

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 RESPONSE**

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U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**PATENT OWNER'S UPDATED EXHIBIT LIST**

| <b>Exhibit Number</b> | <b>Description</b>                                                                                                                                                            |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2001                  | Declaration of Joshua A. Krevitt in Support of Patent Owners' Motion for Pro Hac Vice Admission                                                                               |
| 2002                  | Declaration of Dr. John Mongan, dated January 30, 2024                                                                                                                        |
| 2003                  | Curriculum Vitae of John T. Mongan, MD, PhD                                                                                                                                   |
| 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., <i>Machine learning in orthodontics: Challenges and perspectives</i> , 30(10) Advances in Clinical and Experimental Medicine 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 Inter Partes 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 Deadlines (N.D. Cal., Oct. 26, 2023)             |
| 2014                  | Docket Navigator Report on Time to Trial in cases before Judge Alsup (Excluding Outliers)                                                                                     |

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| 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> )                                                              |
| 2021 | The NYUD v2 Datasets (July 13, 2017 version available at <a href="https://web.archive.org/web/20170705142032/https://cs.nyu.edu/~silberman/datasets/nyu_depth_v2.html">https://web.archive.org/web/20170705142032/https://cs.nyu.edu/~silberman/datasets/nyu_depth_v2.html</a> )                                                                          |
| 2022 | Timothy T. Wheeler, <i>Orthodontic Clear Aligner Treatment</i> , 23(1) Seminars in Orthodontics 83 (2017)                                                                                                                                                                                                                                                 |
| 2023 | Emilia Taneva, Budi Kusnoto, Carla A. Evans, Chapter 9: 3D Scanning, Imaging, and Printing in Orthodontics, Issues in Contemporary Orthodontics (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)                                                                                                                                                     |

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| 2026 | Barry J. Glaser, <i>The Insider's Guide to Invisalign Treatment</i> , (3L Publishing, 2017)                                                                              |
| 2027 | Excerpt from Deposition Transcript of Dr. Maureen Valley in IPR-2019-000132                                                                                              |
| 2028 | Expert Declaration of Dr. John Mongan, M.D., Ph.D., in support of Dental Monitoring's Patent Owner's Response                                                            |
| 2029 | Updated Curriculum Vitae of John T. Mongan, M.D., Ph.D.                                                                                                                  |
| 2030 | Expert Declaration of Dr. Budi Kusnoto, D.D.S., M.S., in support of Dental Monitoring's Patent Owner's Response                                                          |
| 2031 | Updated Curriculum Vitae of Budi Kusnoto, D.D.S., M.S.                                                                                                                   |
| 2032 | American Association of Orthodontists, <i>2023 Economics of Orthodontics Analysis Reporting on 2022 Practice &amp; Patient Statistics: Member Report</i> (Aug. 28, 2023) |
| 2033 | American Board of Orthodontists, <i>Ideal Photographs and Radiographs</i>                                                                                                |
| 2034 | Institute of Medical Illustrators, <i>IMI National Guidelines: Orthodontic Photography</i> (Feb. 2008).                                                                  |
| 2035 | Canon, <i>Canon Dental Photography Guide</i> (2015)                                                                                                                      |
| 2036 | Excerpts from Transcript of Deposition of Dr. Maureen A. Valley in IPR2019-00132 (Dec. 18, 2019)                                                                         |
| 2037 | Excerpts from Declaration of Dr. Maureen A. Valley in <i>Dental Monitoring SAS v. Align Technology, Inc.</i> , 3:22-cv-07335-WHA (Dkt. 104-5)                            |
| 2038 | R. Kaplan, <i>Standardization for Serial Intraoral Photography</i> , The C.V. Mosby Co. 431 (1979)                                                                       |
| 2039 | [RESERVED]                                                                                                                                                               |
| 2040 | S. Samawi, <i>Clinical Digital Photography in Orthodontics: Professional Photographic Records in Daily Practice</i> , 18 Jordan Dental J. 20 (2012)                      |
| 2041 | O. Russakovsky et al., <i>ImageNet Large Scale Visual Recognition Challenge</i> , <a href="https://arxiv.org/pdf/1409.0575">https://arxiv.org/pdf/1409.0575</a>          |
| 2042 | S. Xie & Z. Tu, <i>Holistically-Nested Edge Detection</i> , <a href="https://arxiv.org/pdf/1504.06375">https://arxiv.org/pdf/1504.06375</a>                              |
| 2043 | [RESERVED]                                                                                                                                                               |

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| 2046              | I. Ahmad, <i>Digital Dental Photography, Part 2: Purposes and Uses</i> , 206(9) British Dental J. 459 (May 2009)                                                                                                                                                 |
| 2047              | S. Finlay, <i>Photographic Analysis and Diagnosis: Step One</i> , 2(3) Inside Dentistry (Oct. 2009)                                                                                                                                                              |
| 2048 <sup>1</sup> | Deposition Transcript of Dr. Hassan Foroosh, Ph.D., in IPR2023-01369 (May 17, 2024)                                                                                                                                                                              |
| 2049              | [RESERVED]                                                                                                                                                                                                                                                       |
| 2050              | [RESERVED]                                                                                                                                                                                                                                                       |
| 2051              | [RESERVED]                                                                                                                                                                                                                                                       |
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| 2053              | Declaration of N. E. Frank-White (attaching S. Frey, <i>A Quick Look at Dental Monitoring, The Ortho Cosmos</i> , <a href="http://theorthocosmos.com/quick-look-dental-monitoring/">http://theorthocosmos.com/quick-look-dental-monitoring/</a> (Apr. 17, 2017)) |
| 2054 <sup>2</sup> | Deposition Transcript of Dr. Hassan Foroosh, Ph.D., in IPR2024-00110 and IPR2024-00052 (June 28, 2024)                                                                                                                                                           |
| 2055              | <i>Making Sure Your Invisalign Aligners Fit Correctly</i> , Morita Orthodontics (2016)                                                                                                                                                                           |

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

<sup>2</sup> Patent Owner is not yet in receipt of the witness's signature or the officer's certification and will coordinate with Petitioner to file an updated exhibit once complete. 42.53(f)(5)-(6).

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| 2056 | Apple, <i>Apple Reinvents the Phone with iPhone</i> , Apple Newsroom (Jan. 9, 2007)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2057 | [RESERVED]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2058 | U.S. Pat. No. 11,109,945                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2059 | Declaration of H. Foroosh in support of Align's petition for <i>inter partes</i> review of U.S. Pat. No. 11,10,945                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2060 | BusinessWire, <i>DentalMonitoring Sets New Standard In Orthodontic Remote Monitoring With De Novo Approval By the U.S. Food and Drug Administration (FDA)</i> , May 20, 2024 Press Release<br>( <a href="https://www.businesswire.com/news/home/20240520240852/en/DentalMonitoring-Sets-New-Standard-In-Orthodontic-Remote-Monitoring-With-De-Novo-Approval-By-the-U.S.-Food-and-Drug-Administration-FDA-">https://www.businesswire.com/news/home/20240520240852/en/DentalMonitoring-Sets-New-Standard-In-Orthodontic-Remote-Monitoring-With-De-Novo-Approval-By-the-U.S.-Food-and-Drug-Administration-FDA-</a> ) |
| 2061 | [RESERVED]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2062 | [RESERVED]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2063 | N. Smith, <i>Clear aligner therapy: An esthetic approach to total patient care</i> , Dentistry IQ (Sept. 25, 2017)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2064 | Provisional Patent Application No. 62/417,985 to Carrier et al.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

## I. Introduction

Patent Owner, Dental Monitoring SAS, respectfully submits that all the challenged claims of U.S. 11,049,248 (“’248 patent”) are patentable over the ground raised in the Petition.

The ’248 patent claims groundbreaking methods using deep learning techniques to assess the fit of an aligner using images captured on a cellphone. Petitioner and its expert cite no prior art that suggests these techniques. They cannot do so. The techniques of the ’248 patent are so new and significant that Patent Owner Dental Monitoring SAS’s corresponding product was the *first ever* software-based device to receive De Novo approval from the FDA Dental panel. EX2060.

Instead, Petitioner proposes just one combination of four references, cobbling together disparate teachings to try to recreate with hindsight the invention in the ’248 patent. *None* of Petitioner’s references relates to remotely assessing aligner fit and a POSA *would not* have combined them as Petitioner suggests. Petitioner’s combination is in fact inoperable because it relies on Maninis—a reference having nothing to do with the dental field—disclosing a deep learning technique that simply cannot perform the analysis recited in the challenged claims.

The failure of Petitioner’s combination is compounded by its expert’s complete lack of dental experience. Dr. Foroosh has no background in dentistry or

orthodontics and *admitted* to being *unable to understand* key teachings of the three references that relate to the dental field. For instance, he interprets Kim as disclosing patient-created photographs of teeth with aligners, when in fact Kim has no such disclosure and teaches that only photographs of teeth are useful for diagnosis and treatment. Dr. Foroosh also repeatedly relies on a single image from Invisalign despite having “*no idea*” if it was representative of real life, and also ignores the teachings of Invisalign requiring in-person assessment of aligner fit. He further alleges that Salah’s methods—directed to tracking tooth movement (without aligners) over time and reliant on detecting areas of high contrast in images—could be applied to clear aligners on teeth, which any orthodontist would have known would not contrast, but rather blend, with teeth.

Even when opining on Maninis, which *is* in his field of expertise, Dr. Foroosh critically misunderstood Maninis’s neural network as detecting whether an object in an image is a tooth or an aligner—it cannot do so. Instead, Maninis can only determine generic contours in an image. But those contours define zones within the image, and are not attributes of teeth or the image as a whole, as the challenged claims require.

For these and the other reasons discussed below, Patent Owner respectfully submits that the Board should find all the challenged claims are patentable over the ground raised in the Petition.

## II. Level of Ordinary Skill in the Art

In its Institution Decision, the Board adopted Petitioner’s then-uncontested assertion that a person having ordinary skill in the art (“POSA”) would “have an advanced degree, such as a Masters’ Degree or Ph.D. in computer science, computer engineering, electrical engineering, or a related field,” “at least two years of work in computer vision, image analysis, medical imaging, or related areas” and “*could* be a member of an interdisciplinary team including persons with backgrounds such as electrical engineering, computer science, optical imaging, and dentistry or orthodontics, and *could* call upon the knowledge of other team members *as appropriate*.” Paper 10, 13-14.<sup>3</sup>

Patent Owner’s experts provided a slightly different definition. EX2028, ¶¶47-50 (A POSA “would have had a bachelor’s degree or higher in computer science, bioinformatics, or a related engineering discipline, and several years of work experience relating to the development of machine learning or artificial intelligence models or algorithms. A POSA *would* have also worked as part of a multi-disciplinary team, which *would have included individuals familiar with medical imaging, dental imaging, dentistry, and/or orthodontics*.”); EX2030,

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<sup>3</sup> All emphases herein are added unless otherwise indicated.

¶¶54-57. Although these definitions are not materially different, the POSA definition is material to the merits of Petitioner’s ground.

Here, the relevant field is aligner treatment. EX2030, ¶57. Kim, Invisalign, and Salah relate to orthodontic treatment, Kim and Salah discuss dental imaging, and all three references are directed to and assume the knowledge of dental professionals. EX1002, ¶¶45-48, 51; EX2030, ¶¶58, 70, 80-82; EX2028, ¶50. Indeed, Invisalign is a clinical guide “to help the Invisalign practitioner,” and Petitioner’s declarant Dr. Derakhshan states she “provided orthodontists and dentists” with Invisalign to “provide instruction to orthodontists and dentists to certify them in the use of ... Invisalign clear plastic aligners.” EX1011, ¶¶2, 5-6; EX1008, i; EX2030, ¶58; EX2028, ¶87. Patent Owner’s Response is thus supported by the Declaration of Dr. Budi Kusnoto—a practicing clinician, researcher, and academic in orthodontics for twenty-five years—with whom Dr. Mongan consulted in forming his opinions. EX2028, ¶50; EX2030, ¶¶3-12.

Petitioner’s definition recognizes that a POSA “*could* call upon the knowledge of other team members *as appropriate*.” Paper 2, 14. To understand Invisalign, Kim, and Salah, it would have been appropriate, and in fact necessary, for a POSA to consult with an individual having experience in dentistry and/or orthodontics. EX2030, ¶¶56-57; EX2028, ¶50.

However, Petitioner's expert, Dr. Foroosh, has no training or experience with dentistry or orthodontics, and did not consult with such a person in forming his opinions. EX2048, 11:9-11, 12:19-22, 13:12-23; EX2054, 124:16-19. Dr. Foroosh's lack of relevant experience led him to misinterpret or ignore portions of the prior art. For example, Dr. Foroosh alleged that Invisalign Figure A is illustrative of what "a person would see when viewing teeth and an aligner," when in reality, he had "*no idea*" whether that photograph is a common position for an aligner. EX2054, 60:18-61:4, 45:17-19, 74:9-14. Dr. Foroosh also could not say how an orthodontist allegedly assessed aligner fit in 2017, despite alleging a motivation to transition patients from in-person to remote treatment based on Invisalign. *E.g.*, EX2054, 42:4-7, 58:24-59:5, 65:12-23; *infra* §VIII.A.

"[T]he level of ordinary skill in the art is 'a prism or lens through which ... the Board views the prior art and the claimed invention' to prevent hindsight bias." *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *see also* Paper 10, 14 (citing *Okajima*). Because Petitioner failed to consider the ground references from the perspective of a properly informed POSA, its ground should be rejected.

### **III. State of the Art**

#### **A. Dental Photography**

For decades before the '248 patent, dental photographs captured by dental professionals during in-office consultations were an integral part of dental care.

EX2030, ¶¶24-36. Acquiring standard orthodontic images required specialized training and equipment, *e.g.*, cheek retractors and dental mirrors, as well as a DSLR camera to ensure high-resolution photographs. EX2040, 23-25, 28-31; EX1008, Figs. 5A-5B; EX2064, [0051], Figs. 1A, 9; EX2034, 21; EX2030, ¶¶28-34. Although some dentists had attempted to use cellphones, this was rare due to challenges with obtaining the necessary high-quality images. EX2030, ¶¶32, 51. For example, holding the phone “close to the teeth” to get a “high level of detail,” could result in “blurry” images and “optical distortion.” EX2064, [0004]; EX2028 ¶83. But holding the phone “too far” from the teeth, resulted in photos that “cannot meet the orthodontic standards.” EX2064, [0004]; EX2028, ¶83.

As of 2017, artificial intelligence (*e.g.*, machine learning or deep learning) was not used in acquiring or analyzing dental photographs. EX2030, ¶¶85-86; EX2037, ¶34 (conceding that deep learning was not part of the standard of care in 2017). At that time, dental professionals were cautious of new technologies because of their potential impact on patient outcomes. EX2030, ¶86; EX2036, 50:3-5, 50:19-24.

## **B. Aligner Treatment**

Aligners are one type of orthodontic device designed to exert gentle pressure to reposition a patient’s teeth. EX1001, 4:52-62; EX2030, ¶¶37. In 2017, aligner treatment generally began with an in-person consultation to establish a proper

diagnosis. If the orthodontist determined that the patient could benefit from aligner treatment, the orthodontist would scan the patient's starting dentition. EX1001, 27:26-30; EX2030, ¶¶38-39. These in-office scans were typically conducted by a dental professional on specialized machines that generated digital three-dimensional ("3D") models of a patient's dentition. EX2030, ¶39; EX2023, 147-80.

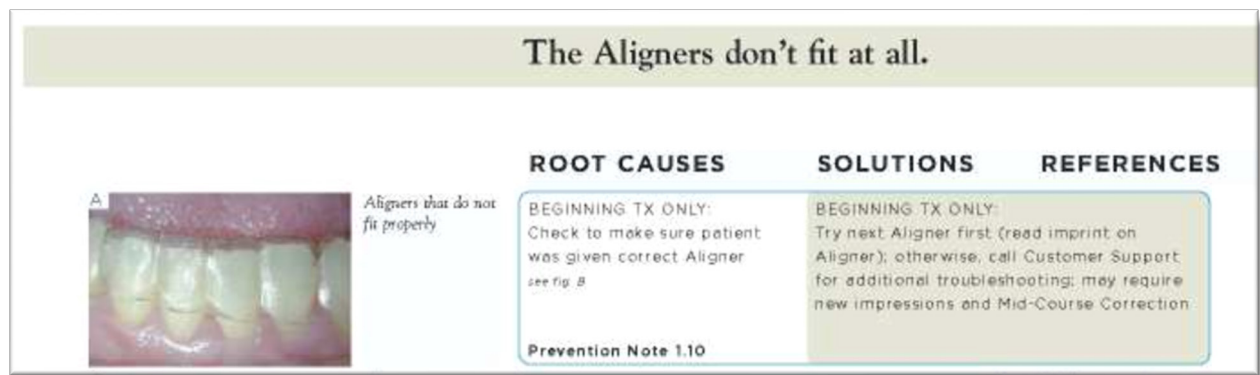
Based on these scans, a sequence of aligners would be designed and fabricated by a company, such as Petitioner. EX1001, 27:31-46; EX2030, ¶40. Upon receipt, the patient would wear one aligner for a predetermined interval of time and then change to the next aligner to continue shifting their teeth according to the treatment plan. EX1001, 27:46-47; EX2030, ¶¶42-43. In 2017, effective aligner treatment required frequent in-person examinations to determine whether treatment was on-track. EX1001, 17:39-49, 27:55-59; EX2030, ¶¶44-45. These in-person examinations did not involve quantitative assessments of aligner fit, such as measurements of separations between the aligner and teeth. EX2030, ¶¶45-46.

As explained by Dr. Kusnoto, conventional examinations in 2017 involved two primary qualitative and subjective assessments. EX2030, ¶¶46-49. First, orthodontists would visually inspect the current state of dentition and compare it to the anticipated dentition for that point in the aligner treatment. *Id.*; EX1001, 27:55-59. Second, orthodontists assessed the aligner treatment for problems with, *e.g.*, aligner fit, tooth attachments, or dentition complications. EX2030, ¶¶48-49;

EX2026, 39-40, 275-76; EX1006. Generally, a patient would be asked to try on their current aligner and it was visually and manually examined for large gaps between the aligner and the teeth. EX2030, ¶49. Using their hands, the orthodontist would manually examine the aligner for rocking (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 and manual inspections were susceptible to inconsistency and inaccuracy, for example, due to level of experience, length of appointment, speed of review, etc. EX2030, ¶47. Reliance on periodic in-person examinations also meant that treatment issues could go undiagnosed for multiple weeks between check-ins. *Id.*; EX1001, 17:48-53, 28:1-6. When an orthodontist identified significant issues with the patient's progress, the teeth would have to be rescanned, a new series of aligners manufactured, and the remaining aligners from the previous series discarded. EX1001, 27:60-67; EX2030, ¶52. As a result, aligner treatment was often prolonged. EX1001, 27:66-67; EX2030, ¶52.

In 2017, it was not the standard of care to use images of aligners on the teeth, let alone such images captured using a cellphone, to evaluate aligner fit.<sup>4</sup> EX2030, ¶51. Indeed, aligner fit issues were often difficult to detect with the naked eye, especially when just emerging. As Invisalign shows, the separation is subtle, even when “Aligners don’t fit at all.”



EX1006, 6; EX2030, ¶63.

### C. Neural Networks

In 2017, it was known that neural networks for image analysis were algorithms trained to evaluate images and output probabilities associated with the attributes they had been trained to recognize. EX2028, ¶61; EX2054, 169:16-21. A POSA would have understood, however, that neural networks are not general-

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<sup>4</sup> Petitioner identified only one reference discussing remote evaluation of aligner fit using a cellphone video, Frey—which is not prior art because it was derived from the '248 patent inventors. *Infra* § VIII.A.4.

purpose tools and were only useful to the extent of their training. EX2028, ¶¶61-67. It was also known that each neural network trained for an image recognition task is unique to the annotated images on which it was trained, and its success depends on the quality of that training and the challenge(s) of the attributes the neural network is tasked with recognizing. *Id.* In his declaration, Dr. Mongan—a professor at University of California San Francisco, who has been involved with machine learning, deep learning, and neural networks his entire career—describes a simple example of training a neural network. *Id.*, ¶¶62-66.

#### **IV. Overview of the '248 Patent**

The '248 patent claims priority to July 21, 2017. Petitioner does not challenge this priority date.

The challenged claims provide new methods for “assessing the shape of an orthodontic aligner” that employ a “deep learning device” to analyze aligner images and assess aligner fit. EX1001, 28:34-38, 30:60-62, 32:6-23; EX2028, ¶¶52-60. The methods include “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, 28:13-15. The analysis image can be captured remotely, for example, on a patient’s cellphone. *Id.*, 15:30-35, 19:41-44, 25:60-63. The '248 patent “makes it possible, from simple photos or a simple film, to determine whether the aligner is abnormally detached,” we well as “determine

regions in which the aligner is separated from the teeth and assess the scale of this separation.” *Id.*, 31:30-37.

The “analysis image” is analyzed by a “deep learning device,” preferably a neural network. *Id.*, 1:39-43. The deep learning device is specifically trained for this purpose, using a “learning base” that may comprise “more than 1000” “historical images” of dental arches with aligners in a service position, annotated with information that the deep learning device is to identify in its analysis. *Id.*, 34:23-31, 15:65-16:4, 16:37-43. “Through its training..., the deep learning device is capable of analyzing the analysis image and of recognizing said patterns therein.” *Id.*, 16:46-48, 17:30-32, 24:26-47.

The ’248 patent discloses two distinct analyses. EX2028, ¶54.

In the “**detailed analysis**” (or “Analysis by Tooth”), the deep learning device is trained on historical images labeled with “tooth zones” representing the individual teeth that have been assigned values for a “**tooth attribute**.” *Id.*, 16:5-45, 32:14-19; EX2028, ¶¶55-57. 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, 28:21-24, 32:19-21. The tooth attribute value thus “provides an information item relating to the shape of the aligner relative to the shape of the teeth of the patient.” *Id.*, 30:42-44. The tooth

attribute “can be a measurement of the separation,” or a tooth number, type, or other parameter. *Id.*, 16:46-17:4, 30:42-54; *see also id.*, 7:64-8:7, 28:48-61.

In the “**global analysis**,” the learning base contains “historical images whose description provides a global attribute value for the image” called an “**image attribute**.” *Id.*, 3:19-4:39, 17:9-18:53; EX2028, ¶¶58-59. 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 teeth and aligner. EX1001, 28:48-61, 31:20-29. Thus, the deep learning device determines a value for an image attribute relating to a separation between a tooth and aligner and is trained using images labeled with the same image attribute value pertaining to the image as a whole. *Id.*, 17:9-34, 29:31-53, 30:13-29.

The '248 patent provides for ongoing, accurate, and remote assessment of aligner fit between in-office orthodontist check-ins. *Id.*, 31:30-37; EX2028, ¶52. Because they are not dependent on in-person assessments, which typically occurred only every 10 weeks, they claimed methods provide improvements over conventional aligner treatment available in 2017. EX2030, ¶45.

First, the challenged claims enable earlier detection of aligner fit issues, accelerating the discovery that new aligners are needed or avoiding the need altogether. EX1001, 31:37-41; EX2030, ¶¶47, 52. Second, the challenged claims allow orthodontists to tailor aligner intervals to a patient’s needs for a personalized

and dynamic treatment. EX2030, ¶43. For example, if a patient exhibits slower dentition progression, with remote monitoring, an orthodontist can prescribe a longer aligner change interval. EX1001, 31:37-47; EX2030, ¶43. 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. EX2030, ¶¶45, 64.

## V. Claim Construction

Patent Owner requests construction of the following terms.

### A. “tooth attribute” (claims 1-2, 7, and 14)

Petitioner contends that “tooth attribute” “refers to any attribute related to a tooth” “including attributes specific to the tooth or to the aligner, such as their *respective positions or edges*.” Paper 2, 16; EX1002, ¶¶64-65. Petitioner’s construction is overbroad and should be rejected. EX2030, ¶¶143-49.

The ’248 patent describes a detailed analysis method that uses a deep learning device trained on a learning base comprising historical aligner images “comprising one or more zones each representing a tooth, or ‘historical tooth zones,’ to each of which is assigned, ... a tooth attribute value.” EX1001, 28:62-29:13. Then, the “deep learning device ... determine[s] at least one probability relating to: the presence, at a location in [an] analysis image, of an analysis tooth zone, and the tooth attribute value of the tooth represented on said analysis tooth zone.” EX1001, 29:16-

26; *see also id.*, 15:57-16:6, 16:37-54, 30:35-53, cls. 1, 7, 14. The '248 patent thus distinguishes between a “tooth zone,” which corresponds to the “zone” or “location” of a tooth in the analysis image, and a “tooth attribute,” which is an “attribute” of the tooth. In other words, the “tooth zone” defines where the tooth is, and the “tooth attribute” describes the tooth in that zone. EX2030, ¶¶144-45.

The contours of regions containing teeth correspond to the outline of the claimed “analysis tooth zone.” Those contours do not describe any attribute of the tooth in that zone. Indeed, the '248 patent provides a list of exemplary tooth attributes, including tooth number, tooth type, or tooth parameters such as a color, translucency, or other quality. EX1001, 7:64-8:7; EX2028, ¶145. Each of these possible tooth attributes can be expressed as a single value, either a number or descriptive parameter such as “incisor” or “broken.” EX1001, 7:64-8:16; EX2028, ¶145. By contrast, the respective positions or edges of a tooth and aligner cannot be expressed as a single “tooth attribute value,” but rather, only as a vector of many values. EX2028, ¶¶146-47.

Accordingly, Petitioner’s construction equating “tooth zone” and “tooth attribute” should be rejected, and “tooth attribute” construed as: attribute of a tooth. *E.g., SIPCO, LLC v. Emerson Electric Co.*, 794 Fed. App’x 946, 949 (Fed. Cir. 2019); *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005).

**B. “image attribute” (claims 8 and 15-16)**

Patent Owner does not contest that the claimed “image attribute” relates to the “image as a whole” and may be “a function of the tooth attribute values.” Paper 2, 16-17. However, Patent Owner disagrees with Petitioner’s construction to the extent in incorporates Petitioner’s overbroad definition of “tooth attribute.” Moreover, Petitioner’s expert Dr. Foroosh also asserts that the “locations of each tooth and each corresponding aligner part would be image attributes.” EX1002, ¶140. These locations do not relate to the image as a whole, and are instead “zones,” not “attributes.” EX2028, ¶150. Accordingly, Petitioner’s overbroad construction should again be rejected and “image attribute” construed as: attribute of the image as a whole. *E.g., SIPCO*, 794 Fed. App’x at 949; *Merck & Co.*, 395 F.3d at 1372.

**C. “deep learning device” (claims 1, 7, 8, and 13-16)**

A POSA would have understood that “deep learning device” refers to a device that, through training, is capable of analyzing an image and recognizing patterns therein. EX1001, 16:46-48 (“Through its training ... the deep learning device is capable of analyzing the analysis image and of recognizing said patterns therein.”); *id.*, 17:30-32, 24:26-48; EX2028, ¶¶153-56; EX2054, 169:22-171:11.

**D. “shape of an orthodontic aligner” (claims 1 and 15)**

The Petition does not take a position on whether the preambles of claims 1 and 15 are limiting. Paper 2, 28, 55. To the extent they are limiting, the phrase

“shape of an orthodontic aligner” should be construed to mean “the shape of the aligner relative to the shape of the teeth of the patient.” EX2028, ¶¶157-60.

The specification describes a method of “assessing the shape of an orthodontic aligner” for purposes of aligner treatment. *E.g.*, EX1001, 28:35-37, 30:60-62. It explains that the shape of the aligner is assessed relative to the patient’s teeth to determine suitability for treatment. *Id.*, 4:54-62. And it can be assessed by determining “a value for at least one tooth attribute ... relating to a separation between the tooth represented by the analysis tooth zone, and the aligner represented on the analysis image.” *Id.*, 28:10-33, FIG. 9. The “value for this tooth attribute therefore provides an information item relating to the shape of the aligner relative to the shape of the teeth of the patient.” *Id.*, 30:42-45.

Petitioner’s expert further confirms that the claimed “method of assessing the shape of an aligner” refers to assessing aligner fit. EX1002, ¶84 (alleging that “determining a distance between the teeth and the aligner when worn by the patient” discloses a method of “assessing the fit of the aligner”); *see also* EX2028, ¶160.

## **VI. Petitioner’s Ground References**

### **A. Kim**

Kim discloses a method for “providing remote teeth alignment services.” EX1005, [0010]; EX2028, ¶¶68-86; EX2030, ¶¶70-71. According to Kim, an

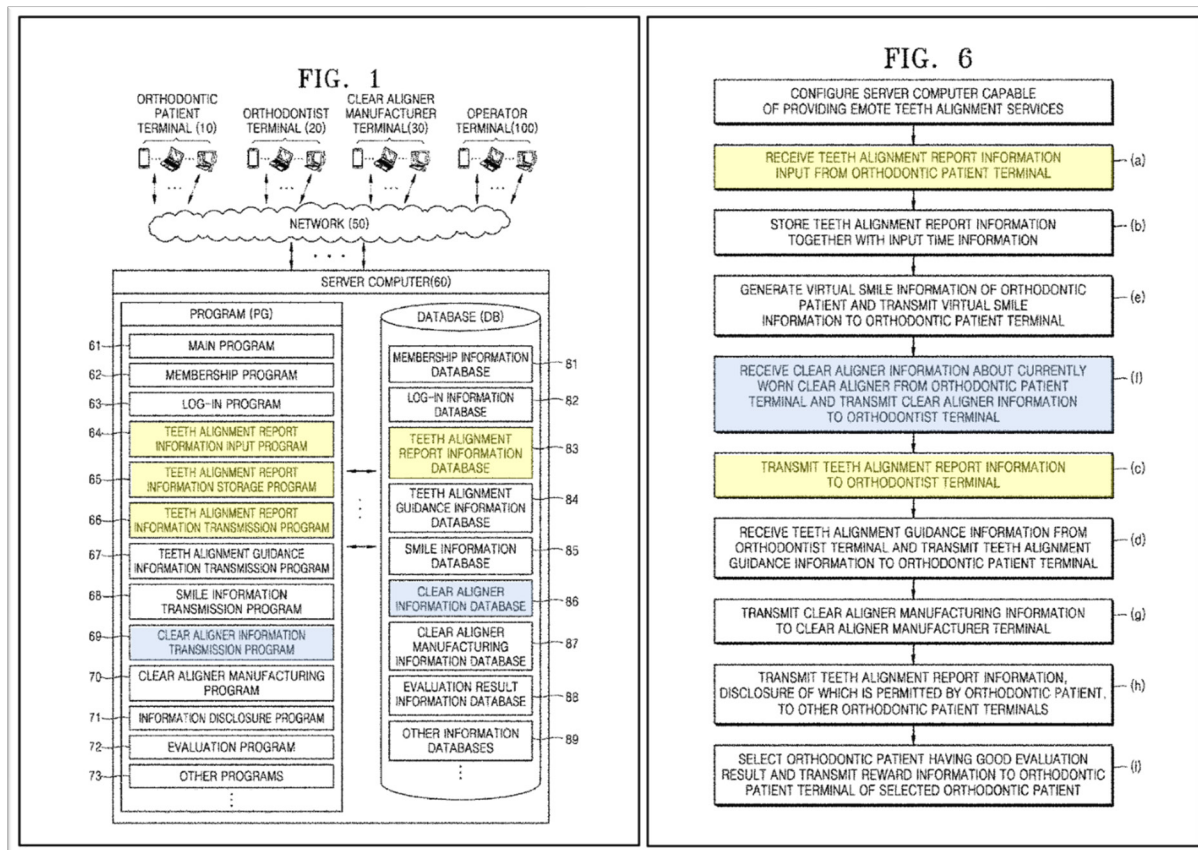
orthodontic patient sends “teeth alignment information using a device, e.g., a smartphone.” EX1005, [0010]; *see also id.*, [0013], [0041]-[0042], [0056], [0058], FIG. 6. “[B]ased on the teeth alignment information,” an orthodontist may “remotely and accurately diagnose the condition of the patient” and “may remotely provide information about an accurate step of a clear aligner to be currently worn by the orthodontic patient.” EX1005, [0010]. The teeth alignment information can include multiple views of the patient’s teeth. EX1005, [0013], [0056], FIGS. 8-13, FIG. 16, FIG. 19, FIG. 23; EX2028, ¶71.

In 2017, assessing teeth alignment was distinct from assessing aligner fit. Assessing teeth alignment involved an overall evaluation of the patient’s dentition based on tooth positions. EX2030, ¶¶47-48, 76. Assessing aligner fit involved checking that the aligner provided adequate and effective pressure on the patient’s teeth to cause the desired tooth movement. *Id.*, ¶76. Typically, this involved a combination of visual and manual inspections performed by an orthodontist during in-person appointments. *Id.*

Kim expressly relates to “remote teeth alignment services.” EX1005, [0010]. A POSA would *not* have understood Kim to disclose a method for assessing aligner fit. EX2028, ¶72; EX2030, ¶¶71-75. Although Kim discloses “clear aligner information,” which could include “a photo or a video of the clear aligner currently worn” (EX1005, [0066]), a POSA would have understood Kim to refer only to an

image of the aligner itself, not an image of the aligner in a service position. EX2028, ¶¶73-81; EX2030, ¶74.

Kim draws a clear distinction between “teeth alignment information” and “clear aligner information.” EX2028, ¶¶73-81; EX2030, ¶¶74-77. The clear aligner information is collected and transmitted in different steps of Kim’s method from the teeth alignment information, and the information is stored in different databases, as shown below:



EX1005, FIGS. 1&6 (annotations added); *see also* EX2028, ¶¶74-79; EX2054, 15:12-23.

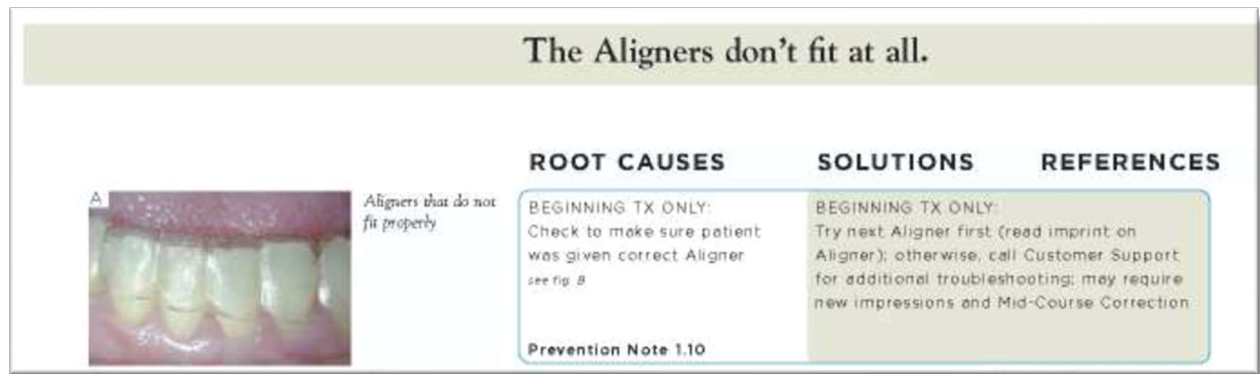
The teeth alignment information, **not** the clear aligner information, is used to diagnose patients and provide aligner advice based on the position of the teeth, **not** the aligner fit itself. *Id.*, [0010], [0063], [0087]. This is consistent with the standard of care in 2017, *i.e.*, that images of aligners in a service position were **not** used to assess aligner fit. EX2030, ¶¶51, 76. Instead, to assess treatment progress, the position of the patient's teeth was compared with the expected position. EX2030, ¶¶47, 72.

Kim discloses that “an orthodontist may obtain accurate teeth alignment information using a device, e.g., a smartphone, of an orthodontic patient, may remotely and accurately diagnose the condition of the patient ***based on the teeth alignment information***, and may remotely provide information about an accurate step of a clear aligner to be currently worn by the orthodontic patient, thereby greatly ***reducing a diagnosis time and cost of the orthodontic patient and the orthodontist.***” *Id.*, [0093]. Kim thus teaches that its benefits flow from the use of teeth alignment information, **not** clear aligner information. EX2030, ¶165. At deposition, Dr. Foroosh confirmed that Kim's teeth alignment information is used to diagnose and treat patients. EX2054, 13:11-19. Kim never suggests that the clear aligner information is used for diagnosis or provides the benefits that Dr. Foroosh relies upon.

Similarly, Kim discloses that the “clear aligner manufacturing program” may transmit information to a clear aligner manufacturer “upon determining that an additional or modified clear aligner is needed, *based on the teeth alignment report* information.” *Id.* at [0067]; *see also id.*, [0020], [0090]. Again, Kim is consistent with how clear aligners were designed and manufactured in 2017, *i.e.*, using the position of the teeth. EX1006, iii; EX2023, 147-80; EX2030, ¶77.

The clear aligner information in Kim is used only to “determine[] whether the clear aligner is normal and corresponds to an appropriate step,” that is, whether the aligner appears to be in working condition and the patient is using the correct aligner for their current treatment step. EX1005, [0066]; EX2028, ¶81; EX2030, ¶74; *cf.* EX2054, 22:6-19 (no basis in Kim to interpret “normal” as “fitting well”).

Kim addresses the problems that could occur when a patient could not frequently visit the orthodontist by providing for “remote teeth alignment.” EX1005, [0009], [0010]; EX2028, ¶69; EX2030, ¶70. Kim never purports to provide a novel way to assess aligner fit, nor explains how that could be done. EX2028, ¶75; EX2030, ¶73. A POSA would have known that aligner fit issues were often difficult to detect with the naked eye, and thus, in-person manual manipulation of the aligner was also used to assess fit. EX2030, ¶75. As illustrated below, the separation is subtle, even when “Aligners don’t fit at all.”



EX1006, 6; EX2030, ¶63.

A POSA would have further recognized that images captured according to Kim—by an untrained person using a cellphone in 2017—were unlikely to be of high quality. EX2028, ¶83; EX2064, [0004] (holding the cellphone “close to the teeth” could result in “blurry” images and “optical distortion”). Although Kim discloses a program to guide the patient on positioning their head or teeth (EX1005, [0014]), there is no guidance on how to acquire an image showing the aligner on teeth. EX2028, ¶83. This confirms that Kim is not directed to assessing aligner fit from an aligner image. *Id.*

To the extent Petitioner says the phrase “currently worn” aligner suggests that the aligner is worn when the patient takes a photograph, a POSA would have had no such understanding. “[C]urrently worn” refers to the aligner that the patient is wearing or should be wearing during the current phase of treatment, not when taking photographs. EX2028, ¶82. Indeed, Kim discloses that the patient may receive

“teeth alignment guidance information” from the orthodontist, which may include “an appropriate step of a clear aligner to be **currently worn** by the orthodontic patient.” EX1005, [0063]; *see also id.* [0041], [0093].

Finally, Kim does not disclose any non-human analysis of images, let alone using a deep learning device. EX2028, ¶¶84-86; EX1005, [0085]. Likewise, Kim does not suggest determining a value for a tooth or image attribute relating to the separation between the teeth and aligner. EX2028, ¶84.

## **B. Invisalign**

Invisalign is a “Clinical Monitoring Guide” published by Petitioner “to help the Invisalign practitioner successfully monitor Invisalign treatments and address issues that may arise.” EX1006, i.

Invisalign does not relate to remotely assessing aligner fit. On the contrary, Invisalign concerns in-office check-ups. EX2028, ¶88; EX2030, ¶58. To that end, Invisalign outlines steps that clinicians should take “***at every patient appointment.***” EX1006, ii. These include having the “patient arrive with the previous stage Aligner and the current Aligner” to assess any treatment concerns and “[e]valuating for tight contacts with unwaxed floss and relieve with finishing strips if present.” *Id.*, ii, II. Invisalign also instructs clinicians to use a dental scaler to “check retention” of the aligner. EX1006, 1; EX2030, ¶58. These steps cannot be performed remotely.

EX2030, ¶58. Indeed, Petitioner did not offer any product for remotely assessing aligner treatment until 2020. EX2008.

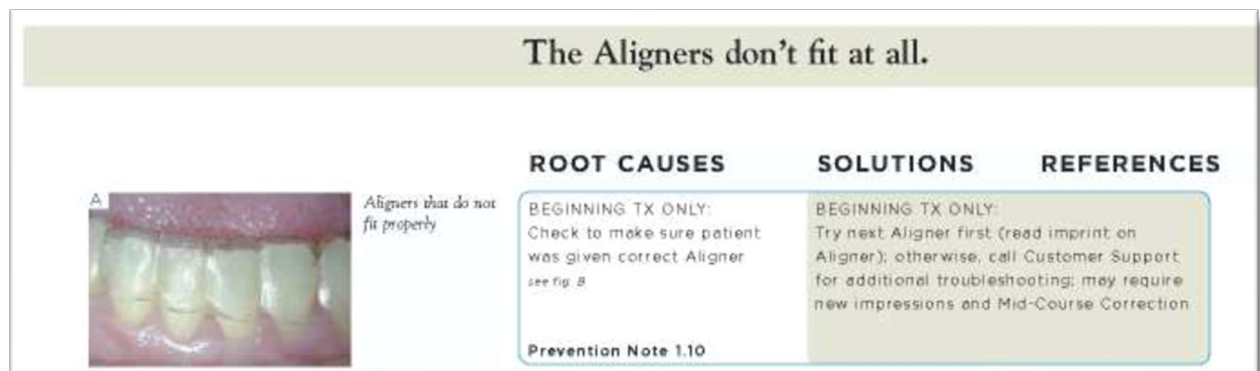
Petitioner cherry-picks one image from Invisalign, Figure A below, and reproduces it repeatedly. Paper 2, 22, 39; EX1002, ¶¶49, 71, 103.



EX1006, 1. In its Institution Decision, the Board found persuasive Dr. Foroosh's assertion that Figure A was illustrative of what "a person would see when viewing teeth and an aligner in real life." Paper 10, 33. At deposition, however, Dr. Foroosh admitted to having "*no idea*" whether this figure is representative. EX2054, 60:18-61:4. Instead, he said he was "not relying on what an orthodontist would encounter" and did not "know the answer" to "what an orthodontist would encounter." *Id.*, 45:8-21; *see also id.*, 74:9-15 (describing this as "out of the scope of [his] expertise").

Unlike Dr. Foroosh, Dr. Kusnoto does know what an orthodontist would have encountered. As Dr. Kusnoto explains, Figure A shows an aligner that has been partially inserted to demonstrate a gap between teeth and aligners; it is *not* representative of an aligner fit situation that an orthodontist would have seen in 2017. EX2030, ¶¶61-64. Instead, Figure B—shown alongside Figure A above, and which is not cited by Petitioner—is a better representation of what orthodontists encountered during the normal course of aligner treatment. EX1006, 1; EX2028, ¶89; EX2030, ¶64.

Invisalign appears to recognize the extreme and artificial nature of Figure A, as it depicts an aligner that does not “fit at all” with significantly smaller gaps.



EX1006, 6.

Although Invisalign indicates a separation of greater than 1 mm reflects a general aligner fit issue, it provides no method to quantitatively measure that separation, and only a visual approximation during an in-person checkup was used

in 2017. EX2028, ¶93; EX2030, ¶59. At that time, an orthodontist could not reliably distinguish in-person between, for example, separations of 0.9 mm (on-track) and 1.1 mm (off-track) based on the visual examination taught in Invisalign. EX2030, ¶59. For this reason, Invisalign suggests that, in the case of a separation that appears to be less than 1 mm, the orthodontist should simply continue to monitor aligner fit. *Id.*

Invisalign makes no mention of capturing images to assess aligner fit, let alone with a cellphone. In the Institution Decision, the Board credited Dr. Foroosh’s testimony that “the photographs of ... Invisalign are ordinary camera images such as those acquired by a cellphone.” Paper 10, 33. Dr. Foroosh has since conceded the photographs in Invisalign were captured with a DSLR camera. EX2054, 134:10-135:11, 135:17-24. In 2017, training and a sophisticated camera setup were required to capture high-quality dental images, given the state of cellphone camera technology at that time. EX2030, ¶¶32-34.

Petitioner’s CEO confirmed this, stating: “[e]arly on [in the 2020 COVID-19 pandemic], many doctors *began* using video calls, texts, and patient-submitted photos ... to help monitor patient progress.” EX2008. This was certainly not the standard of care in 2017. EX2030, ¶51. To the extent Invisalign discloses capturing images at all, it is solely for the purposes of aligner design and manufacture—before the aligners ever exist. EX2028, ¶94; EX2030, ¶68; EX2054, 70:2-7.

Finally, Invisalign does not disclose analysis of any image by means of a deep learning device trained by means of a learning base. EX2028, ¶96.

### **C. Salah**

Salah is directed to monitoring the position of teeth over time. EX1008, 1:25-2:19; EX2028 ¶¶99-100; EX2030, ¶82; EX2054, 90:6-9. Salah's method includes creating a 3D digital reference model ("initial reference model"), acquiring a 2D image of the patient's arches ("updated image"), and, by comparing the initial reference model and a "final reference model" created from the "updated image," determining deformation or displacement of teeth. EX1008, 1:25-2:19; EX2028, ¶¶99-121; EX2030, ¶¶80-81. Salah is thus directed to assessing teeth alignment, which is distinct from assessing aligner fit. EX2028, ¶¶115, 120; EX2030, ¶¶80-84.

As to image acquisition, Salah is clear—the goal is to enable "image acquisition [to] be carried out by the patient himself or by one of their relatives, using a simple cell phone, anywhere, and especially outside a medical, dental or orthodontic practice." EX1008, 31:4-7. For these simple images to be useful, Salah first requires a detailed 3D model of the patient's teeth formed using physical modeling or "preferably ... using a professional device, such as a 3D scanner." *Id.*, 19:25-20:21. Salah's accuracy depends on this detailed 3D model, as it becomes a point of comparison for lower-quality images taken later in time. EX2028, ¶102.

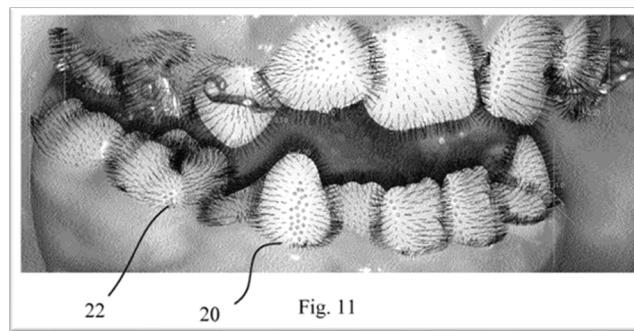
Salah never suggests that the lower quality images are useful in the absence of the detailed reference model. *Id.*

To analyze the 2D updated image relative to the 3D reference model, Salah discloses preparing from the 2D image “an updated map relating to at least one piece of discriminant information,” which Salah defines as “characteristic information that can be extracted from an image (‘image feature’)” such as “contour information” or “[b]rightness information.” EX1008, 33:9-10, 18:11-17. Salah identifies eighteen “preferred methods” and eighteen methods that are “not preferred” but “can also be used,” for determining discriminant information. EX2028, ¶107. The preferred methods include long-established contour detection techniques, such as the Canny algorithm. *Id.*; EX1008, 34:15-16. The non-preferred methods include other techniques for determining and refining contours, including deep learning. EX2028, ¶107; EX1008, 36:14. However, a POSA would have been discouraged from using a resource-intensive “deep learning” approach to determine a contour map in light of Salah’s teaching that its analysis is “best carried out ... on the patient’s own device, preferably using the [image acquisition device],” *i.e.*, a cellphone. EX1009, 33:6-8; EX2028, ¶109.

Nowhere does Salah indicate that the contour map for the “updated image” would reflect identification of contours associated with individual identified teeth. EX2028, ¶108. To the contrary, the definition of “discriminant information”

contemplates that contour values are stored at the pixel level (0 and 1 indicating whether a pixel is part of a contour or not), and Salah does not mention any other potential values. *Id.*; EX1008, 18:14-15. Although individual teeth may be identifiable in the contour map, Salah does not suggest they are annotated or otherwise associated with the “updated image.” EX2028, ¶108; EX1008, FIG. 6b.

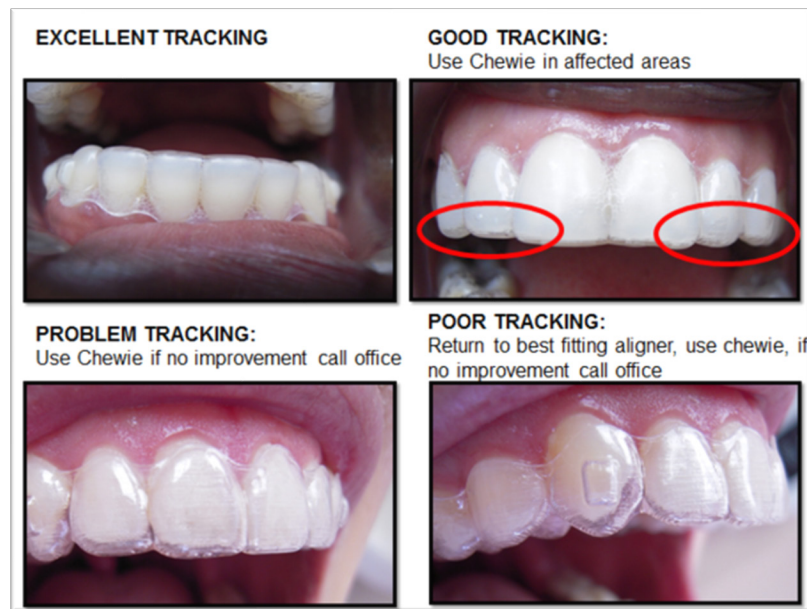
Finally, Salah is about tracking the movement of teeth, not an apparatus moving them. EX1008, 36:17-47:24; EX2028, ¶¶83-84. As Dr. Foroosh testified: “Salah is not talking about clear aligners; so obviously could not talk about how it fits -- how a clear aligner fits or seating on the teeth.” EX2054, 117:1-4; EX2028, ¶98. Nonetheless, citing Figure 11 (reproduced below), Dr. Foroosh alleges that Salah teaches acquiring images of teeth fitted with “orthodontic appliances.” EX1002, ¶89.



EX1008, FIG. 11; EX1002, ¶89. Salah never discusses imaging “orthodontic appliances” generally, and Dr. Foroosh has “no idea” if an orthodontist would use that term to describe the device in Figure 11. EX2054, 96:5-14. According to

Patent Owner's orthodontic expert, the device is a "bonded expander." EX2030, ¶83. Dr. Foroosh's efforts to extrapolate from a bonded expander to all orthodontic appliances, without even understanding what the device in Salah *is*, should be rejected. Unlike a clear aligner, a bonded expander is fixed to the teeth and cannot be readily removed. *Id.* A POSA would thus have understood that Salah's assessment of tooth movement can be used *despite* wires affixed to the teeth. EX1008, 64:29-32. Salah does not suggest that the device itself is evaluated.

Salah never discusses images with removable aligners, nor the unique challenges of imaging and analyzing them. Moreover, Salah teaches that discriminant information is best extracted from areas of high contrast, but a clear aligner presents a low contrast with the teeth because it is intended to visually blend with the teeth. EX1008, 60:17-22; EX2028, ¶124, EX2030, ¶84. For example, in the images below, the edges of the aligner are nearly the same color as the teeth. In the case of the "EXCELLENT TRACKING" and "GOOD TRACKING" photographs, the teeth and aligners are nearly-indistinguishable.



EX2055, 2. Thus, nothing in Salah would have guided a POSA to acquire an image of teeth with a clear aligner, let alone evaluate such an image to assess aligner fit or determine teeth or image attribute values relating to a separation between the teeth and aligner.

#### **D. Maninis**

Maninis proposes a technique, which its authors call Convolutional Oriented Boundaries (“COB”), for determining boundaries in an image using a convolutional neural network (“CNN”) (herein the “COB neural network”). Maninis discloses that its COB neural network can be applied in combination with other neural networks to determine semantic contours, but it contains no reference to the field of dental imaging or analysis. EX1007, 1; EX2028, ¶¶125-26.

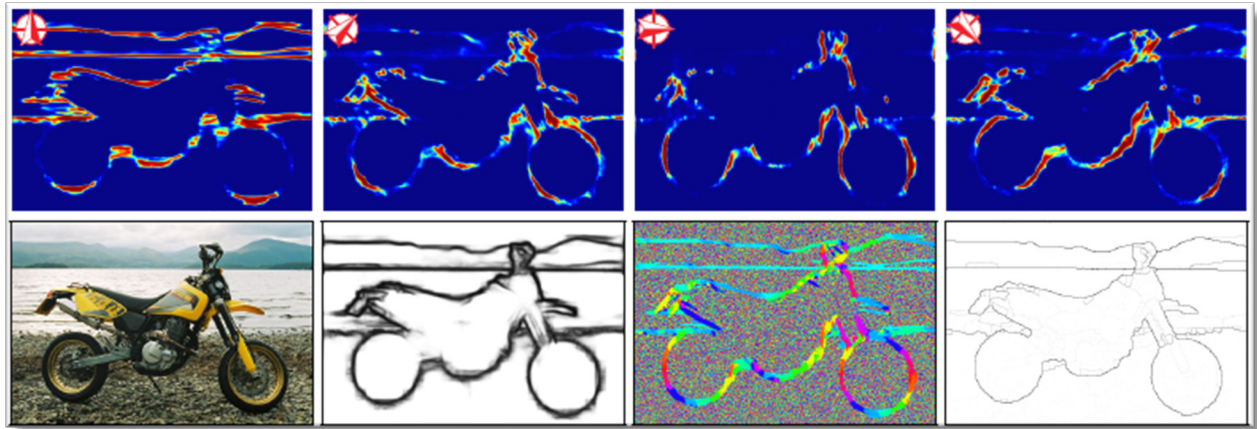
## 1. Overview of Maninis's Techniques

In Maninis, the COB neural network is used to identify generic contours.<sup>5</sup> EX1007, 1-2. Maninis uses those contours to form an ultrametric contour map (UCM) that is fused into a hierarchical segmentation. *Id.*, 1-3, 5. This hierarchical segmentation identifies boundaries that belong to the outline of an object (*e.g.*, a

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<sup>5</sup> As of 2017, a POSA would have understood that “boundaries” or “contours” are the outlines of objects depicted in an image, and contour (or edge) detection is the process of detecting the location of those contours in the image. In practical terms, this means identifying whether each pixel in an image is part of a contour or not. A segment is a region within a contour. “Semantic segmentation” is the labeling of pixels in an image as associated with a particular identified object and “semantic boundaries” are the contours (or edges) that define a particular identified object. EX2028, ¶130 n.4.

motorcycle) as opposed to a sub-part of that object (*e.g.*, the motorcycle's seat), as illustrated below:



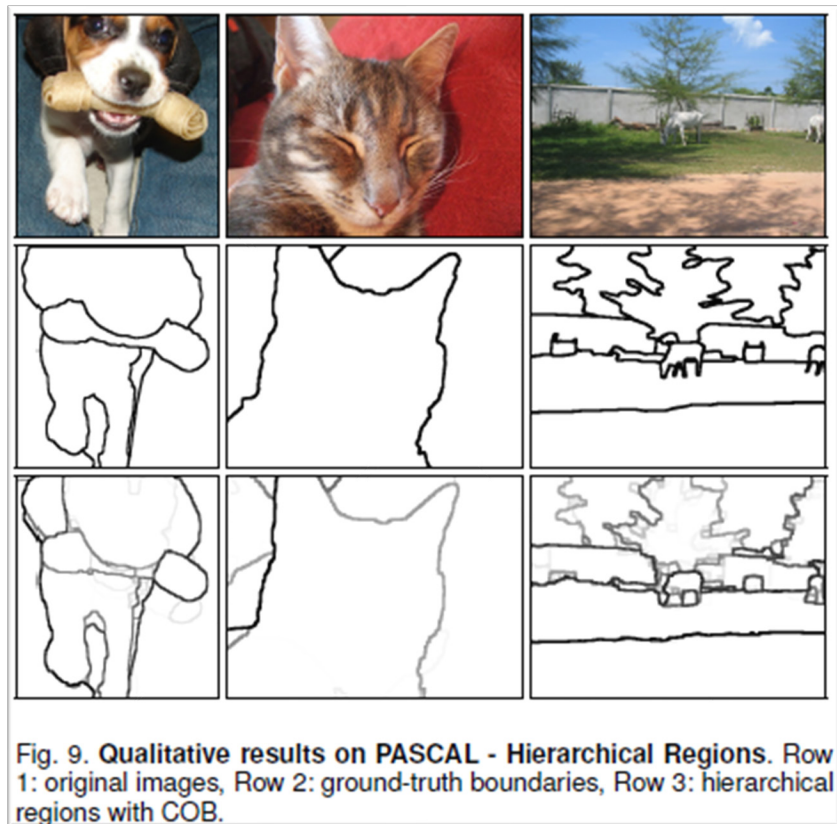
*Id.* at 4, Fig. 3 (hierarchical regions depicted in bottom right image); EX2028, ¶¶127-28.

Although Maninis's COB neural network can identify the contours of objects in images, it *cannot* determine what object is defined by that boundary. For example, Maninis discloses that its COB neural network achieves “Low Level Applications,” like “generic image segmentation” and “object boundary detection,” neither of which include object recognition or identification. EX2028, ¶¶129-30; EX1007, 5, 7 (In “object boundary detection,” “[t]he goal is to detect the boundaries of the objects ... *without distinguishing the semantics.*”), 10.

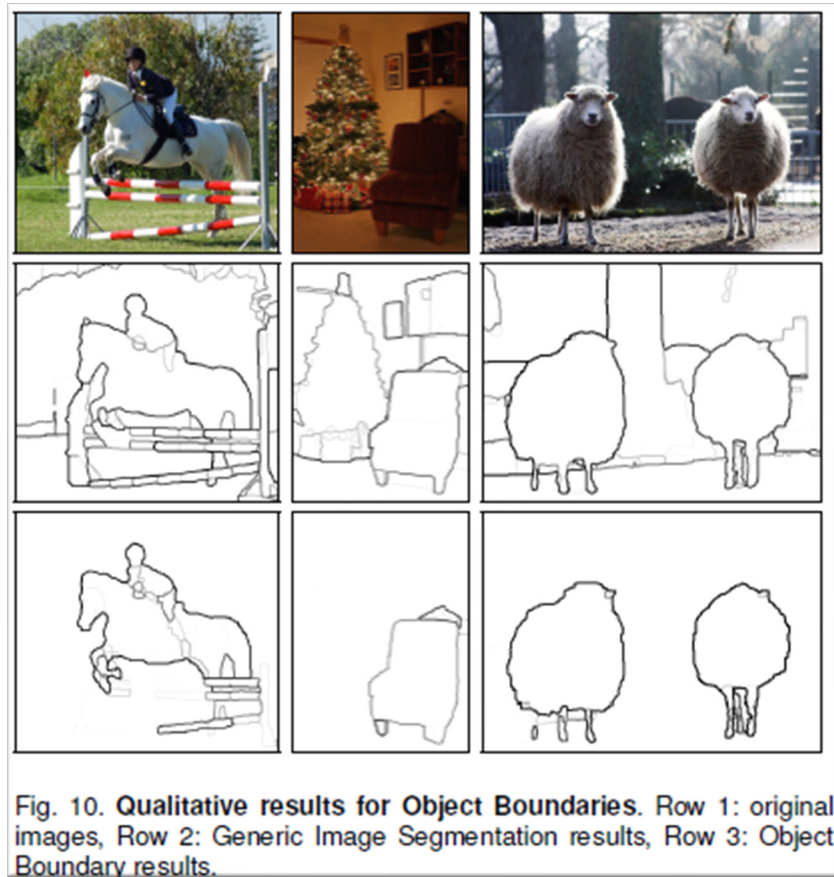
To achieve “High Level Applications,” including the “semantic segmentation” on which Petitioner relies, Maninis indicates that it is necessary to use other techniques—specifically, they use other neural networks (“Dilated

Network” and “PSPNet”) described in other publications by other authors. EX2028, ¶131; EX1007, 9 (“... we study the interplay of our boundary detector with semantic contours and semantic segmentation *by combining COB with Dilated Network [68] and PSPNet [69][.]*”), 13 (COB neural network used “*in combination with*” other neural networks that perform the “high-level vision tasks (object proposals, object detection, and semantic contours and segmentation).”).

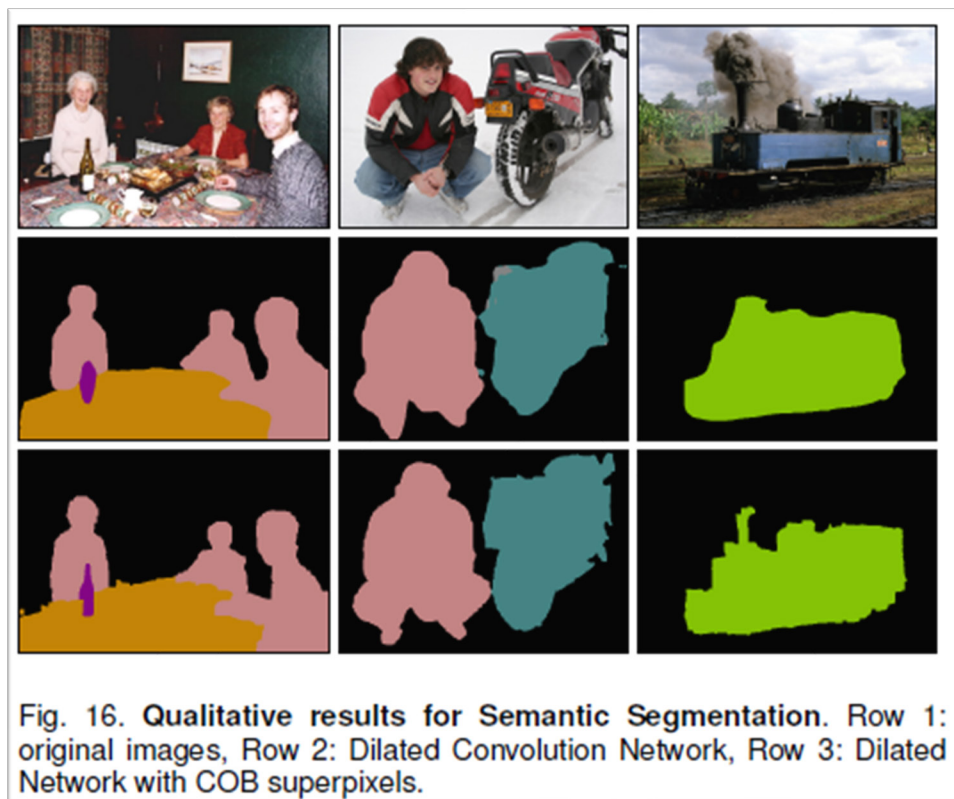
This distinction between the capabilities of the different neural networks in Maninis is illustrated by comparing Figures 9 and 10 with Figure 16. EX2028, ¶¶130-33. Figure 9 shows the results of Maninis’s “generic image segmentation” with row 3 depicting the hierarchical boundaries determined using the results of its COB neural network. EX1007, 7, 9, Fig. 9 (below).



Although Maninis describes these contours as “semantically meaningful,” a POSA would have recognized that no “semantic segmentation” or object classification was performed by the Maninis COB neural network. EX2028, ¶130; EX1007, 7. Likewise, Figure 10 illustrates “generic segmentation and object boundary detection,” but not semantic segmentation or object identification. EX1007, 7-9, Fig. 10 (below); EX2028, ¶130.



By contrast, Figure 16 depicts semantic segmentation where each region has a color identifying it as background or as associated with a particular object—*e.g.*, the color green for a train—achieved *only* by using the Maninis COB neural network in combination with another neural network described elsewhere. EX1007, 9-12, Fig. 16; EX2028, ¶131. The second row shows the semantic segmentations—which are the output of a separate neural network called “Dilated Convolution Network”—and the third row shows how that segmentation was refined with contours produced by the Maninis COB neural network.



EX1007, 11-12, Fig. 16; EX2028, ¶131. In other words, the COB neural network only refined the segment boundaries; it did not itself identify what was depicted within each segment. EX2028, ¶131.

Thus, to determine “semantic boundaries,” which “requires not only detecting the boundaries, but also associating a semantic class to them,” a POSA would have recognized the need to employ *both* the Maninis COB neural network *and* a separate neural network capable of semantic segmentation and then “fuse the results of the two tasks.” EX1007, 11; EX2028, ¶133. Maninis similarly discloses that yet another neural network (“Fast-RCNN”) was required for object detection. EX1007, 12-13; EX2028, ¶134.

That Maninis's COB neural network determines only generic boundaries is confirmed by its training. EX2028, ¶135. That training was governed by an equation that mathematically precludes training on semantic contours or object classifications. *Id.*; EX1007, 3 ("Equation 1" restricting pixel values to two, binary choices: "0" (not part of a contour) and "1" (part of a contour)), 4; EX2042, 3. Thus, even though Maninis relied on training databases that include semantic contours and object labels, it "extract[ed the] contours" to the exclusion of the semantics when training the COB neural network. EX2028, ¶135; EX1007, 7. A POSA would have recognized that, because the Maninis COB neural network is trained only on simple contours, it can recognize only simple contours when analyzing new images. EX2028, ¶135.

Accordingly, when Maninis reports an "Efficiency Analysis" including the "Total Time" (0.79 seconds) it took to determine hierarchical regions ("OWT, UCM") in an image, these times account *only* for generic image segmentation. EX2028, ¶136; EX1007, 9, Table 3. Maninis does not disclose how long it took to determine semantic contours or recognize objects (*e.g.*, cat, sheep, motorcycle) using the other two neural networks (or using any other neural network). EX2028, ¶136. Indeed, Petitioner has not provided any evidence related to the time it would take to run the Maninis COB neural network together with any of the other

techniques Maninis identifies as necessary to achieve semantic contours or object recognition, under any conditions.

Furthermore, Maninis’s analysis time for the COB neural network to determine generic image segmentations was computed “on a NVidia Titan X GPU”—an expensive, state-of-the-art GPU as of 2017 that could perform 11 trillion floating point operations per second (“TFLOPS”) and was designed for large, desktop computers. EX2028, ¶137; EX2045, 1. A POSA would have understood that the capability of graphics cards to handle many calculations simultaneously is critical for running the Maninis COB neural network, which requires billions if not trillions of individual calculations to analyze images. EX2028, ¶137; *cf.* EX1002, ¶31. This confirms that the neural network in Maninis is highly resource intensive.

## **2. Maninis Requires a “Learning Base”**

Maninis’s COB neural network and the other neural networks for semantic contours and object detection mentioned in Maninis must be trained on a “learning base”—a set of images labeled with the information the neural network is being trained to identify. EX2028, ¶138. In Dr. Foroosh’s proposed combination, the “learning base” comprises at least 10,000 dental images of aligners in a service position, acquired with cellphones, with pixel-wise labels of teeth, aligner, and the separation between them. EX1002, ¶122; EX2054, 154:3-12.

A significant driver for the rising popularity of deep learning devices outside of dentistry and orthodontics<sup>6</sup> was the availability of large, pre-existing databases of annotated images. EX2028, ¶139; EX1002, ¶31; EX2041. However, no learning base used to train the Maninis COB neural network included aligner images or images of teeth. EX2048, 212:16-214:5; *see also* EX2028, ¶139; EX2010, 1072. And Petitioner fails to identify any collection of images matching Dr. Foroosh's proposed learning base, or even a single example of a neural network trained on aligner images. EX2028, ¶139.

It was not a regular practice for orthodontist in 2017 to acquire aligner images with cellphones. EX2028, ¶140. Even if practitioners were collecting such images, it would have been costly to de-identify patient data to comply with privacy laws before the images could be used in a learning base. EX2028, ¶140; EX2030, ¶88. A POSA seeking a learning base of aligner images with pixel-wise labels of teeth, aligner, and the separation between them would have recognized that the cost associated with such a learning base could range from tens of thousands to hundreds of thousands of dollars depending on the total number of training images required, and time associated with acquisition and labelling could also be significant. *Id.*

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<sup>6</sup> Petitioner did not identify any prior art application of deep learning in the dental field.

### 3. Petitioner Has Not Demonstrated That Maninis Is Prior Art

To qualify as a printed publication, a reference “must have been sufficiently accessible to the public interested in the art.” *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989). “Because there are many ways in which a reference may be disseminated to the interested public, ‘public accessibility’ has been called the touchstone in determining whether a reference constitutes a ‘printed publication.’” *In re Hall*, 781 F.2d 897, 898-99 (Fed. Cir. 1986). Whether a reference is publicly accessible is determined on a case-by-case basis from the “facts and circumstances surrounding the reference’s disclosure to members of the public.” *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004).

Maninis was downloaded by Petitioner from the website arXiv.org. EX1002, ¶53. It bears a stamp indicating it was *submitted*, but not *published* or otherwise available to a POSA, on April 28, 2017. EX1007, 1; EX1002, ¶55; EX2048, 236:17-24. Petitioner has not identified the date on which it was published but offers two pieces of circumstantial evidence to suggest it was published sometime between April 28, 2017 and the July 21, 2017 priority date of the ’248 patent. Neither suffices.

First, Petitioner cites what it contends are archived copies of the arXiv.org website from 2016 and 2017 reflecting the “policy” of arXiv.org to endeavor to publish articles shortly after they are submitted. EX1022; EX1023; EX1026;

EX1002, ¶¶53-56. Petitioner offers only this unauthenticated hearsay without any testimony from an individual with personal knowledge of either those policies or how the Maninis paper was handled. EX2048, 231:2-234:24. Submissions are subject to review before publication, but Petitioner identifies no evidence regarding the timing of any review of Maninis. *Id.*, 232:1-15. Petitioner's expert's anecdotal suggestion that his own papers were published quickly is unsupported and unhelpful. EX1002, ¶56.

Second, Petitioner cites an archived copy of the author's institutional webpage prior to July 21, 2017, which links to the arXiv.org URL for Maninis. EX1024; EX1002, ¶58. However, there was an *earlier* version of Maninis, on which Petitioner does not rely. EX1002, ¶57. Both versions of Maninis's paper share the same URL, so the existence of a link to that URL suggests only that *one* of the two versions had published as of the archived date—*i.e.*, the first version. EX2048, 235:5-236:8.

With less than three months between the Maninis submission date and the '248 patent priority date, it is not trivial that Petitioner offered no evidence of a publication date for Maninis—a reference Petitioner relies on as disclosing several limitations of each challenged claim. Because Petitioner has not met its burden to establish Maninis is prior art, Petitioner's validity challenge should be rejected as to all claims. *See, e.g., Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-

01039, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential); *see also Louisiana Pac. Group v. Huber Engineered Woods LLC*, IPR2020-00600, Paper 14 at 15-16 (PTAB Aug. 20, 2020).

## **VII. Petitioner’s Proposed Combination Is Inoperable**

Petitioner argues it would have been obvious to use the Maninis COB neural network trained on a learning base comprising historical images labelled with semantic contours (*i.e.*, the contours of individual objects and the objects they represent) to analyze images to determine the same. Paper 2, 26; EX1002, ¶78. Specifically, Petitioner’s expert proposes that the Maninis COB neural network would be trained on “localized pixel-wise semantic annotations,” which are “indications, pixel-by-pixel, of the locations of different objects in each image, identifying what object is depicted in each part of the image.” EX1002, ¶100. According to Dr. Foroosh, a POSA would have been motivated to train the Maninis neural network to “identify teeth and aligners depicted in orthodontic images by detecting their contours and identifying the objects found within each contour.” *Id.*, ¶102. Dr. Foroosh’s proposed learning base thus comprises “images of dental arches of patients wearing aligners in a service position...taken in the context of Kim and Salah’s cellphone imaging techniques” and “labeled with appropriate annotations,” including pixel-wise annotations of each tooth, the aligner, and the “gap[s]” or “spaces between them.” *Id.*, ¶¶102-103.

The Maninis COB neural network is incapable of being trained this way or performing such an analysis. *Supra* §VI.D; EX2028, ¶¶172-183. As a result, Petitioner's arguments fail across the board and should be rejected.

Dr. Foroosh's fundamental misunderstanding of Maninis is evident from his deposition in *Align Tech. Inc. v. Dental Monitoring S.A.S.*, IPR2023-01369, in which Petitioner has challenged U.S. 10,755,409. There, Dr. Foroosh confirmed that, in his view, the Maninis COB neural network always produces semantic contours or semantic boundaries, even when deployed alone:

Q: And you understand that the results reported in Table 3 for the 0.79 seconds is a determination of hierarchal contours, but not object recognition?

A: No, that's not true. ... the way it happens is not sequential. You know, ***the neural network is providing category-specific contours. So what that means is that if -- if it's providing a contour of a cat, it's labeled as a cat that's contoured.*** So it's—simultaneously, we know where the cat is in the image.

Q: I see. Okay. So, just to confirm, it's—it's your understanding that when Maninis is discussing the low-level applications in Section 5, that ***while it's producing the contours or boundaries, it is also identifying those contours or boundaries as associated with a particular object?***

A: ***Absolutely, definitely.***

EX2048, 211:20-212:15; *see also id.*, 216:4-22 (indicating his misunderstanding that Fast-RCNN is not necessary for the object detection in Maninis Section 6.3).

This is incorrect. *Supra* §VI.D.1. The Maninis COB neural network can be trained *only* on contours and can identify in an image *only* contours. Although those contours are aggregated into hierarchies (“UCM”) to identify regions (“segments”) depicting objects that are the likely subject of the image, the Maninis COB neural network is incapable of determining *what those objects might be*. EX2028, ¶¶178-79. In other words, the Maninis COB neural network can detect *the contour* of a cat in an image, but it has no way to determine that it *is* a cat. *Id.* As Maninis itself discloses, another neural network is required to make that kind of “semantic” determination. *Id.*

A POSA would not have been motivated to train or use the Maninis COB neural network to perform a task it is incapable of performing, *i.e.*, “identifying objects (such as the teeth and aligners depicted in each image),” and would not have had a reasonable expectation of success in doing so. EX2028, ¶¶180-81. For the same reasons, Petitioner’s ground references do not disclose or render obvious “analysis of the analysis image by means of a deep learning device, trained by means of a learning base,” as claimed. EX2028, ¶180.

Although Maninis refers to *other* neural networks, which are described by *different* authors in *different* papers *not in evidence* in this proceeding, Petitioner

cannot rely on that disclosure now. *See* 35 U.S.C. § 312(a)(3); U.S. Patent Trial and Appeal Board, Consolidated Trial Practice Guide, 73 (Nov. 2019) (A petitioner “may not submit new evidence or argument in reply that it could have presented earlier, *e.g.* to make out a prima facie case of unpatentability.”); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016). The Petition contains no evidence of whether: (1) those other neural networks satisfy the limitations of the claims; (2) a POSA would have been motivated to use them in the proposed combination; or (3) a POSA would have had a reasonable expectation of success in doing so.

To the extent Petitioner now proposes that a POSA would have used those networks *in addition* to the Maninis COB neural network—something never suggested in the Petition—Petitioner has additionally failed to offer any evidence regarding the motivations and expectations of a POSA in working with *two* neural networks, or which neural network Petitioner relies on to satisfy any particular claim limitation (*e.g.* which “deep learning device” is “trained” by means of which “learning base” and performs which “analysis” to obtain which “results”). EX2028, ¶183.

Moreover, Petitioner cannot rely on the Maninis COB neural network’s detection of generic contours alone because generic contours do not satisfy the claim requirement for either a tooth attribute value (including for claims 1, 7 and

14) or an image attribute value (including for claim 8 and 15). *Supra* §VI.D.; *infra* §VIII.B.4-5.

To the extent Petitioner nonetheless maintains that Maninis functions within its proposed obviousness combination, Patent Owner addresses additional, critical deficiencies in Petitioner’s ground below.

### **VIII. Petitioner Has Failed to Prove That the Ground References Render the Challenged Claims Obvious**

The burden is on Petitioner to show that a POSA would have been motivated to combine the prior art to achieve the claimed invention with a reasonable expectation of success. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). This inquiry 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). The mere fact that a possible arrangement existed in the prior art does not provide a reason that a POSA would have attempted such an arrangement. *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 887 (Fed. Cir. 2024). Here, Petitioner has failed to identify why a POSA would have made the specific asserted combination, and instead relies on the type of hindsight *KSR* warned against. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

**A. A POSA Would Not Have Been Motivated to Combine Kim, Invisalign, and Salah**

Petitioner's ground is based on an unqualified expert's misinterpretation of the ground references. When properly understood and correctly analyzed, however, Petitioner's references do not render the challenged claims obvious.

**1. Petitioner's Expert Repeatedly Misinterprets Kim**

Petitioner's motivation to combine Kim with Invisalign is premised on the incorrect assertion that Kim teaches the use of photographs of seated aligners. Paper 2, 21-22; EX1002, ¶¶71-72. Petitioner's only basis for this assertion is the "clear aligner information" described in a single paragraph of Kim (EX1005, [0066]), but that teaching concerns images of the aligner itself, not a patient wearing the aligner. *Supra* § VI.A. Petitioner appears to recognize as much. Paper 2, 21.

Even if the clear aligner information did include an image of an aligner positioned on teeth—which it does not—that image is *not* used for diagnostic or treatment purposes. *Id.* Only the separate teeth alignment information, comprising photographs of teeth alone, is used for those purposes. EX1005, [0063], [0085], [0087], [0093]. And the purported benefits of Kim—enhancing accuracy, reducing the time and cost of treatment, and facilitating remote assessment—stem from its use of teeth alignment information. *Supra*, § VI.A.

At deposition, Dr. Foroosh agreed that Kim’s teeth alignment information and clear aligner information are distinct, and it is the teeth alignment information that is used to diagnose and treat patients. EX2054, 13:11-19, 15:12-23. Dr. Foroosh further admitted that there was no basis in Kim for his opinion that Kim discloses checking an aligner image to determine whether the aligner was “fitting well.” *Id.* 22:6-19.

Because Petitioner and its expert misinterpret Kim as assessing aligner fit from an image, the purported motivation to combine Kim with Invisalign based on that misinterpretation should be rejected. *E.g., Grit Energy Sols. v. Oren Techs., LLC*, 957 F.3d 1309, 1322 (Fed. Cir. 2020) (discounting expert testimony inconsistent with express disclosures of the prior art); *Biedermann Techs. v. K2M, Inc.*, 678 F. Supp. 3d 716, 723-24 (E.D. Va. 2023) (expert testimony insufficient to support anticipation when expert erred in analysis of prior art).

Petitioner’s motivation to combine Kim with Salah is also based on the faulty premise that Kim “teaches application of **computer image analysis** to dental images.” Paper 2, 24; EX1002, ¶74. But Dr. Foroosh confirmed at deposition that Kim discloses no computer image analysis, and he withdrew this as a motivation to combine Kim with Salah. EX2054, 30:12-15; *see also* EX2028, ¶¶185-89. Petitioner identifies **no** other reason to combine Kim and Salah, and Dr. Foroosh’s misinterpretation of Kim should defeat this proposed combination as well.

**2. Petitioner's Expert Admitted to Not Understanding Key Portions of Invisalign**

Invisalign is a “Clinical Monitoring Guide” intended “to help the Invisalign practitioner.” EX1006, i; *see also supra*, § VI.B. By his own admission, Dr. Foroosh is not an Invisalign practitioner and has no recollection of *ever* reading similar clinical guidelines before this case. EX2054, 32:20-33:3, 33:14-16. Because of his lack of orthodontic experience, Dr. Foroosh was unable to understand key portions of Invisalign or explain the meaning of terms appearing on the same pages of Invisalign that he cites. *E.g.*, EX2054, 33:14-34:11, 36:5-17, 38:18-39:24; *cf.* EX1002, ¶¶47-48 (citing Invisalign pages i-ii).

Notably, Dr. Foroosh could not explain whether “an unengaged attachment” in Invisalign means the same thing as phrases used throughout his declaration, including “poorly seated aligner” or “poorly fitted aligner.” EX2054, 37:22-38:8; *cf.* EX1002, ¶¶71, 88, 140. Dr. Foroosh also did not understand portions of Invisalign directly related to aligner fit. Although Invisalign discloses using a scaler in-person to “check retention,” Dr. Foroosh “[did]n’t know what – what the document is referring to in this case and what operations a dentist should perform” and indeed “cannot know” how to use a scaler to check retention since he is “not trained as a dentist.” EX2054, 65:12-23. He thus ignored this portion of Invisalign, stating that it “didn’t” “factor into [his] opinions.” *Id.* 66:8-15. This teaching from

Invisalign is highly relevant because it confirms that Invisalign describes methods for assessing aligner fit that can only be performed in person.

Dr. Foroosh also admitted to disregarding other aspects of Invisalign directed to in-office treatment, focusing instead on its “pictures” and “specific quantification methods” to “motivate a POSA for the combination that [he is] providing.” EX2054, 63:4-17; *see also id.*, 62:20-23 (“I rely on some of the disclosures in the form of images or quantification methods that Invisalign is providing.”), 88:6-9 (“in my combination, *I didn’t even use the fact that this is disclosing, you know – in fact, this is disclosing an in-office treatment*”). Dr. Foroosh’s approach is improper. An expert cannot just “selectively cull[] from the prior art to fit the parameters of the patented invention.” *Cheese Sys., Inc. v. Tetra Pak Cheese and Powder Sys., Inc.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013).

In its Institution Decision, the Board found persuasive Dr. Foroosh’s assertion that Invisalign Figure A was illustrative of what “a person would see when viewing teeth and an aligner in real life.” Paper 10, 33. But Dr. Foroosh has since admitted that he has “*no idea*” whether that photograph is representative of an aligner on a patient’s teeth and he cannot say how an orthodontist would have allegedly measured the separation between tooth and aligner from Invisalign. EX2054, 60:18-61:4, 45:17-19, 58:24-59:7, 74:9-14 (describing such an understanding as “out of the

scope of [his] expertise”). A POSA would know, however, that orthodontists did not quantitatively assess aligner fit from photographs in 2017. EX2030, ¶¶45, 64.

Accordingly, Dr. Foroosh failed to properly analyze Invisalign as a prior art reference, which requires “full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965). Because Dr. Foroosh was not qualified to consider Invisalign and failed to consider it as a whole, his uninformed and incorrect opinions on how a POSA would have understood this reference should be rejected. *See Medtronic Inc. v. Intermedics, Inc.*, 799 F.2d 734, 741 (Fed. Cir. 1986) (expert testimony should be “circumscribed ... on the basis of the witness’s range of expertise”).

### **3. A POSA Would Not Have Been Motivated to Assess Aligner Fit Using an Aligner Image**

Contrary to Petitioner’s assertions, Kim does not disclose the use (or usefulness) of photographs showing seated aligners. EX2028, ¶¶185-86. Rather, Kim expressly relates to “remote teeth alignment services.” EX1005, [0010]; EX2028, ¶¶69-70; EX2030, ¶76. In 2017, assessing teeth alignment and assessing aligner fit were two distinct analyses. Typically, assessing aligner fit involved a combination of visual and manual inspections performed by an orthodontist during in-person appointments. *Id.*, ¶¶49, 76. Kim never purports to provide a new way to assess aligner fit from a photograph nor suggests that could be successfully achieved.

Consistent with the state of the art, Invisalign is concerned with in-person analyses and instructs orthodontists to perform certain steps at each appointment that could not be performed remotely. EX2030, ¶58. As Dr. Foroosh admitted, Invisalign discusses acquiring images only for purposes of aligner design and manufacture, *i.e.*, before the aligners exist, and also does not teach analysis of any images. EX1002, ¶88; EX2054, 70:2-7, 142:6-16; EX2028, ¶94; EX2030, ¶68.

In the Institution Decision, the Board credited Dr. Foroosh's opinion that "Invisalign provides a reason to acquire an image of the patient's teeth with an aligner being worn, *i.e.*, in order to assess the gap between the tooth and aligner." Paper 10, 25. But Dr. Foroosh was not qualified to offer that opinion, and the image Dr. Foroosh relied upon was neither acquired on a cellphone nor representative of an aligner fit situation that orthodontists would have encountered in 2017. EX2028, ¶¶90-91; EX2030, ¶¶61-62.

Furthermore, a POSA would have recognized that the images in Invisalign were taken by trained professionals with a more sophisticated camera than a 2017 cellphone to ensure their quality. EX2054, 71:11-14, 134:10-135:11; EX2030, ¶67. Nothing in Invisalign indicates cellphone images would be suitable for assessing

aligner fit.<sup>7</sup> EX2028, ¶187. Although Invisalign notes that separation of greater than 1 mm is indicative of an issue, it does not suggest measuring that separation on an image to assess aligner fit. Rather, as Dr. Kusnoto explains, fit issues were difficult to diagnose with the naked eye and orthodontists used a combination of visual examination and manual manipulations. EX2028, ¶188; EX2030, ¶¶63, 75-76.

For these reasons, a POSA would not have been motivated to modify the approach in Kim to obtain images of an aligner in a service position or measure the distance between tooth and aligner from a cellphone image captured by an untrained person, and nothing in Kim or Invisalign suggests that the in-person techniques of Invisalign could be successfully replaced with computer-implemented analyses on patient-initiated photographs captured using a cellphone. EX2028, ¶189.

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<sup>7</sup> The Board was also “persuaded by Petitioner’s contentions that using cellphones to acquire images depicting teeth wearing an aligner ‘was known to be a useful practice for assessment of a patient’s orthodontic treatment status.’” Paper 10, 25. The sole basis for Petitioner’s contentions, however, is Frey—a reference that is not prior art. *Infra*, § VIII.A.4.

In its Institution Decision, the Board also credited Petitioner’s assertion that the combination of Kim and Invisalign “would be applying known methods for orthodontic evaluation of aligner fit.” Paper 10, 23, 25-27. Again, Dr. Foroosh is not qualified to offer an opinion on the known methods for orthodontic evaluation in 2017. *See supra* § II. Dr. Foroosh is also wrong—in 2017, aligner fit was not quantitatively evaluated based upon images or by measuring the separation between the tooth and aligner, and no methods existed in the prior art to perform such an analysis. EX2030, ¶¶45, 69.

Even adding Salah would not have motivated a POSA to acquire images showing an aligner in a service position using a cellphone to assess aligner fit. Although Salah includes one image showing a device positioned on the teeth, that device is a bonded expander that could not have been readily removed before taking the photograph—not a removable aligner. EX1008, FIG. 11; EX2028, ¶190; EX2030, ¶¶83-84.

Salah does not describe any method for assessing the fit of a device. Rather, Salah assesses tooth positions over time by updating 3D models of a patient’s teeth. Salah further teaches that, to the extent contours are used to update those 3D models, only high contrast areas should be used to ensure a high-quality analysis. EX1008, 60:17-22; EX2028, ¶191. Specifically, Salah teaches that “an area of high contrast” can produce high-quality contours, whereas a “low-contrast area” will produce low

quality contours. EX1008, 60:17-24; EX2028, ¶191. Salah thus recommends processing the image to retain only the outlines identified with a high probability. EX1008, 61:2-3; EX2028, ¶191. That is because, if the “quality threshold is low, the discriminant information retained will be abundant, but *unreliable*” and this “will then lead to the *retention of ‘false’ contour points*, i.e. points which, will be *mistakenly* considered as belonging to the contour of teeth and gums.” EX1008, 60:25-61:1. Salah thus teaches that preferably, “the quality threshold is high in order to retain only highly reliable discriminating test information.” *Id.*, 61:2-3.

Because aligners visually blend with teeth, they represent areas of low contrast. EX2030, ¶84; EX2028, ¶124. A POSA would have thus understood Salah to teach away from using contour detection with aligner images. EX2028, ¶¶171, 191. *KSR*, 550 U.S. at 416; *Intelligent Bio-Sys.*, 821 F.3d at 1369 (substituting a method into the prior art that “would have been expected to perform inefficiently in that role” undermines motivation); *see also Plas-Pak Industries, Inc. v. Sulzer Mixpac AG*, 600 Fed. Appx. 755, 758 (Fed. Cir. 2015) (changing “‘principle of operation’ is unlikely to motivate a person of ordinary skill to pursue a combination with that reference”).

In sum, Petitioner relies only on Kim, Invisalign, and Salah to allege the obviousness of step a" of claims 1 and 15. The lack of motivation to combine these three references defeats Petitioner’s arguments as to all challenged claims. Paper 2,

29, 34, 55. Even when combined, however, none of Petitioner’s references teach or render obvious the novel claimed method of assessing the shape of an aligner comprising acquiring an image of an aligner in a service position using a cellphone.<sup>8</sup>

#### **4. Frey Is Not Prior Art and Cannot “Confirm” Motivation**

Petitioner contends that Frey “confirms that acquiring digital photographs of patient’s teeth, including patient-acquired cellphone images of teeth of patients wearing aligners in a service position, was known to be a useful practice for assessment of a patient’s orthodontic treatment status.” Paper 2, 23-24; EX1002, ¶¶90. However, Frey cannot confirm any motivation because it is not itself prior art.

Frey is a blog post entitled “DIY Dental Monitoring Solution” from April 29, 2017. EX1009, 17. Frey acknowledges Patent Owner’s software and proposes a “do-it-yourself teleorthodontics system” derived from Patent Owner’s techniques. *Id.*, 17-18, 26. Frey links to an earlier post, which confirms that, shortly before April 29, 2017, he “had the Dental Monitoring folks come by the office” and describes Patent Owner’s various products and services. EX2053, 1.

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<sup>8</sup> While claim 15 does not require acquisition of an aligner image using a cellphone, Dr. Foroosh does not suggest that a POSA would have been motivated to use any other acquisition device to capture an image.

Under § 102(b)(1), a disclosure made within a year of the priority date—like Frey—is not prior art if it was made “by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor” (§ 102(b)(1)(A)) or “the subject matter disclosed had ... been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor” (§ 102(b)(1)(B)). Both exceptions apply. First, by his own admission, Frey derived his post from the ’248 patent inventors’ own disclosures and the reference is therefore excluded under § 102(b)(1)(A). EX1009, 17; EX2053, 1. Second, under § 102(b)(1)(B), the ’248 patent inventors publicized the same subject matter as Frey—as is evident from Frey relying on their marketing disclosures—and the exception therefore “applies to the subject matter in [Frey] being relied upon as prior art ... that was also publicly disclosed by [the inventors] before” April 29, 2017. M.P.E.P. § 2153.02. Thus, to the extent Frey discloses any part of the invention of ’248 patent, the ’248 patent confirms that Patent Owner’s products referred to and copied in Frey were invented by the same four inventors as the ’248 patent.

Even if Frey could be considered, it does not suggest using a computer or deep learning device to analyze any images. EX1009, 17-27; EX2028, ¶169; EX2054, 149:16-150:1. Frey only suggests remotely obtaining a video that the orthodontist would visually inspect. Thus, it cannot confirm a motivation to apply computer-

implemented image analysis to photographs of aligners in a service position on teeth, and Petitioner’s arguments based on the ’248 patent inventors’ inventive path is based on impermissible hindsight. *E.g., Otsuka Pharm. Co., v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) (“The inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight.”).

**B. The Combination of Kim, Invisalign, Salah, and Maninis Does Not Disclose the Claimed Analysis Using a Deep Learning Device Trained by a Learning Base**

Even if a POSA combined Kim, Invisalign, and Salah—they would not—there would be no motivation to further combine these references with Maninis’s COB neural network (or any other neural network in Maninis).

**1. Petitioner’s Expert Admitted to Relying on Hindsight**

Dr. Foroosh selected his combination using impermissible hindsight, driven by what is claimed in the ’248 patent and not the motivations and teachings of the art in 2017. *See KSR*, 550 U.S. at 421 (warning against “the distortion caused by hindsight bias” caused by “arguments reliant upon *ex post* reasoning”); *Ortho-McNeil Pharma., Inc. v. Mylan Lab’ys, Inc.*, 520 F.3d 1358, 1364-65 (Fed. Cir. 2008); *Otsuka*, 678 F.3d at 1296.

Dr. Foroosh’s hindsight is apparent when you compare his approach for the ’248 patent to that for U.S. 11,109,945 (“the ’945 patent”), which Petitioner also challenged. *Align Tech. Inc. v. Dental Monitoring S.A.S.*, IPR2024-00010. Like

the '248 patent, the '945 patent claims a method for evaluating the shape of an orthodontic aligner. EX1001, cl. 1; EX2058, cl. 1. But critically, the '248 patent requires use of a deep learning device, whereas the '945 patent requires image processing software. *Id.*

In both IPRs, Dr. Foroosh relies on Kim, Invisalign, and Salah. With respect to the '248 patent—requiring deep learning—Dr. Foroosh alleges that a POSA would have been motivated to use the Maninis COB neural network, including based on the teachings of Salah. But for the '945 patent, “deep learning is not in the picture” and Dr. Foroosh is “not considering deep learning.” EX2054, 157:21-158:23. Instead, Dr. Foroosh says a POSA would use a different, non-deep learning method identified as “preferred” in Salah, the Canny algorithm. EX2059, ¶83; EX2054, 178:20-179:2 (“[I]n this patent the '945, I'm saying that the POSA would say -- he or she would go with the alternative of known [*sic*] deep learning method, and Salah is disclosing a whole group of those nondeep learning methods.”). Dr. Foroosh does not explain why a POSA would have been motivated to select two different techniques from Salah for the two different patents. To the contrary, his alleged motivations of a POSA are the same for both patents. EX2054, 157:21-158:23, 159:10-13.

Dr. Foroosh’s selection of two different methods—one preferred, one not—depending on the challenged patent exposes his improper hindsight-driven

approach. Because they rely on hindsight, Dr. Foroosh's opinions should be afforded little weight. *Fox Factory, Inc., v. SRAM, LLC*, IPR2016-01876, Paper 59 at 18 (P.T.A.B. April 2, 2018) (giving "little weight to [expert's] testimony on rationale to combine" where motivated by hindsight).

**2. A POSA Would Not Have Been Motivated  
to Assess Aligner Fit Using A Deep Learning Device**

Salah is the only reference that even refers to "deep learning" in the context of dental image analysis, and Salah teaches that "deep learning" is "not preferred." *Supra* §VI.C; EX2028, ¶197. Petitioner further ignores that Salah's image analysis is "best carried out...on the patient's own device" (*i.e.*, a cellphone), which would have discouraged a POSA from using a resource-intensive methodology, like deep learning. EX2030, ¶171.

Moreover, Salah is directed to monitoring the position of teeth over time. EX1008, 1:25-2:19; EX2028 ¶¶99-100; EX2030, ¶82; EX2054, 90:6-9. A POSA would not have viewed Salah as a general teaching to apply "computer image analysis to dental images for orthodontic treatment purposes" because Salah's image analysis requires a high-quality 3D model of the patient's teeth against which the contours identified in subsequent low-quality images are compared. EX2028, ¶¶102, 198. Salah never suggests a use for contour detection on patient-initiated images absent a high-quality 3D model for comparison. *Id.*

Salah discloses only the determination of generic contours. EX2028, ¶199. Dr. Foroosh does not suggest that a POSA would have been motivated to, or had a reasonable expectation of, assessing aligner fit from generic contours, *i.e.*, without knowing whether the contours correspond to a tooth, aligner, gum, tongue etc. Instead, Dr. Foroosh opines “[a] POSA would view Maninis as providing good reasons to employ deep learning techniques for object and contour detection,” including because it “is compatible with different CNNs.” EX1002, ¶77. But the fact that the Maninis COB neural network can be combined with other neural networks is irrelevant to whether it would have been desirable to incorporate deep learning into this particular combination. EX2028, ¶200.

Dr. Foroosh also states that Maninis offers “improvements” over state-of-the-art deep learning techniques, specifically “substantially faster object edge and contour detection and image classification” and improvements in semantic segmentation. EX1002, ¶77. Again, Dr. Foroosh misunderstands Maninis. Maninis’s COB neural network is only able to determine generic contours and cannot conduct semantic segmentation. EX2028, ¶201. The reported speed on which Dr. Foroosh relies to support his alleged motivation reflects the identification of generic contours—not the objects they define. *Id.*, ¶¶201-02. Even if Maninis was better than the state-of-the-art deep learning techniques for contour detection,

that purported motivation assumes a POSA had already decided to use deep learning. Such circular reasoning cannot justify combining the references.

Beyond Maninis, Petitioner relies only on a vague reference to image analysis trends. Paper 2, 25. But as of 2017, artificial intelligence was not used in acquiring or analyzing dental photographs. EX2030, ¶86; EX2037, ¶34 (Petitioner's district court dental expert conceding that deep learning was not part of the standard of care in 2017). Instead, dental professionals were very cautious of new technologies because of the potential impact on patient outcomes. EX2030, ¶86; EX2036, 50:3-5, 50:19-24.

**3. The Significant Time and Expense Associated With Implementing Maninis To Assess Aligner Images Weigh Heavily Against Any Motivation Here**

Neural networks are only useful once they have been trained, and they can only recognize what they have been trained to recognize. *Supra* §III.C. Petitioner's expert argues that, to implement Maninis, the neural network would have been trained on more than 10,000 images of patient's teeth with seated aligners captured with cellphones. EX1002, ¶100; EX2048, 103:23-106:5, 222:7-12; EX2028, ¶138; EX2054, 154:3-12. Petitioner has identified no such collection of images that existed in 2017. EX2048, 109:3-19; EX2028, ¶¶139-40; EX2030, ¶87; EX2010, 8; EX2041. Instead, Dr. Foroosh seemingly suggests a POSA would have practiced the combination of Kim, Invisalign, and Salah *without* Maninis to gather the images

over time. But none of Kim, Invisalign, or Salah discloses photographing seated aligners using a cellphone, and as such, they could not be used to generate such a learning base. EX2028, ¶¶91, 203.

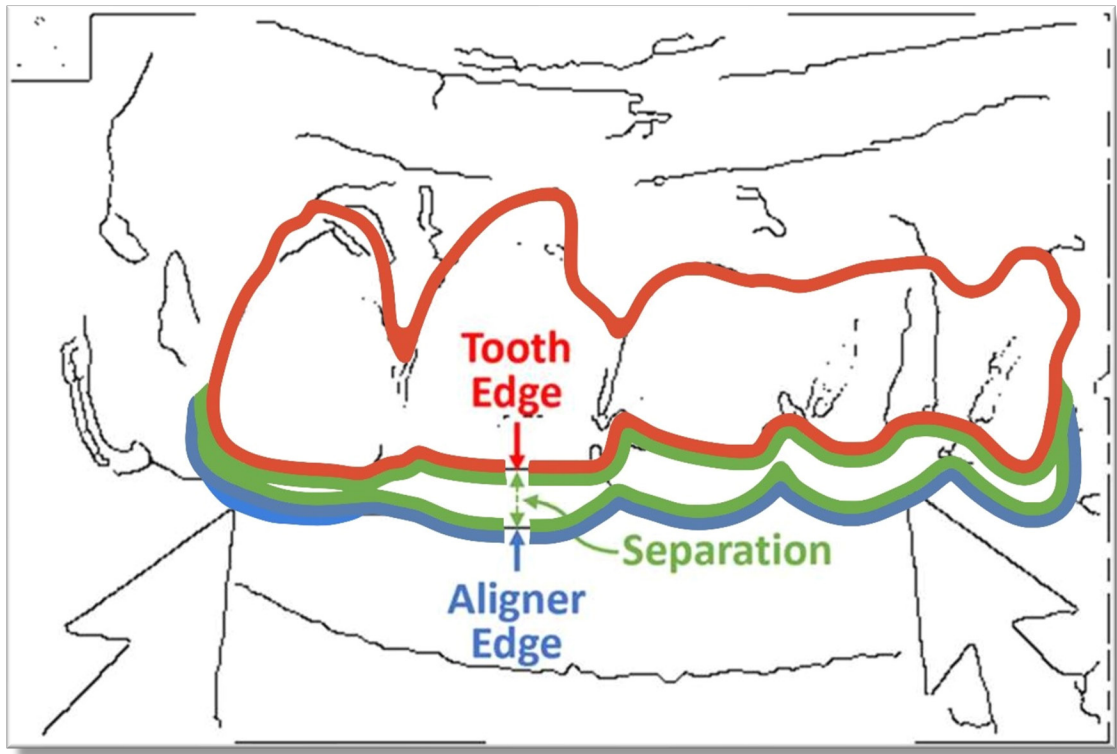
If a dentist began capturing such images, they would still need to be anonymized—a necessary step for compliance with privacy laws, like HIPAA—at significant cost. EX2028, ¶140; EX2030, ¶88. Once acquired and anonymized, the dental images would then need to be labeled with pixel-wise contours identifying the edges of teeth, aligners, and the space between, consistent with the training Dr. Foroosh proposes. *Supra* §VII.A. A POSA would have appreciated that these labels are challenging and expensive to apply because they require precise and sophisticated annotation. EX2028, ¶140; EX2030, ¶89.

The significant cost, time, and complexity that would have been required to obtain Dr. Foroosh’s proposed learning base weigh heavily against a motivation. EX2028, ¶140; EX2030, ¶90; *see, e.g., Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1166 (Fed. Cir. 2006) (holding prior art must be considered as a whole, including its benefits and disadvantages).

**4. Petitioner’s Semantic Contours Are Not “Tooth Attributes” (Claims 7 and 14)**

Petitioner fails to identify any “tooth attribute value” assigned to the historical images as required in claims 7 and 14, and its proposed combination thus fails.

Claims 7 and 14 depend from claim 1 and require that the “learning base” for the deep learning device include “more than 1000 historical images,” each “historical image” comprising “historical tooth zones” representing a tooth to which at least one “*tooth attribute value*” is assigned.” Petitioner proposes that a POSA would have been motivated to use “historical images” labeled with contours on a pixel-wise basis, with each pixel identified as “corresponding to teeth,” “corresponding to aligners,” or “corresponding to the gap between the two.” Paper 2, 45-47, 54-55. Using Dr. Foroosh’s own example, below is an approximate illustration of the semantic contours Dr. Foroosh suggests would be labeled on a historical image, with the pixels identified as teeth contours in red, the pixels identified as aligner contours in blue, and the pixels identified as gap contours in green:



EX2028, ¶¶209-10. Petitioner asserts that these boundaries are “tooth attribute values”—Petitioner is wrong.

These contours defines “zones,” they are not “attributes.” As detailed above, claims 7 and 14 distinguish between a “tooth zone,” which corresponds to the “zone” or “location” of a tooth in either the historical or the analysis image, and a “tooth attribute,” which is an “attribute” of the tooth represented “on said ... tooth zone.” *Supra*, § V.A; EX2028, ¶¶207-08. The “tooth zone” defines where the tooth is, and the “tooth attribute” describes the tooth in that zone.

Boundaries and edges are also not “values” as required by the claims—they are images (*i.e.*, bitmaps of individual pixel values) and are provided to the neural

network as vectors having as many dimensions as there are pixels in the analysis image. EX2028, ¶¶211-14. Petitioner has thus failed to identify any “value” that would have been labeled in the historical image or identified in the analysis image. *Id.*

Because the “tooth and aligner edges” are not tooth attribute values of the historical images or the analysis images, Petitioner has failed to demonstrate that claim elements 7(1), 7(3), 14(1), and 14(3) are satisfied by his proposed combination. Additionally, a POSA would not have been motivated to and would not have had a reasonable expectation of successfully practicing claims 7 or 14 as Petitioner proposes.

**5. Petitioner’s Semantic Contours Are Not “Image Attributes” (Claim 8)**

Petitioner also fails to identify the “image attribute value” required by claim 8. In contrast to claims 7 and 14, which relate to the detailed analysis method of the ’248 patent, claim 8 relates to the global analysis method. It thus requires in Step 8(1') that an “*image attribute value*” be labeled in the “historical images” used to train the “deep learning device.” During analysis, Step 8(3') then requires the deep learning device to determine “at least one probability relating to *said* image attribute value.” Accordingly, the same “image attribute value” must be both labeled on the

historical images and determined by the deep learning device from the analysis image.

Dr. Foroosh points to multiple purported “image attributes” in connection with Steps 8(1') and 8(3') but ignores that the claim requires they be the *same* attribute. Any alleged “image attribute” that is not the same in both steps fails to satisfy claim 8.<sup>9</sup> EX1002, ¶¶139-44; EX2028, ¶¶215-18.

As to the candidates that Dr. Foroosh identifies for both steps 8(1') and 8(3'), none are “image attributes” within the meaning of claim 8. For example, Dr. Foroosh identifies the annotations of “the locations of each tooth and each corresponding aligner part” and the “gaps” between them. EX1002, ¶140. These annotations are made on a pixel-wise basis and are *regional* attributes, not *image* attributes—a distinction made clear in the '248 patent specification. EX2028, ¶219; EX1001, 26:3-14; *supra*, § V.B. Nothing about pixels being identified as corresponding to a “tooth” or “aligner” constitutes a value for an attribute of the image *as a whole*.

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<sup>9</sup> This includes all the proposed image attributes Dr. Foroosh adds in his analysis of limitation 8(3'). EX1002, ¶144 (incorporating image attributes from 8(1') by reference in 8(3') but listing further possible attributes in 8(3') only), ¶140.

Dr. Foroosh also refers to the “presence of an aligner” and the “presence of a separation” as possible image attributes, but neither is compatible with his proposed combination. EX2028, ¶¶220-21. For these purported image attributes, Dr. Foroosh would assign to the historical images values for a specific pixel, *not* for the image as a whole. But a deep learning device trained to determine whether pixels correspond to various objects produces a distinct output from a device trained to determine whether the image as a whole contains those objects. *Id.* That is, the device would neither be trained on an attribute relating to the whole image, nor output a value relating to the whole image. *Id.*, ¶220.

Furthermore, neither the Maninis COB neural network nor the other neural networks mentioned in Maninis can be trained on historical images labeled with an “image attribute value.” EX2028, ¶¶221-24. As discussed above, the labels for training the Mannis COB neural network are pixel-by-pixel binary values (0 or 1) indicating whether that pixel is part of a contour. *Supra* § VI.D.1. Maninis’s COB neural network cannot accept any inputs other than a vector of values, each value representing a pixel in an analysis image. These vectors are not the “image attributes” of the claimed global analysis as they do not “relate to the whole image” but rather, each value in the vector relates to a *regional* attribute: whether a single pixel is part of a contour. EX2028, ¶221.

Similarly, to produce semantic contours, Maninis proposes running *another* neural network in combination with its COB neural network. EX2028, ¶¶222-23. The training labels used for semantic segmentations in those other neural networks are similar to those of the COB neural network: namely, bitmap vectors with values assigned for each pixel. However, rather than being limited to 0 or 1, the values would include other numbers, each corresponding to the class of object to be recognized (teeth, aligner, or gap). *Id.* These training labels are thus also pixel-specific and thus not “image attribute values.” *Id.*

Because Dr. Foroosh has proposed that the “deep learning device” determines contours or semantic contours rather than holistic image features, a POSA would have understood it is impossible for the device to be trained on “historical image[s] comprising an ... image attribute value.” EX2028, ¶224; *see also* EX1001, 3:26-27; EX1002, ¶75. That is, the neural networks of Dr. Foroosh’s combination can be trained only on pixel-wise annotations, not “image attribute values.” EX2028, ¶225. Although an image attribute value can in some embodiments be determined from tooth attribute values *after* the image has been analyzed, that would require doing a “detailed” analysis (as in claims 7 and 14) to obtain the tooth attribute values, and not a “global” analysis. *Id.* In other words, claim 8 embodies the “global analysis” approach—and Maninis discloses deep learning devices that are incapable of “global analysis.” *Supra* § IV.

As a result, Petitioner has failed to demonstrate that the limitation of Step 8(1') is satisfied by his proposed combination. Furthermore, a POSA would not have been motivated to use Maninis as Dr. Foroosh proposes with any reasonable expectation of success because it would be inoperable. EX2028, ¶226.

## **IX. Conclusion**

Patent Owner respectfully submits that the Board should find all the challenged claims patentable over the ground raised in the Petition.

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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 RESPONSE** specified in 37 C.F.R. § 42.24 has 13,907 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 for Microsoft 365 MSO.

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**Certificate of Service**

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on July 12, 2024, a complete copy of **DENTAL MONITORING SAS'S PATENT OWNER'S RESPONSE** was served via electronic mail on the following counsel of record for Petitioner at the email addresses: mrosato@wsgr.com, margenti@wsgr.com, and pmedley@wsgr.com, as indicated in the Petition for electronic service to the following Petitioner counsel:

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