

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALIGN TECHNOLOGY, INC.,

Petitioner,

v.

DENTAL MONITORING SAS,

Patent Owner.

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Case No. IPR2024-00052

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

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**PATENT OWNER'S PRELIMINARY RESPONSE**

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## TABLE OF CONTENTS

|                                                                                                                                                                                                                                                   | <u>Page</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| I. Introduction .....                                                                                                                                                                                                                             | 1           |
| II. Aligner Treatment .....                                                                                                                                                                                                                       | 3           |
| III. The '248 Patent.....                                                                                                                                                                                                                         | 6           |
| IV. Prosecution History .....                                                                                                                                                                                                                     | 13          |
| V. Claim Constructions and POSA Definition.....                                                                                                                                                                                                   | 17          |
| VI. Overview of References .....                                                                                                                                                                                                                  | 17          |
| A. U.S. Patent Publication No. 2017/0281313 to<br>Kim et al. (“Kim”) .....                                                                                                                                                                        | 17          |
| B. Invisalign Clinical Monitoring Guide<br>(“Invisalign”) .....                                                                                                                                                                                   | 21          |
| C. PCT Publication No. WO2016066651 to Salah<br>et al. (“Salah”).....                                                                                                                                                                             | 24          |
| D. “Convolutional Oriented Boundaries: From<br>Image Segmentation to High-Level Tasks”<br>(“Maninis”) .....                                                                                                                                       | 27          |
| VII. The Board Should Decline to Institute Because a POSA<br>Would Not Have Been Motivated to Combine Kim,<br>Invisalign, Salah, and Maninis .....                                                                                                | 28          |
| VIII. The Board Should Decline to Institute Because<br>Petitioner’s References Do Not Disclose Acquisition of<br>an Analysis Image .....                                                                                                          | 34          |
| IX. The Board Should Decline to Institute Because<br>Petitioner’s References Do Not Disclose Analysis With a<br>Deep Learning Device So As to Determine an Attribute<br>Value Relating to a Separation Between the Tooth and<br>the Aligner ..... | 38          |
| X. The Board Should Decline to Institute Because a POSA<br>Would Not Have Had a Reasonable Expectation of<br>Success in Combining Kim, Invisalign, Salah, and<br>Maninis .....                                                                    | 43          |

|      |                                                                                                     |    |
|------|-----------------------------------------------------------------------------------------------------|----|
| XI.  | The Director Should Invoke Her Discretionary Authority<br>to Deny Institution of the Petition ..... | 47 |
| A.   | The Same or Substantially the Same Art Was<br>Previously Presented to the Office .....              | 47 |
| B.   | The Fintiv Factors Also Weigh Against Institution .....                                             | 51 |
| XII. | Conclusion .....                                                                                    | 57 |

## TABLE OF AUTHORITIES

|                                                                                                                             | <u>Page(s)</u> |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Cases</b>                                                                                                                |                |
| <i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i><br>IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020)..... | 27, 47         |
| <i>Apple, Inc. v. Fintiv, Inc.,</i><br>2020 WL 2126495 .....                                                                | 51, 52         |
| <i>Asia Vital Components Co., Ltd. v. Asetek Danmark A/S,</i><br>377 F. Supp. 3d 990 (N.D. Cal. 2019).....                  | 32             |
| <i>Becton, Dickinson &amp; Co. v. B. Braun Melsungen AG,</i><br>IPR2017-01586, Paper 8 (Dec. 15, 2017) .....                | 50             |
| <i>Belden Inc. v. Berk-Tek LLC,</i><br>805 F.3d 1064 (Fed. Cir. 2015) .....                                                 | 32             |
| <i>Comcast Cable Commun., LLC v. Rovi Guides, Inc.,</i><br>IPR2017-00742, Paper 32 (PTAB Aug. 7, 2018).....                 | 44             |
| <i>Cooler Masters Co., Ltd. v. Aavid Thermalloy LLC,</i><br>IPR2019-00144, Paper 55 (PTAB June 4, 2020) .....               | 35, 38         |
| <i>Cuozzo Speed Techs., LLC v. Lee,</i><br>136 S. Ct. 2131 (2016).....                                                      | 47             |
| <i>Dental Monitoring SAS v. Align Technology, Inc.,</i><br>No. 3-22-cv-07335 (NDCA).....                                    | 51             |
| <i>Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.,</i><br>800 F.3d 1375 (Fed. Cir. 2015) .....                              | 43             |
| <i>Harmonic Inc. v. Avid Tech, Inc.,</i><br>815 F.3d 1356 (Fed. Cir. 2016) .....                                            | 47             |
| <i>KSR Int’l Co. v. Teleflex Inc.,</i><br>550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007).....                      | 33             |

## TABLE OF AUTHORITIES

(continued)

|                                                                                                                                               | <u>Page(s)</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <i>MaxLite, Inc. v Jiaxing Super Lighting Elec. Appliance Co.</i> ,<br>IPR2020-00208, Paper 10 (PTAB June 24, 2020) .....                     | 13             |
| <i>Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH</i> ,<br>139 F.3d 877 (Fed. Cir. 1998) .....                                             | 31             |
| <i>Monsanto Co. v. Pioneer Hi-Bred Int’l, Inc.</i> ,<br>IPR2013-00022, Paper 43 (PTAB Apr. 11, 2013) .....                                    | 44             |
| <i>Nautilus v. Hyosung Inc. v. Diebold Self-service Systems division of<br/>Diebold</i> ,<br>IPR2016-00633, Paper 9 (PTAB Aug. 22, 2016)..... | 31             |
| <i>NetApp Inc. v. Crossroads Sys., Inc.</i> ,<br>IPR2014-01233, 2015 WL 996342 (Patent Tr. & App. Bd. Feb. 10,<br>2015).....                  | 34             |
| <i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> ,<br>520 F.3d 1358 (Fed. Cir. 2008) .....                                               | 33             |
| <i>Orthopediatrics Corp. v. K2m, Inc.</i> ,<br>IPR2018-00521, Paper 38 (PTAB June 4, 2019) .....                                              | 34, 38         |
| <i>Samsung Elecs. Co., Ltd. v. Promos Techs., Inc.</i> ,<br>IPR2017-01418, Paper 33 (PTAB Nov. 27, 2018).....                                 | 29, 30         |
| <i>Samsung Electronics Co. Ltd. v. California Institute of Technology</i> ,<br>IPR2023-00130, Paper 10 (PTAB May 4, 2023) .....               | 54             |
| <i>Sand Revolution II, LLC v. Continental Intermodal Group – Trucking<br/>LLC</i> ,<br>IPR2019-01393, Paper 24 (PTAB June 16, 2020) .....     | 55             |
| <i>SAS Inst. Inc. v. Iancu</i> ,<br>138 S. Ct. 1348 (2018).....                                                                               | 46             |
| <i>Sotera Wireless, Inc. v. Masimo Corp.</i> ,<br>IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) .....                                           | 55             |

**TABLE OF AUTHORITIES**  
(continued)

|                                                                                                                                                    | <u>Page(s)</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <i>Velander v. Garner</i> ,<br>348 F.3d 1359 (Fed. Cir. 2003) .....                                                                                | 44             |
| <i>W.L. Gore &amp; Assoc., Inc. v. Garlock, Inc.</i> ,<br>721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469<br>U.S. 851 (1984) ..... | 33             |
| <i>WBIP, LLC v. Kohler Co.</i> ,<br>829 F.3d 1317 (Fed. Cir. 2016) .....                                                                           | 31             |
| <b>Statutes</b>                                                                                                                                    |                |
| 35 U.S.C. § 314(a) .....                                                                                                                           | 46             |
| 35 U.S.C. § 316(a)(11) .....                                                                                                                       | 53             |
| <b>Other Authorities</b>                                                                                                                           |                |
| MPEP 2141.02.VI.....                                                                                                                               | 33             |
| <b>Regulations</b>                                                                                                                                 |                |
| 37 C.F.R. § 42.104(b)(4) .....                                                                                                                     | 34             |

**EXHIBIT LIST**

| <b>Exhibit Number</b> | <b>Description</b>                                                                                                                                                                   |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2002                  | Declaration of John T. Mongan, M.D., Ph.D., dated January 30, 2024                                                                                                                   |
| 2003                  | Curriculum Vitae of John T. Mongan, M.D., Ph.D.                                                                                                                                      |
| 2004                  | Declaration of Budi Kusnoto, D.D.S., M.S., dated January 30, 2024                                                                                                                    |
| 2005                  | Curriculum Vitae of Budi Kusnoto, D.D.S., M.S.                                                                                                                                       |
| 2006                  | September 28, 2022 Press Release of Petitioner, Align Technology, Inc.                                                                                                               |
| 2007                  | Rui Zhao et al., <i>Changing Clear Aligners Every 10 Days or 14 Days? A Randomised Controlled Trial</i> , 39(1) Australasian Orthodontic J. (2023)                                   |
| 2008                  | May 7, 2020 Press Release of Petitioner, Align Technology, Inc.                                                                                                                      |
| 2009                  | U.S. Pat. Pub. 2017/0325689 (Dental Monitoring's English Language Translation of the International Patent Application published as Salah (PCT Publication No. WO2016066651))         |
| 2010                  | J. Liu et al., Machine learning in orthodontics: Challenges and perspectives, 30(10) <i>Advances in Clinical and Experimental Medicine</i> 1065                                      |
| 2011                  | <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 59, Order Denying Second Motion to Dismiss (N.D. Cal., July 19, 2023)                        |
| 2012                  | <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 97, Align's Notice of Pending <i>Inter Partes</i> Review Petition (N.D. Cal., Dec. 18, 2023) |
| 2013                  | <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 92, Order Re Updated Patent Showdown                                                         |

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|      | Deadlines (N.D. Cal., Oct. 26, 2023)                                                                                                                                                                                                                                                                                                                      |
| 2014 | <i>Docket Navigator Report on Time to Trial in cases before Judge Alsup (Excluding Outliers)</i>                                                                                                                                                                                                                                                          |
| 2015 | <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Dkt. No. 56, Patent Showdown Scheduling Order (N.D. Cal., July 14, 2023)                                                                                                                                                                                                   |
| 2016 | <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , Case No. 22-cv-07335, Defendant's Patent Local Rule 3-3 and 3-4 Initial Invalidity Contentions and Disclosures (N.D. Cal., Sept. 11, 2023)                                                                                                                                                       |
| 2017 | The PASCAL-Context Dataset (June 13, 2017 version available at <a href="https://web.archive.org/web/20170613074321/https://cs.stanford.edu/~roozbeh/pascal-context/">https://web.archive.org/web/20170613074321/https://cs.stanford.edu/~roozbeh/pascal-context/</a> )                                                                                    |
| 2018 | The PASCAL VOC 2010 Dataset (July 7, 2017 version available at <a href="https://web.archive.org/web/20170707024736/http://host.robots.ox.ac.uk/pascal/VOC/voc2010/#data">https://web.archive.org/web/20170707024736/http://host.robots.ox.ac.uk/pascal/VOC/voc2010/#data</a> )                                                                            |
| 2019 | The Berkeley Segmentation Data Set (BSDS 500) (July 22, 2016 version available at <a href="https://web.archive.org/web/20160722194737/http://www.eecs.berkeley.edu/Research/Projects/CS/vision/grouping/resources.html">https://web.archive.org/web/20160722194737/http://www.eecs.berkeley.edu/Research/Projects/CS/vision/grouping/resources.html</a> ) |
| 2020 | The PASCAL VOC 2012 Segmentation dataset (July 13, 2017 version available at <a href="https://web.archive.org/web/20170713000522/http://host.robots.ox.ac.uk/pascal/VOC/voc2012/#data">https://web.archive.org/web/20170713000522/http://host.robots.ox.ac.uk/pascal/VOC/voc2012/#data</a> )                                                              |
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| 2023 | Emilia Taneva, Budi Kusnoto, Carla A. Evans, <i>Chapter 9: 3D Scanning, Imaging, and Printing in Orthodontics, Issues in Contemporary Orthodontics</i> (Farid Bourzgui 2015)                          |
| 2024 | Orhan Tuncay et al., <i>Effectiveness of a Compliance Indicator for Clear Aligners</i> , 43(4) J. Clin. Orthod. 263 (2009)                                                                            |
| 2025 | Silvia Caruso, Sara Caruso, et al., <i>A Knowledge-Based Algorithm for Automatic Monitoring of Orthodontic Treatment: The Dental Monitoring System. Two Cases</i> , 21(5) Sensors (Basel) 1856 (2021) |
| 2026 | Barry J. Glaser, “The Insider’s Guide to Invisalign Treatment,” (3L Publishing, 2017)                                                                                                                 |
| 2027 | Excerpt from Deposition Transcript of Dr. Maureen Valley in IPR-2019-000132                                                                                                                           |

## I. Introduction

Patent Owner, Dental Monitoring SAS, respectfully requests that the Board decline to institute *inter partes* review of U.S. Patent No. 11,049,248 (“the ’248 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, 4, 7–8, and 13–16 of the ’248 Patent (“the Challenged Claims”).

The ’248 Patent relates to new and improved methods of providing orthodontic aligner treatment. Those methods allow for ongoing, accurate, and remote assessment of aligner fit in between in-office orthodontist check-ups, and they offer multiple advantages over the conventional treatment methods as of July 2017. 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 combination of prior art references. Instead, Petitioner combines incompatible methodologies and relies on hindsight to select a ***non-preferred*** image processing method from a long list including well-known and expressly preferred methods. Contrary to Petitioner’s assertions, however, a POSA would not have been motivated to combine Invisalign’s visual ***in-person approximation*** with the remote dental assessments in Kim or Salah because neither Invisalign, nor any of the cited prior art, suggests that aligner fit can be

reliably assessed *remotely* from an aligner image or describes how that could be done.

Petitioner has similarly failed to meet its burden to show that the prior art discloses all of the elements of the Challenged Claims. Petitioner's references disclose a fundamentally different approach to remote orthodontic treatment—one that monitors tooth positions, not aligner fit as in the '248 Patent—and rely on images of a patient's teeth *without aligners*. The asserted prior art neither discloses acquisition of an image of an aligner, as worn by a patient, for the purposes of aligner fit assessment, nor analysis of such an image by means of “a deep learning device, trained by means of a learning base, so as to determine a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner,” as required by all Challenged Claims.

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 generally—or deep learning specifically—to detect aligners, let alone a value for a tooth or image attribute relating to a separation between the tooth and the aligner. Petitioner's efforts to reconstruct the invention using one of the “well-known and *preferred* methods” for image processing in Salah, also does nothing to

establish that a POSA would have reasonably expected success with a different, *non-preferred* methodology listed in Salah.

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 '248 Patent. Similarly, the *Fintiv* factors also support discretionary denial. The parties have already expended, and continue to expend, significant resources in the parallel district court action, in which these identical prior art references and validity issues have been presented. The parties are currently engaged in a “patent showdown” procedure, pursuant to which the parties each select a claim for expedited summary judgment motions. Patent Owner has selected one claim from the '248 Patent, claim 14, for its showdown claim. The hearing on the summary judgment motions is scheduled prior to the institution decision, and if issues remain unresolved, the case is expected to proceed to trial expeditiously thereafter. Accordingly, the district court is the most efficient forum for the parties to litigate these issues.

## **II. Aligner Treatment**

Aligners are one type of orthodontic device designed to exert gentle pressure and thereby reposition a patient's teeth. EX1001 at 4:52–62; EX2002, ¶50; EX2004, ¶¶16, 21. As of July 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 27:26–30; 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 27:26–30; EX2002, ¶50; 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; EX2023 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 27:31–46; EX2002, ¶50; EX2004, ¶19. 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 27:46–47; EX2002, ¶50; EX2004, ¶21. In 2017, effective aligner treatment required frequent in-person orthodontic examinations to determine whether treatment was on track. EX1001 at 17:39–49, 27:55–59; EX2002, ¶50; EX2004, ¶23. 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, ¶24.

Instead, as explained by Dr. Kusnoto—a practicing clinician, researcher, and academic in orthodontics for twenty-five years—conventional aligner treatment examinations as of July 2017 involved two primary qualitative and subjective assessments. EX2004, ¶25. 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 27:55–59 (“At regular intervals, the patient goes to the orthodontist for a visual inspection, notably to check whether the displacement of the teeth conforms to the expectations and whether the aligner worn by the patient is still suited to the treatment.”). Second, orthodontists assessed the aligner treatment for problems with, e.g., aligner fit, tooth attachments, or dentition complications. EX2004, ¶26; EX2026 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, ¶27. 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, ¶25. Reliance on periodic in-person examinations also meant that treatment issues could go undiagnosed for multiple weeks between check-ins. EX1001 17:48–53, 28:1–6; EX2002, ¶50; EX2004, ¶40. 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 27:60–67; EX2002, ¶50; EX2004, ¶28. As a result, aligner treatment was often delayed and prolonged. *Id.* at 27:66–67; EX2002, ¶50; EX2004, ¶28.

### **III. The ’248 Patent**

The ’248 Patent relates to new and improved methods of “assessing the shape of an orthodontic aligner” for purposes of aligner treatment. *See, e.g.*, EX1001 at 28:34–38 (describing the invention as “considerably simplify[ing] the assessment of the good suitability of the aligner to the treatment, while making this assessment particularly reliable”); *see also id.* at 30:60–62 (“The suitability of the aligner can be assessed in the context of an orthodontic treatment (separation [i.e., space between the aligner and the teeth] compatible or not with the orthodontic treatment).”); EX2002, ¶51; EX2004, ¶36.

In particular, the '248 Patent discloses a method comprising “acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, called ‘analysis image.’” EX1001 at 28:13–15; EX2002, ¶52. This step can be “performed at the moment when the assessment of the shape of an aligner is desired, for example more than 1 week after the start of the treatment with the aligner.” EX1001 at 30:27–30; EX2002, ¶52. Importantly, the analysis image can be captured remotely, for example, on a patient’s cellphone. EX1001 at 15:30–35; *see also, e.g., id.* at 19:41–44, 25:60–63; EX2002, ¶52.

The “analysis image” is then analyzed by a specific “deep learning device,” preferably a neural network, that was trained on a specific dataset, a “learning base.” EX1001 at 1:39–43; *see also, e.g., id.* at 1:66–2:1, 16:5–6, 24:3–5; EX2002, ¶53. The '248 Patent describes “training” as a process where, “[b]y presenting, as input for the deep learning device, historical images (images+descriptions), the deep learning device progressively learns to recognize patterns on an image.” EX1001 at 16:38–41; *see also id.* at 16:46–48 (“Through its training in the step 2), the deep learning device is capable of analyzing the analysis image and of recognizing said patterns therein.”); EX2002, ¶53. A deep learning device “trained by means of a learning base” is thus a deep learning device that has undergone the process of training using a collection of images and corresponding attribute values for those images. *See* EX1001 at 16:46–48; EX2002, ¶53. The '248 Patent further discloses

a “detailed analysis method” and a “global analysis method” using the deep learning device. *E.g.*, EX1001 at 1:29–3:18 (detailed), 3:19–4:39 (global); EX2002, ¶53.

In the detailed analysis method, the “analysis image” is analyzed by the deep learning device “so as to determine a value for at least one tooth attribute of an ‘analysis tooth zone’ representing, at least partially, a tooth on said analysis image.” EX1001 at 32:15–19; EX2002, ¶54. The tooth attribute relates “to a separation between the tooth represented by the analysis tooth zone, and the aligner represented on the analysis image.” EX1001 at Abstract, 28:21–24, 32:19–21; EX2002, ¶54. The tooth attribute value thus “provides an information item relating to the shape of the aligner relative to the shape of the teeth of the patient.” EX1001 at 30:42–44; EX2002, ¶54. It “can be a measurement of the separation, for example a measurement of the maximum separation, or of the mean separation for the tooth represented by the historical tooth zone.” EX1001 at 30:45–48; EX2002, ¶54. Alternatively, the tooth attribute values can be, *e.g.*, a tooth number, a tooth type, and a tooth shape parameter. EX1001 at 7:64–8:7, 28:48–61, 30:42–54; EX2002, ¶54.

The deep learning device is trained by means of a learning base comprising, for example, more than 1000 images of dental arches, or “historical images,” each historical image representing an aligner worn by a “historical” patient. EX1001 at 34:23–31; *see also, e.g., id.* at 15:65–16:4, 16:37–43; EX2002, ¶55. Each “historical

image” comprises “one or more zones each representing a tooth, or ‘historical tooth zones’ to each of which, for at least one tooth attribute relating to a separation between the tooth represented by the historical tooth zone considered, and the aligner represented, a tooth attribute value is assigned.” EX1001 at 34:23–31; *see also, e.g., id.* at 1:33–38; EX2002, ¶55.

In one embodiment of the detailed analysis method, the deep learning device analyzes the analysis image—the image of the patient’s dental arch with an aligner in the service position—to determine “at least one probability relating to” “the presence, in a location of said analysis image, of an analysis tooth zone; and the attribute value of the tooth represented on that said analysis tooth zone.” EX1001 at 34:34–40; EX2002, ¶56. As a function of that probability, an amplitude of the separation between the patient’s teeth and the aligner is determined. EX1001 at 34:41–42; EX2002, ¶56.

The analysis may also be performed globally, without identification of the individual situation of each of the teeth represented. *E.g.*, EX1001 at 3:19–4:39; EX2002, ¶57. In this global analysis method, the analysis image is analyzed by a specially trained “deep learning device” so as to determine a value for an image attribute relating to a separation between at least one tooth and the aligner. *E.g.*, EX1001 at Abstract, 29:31–53; EX2002, ¶57. The image attribute relates to the image as a whole and includes the maximal separation, the mean separation, and the

overall acceptability of the separation between the teeth and the aligner. EX1001 at 28:48–61; *see also id.* at 31:20–29 (“For example, the value of the image attribute may be ‘globally acceptable’ or ‘globally unacceptable’. The value of the image attribute can also, for example, be a measurement of the separation, for example a measurement of the maximum separation, or of the mean separation between the teeth represented on the analysis image and the aligner.”); EX2002, ¶57.

Preferably, an “assessment of the suitability of the aligner” is made as a function of the tooth or image attribute value. *E.g.*, EX1001 at Fig. 9, 28:29–31, 32:26–27, 34:60–61; EX2002, ¶58. For example, a search may be “conducted to see if the separation of the aligner with at least one tooth exceeds an acceptability threshold” and, if so, the patient’s aligner replaced by a better suited one. EX1001 at 30:56–59; EX2002, ¶58. As a function of the suitability assessment, an information message may be sent to the patient and/or the orthodontist. EX1001 at 32:35–36; *see also, e.g., id.* at 26:35–27:3; EX2002, ¶58. “The orthodontist can then use this information, possibly in combination with additional information, for example the age of the patient or the duration for which the aligner has been worn, to establish a diagnosis and, if necessary, decide on a suitable treatment.” EX1001 at 31:7–11; EX2002, ¶58.

As described above, the ’248 Patent, and the methods recited in the Challenged Claims, provide for ongoing, accurate, and remote assessment of aligner

fit in between in-office orthodontist check-ins. *Id.* at 31:30–36; EX2004, ¶39. As Petitioner’s Senior Vice President, Dr. Mitra Derakhshan, acknowledged, aligner fit is an “important clinical indicator[] of Invisalign treatment progress tracking and compliance.” EX2006 at 1. Dr. David R. Boschken, a member of Petitioner’s Global Faculty, further stated that an “objective measurement of aligner spaces,” is “the *single most important indicator* of [aligner] treatment tracking.” EX2006 at 2 (emphasis added).

As Dr. Kusnoto explains, because the methods recited in the Challenged Claims of the ’248 Patent are not dependent on in-person assessments, which typically occurred only every 10 weeks, they provide several improvements over conventional aligner treatment methods that were available in July 2017. EX2004, ¶39.

First, with the conventional aligner treatment methods available as of July 2017, a patient could progress through multiple ill-fitting aligners before fit-issues were discovered, and by the time those issues were discovered at an orthodontist’s office, refined aligners might be necessary and aligner fit issues may have worsened—ultimately adding delay and expense to the treatment. EX2004, ¶40. The Challenged Claims, however, provide for accurate and remote assessment of aligner treatment in between in-person orthodontist visits and thereby earlier detection of aligner fit issues. *Id.* This can in some cases fix the issues and avoid

the need for refined aligners or, in other cases, accelerate the process of determining that such refined aligners are necessary. *See, e.g.*, EX1001 at 31:37–41 (“The invention also relates to a method for adapting an orthodontic treatment, a method in which a method for assessing the shape of an orthodontic aligner according to the invention is implemented, then, as a function of the result of said assessment, a new aligner is manufactured . . . .”); EX2004, ¶40

Second, in July 2017, orthodontists typically instructed patients to change aligners every one to two weeks. EX2007 at 1; EX2004, ¶41. By providing for accurate and remote assessment of aligner treatment in between in-person orthodontist visits, the Challenged Claims allow orthodontists to custom tailor aligner intervals to a particular patient’s needs. EX2004, ¶41. For example, if a patient exhibits slower dentition progression, with aligner treatment employing remote monitoring, an orthodontist can prescribe a longer aligner change interval. *See, e.g.*, EX1001 at 31:37–47 (“The invention also relates to a method for adapting an orthodontic treatment, a method in which a method for assessing the shape of an orthodontic aligner according to the invention is implemented, then, as a function of the result of said assessment, . . . the patient is counseled, for example for him or her to improve the conditions of use of his or her orthodontic aligner, in particular the positioning and/or the time bands when it should be worn and/or the maintenance of his or her orthodontic aligner, in order to optimize the treatment.”); EX2004, ¶41.

Alternatively, if aligners become passive on a particular patient very quickly, remote monitoring can allow for shorter intervals, making overall treatment progress more efficient. EX2004, ¶41. The Challenged Claims thus provide for a more personalized and dynamic form of treatment than conventional treatment methods that existed as of July 2017. *Id.*

Third, the Challenged Claims can provide for reliable and quantitative assessment of aligner fit on a tooth-by-tooth basis, which could not be performed by orthodontists during in-person visits. EX2004, ¶42. As described in, for example, Invisalign (EX1006), in 2017, during in-person check-ins, an orthodontist would conventionally conduct a visual examination of a patient's aligner fit. EX2004, ¶42. Unlike the prior art treatment methods, the '248 Patent discloses a method that measures separations to a degree of precision that a dental professional did not—and could not—previously achieve with their naked eye (e.g., spaces less than 1 mm). *Id.*

#### **IV. Prosecution History**

The '248 Patent issued on June 29, 2021 and claims priority to French application No. 1756956, filed July 21, 2017. EX1001; EX2002, ¶69. Petitioner has not challenged, and cannot now challenge, the entitlement of the '248 Patent to this priority date. *See MaxLite, Inc. v Jiaying 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”).

The '248 Patent application was rejected three times before it was granted. In a Non-Final Rejection (February 27, 2020), the Examiner rejected claims 1–4 under 35 U.S.C. § 102 as anticipated by Matov (U.S. Pat. Pub. No. 2013/0230818). EX1004 at 811–18; EX2002, ¶70. Claims 5–6 and 9 were rejected under § 103 over Matov in view of Kuo. EX1004 at 818–22; EX2002, ¶70. Similarly, claims 10–12 were rejected under § 103 over Matov in view of Borovinskih (U.S. Pat. Pub. No. 2017/0049311). EX1004 at 822–24; EX2002, ¶70. Claims 7 and 8 were objected to as depending on rejected claims, but were otherwise found allowable. EX1004 at 824; EX2002, ¶70.

Patent Owner responded (May 27, 2020) by amending the claims and explaining that Matov did not render the application anticipated or, in combination with other prior art, obvious. EX1004 at 839–50; EX2002, ¶71. Patent Owner noted that “Matov does not disclose the acquisition of an image at least partially representing the aligner, and even less in a service position,” as required by claim 1. EX1004 at 842; EX2002, ¶71. And “[t]he aim of Matov is to determine the shape and the positioning of a dental appliance by determining the movement between an

initial position of a tooth and a target position of said tooth” using X-ray images and images to provide information about tooth roots. EX1004 at 843–44; EX2002, ¶71. Patent Owner also pointed out that Matov did “not disclose the submission of an image to a deep learning device,” and any discussion of neural networks was not linked to the images, let alone to determining tooth or image attributes. EX1004 at 844; EX2002, ¶71.

In a Final Rejection (June 19, 2020), the Examiner rejected claims 1–6 and 9–14 under §§ 102 and 103 based again on Matov alone or in combination with Kuo (adding a learning base of more than 1000 images) and Borovinskih (adding a cellphone). EX1004 at 844, 851–72; EX2002, ¶72. Patent Owner responded (September 4, 2020), *id.* at 891–99, by amending the claims to require that the method occur during aligner treatment, i.e., more than 1 week after its start. EX1004 at 893; EX2002, ¶72. Patent Owner further distinguished Matov on the grounds that Matov was directed to the design and selection of an aligner, not to determining the fit of an existing aligner, and Matov did not disclose acquisition of an image with an aligner during treatment. EX1004 at 893; EX2002, ¶72. Patent Owner further argued that Matov did not disclose submitting any image—let alone one with an aligner—to a deep learning device. EX1004 at 893; EX2002, ¶72.

In a Non-Final Rejection (September 28, 2020), *id.* at 902–27, the Examiner again rejected claims 1–6 and 9–16 on the grounds that an image “acquired more

than 1 week after the start of treatment with the aligner” was described in Wen (U.S. Pat. Pub. No. 2017/0300207). EX1004 at 908–09; EX2002, ¶73. Thus, the Examiner rejected the claims under § 103 over Matov in view of Wen (adding acquisition of an image during treatment), Kuo (adding a learning base of more than 1000 images), and Borovinskih (adding a cellphone). EX1004 at 911–26; EX2002, ¶73.

Patent Owner responded (December 28, 2020) noting again that Matov is directed to designing an aligner *before* its manufacture, thus precluding the patient from wearing an aligner in an image. EX1004 at 940–51; EX2002, ¶74. Patent Owner also observed that Matov never suggests the submission of an image with an aligner (or any image) to a deep learning device to determine a value for a tooth attribute relating to a separation between the tooth and the aligner. EX1004 at 940–51; EX2002, ¶74. With respect to Wen, Patent Owner argued that it neither describes the acquisition of an image with an aligner as it is directed to simulating tooth movement, nor determining a tooth attribute relating to separation. EX1004 at 950; EX2002, ¶74.

Following this argument and a telephonic interview, the Examiner issued a Notice of Allowance (February 22, 2021). EX1004 at 954–69; EX2002, ¶75. The Examiner accepted Patent Owner’s December 28, 2020 arguments. EX1004 at 960–61; EX2002, ¶75. Notably, the Examiner acknowledged that “neither Matov nor

Wen teach or suggest, among other things, more than 1 week after the start of the treatment with the aligner, acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, and [a] tooth attribute relating to a separation between the tooth represented by the analysis tooth zone, and the aligner represented on the analysis image, [or that] a cellphone is used to acquire the analysis image.” EX1004 at 960–61 (cleaned up); EX2002, ¶75.

## **V. Claim Constructions and POSA Definition**

Patent Owner does not respond here to Petitioner’s proposed claim constructions (Pet. Section V.D) 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. 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. Kim

was filed April 5, 2016, and was published after the '248 Patent priority date, on October 5, 2017. EX1005, ¶76. Consistent with the '248 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, ¶76; EX2004, ¶23–28.

Kim discloses "a method and system for providing remote teeth alignment services." EX1005 at [0010]; EX2002, ¶77. That method involves an orthodontic patient sending the orthodontist "teeth alignment information using a device, e.g., a smartphone." EX1005 at [0010]; EX2002, ¶77. 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, ¶77.

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, ¶78.

Kim does not expressly disclose “acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient,” as required by all Challenged Claims. EX2002, ¶79. Petitioner appears to recognize as much. Pet. at 21 (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, taking such an image would have been readily apparent in view of Invisalign’s teachings.”). While Kim states that “the orthodontist checks a photo or a video of the clear aligner currently worn,” *id.* at [0066], a POSA would not understand this to refer to an image of the patient wearing the aligner. EX2002, ¶79. Instead, a POSA would understand this language to refer to a photo or video of the aligner that would be used to determine whether the aligner is the correct aligner and whether the aligner has abnormalities, such as damage. *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, ¶79. The images or a video of the aligner is transmitted “in such a manner that the orthodontist checks a photo or a video” and “determines whether the clear aligner is normal and corresponds to an appropriate step.” *Id.*

Kim discloses that the orthodontist provides aligner advice based on the position of the teeth, not the aligner fit itself. *Id.* at [0063] (“the orthodontist accurately determines a current teeth alignment state . . . and advises, for example, an appropriate step of a clear aligner to be currently worn by the orthodontic patient.”); EX2002, ¶80. Kim does not suggest determining a value relating to the separation between the teeth and the aligner, and it does not suggest any non-human analysis of the images. *See, e.g.*, 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, ¶80.

Finally, Kim does not disclose analysis of any image by a deep learning device trained by a learning base. EX2002, ¶81. 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, ¶82; EX2004, ¶43. Invisalign teaches that, “[t]o prevent issues from occurring,” Petitioner recommends that dental professionals “perform the following [certain steps] *at every patient appointment.*” EX1006 at ii (emphasis added); EX2002, ¶82; EX2004, ¶43. For example, Invisalign discloses that dental professionals should have the “*patient arrive* with the previous stage Aligner and the current Aligner” so the dental professional can evaluate any treatment concerns that may arise. EX1006 at (emphasis added); EX2002, ¶82; EX2004, ¶43.

Unlike the Challenged Claims of the ’248 Patent, Invisalign does not disclose any method for remote assessment of aligner fit that can be performed in between in-office orthodontist check-ups. EX2002, ¶83; EX2004, ¶45. This is not surprising because, until 2020, Petitioner did not offer any product to virtually assess aligner treatment progress. EX2008; EX2002, ¶83; EX2004, ¶45.

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. 8 (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, ¶84; EX2004, ¶45. Invisalign makes no suggestion that any image was taken remotely using a cellphone, nor that images should be remotely acquired using a cellphone to assess aligner treatment. EX2002, ¶84; EX2004, ¶45.

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, ¶85; EX2004, ¶44. 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, even in-office. EX2002, ¶85; EX2004, ¶44. As Dr. Kusnoto explains, subjective visual inspections are, however, 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, ¶44.

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 8 (citing EX1002, ¶49). 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 July 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, ¶44. And a POSA would not have been able to make any measurement from the images in Invisalign without the ability to determine the scale of the image. EX2002, ¶85. 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, ¶85. 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, ¶85; EX2004, ¶44.

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 8 (citing EX1006 at ii–iv). That is incorrect. Invisalign discusses only the collection of images for the purposes of aligner design and manufacture. EX2002, ¶86; EX2004, ¶46. 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, 46. Unlike the '248 Patent Challenged Claims, Invisalign does not suggest acquisition of images showing the aligner in the service position in which it is worn by the patient for the purposes of assessing aligner fit. EX2002, ¶86; EX2004, ¶47.

Finally, Invisalign does not disclose analysis of any image by means of a deep learning device trained by a learning base. EX2002, ¶87. 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 '248 Patent. EX2002, ¶88. 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, ¶88.

The method for “checking the positioning and/or shape of teeth according to the invention,” EX1008 at 2:21–22, in Salah starts with the creation of a 3D “initial

reference model” of the patient’s dental arch. EX1008 at 1:28–32; EX2002, ¶89. 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, ¶89. 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, ¶89.

This process involves generating a succession of “to-be-tested” reference models, preferably by a metaheuristic procedure. EX1008 at 39:16–20; EX2002, ¶90. Each model is then used to generate a reference image under virtual acquisition conditions that corresponds 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, ¶90. 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, ¶90. 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,

¶90. 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, ¶90.

In order to compare the images, discriminant information is extracted from each of them. EX1008 at 40:19–20; EX2002, ¶91. Salah discloses multiple different types of discriminant information that can be used: contour information, color information, density information, a distance information, brightness information, saturation information, reflection information and combinations of these. EX1008 at 34:8–10; EX2002, ¶91. This discriminant information is preferably obtained by one of eighteen well-known and preferred methods. EX1008 at 34:15–35:11; EX2002, ¶91. Salah also identifies eighteen other *non-preferred* methods for extracting discriminant information, the last of which is deep learning. EX1008 at 35:12–36:14; EX2002, ¶91.

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, ¶92.

As is apparent from the above, the method for monitoring tooth displacement in Salah is wholly distinct from the method for assessing aligner fit in the '248 Patent. EX2002, ¶93. Salah does not use images showing an aligner in the service position, and it nowhere suggests determining a value for a tooth or image attribute relating to the separation between the aligner and the patient's teeth, nor assessing

the suitability of an aligner treatment, as required by all the Challenged Claims. EX2002, ¶93.

Salah is cited extensively throughout the '248 Patent, and was disclosed in an Information Disclosure Statement (“IDS”) by Patent Owner during prosecution. EX1001 at References Cited, 2:43, 3:10, 7:11, 7:16, 7: 24, 7:41, 8:46, 9:29, 14:41, 17:58, 19:27, 20:43, 22:2, 23:34, 23:39, 23:51, 23:58, 25:9–10, 27:7, 27:15; EX1004 at 80; EX2002, ¶94. 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).

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

Kevis-Kokitsi Maninis et al.’s article entitled “Convolutional Oriented Boundaries: From Image Segmentation to High-Level Tasks” (“Maninis,” EX1007), discloses an approach to perceptual grouping via boundary detection using two different convolutional neural network (“CNN”) architectures. EX1007 at 13; EX2002, ¶95.

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

Maninis is an academic paper. EX2002, ¶97. It makes no mention of the use of its deep learning architecture for any medical application, let alone specifically for aligner treatment or determining a value for at least one tooth or image attribute relating to a separation between the tooth and the aligner. EX2002, ¶97.

## **VII. The Board Should Decline to Institute Because a POSA Would Not Have Been Motivated to Combine Kim, Invisalign, Salah, and Maninis**

A POSA would not have been motivated to combine Kim, Salah, Invisalign and Maninis. EX2002, ¶¶98–101.

First, a POSA would not have been motivated to combine Kim or Salah with Invisalign. Kim and Salah disclose a fundamentally different approach from Invisalign, and there is nothing in the prior art that suggests their methods could be combined. EX2002, ¶99. 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, ¶99. 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, ¶99; EX2004, ¶43. In Invisalign, Petitioner does not disclose any way to remotely monitor aligner fit using images *with or without aligners* in place. EX2002, ¶99; EX2004, ¶45. Indeed, as of July 2017, Petitioner had no product that could be used with its clear aligners to virtually assess treatment progress. EX2008.

A POSA would not have been motivated to combine Invisalign's visual *in-person approximation* with the remote assessments in Kim or Salah because neither Invisalign, nor any of the cited prior art, suggests that aligner fit can be *remotely* assessed from an aligner image or describes how that could be done. EX2002, ¶99; *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). Indeed, determining whether the separation between the aligner and teeth was greater or less than 1 mm would not have been possible without a method for determining the scale of the

image—a method described nowhere in the Petitioner’s references.<sup>1</sup> EX2002, ¶¶99; EX2004, ¶44.

Second, a POSA would not have been motivated to combine Kim, Salah, and/or Invisalign with Maninis. Petitioner asserts that, “to the extent that Salah does not expressly teach using a deep learning device,” “this would have been obvious to a POSA and is taught by Maninis.” Pet. at 24–25. As an initial matter, Petitioner lacks any reasoned basis why a POSA would have been aware of Maninis or selected it from the wealth of computer vision art. This approach runs directly contrary to

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<sup>1</sup> Petitioner points to yet another reference, Frey, in support of its motivation to use images of aligners. But Frey also does not provide a motivation here as it states that videos work better than individual photos. EX1009 at 19. It also does not explain how to implement a remote aligner fit assessment, and instead calls out the benefit of remote monitoring to address other issues: “loose/broken appliances, wire pokes, and other patient concerns so that [the orthodontist’s] team can schedule repair *appointments* more effectively,” and “[r]educd appointments when using appliances that do not require doctor activation (Invisalign, *elastic bite correction*, *jack screw expanders*, *habit appliances*, etc.).” *Id.* at 26 (emphasis added); EX2002, ¶¶99.

the case law counseling against hindsight bias. *See, e.g., Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998) (“Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.”); *see also WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016) (“The real question is whether that skilled artisan would have plucked one reference out of the sea of prior art [. . .]. Whether a skilled artisan would be motivated to make a combination includes whether he would select particular references in order to combine their elements.”). Maninis nowhere mentions the use of its disclosed deep learning architecture for any medical application, let alone specifically for dental or aligner images. EX2002, ¶100. Because Petitioner does not provide any reasoned basis why a POSA would have been aware of or selected Maninis, the Board should reject the alleged motivation to combine as based on improper hindsight. *See WBIP, LLC*, 829 F.3d at 1337.

Furthermore, Petitioner’s reliance on vague “image analysis trends” to provide the motivation to combine Kim, Salah, and Invisalign with Maninis (Pet. 25) is inherently suspect and highly subject to hindsight bias. *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”); *see also Asia Vital Components Co., Ltd. v. Asetek Danmark A/S*, 377 F. Supp. 3d 990, 1005–06 (N.D. Cal. 2019) (striking expert testimony where the expert failed to show a motivation to combine references based on an industry-level trend toward miniaturization). As the Federal Circuit has explained, “obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (emphases in original).

Thus, to prove obviousness, a petitioner must identify concrete reasons why a POSA would have made the specific asserted combination, so as to avoid *ex post* reasoning that the Supreme Court in *KSR* warned against. *See* 550 U.S. 398, 421. The only reference that Petitioner cites from the dental arts that mentions deep learning is Salah. EX2002, ¶100. Salah would not have motivated a POSA to specifically select deep learning for contour detection or combine the dental art with Maninis. EX2002, ¶100. Salah mentions deep learning only once, and even then, as the *last, non-preferred option* in a list of almost 40 potential methods for determining discriminate information. EX1008 at 35:12–36:14, 34:5–36:14; EX2002, ¶100. Salah further discloses multiple different types of discriminant

information that could be used to update 3D dental arch models: “contour information, color information, density information, a distance information, brightness information, saturation information, reflection information and combinations of these.” EX1008 at 34:8–10; EX2002, ¶100. A POSA would have had no reason to combine Salah and Maninis because that combination merely provides a specific non-preferred deep learning architecture for the analysis of tooth positions disclosed in Salah. EX2002, ¶100.

Petitioner does not address any of those other methods or types of discriminate information, nor explain why a POSA would have zeroed in on deep learning for contour detection, as opposed to any of the well-known and *preferred* methods or other types of discriminant information disclosed by Salah. *See, e.g., Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 127 S. Ct. 1727, 1742, 167 L. Ed. 2d 705 (2007) (holding that, for a finding of obviousness, the possible options must be “finite,” “small,” or “easily traversed,” and skilled artisans must have had a reason to select the route that produced the claimed invention)). Petitioner’s failure to consider the prior art as a whole is contrary to the law and exposes the hindsight bias underlying its analysis. *See* MPEP 2141.02.VI (“A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.”) (citing *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721

F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)). Petitioner’s assertions are also contradicted by the testimony of its own dental expert, Dr. Valley. In a prior *inter partes* review proceeding, Dr. Valley testified that “the dental and orthodontic field” is “a very conservative field” and “[i]t takes a while before new methods become mainstream.” EX2027 at 50:3–5; *see also id.* at 50:19–24 (“[I]t takes a while for a conservative group of people -- that is, those in the dental art -- to take in new technologies.”).

Finally, a POSA similarly would have had no reason to combine Maninis with Kim or Invisalign because the cited art contains no suggestion that a deep learning architecture as in Maninis could or should be combined with Kim’s analysis of teeth positions or the Invisalign in-person approximations. EX2002, ¶100.

For all of the reasons above, Petitioner’s purported motivation to combine employs hindsight bias to piece together unrelated and incompatible references and should be rejected.

#### **VIII. The Board Should Decline to Institute Because Petitioner’s References Do Not Disclose Acquisition of an Analysis 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 assessment of aligner treatment. This is fatal to Petitioner’s case because all of the Challenged Claims recite in Step 1(b’): “more than 1 week after the start of the treatment with the aligner, acquisition [using a cellphone] of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, called ‘analysis image’, the analysis image being a photograph, or an image extracted from a film.”

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, ¶104.

As noted above, Petitioner appears to accept that Kim does not disclose acquisition of an image showing an aligner in a service position. *See* Section VI.A; EX2002, ¶¶76–81, 102–108. As such, Petitioner points to Invisalign to try to fill this hole. *Id.* But Invisalign also does not disclose acquisition of an analysis image at least partially representing the aligner in a service position during assessment of aligner treatment. EX2002, ¶¶82–87, 105. Instead, Invisalign describes aligner issues for which dental practitioners should visually check during in-person, in-office appointments. EX1006 at i–ii; EX2002, ¶¶82–87, 105; EX2004, ¶43. To the extent that Invisalign teaches any image capture, that image capture is done for the

purposes of creating aligners, not assessing the fit of those aligners in a patient's mouth. *Id.* at iii, 4, 6, 9 (discussing the importance of initial photos and impressions to designing or redesigning aligners to avoid aligner fit problems); EX2002, ¶105; EX2004, ¶46. During prosecution, Patent Owner explained—and the Examiner agreed—that methods for designing aligners are distinct from the Challenged Claims. EX1004 at 893, 940–51, 960–61; EX2002, ¶105.

Salah also does not disclose acquisition of an analysis image at least partially representing the aligner in a service position. While Petitioner alleges that Salah discloses an example of an image showing an intraoral appliance (Pet. at 30), that intraoral appliance is not an aligner. *See* EX1008 at Fig. 11; EX2002, ¶106. Moreover, Salah concerns the use of an updated 2D image of a patient's teeth ***without aligners*** to identify a final 3D reference model that corresponds to the position of the teeth in the updated 2D image, and compares that final 3D model with the initial 3D reference model to determine tooth displacement. EX1008 at 1:1–2:19; EX2002, ¶106. This is a fundamentally different approach from the Challenged Claims, and nothing in Salah suggests that aligner images could be acquired for assessing aligner treatment. EX2002, ¶106.

Finally, Maninis does not disclose acquisition of an analysis image at least partially representing the aligner in a service position. Maninis has nothing to do

with image acquisition, let alone dental or aligner treatment. *See* EX1007; EX2002, ¶107. Petitioner does not argue otherwise.

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

**IX. The Board Should Decline to Institute Because Petitioner’s References Do Not Disclose Analysis With a Deep Learning Device So As to Determine an Attribute Value Relating to a Separation Between the Tooth and the Aligner**

Again, even if a POSA were motivated to combine Petitioner’s references, that combination does not disclose nor render obvious Step 1(b’): “analysis of the analysis image by means of a deep learning device, trained by means of a learning base, so as to determine a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner,” as required by all Challenged Claims. *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 34–35 (citing EX1008 at 55:21–56:7 (relating to a method for checking the appearance of teeth (*id.* at 52:6)), 34:5–14 (relating to a method for controlling tooth

positioning (*id.* at 19:22)), and Fig. 11 (relating to a method using reflection information (*id.* at 64:7–8))); EX2002, ¶110. Petitioner further notes that Salah discloses a contour map of detected tooth edges showing the outline of teeth in Fig. 6b. Pet. at 35. But Salah nowhere suggests the use of image processing generally—or deep learning specifically—to detect aligners, let alone a value for a tooth or image attribute relating to a separation between the tooth and the aligner. EX2002, ¶111.

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, ¶111. Salah thus discloses an entirely different approach to the Challenged Claims—one that monitors tooth positions, and not aligner fit as in the ’248 Patent. EX2002, ¶111. During prosecution, Patent Owner explained, and the Examiner agreed, that methods of monitoring tooth movement are distinct from the claimed methods that require determination of “a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner.” EX1004 at 947–51, 960–61; EX2002, ¶111.

Nonetheless, Petitioner alleges that Salah discloses an example of a reference map generated for an image with an intraoral appliance. Pet. at 35 (citing EX1008 at Fig. 11). That intraoral appliance, however, is not an aligner. *See* EX1008 at Fig. 11; EX2002, ¶112. And the discriminant information used to generate this map was reflection information, not contour information. EX1008 at 64:7–8; EX2002, ¶112. 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, ¶112.

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.” EX2009 at [0531]; EX1008 at 60:17–24; EX2002, ¶112. “[A] zone of strong contrast can be likened to a zone corresponding to an outline with a high probability,” whereas “a zone of weak contrast, for example a blurred zone, can be likened to a zone corresponding to an outline with a low probability.” EX2009 at [0531]; EX1008 at 60:17–24; EX2002, ¶112. Salah thus recommends processing the reference image to retain only the outlines identified with a high probability. EX2009 at [0533]; EX1008 at 61:2–4; EX2002, ¶112. 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, ¶112.

Accordingly, a POSA would not have understood Salah to teach or suggest analysis of an *aligner* image by means of a deep learning device so as to determine a value for a tooth or image attribute relating to a separation between the tooth and the aligner. EX2002, ¶112.

Maninis does not save Petitioner from the shortcomings of Salah. Maninis discloses boundary detection using two different convolutional neural network (“CNN”) architectures. EX1007 at 13; EX2002, ¶¶95, 113. But it makes no mention of the use of its deep learning architecture for any medical application, let alone specifically for aligner treatment or determining a value for a tooth or image attribute relating to a separation between the tooth and the aligner. EX2002, ¶113. As noted above, adding Maninis to Salah merely provides a specific non-preferred deep learning architecture for the analysis of tooth positions disclosed in Salah. The combination does not disclose or suggest the fundamentally different use of a deep learning device recited in the Challenged Claims of the ’248 Patent, i.e., for “analysis of the analysis image . . . so as to determine a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner.” *Id.*

Kim also 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, ¶114. Indeed, in its analysis of Step 1(b”), Petitioner makes only passing reference to Kim. Pet. at 39–40. Petitioner rightly does not contend that Kim discloses analysis with a deep learning device, or determining a tooth or image attribute value relating to a separation between the tooth and the aligner. It does not. EX2002, ¶114.

Finally, Invisalign also does not disclose analysis of an aligner image by means of a deep learning device so as to determine a tooth or image attribute value relating to a separation between the tooth and the aligner. Rather, Invisalign discloses a visual approximation performed in person by a dental practitioner. EX1006 at ii (dental professionals should have “*patients arrive* with the previous stage Aligner and the current Aligner” so the dental professional can evaluate any treatment concerns that may arise); EX2002, ¶115; EX2004, ¶43. Invisalign does not suggest that such an approach could be applied to the analysis of aligner images using a deep learning device. EX2002, ¶115. And as set forth above, Salah would have taught a POSA that, given the lack of strong contrast, it could not. EX2002, ¶115.

Petitioner’s references thus fail to disclose all elements of the Challenged Claims, and its 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, Salah, and Maninis**

Petitioner has also failed to show that a POSA would have had a reasonable expectation of success in combining Kim, Invisalign, Salah, and/or Maninis. 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 “[a]djusting Maninis’s deep learning device to perform the specific task of identifying teeth and orthodontic aligners would have been straightforward and well within the skill of the POSA.” Pet. at 38. But Maninis does not disclose analysis of any dental images. EX2002, ¶117. Such an analysis is described only in Salah, and even then, the analysis method is fundamentally different—comparing the position of the same discriminant information on different images. EX2002, ¶117. Moreover, as set forth above, a POSA would not have had

a reasonable expectation of success because Salah discloses that “a zone of weak contrast,” such as between the aligner and the teeth, can only be “likened to a zone corresponding to an outline with a low probability,” EX2009 at [0531]; EX1008 at 60:17–24, and preferably should not be used for the analysis. EX2009 at [0533]; EX1008 at 61:2–4.; EX2002, ¶117.

Petitioner also asserts that a POSA would have modified the teaching in Maninis to “provid[e] an appropriately annotated training set and set[] output layers to provide the required object identifications corresponding to the labels used to identify the locations of teeth, aligners, and the gaps between them.” Pet. at 38. But Maninis used only pre-existing, pre-labeled collections of images, all of which were standard datasets for academic research and publicly available for download as of July 2017. EX1007 at 6; EX2017; EX2018; EX2019; EX2020; EX2021. Neither Petitioner, nor its expert, identifies any prior art teaching as to what constitutes an *appropriately* annotated training set, for example, the number and nature of the images, or the labels to apply, in order to train a deep learning device for this specific dental application. EX2002, ¶118. Indeed, even years after the priority date of the ’248 Patent, the art recognized that, “[c]ompared to other medical fields, the high-quality datasets for orthodontic research [we]re limited.” EX2010 at 1072; EX2002, ¶118.

Petitioners unsupported allegations of expected success should be rejected. *See Monsanto Co. v. Pioneer Hi-Bred Int’l, Inc.*, IPR2013-00022, Paper 43 at 6–7 (PTAB Apr. 11, 2013) (denying institution and holding that an unsupported expert opinion was entitled to little weight); *Comcast Cable Commun., LLC v. Rovi Guides, Inc.*, IPR2017-00742, Paper 32 at 34 (PTAB Aug. 7, 2018) (giving little weight to conclusory testimony regarding the meaning of a claim term to a POSA); *Velandier v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (the Board has discretion to accord appropriate weight to broad conclusory statements from expert witness).

Guided by its current knowledge of the ’248 Patent, Petitioner and its expert also seek to reconstruct the analysis recited in the Challenged Claims from the disclosure of Salah. Pet. at 38–39 (citing EX1002, ¶103). But Petitioner’s hindsight-based efforts to show that a POSA *could* have performed the methods recited in the ’248 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 ’248 Patent in hand. Regardless, Petitioner’s expert’s opinion is based on an analysis he only recently performed using a “Canny edge detection technique.” EX1002, ¶103; EX2002, ¶119. As Dr. Foroosh concedes, Canny edge detection does not involve deep learning (EX1002, ¶103), and in contrast to deep learning, it is one of the “well-known and *preferred* methods” for image processing disclosed in Salah. EX1008 at 34:15–16 (emphasis added);

EX2002, ¶119. Moreover, it is not enough to simply detect contours. All of the Challenged Claims require analysis by means of a deep learning device, trained by means of a learning base, “so as to determine a value for at least one tooth [or image] attribute . . . relating to a separation between the tooth . . . and the aligner.” As Dr. Foroosh concedes, *he* “added [the] simple annotations indicating the locations of the edge of a tooth and the edge of a corresponding part of the aligner, as well as showing the separation between the two.” EX1002, ¶103; EX2002, ¶119. Thus, Petitioner’s evidence using Canny edge detection to detect contours does not establish that a POSA would have reasonably expected success in determining the claimed attribute values with a different, *non-preferred* methodology listed in Salah.

Finally, Petitioner asserts that “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.” Pet at 40. Leaving aside that Salah does not suggest detecting the outline or an aligner, nor suggest success in doing so (*see* Section IX), Petitioner nowhere explains how this measurement would be successfully performed. EX2002, ¶119.

Accordingly, 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 because (1) Petitioner has not met its burden of showing that the same or substantially the same art or arguments were not already considered and appropriately rejected by the Examiner; and (2) little, if any, efficiency will be gained by reviewing the Petition in parallel with co-pending litigation, which is unlikely to be stayed and is expected to address the same or substantially the same questions regarding validity, all of which weighs against instituting these proceedings.

### **A. The Same or Substantially the Same Art Was Previously Presented to the Office**

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 '248 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. *Id.* 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 60–61. 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, cited extensively in the specification of the '248 Patent, and was disclosed in an IDS by Patent Owner during prosecution. EX1001 at References Cited, 2:43, 3:10,

7:11, 7:16, 7:24, 7:41, 8:46, 9:29, 14:41, 17:58, 19:27, 20:43, 22:2, 23:34, 23:39, 23:51, 23:58, 25:9–10, 27:7, 27:15; EX1004 at 80; EX2002, ¶122. Petitioner admits as much. Without citing any cases or factual reasons why it matters, Petitioner appears to contend 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. EX2009. 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 24, 30. Thus, Kim is duplicative of Salah in those respects. EX2002, ¶123. Petitioner also cites Kim, as well as Invisalign, for alleged disclosure of the element of determining aligner separation that is missing from Salah and Maninis. Pet. at, e.g., 20–21, 28–29, 32–34. But the ’248 Patent itself discusses the state of the art, stating that “[a]t regular intervals, the patient goes to the orthodontist for a visual inspection, notably to check . . . whether the aligner worn by the patient is still suited to the treatment.” EX1001 at 27:55–59; EX2002, ¶123. For the same reasons the claims of the ’248 Patent were not obvious over orthodontist’s practice of in-person checks to see if aligners were still suitable for treatment, they remain nonobvious in light of Kim and Invisalign. EX2002, ¶123.

Finally, with respect to Maninis, the specification of the '248 Patent discloses exemplary neural networks, a type of deep learning architecture, that perform image classification and object detection and classification (e.g., Faster R-CNN). *See, e.g.*, EX1001 at 16:10–35. The neural network described in Maninis is also capable of performing these tasks. EX2002, ¶124. The only material difference between Maninis and neural networks like Faster R-CNN is that the Maninis neural network can generate a hierarchical organization of detected contours and regions. Neither Petitioner nor Dr. Foroosh discusses how this capability is relevant to performing the steps of the claims or how it would get a POSA closer to the Challenged Claims than the exemplary deep learning architectures already disclosed in the '248 specification. Accordingly, nothing additional is disclosed by Maninis that was not already disclosed in the specification of the '248 Patent. *See, e.g.*, EX1001 at 16:10–35; *see also* EX2002, ¶124. And as is apparent from the face of the '248 Patent, the Examiner had before him numerous other references related to neural networks. EX2002, ¶125. For the same reasons the claims of the '248 Patent were not obvious in light of the deep learning models like Faster R-CNN, they remain nonobvious in light of Maninis. EX2002, ¶126. Regarding whether the Examiner materially erred, Petitioner only states that there must have been some error in allowing the claims. Pet. at 61. Petitioner does not address what that error was or how it was material with respect to the art considered. Because Petitioner also fails to show that the

Examiner erred, discretionary denial is proper. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

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.

**B. The *Fintiv* Factors Also Weigh Against Institution**

Patent Owner and Petitioner are parties to a parallel litigation filed by Patent Owner more than one year ago, on November 18, 2022, and pending before Judge Alsup in the Northern District of California. *Dental Monitoring SAS v. Align Technology, Inc.*, No. 3-22-cv-07335 (NDCA). The parties are currently engaged in a “patent showdown” procedure, pursuant to which the parties each select one claim to proceed on an expedited basis to summary judgment motions. Patent Owner has selected one claim from the ’248 Patent, claim 14, for its showdown claim.

Although the framework set forth in *Apple, Inc. v. Fintiv, Inc.*, 2020 WL 2126495, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) typically applies to cases with parallel invalidity defenses, the factors ultimately “relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view

of an earlier trial date in the parallel proceeding.” *Fintiv, Inc.*, 2020 WL 2126495, at \*3.

In exercising its discretion, the Board evaluates six “*Fintiv* factors.” *Id.* In doing so, “the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.* at 6. Patent Owner addresses each factor in turn:

*Factor (1): Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted.*

A stay is unlikely given that the defendant in the parallel proceeding, Align Technology, Inc.—the same party as the Petitioner here—has not yet requested one or provided evidence that it plans to do so, despite providing notice of the Petition to the Court in the parallel proceeding. Judge Alsup, the judge presiding over the parallel case, did not make any response to such notice that would suggest that the Court intends to grant a stay, if a proceeding is instituted.

In fact, Judge Alsup’s order denying the Petitioner’s second motion to dismiss under Section 101 suggests that Judge Alsup would deny a stay if sought. Specifically, Judge Alsup emphasized that “securing a [just, speedy, and inexpensive] determination of this *action* and proceeding requires us to push forward as planned,” and noted that the patent showdown procedure will narrow “if not settle [the case] entirely.” EX2011. As such, evidence suggests that Judge Alsup views

his patent showdown procedure as the most efficient procedure to resolve the dispute between the parties on the '248 Patent. The denial of a stay by Judge Alsup seems especially likely given that (1) the Court will have received all of the briefing on the patent showdown summary judgment motions by February 15, 2024, will hear those motions on March 18, 2024, and will be close to ruling on (or will have already ruled upon) them by the time an institution decision is made, and (2) the parallel litigation and patent showdown involves a second patent and thus a stay would not resolve all issues in the case.

In summary, this factor weighs in favor of exercising discretionary denial because a stay has not been granted and evidence does not exist that a stay will be granted.

*Factor (2): Proximity of the court's trial date to the Board's projected statutory deadline for a final written decision.*

The Board's decision on institution with respect to the Petition is expected by April 30, 2024, making April 2025 the projected one-year statutory deadline for issuing a final written decision. EX2012; 35 U.S.C. § 316(a)(11). As noted above, the summary judgment hearing on the patent showdown is scheduled for March 18, 2024. EX2013. While Petitioner is correct that no trial date has been set, the median time to jury trial—as this case would be—before Judge Alsup is 19 months from filing. EX2014. The Court previously indicated that it would like to proceed to trial

quickly following the patent showdown, if any outstanding issues remain. EX2015. The parties have agreed to be ready for trial by November 2024—four months before the projected deadline for a final written decision.

Thus, the patent showdown, which may resolve the issues raised in the Petition, will conclude almost a year before the projected deadline for a final written decision. Furthermore, the Court has indicated that the trial on any outstanding issues will quickly follow. As such, this factor also weighs in favor of denying the Petition.

*Factor (3): Investment in the parallel proceeding by the court and the parties.*

The parties have invested significantly in the parallel proceeding because, as mentioned above, the parties are engaged in expedited fact discovery and summary judgment motions for the patent showdown. To begin with, the parties devoted significant resources to select a claim for the showdown and have continued to engage in extensive discovery. For example, each side has served and responded to interrogatories and requests for production (totaling over 100), and two inventors of the '248 Patent have been deposed in addition to two witnesses from Petitioner. Patent Owner has also provided Infringement Contentions, while the Petitioner has served Invalidity Contentions.

Furthermore, both parties' opening and rebuttal expert reports on the patent showdown issues have been completed and exchanged, expert depositions have

occurred, and opening summary judgment briefs on the showdown issues have been filed. Finally, the parties will invest significant resources in drafting opposition briefs, reply briefs, and oral arguments for the patent showdown, all before the Board's projected decision on institution. This work is significant and relates directly to the validity of the '248 Patent. *See, e.g., Samsung Electronics Co. Ltd. v. California Institute of Technology*, IPR2023-00130, Paper 10 at 17–18 (PTAB May 4, 2023), *citing See Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 10–11 (PTAB June 16, 2020).

Not only have the parties invested in the parallel proceeding, but so has the Court. The Court has held hearings, reviewed briefing, and issued orders related to the Petitioner's Motions to Dismiss, case management, and discovery disputes. Furthermore, as mentioned above, the Court will receive all of the briefing related to the patent showdown before the Board's projected decision on institution, which will lead to further investment by the Court in preparation for the showdown.

Given the patent showdown, the parties and the Court have invested, and will continue to invest, significantly in the parallel proceeding. This factor weighs against institution as well.

*Factor (4): Overlap between issues raised in the petition and in the parallel proceeding.*

The Director has made clear that the PTAB will not discretionarily deny institution in view of parallel district court litigation where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB. *See* Director's June 21, 2022 Interim Procedure for Discretionary Denials in AIA Post Grant Proceedings with Parallel District Court Litigation (citing *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A)).

Here, Petitioner has not filed a stipulation of any kind in the parallel proceeding. Instead, Petitioner has raised the exact same grounds in the district court proceeding and its Petition. EX2016. While Petitioner has agreed not to raise obviousness during the showdown procedure, it has not agreed to forgo those arguments following the showdown. In fact, Petitioner has presented all of the presently asserted references to the District Court. In particular, it has asked Judge Alsup to determine whether those references—either alone or in combination—described all of the features of the showdown claims before the priority date of the showdown claims. While Align's request is directed to determining whether the showdown claims were well-understood, routine, and conventional for the purposes of determining patent eligibility under 35 U.S.C. § 101, there remains every reason to deny institution here, where Judge Alsup has already been asked to review the same prior art in the parallel case. After all, a stipulation not to pursue in a parallel

proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB is largely meaningless, where, as here, the Petitioner has already saddled the District Court with the burden of considering the same prior art. Accordingly, there is a direct overlap between the issues presented in the Petition and in the parallel proceeding, and this factor favors denial.

*Factor (5): Whether the petitioner and the defendant in the parallel proceeding are the same party.*

The parties in the parallel proceeding are the same, thus this factor also weighs against institution.

*Factor (6): Other circumstances that impact the Board's exercise of discretion, including the merits.*

Patent Owner is not aware of any other circumstances that impact the Board's exercise of discretion, and for the reasons contained herein, Petitioner has not demonstrated that it is highly likely to prevail with respect to at least one challenged claim.

In sum, all of the *Fintiv* factors weigh against institution. Accordingly, the Board should exercise its discretion to deny institution.

## **XII. Conclusion**

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

Date: January 30, 2024

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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 13,585 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.

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**Certificate of Service**

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on January 30, 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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