the reference image and the analysis image are superimposable, the “to-be-tested” reference model accurately reflects the updated position of the patient’s teeth. EX1008 at 40:13–15; EX2002, ¶85. If they are not, additional reference models are generated and tested until a match, that is, a final reference model, is found. EX1008 at 44:24–26; EX2002, ¶85.

In order to compare the images, discriminant information is extracted from each of them. EX1008 at 40:19–20; EX2002, ¶86. Salah discloses multiple different types of discriminant information that can be used: contour information, color information, density information, distance information, brightness information, saturation information, reflection information and combinations of these. EX1008 at 34:8–10; EX2002, ¶86. This discriminant information is preferably obtained by one of almost forty methods. EX1008 at 34:15–36:14; EX2002, ¶86.

Once a final reference model is obtained, it can be compared with the initial reference model in order to determine tooth displacement between acquisition of the initial reference model and the updated image. EX1008 at 46:9–14; EX2002, ¶87.

As is apparent from the above, the method for monitoring tooth displacement in Salah is wholly distinct from the method for “evaluating the shape of an orthodontic aligner” in the ’945 Patent. EX2002, ¶88. Salah does not use images showing an aligner in the service position, and it nowhere suggests “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,” as required by the Challenged Claims. EX2002, ¶88.

Salah is cited in the ’945 Patent, was cited in the original specification, and appears in the prosecution search history. EX1001 at 7:9, 7:26, 7:28, 7:42, 9:7–8; EX1004 at 20, 139, 222, 224, 225, 274, 281, 283; EX2002, ¶89. Thus, Salah is previously presented art for the purposes of 35 U.S.C. § 325(d). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 9–10 (PTAB Feb. 13, 2020) (precedential) (previously presented art includes art made

of record by the Examiner, and art provided to the Office by an applicant, such as on an IDS, in the prosecution history of the challenged patent).

VII. The Board Should Decline to Institute Because a POSA Would Not Have Been Motivated to Combine Kim or Salah with Invisalign

A POSA would not have been motivated to combine Kim or Salah with Invisalign. Kim and Salah disclose a fundamentally different approach from Invisalign, and there is nothing in the prior art that suggests their methods could be combined. EX2002, ¶90. Kim and Salah relate to *remote* monitoring of *teeth positions* using images of the patient’s teeth captured *without aligners* in place. EX1005 at [0010]; EX1008 at 2:21–27; EX2002, ¶90. By contrast, Petitioner’s own prior art, Invisalign, describes a visual approximation performed *in person* when the patient visits the orthodontist’s office. EX1006 at ii (recommending that dental professionals should “perform the following [certain steps] *at every patient appointment*” (emphasis added)); EX2002, ¶90; EX2004, ¶29. In Invisalign, Petitioner does not disclose any way to remotely “evaluat[e] the shape of an orthodontic aligner” using images *with or without aligners* in place. EX2002, ¶90; EX2004, ¶31. Indeed, as of June 2017, Petitioner had no product that could be used with its clear aligners to virtually assess treatment progress. EX2007. A POSA would not have been motivated to combine Invisalign’s visual *in-person approximation* with the remote assessments in Kim or Salah because neither

Invisalign, nor any of the cited prior art, suggests that “the shape of an orthodontic aligner” can be *remotely* evaluated *from an aligner image* or describes how that could be done. EX2002, ¶90; *see Samsung Elecs. Co., Ltd. v. Promos Techs., Inc.*, IPR2017-01418, Paper 33 at 68–74 (PTAB Nov. 27, 2018) (holding that Petitioner failed to present “adequate motivation” where the prior art methods were not compatible).

Petitioner’s assertion that the combination of Kim and Invisalign “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” (Pet. at 20), is incorrect for several reasons.

First, Invisalign describes only the practice of in-person aligner treatment that was conventional as of June 2017. As explained by Dr. Kusnoto, during in-person check-ins, an orthodontist would conventionally conduct a qualitative visual or manual examination of a patient’s aligner fit. EX2004 at 30. Dental practitioners did not and could not accurately measure the separation between an aligner and teeth for treatment assessment because they could not detect with their naked eye and had no technology to measure spaces between the aligner and teeth, which generally are less than 1 mm. *Id.* In particular, Petitioner has produced no evidence that

orthodontists would determine interior and exterior tooth outlines from an aligner image, or compare interior and exterior tooth outlines so as to determine at least one score according to said comparison.

Second, Kim does not disclose analysis of a photo or video of the aligner as worn by a patient. Instead, Kim discloses only the acquisition of images of a patient's teeth. Specifically, "[t]he teeth alignment report information" sent by the patient may include "a front-view *teeth* photo, a bottom-view low-angle *teeth* photo, a front-view automatically-recognized mouth gag photo, a front-view automatically-recognized face contour photo, a left-side-angle automatically-recognized mouth gag photo, a left-side-angle automatically-recognized face contour photo, a right-side-angle automatically-recognized mouth gag photo, a right-side-angle automatically-recognized face contour photo, a collection of top, bottom, left, and right side photos surrounding a central front photo, a low-angle upper jaw photo, a high-angle lower jaw photo, and combinations thereof, which are taken using a camera of the orthodontic patient terminal." EX1005 at [0013] (emphasis added); *see also id.* at [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); EX2002, ¶92. As noted above, Petitioner appears to accept that Kim does not

disclose analysis of a photo or video of the aligner as worn by the patient. *See* Section VI.A; EX2002, ¶¶71–76, 90–95.

Third, Kim does not suggest any non-human analysis of the images of a patient's teeth. Contrary to Petitioner's unsupported assertions of predictability, determining the separation between the aligner and teeth, for example, whether the separation was greater or less than 1 mm, would not have been possible without a method for determining the scale of the image—a method described nowhere in Petitioner's references. EX2002, ¶93; EX2004, ¶30.

Finally, Petitioner's reliance on Patent Owner's statements during prosecution to support the combination of Salah with Kim (or Invisalign) is also misplaced. Pet. at 22, 31. When responding to a rejection under 35 U.S.C. § 112, Patent Owner 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. EX1004 at 241–242. However, Patent Owner never admitted that the prior art taught or suggested making a determination of interior or exterior tooth outlines using an aligner image. And as explained further below, neither Salah, nor any of Petitioner's references, describe the detection of contours of an aligner in an image depicting the patient wearing the aligner on the patient's teeth.

For all of the reasons above, Petitioner's purported motivation to combine should be rejected.

VIII. The Board Should Decline to Institute Because Petitioner's References Do Not Disclose Acquisition of an Aligner Image

To succeed on obviousness, a petitioner must “explain adequately how the references teach or render obvious the [claim] limitation[s].” *NetApp Inc. v. Crossroads Sys., Inc.*, IPR2014-01233, 2015 WL 996342, at *5 (Patent Tr. & App. Bd. Feb. 10, 2015). In particular, a petition “must specify where each element of the claim is found in the prior art patents or printed publications relied upon.” 37 C.F.R. § 42.104(b)(4). A claim is not obvious where an element is missing from the prior art combination. *Orthopediatrics Corp. v. K2m, Inc.*, IPR2018-00521, Paper 38 at 19–22 (PTAB June 4, 2019) (holding that Petitioner failed to establish by a preponderance of the evidence that a claim was unpatentable when neither reference disclosed an element of the claim); *Cooler Masters Co., Ltd. v. Aavid Thermalloy LLC*, IPR2019-00144, Paper 55 at 43–47 (PTAB June 4, 2020) (holding that a combination failed to render claims obvious where neither reference disclosed a “hollow column,” as claimed).

Even if a POSA were motivated to combine the references, none disclose acquisition of an image of an aligner, as worn by a patient, during a method of evaluating the shape of an aligner. This is fatal to Petitioner's case because all of the Challenged Claims require “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.”

As discussed above, and recognized by Petitioner (Pet. at 18), Kim discloses only the acquisition of images of a patient’s teeth. Like Kim, Invisalign also does not disclose the acquisition of an aligner image. *See* Section VI.A; EX2002, ¶¶71–76, 90–95. Invisalign describes aligner issues for which dental practitioners should visually check during in-person, in-office appointments. EX1006 at i–ii; EX2002, ¶¶77–82, 95; EX2004, ¶29. To the extent that Invisalign teaches any image capture, that image capture is done for the purposes of creating aligners, i.e., before the aligners are made, not for evaluating the shape of an existing aligner in a patient’s mouth. EX1006 at iii, 4, 6, 9 (discussing the importance of initial photos and impressions to designing or redesigning aligners to avoid aligner fit problems); EX2002, ¶95; EX2004, ¶32. During prosecution, Patent Owner explained—and the Examiner agreed—that methods for designing aligners are distinct from the Challenged Claims. EX1004 at 254–56; EX2002, ¶95.

Petitioner appears to concede that Invisalign also does not disclose acquisition of an aligner image, arguing instead that Invisalign provides a reason to acquire such an image. Pet. at 26. Petitioner is wrong. Neither Invisalign, nor any of the cited prior art, suggests that the shape of an aligner can be evaluated remotely from an aligner image or describes how that could be done. EX2002 at ¶96.

Salah also does not disclose acquisition of an aligner image. While Petitioner alleges that Salah discloses an image showing an intraoral appliance (Pet. at 27), that intraoral appliance is not an aligner. See EX1008 at Fig. 11; EX2002, ¶97. Moreover, Salah is concerned with the use of an updated 2D image of a patient's teeth *without aligners* to identify a final 3D reference model that corresponds to the position of the teeth in the updated 2D image, and compares that final 3D model with the initial 3D reference model to determine tooth displacement. EX1008 at 1:1–2:19; EX2002, ¶97. This is a fundamentally different approach from the Challenged Claims, and nothing in Salah suggests that aligner images could be acquired for evaluating the shape of an aligner.¹ EX2002, ¶97.

¹ Petitioner points to yet another reference, Frey, in support of the alleged obviousness of using aligner images. Pet. at 20. But Frey also does not cure the defects in Petitioner's case because Frey states that videos work better than individual photos. EX1009 at 19. Frey also does not explain how to implement a remote evaluation of the shape of an aligner, and instead calls out the benefit of remote monitoring to address other issues: "loose/broken appliances, wire pokes, and other patient concerns so that [the orthodontist's] team can schedule repair *appointments* more effectively," and "[r]educd appointments when using

(Cont'd on next page)

Accordingly, Petitioner’s references fail to disclose acquisition of an aligner image for purposes of assessing the shape of an aligner, and its Petition should be rejected.

**IX. The Board Should Decline to Institute Because
Petitioner’s References Do Not Disclose Use of Image
Processing Software To Determine Interior and Exterior Tooth Outlines**

Again, even if a POSA were motivated to combine Petitioner’s references, that combination does not disclose nor render obvious 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,” as required by all Challenged Claims. *See Orthopediatrics*, IPR2018-00521, Paper 38 at 19–22; *Cooler Masters*, IPR2019-00144, Paper 55 at 43–47.

Petitioner relies heavily on Salah’s detection of discriminant information, improperly picking and choosing disclosure from different inventions in Salah with the benefit of hindsight knowledge of the inventions in the Challenged Claims. *See* Pet. at 30 (citing EX1008 at 55:21–56:7 (relating to a method for checking the

appliances that do not require doctor activation (Invisalign, *elastic bite correction, jack screw expanders, habit appliances*, etc.).” *Id.* at 26 (emphasis added); EX2002, ¶97.

appearance of teeth (*id.* at 52:6)), 34:5–14 (relating to a method for controlling tooth positioning (*id.* at 19:22)), and Fig. 11 (relating to a method using reflection information (*id.* at 64:7–8))); EX2002, ¶100–101. Petitioner further notes that Salah discloses a contour map of detected tooth edges showing the outline of teeth in Fig. 6b. Pet. at 30. But Salah nowhere suggests the use of image processing to detect aligners, let alone determine exterior tooth outlines representing the outline of the free end of said tooth on the aligner images. EX2002, ¶100.

Salah instead discloses a method of monitoring tooth movements that uses an updated 2D image of a patient’s teeth *without aligners* to identify a final 3D reference model that corresponds to the position of the teeth in the updated 2D image, which final 3D model is then compared with the initial 3D reference model in order to determine tooth displacement for any type of orthodontic or dental treatment, independent of the type of any appliance. EX1008 at 46:9–14, 1:1–2:22; EX2002, ¶100. 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. EX2002, ¶100. 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 at 254–56; EX2002, ¶100.

Nonetheless, Petitioner alleges that Salah discloses an example of a reference map generated for an image with an intraoral appliance. Pet. at 30 (citing EX1008 at Fig. 11). That intraoral appliance, however, is not an aligner. *See* EX1008 at Fig. 11; EX2002, ¶101. And the discriminant information used to generate this map was reflection information, not contour information. EX1008 at 64:7–8; EX2002, ¶101.

Regarding contour information, Salah teaches that image processing can be used to “detect high contrast regions and determine contours.” EX1008 at 34:13–14; EX2002, ¶101. As the inventors’ own translation of Salah goes on to explain, however, “in the example of an outline, the analysis of the contrast provides, for example, more or less reliable information.” EX2008 at [0531]; EX1008 at 60:17–24; EX2002, ¶101. “[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.” EX2008 at [0531]; EX1008 at 60:17–24; EX2002, ¶101. Salah thus recommends processing the reference image to retain only the outlines identified with a high probability. EX2008 at [0533]; EX1008 at 61:2–4; EX2002, ¶101. But aligners are generally transparent and do not represent any strong contrast with a patient’s teeth or the inside of the patient’s mouth. EX1001

at 27:35–43 (“An aligner conventionally takes the form of a removeable single-piece appliance, conventionally made of a transparent polymer material”); EX2002, ¶102. Accordingly, a POSA would not have understood Salah to teach or suggest analysis of an *aligner* image by means of image processing software so as to determine for each of a plurality of teeth an exterior tooth outline representing the outline of the free end of said tooth on the aligner image. EX2002, ¶102.

Kim does not cure this defect in Petitioner’s case. Kim discloses only that the orthodontist conducts some unspecified analysis of images of patient’s teeth without aligners. *See, e.g.*, EX1005 at [0085] (“Then, as illustrated in FIG. 19, the orthodontist may check the transmitted teeth alignment report information per patient using the orthodontist terminal.”), [0066] (teeth alignment report information is transmitted “in such a manner that the orthodontist checks a photo or a video”); EX2002, ¶103. Indeed, in its analysis of Step 1(3), Petitioner makes only passing reference to Kim. Pet. at 32. Petitioner rightly does not contend that Kim discloses “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 required by all Challenged Claims. Kim does not. EX2002, ¶103.

Invisalign also does not disclose analysis of an aligner image by means of 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 at 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); EX2002, ¶104; EX2004, ¶29. Invisalign does not suggest that such an approach could be applied to the analysis of aligner images using image processing software. EX2002, ¶104. And as set forth above, Salah would have taught a POSA that, given the lack of strong contrast, it could not. EX2002, ¶104.

Finally, Petitioner points again to Patent Owner’s statements during prosecution. Pet. at 31. In doing so, Petitioner misstates the file history. As explained above, Patent Owner simply 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. Section VI. Patent Owner never admitted that the prior art taught or suggested making a determination of interior or exterior tooth outlines using an aligner image. *Id.*

In sum, Petitioner’s references fail to disclose “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.” Moreover, because none of the references disclose Step 1(3), Petitioner’s references also fail to disclose Step 1(4): “comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.” For this additional reason, the Petition should be rejected.

**X. The Board Should Decline to Institute
Because a POSA Would Not Have Had a Reasonable
Expectation of Success in Combining Kim, Invisalign, and Salah**

Petitioner has also failed to show that a POSA would have had a reasonable expectation of success in combining Kim, Invisalign, and Salah. It is the burden of the Petitioner to explain in the Petition why the skilled artisan would have had a reasonable expectation of success in achieving the claimed invention by combining references as proposed in the Petition. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015) (“Failure to prove the matter as required . . . means that the party with the burden of persuasion loses on that point—thus, if the fact trier of the issue is left uncertain, the party with the burden [the petitioner] loses.”).

Petitioner asserts that its prior art “combination would use each reference’s teachings to perform substantially the same function as they provide alone.” Pet. at 23. But contrary to Petitioner’s assertion, Salah nowhere discloses “contour detection to detect edges of teeth *and aligners*” and Invisalign nowhere discloses a

method for “**measurement** of distance between these surfaces.” Thus, the ’945 Patent does not simply arrange old elements with each performing the same function it had been known to perform in the prior art. EX2002, ¶¶ 71–89, 107

Salah’s analysis method is also fundamentally different—comparing the position of the same discriminant information on different images, not teeth and aligner edges as in the ’945 Patent. EX2002, ¶108. A POSA would not have had a reasonable expectation of success based on Petitioner’s prior art because Salah discloses that “a zone of weak contrast,” such as between the aligner and the teeth, can only be “likened to a zone corresponding to an outline with a low probability,” and preferably should not be used for any analysis. EX2008 at [0531], [0533]; EX1008 at 60:17–24, 61:2–4.; EX2002, ¶108.

Finally, guided by its current knowledge of the ’945 Patent, Petitioner and its expert seek to reconstruct the analysis recited in the Challenged Claims from the disclosure of Salah. Pet. at 31–32 (citing EX1002, ¶¶83-84). But Petitioner’s hindsight-based efforts to show that a POSA **could** have performed the methods recited in the ’945 Patent Challenged Claims do nothing to demonstrate that a POSA **would** have been motivated to perform the claimed methods with a reasonable expectation of success without the ’945 Patent in hand. *See, e.g., Nautilus v. Hyosung Inc. v. Diebold Self-service Systems division of Diebold*, IPR2016-00633, Paper 9 at 21 (PTAB Aug. 22, 2016) (denying institution for failure to meet

Petitioner’s burden with respect to motivation to combine, stating that “[a]n assertion that something could be done does not articulate a reason why something would be done by one of ordinary skill in the art at the time of the invention and, therefore, raises a specter of impermissible hindsight bias in an obviousness analysis”).

For the above reasons, Petitioner has failed to meet its burden to show that a POSA would have had a reasonable expectation of success in combining references as proposed in the Petition, and the Petition should also be denied on this basis.

XI. The Director Should Invoke Her Discretionary Authority to Deny Institution of the Petition

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016).

Here, the Director should exercise her discretion to deny institution under 35 U.S.C. § 325(d) and *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 9 (PTAB Feb. 13, 2020) (precedential) because Petitioner has not met its burden of showing that the same or substantially the same art and arguments were not already considered and appropriately rejected by the Examiner with respect to the ’945 Patent. Petitioner also failed to make any showing regarding whether the Examiner materially erred.

Under § 325(d), the Board uses the following two-part framework to assess whether discretionary denial is proper: (1) whether the same or substantially the same art previously was presented to the Examiner or whether the same or substantially the same arguments previously were presented to the Examiner; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Examiner erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8–9.

Here, Petitioner provides no evidence that the art asserted in the Petition is nonduplicative of the art considered during prosecution. Instead, Petitioner provides only attorney argument that the art must be nonduplicative in light of its substantive arguments regarding the asserted references. Pet. at 47–48. Notably, Petitioner does not compare any reference to any art considered by the Examiner, or provide any explanation as to any material differences between the art considered by the Examiner and the cited prior art.

Petitioner cannot meet its burden because the art asserted in the Petition is duplicative of the art considered by the Examiner. For example, Salah is considered art, is cited in the '945 Patent, was cited in the original specification, and appears in the prosecution search history. EX1001 at 7:9, 7:26, 7:28, 7:42, 9:7–8; EX1004 at 20, 139, 222, 224, 225, 274, 281, 283; EX2002, ¶110. Petitioner admits as much.

Pet. at 47. Without citing any cases or factual reasons why it matters, Petitioner contends that, because the version in the prosecution history did not include a certified translation in English, Salah should not be considered art. But this is a red herring. The related U.S. patent application was published as U.S. Pub. No. 2017/0325689 in English on November 16, 2017. EX2008. Because the substance of Salah was available to and considered by the Examiner, Petitioner's attempt to obscure the record should be rejected.

Petitioner cites Kim in part for the same reasons as Salah. Pet. at 21. Thus, Kim is duplicative of Salah in those respects. EX2002, ¶110. In addition, as recognized by the Examiner, Greenberg, Wen, and Kitching also relate to the creation of aligners or the comparison of one representation of a patient's teeth to another to track the progress of tooth movement. EX1004 at 256. This is the same disclosure as: Kim, which discloses that the orthodontist provides aligner advice based on the position of the teeth; Salah, which discloses a comparison to an initial reference model in order to determine tooth displacement between acquisition of the initial reference model and the updated image; and Invisalign, which discusses the collection of images for the purposes of aligner design and manufacture. Section VI.

Petitioner also cites Kim, as well as Invisalign, for alleged disclosure of the element of determining aligner separation that is missing from Salah. *E.g.*, Pet. at

17–20. But the '945 Patent itself discusses the state of the art, stating that “[a]t regular intervals, the patient visits the orthodontist for a visual inspection, notably to check . . . whether the aligner being worn by the patient is still suitable for the treatment.” EX1001 at 1:42–45; EX2002, ¶112. For the same reasons the claims of the '945 Patent were not obvious over orthodontist’s practice of in-person checks to see if aligners were still suitable for treatment, they remain nonobvious in light of Kim and Invisalign. EX2002, ¶112.

Accordingly, Petitioner has not and cannot meet its burden to show that the asserted art or corresponding arguments are nonduplicative of those considered by the Examiner, or that there was material error by the Examiner. The Director should thus exercise her discretion to deny institution.

XII. Conclusion

For the foregoing reasons, Patent Owner respectfully submits that the Board should deny institution of this Petition.

Date: February 20, 2024

Respectfully submitted,

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Certificate of Word Count

The undersigned hereby certifies that the portions of the above-captioned **DENTAL MONITORING SAS'S PATENT OWNER'S PRELIMINARY RESPONSE** specified in 37 C.F.R. § 42.24 has 10,184 words in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24. This word count was prepared using Microsoft Word 2016.

Date: February 20, 2024

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Certificate of Service

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on February 20, 2024, a complete copy of **DENTAL MONITORING SAS'S PATENT OWNER'S PRELIMINARY RESPONSE** was served in their entirety on the Patent Owner's counsel of record by email to:

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