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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

DENTAL MONITORING SAS,

Plaintiff/Counterclaim Defendant,

v.

ALIGN TECHNOLOGY, INC.

Defendant/Counterclaim Plaintiff.

Case No. 3:22-cv-07335-WHA

DEFENDANT'S PATENT LOCAL RULE 3-3 AND 3-4 INITIAL INVALIDITY CONTENTIONS AND DISCLOSURES

Dental Monitoring Ex. 2009
Align Technology, Inc., v. Dental Monitoring SAS.
IPR2023-01369

I. INTRODUCTION

Pursuant to Patent L.R. 3-3 and 3-4, Defendant Align Technology, Inc. ("Align" or "Defendant") hereby provides the following initial invalidity contentions and disclosures ("Contentions") to Plaintiff Dental Monitoring SAS ("Dental Monitoring" or "Plaintiff") for U.S. Patent Nos. 10,755,409 (the "'409 patent"); 11,049,248 (the "'248 patent"); and 11,109,945 (the "'945 patent") (the "Asserted Patents"). Align reserves the right to supplement or modify these Contentions, consistent with Patent L.R. 3-6.

Through its Patent L.R. 3-1 and 3-2 infringement contentions and disclosures served on July 28, 2023 ("Infringement Contentions"), Plaintiff has asserted claims 1-7 and 11-15 of the '409 patent, claims 1-8 and 12-16 of the '248 patent, and claims 1-2 and 4-6 of the '945 patent (collectively, the "Asserted Claims"). All Asserted Claims are invalid under at least 35 U.S.C. §§ 101, 102, 103, and/or 112. Align reserves the right to supplement these Contentions to the full extent permissible if Plaintiff is permitted to supplement its Patent L.R. 3-1 and/or 3-2 disclosures or any other contentions in this case.

Align's Invalidity Contentions are based on the facts and information available as of the date of these Contentions. Align takes no position on any matter of claim construction in these Contentions. Any statement herein describing or tending to describe any claim element is provided solely for purposes of understanding the relevant prior art. Align expressly reserves the right to propose any claim construction it considers appropriate and/or to contest any claim construction it considers inappropriate. Align further reserves the right to interpret these terms differently over the course of the litigation and does not adopt any interpretations impliedly or expressly put forth in these Contentions. Accordingly, Align's Contentions, including the attached invalidity claim charts, may reflect alternative positions as to claim construction and scope. Align reserves the right to supplement, without prejudice, these Contentions as appropriate depending upon the Court's construction of any claim term in the Asserted Patents, any findings as to the priority date of the Asserted Patents, and any positions that Plaintiff or its expert witness(es) may take concerning claim interpretation, infringement, or invalidity issues. Nothing in this document should be construed as an admission that any claim of the Asserted Patents is valid, enforceable, or infringed. Align's

Contentions should not be interpreted to rely upon, or in any way affect, the noninfringement arguments Align may make in this case.

Further, discovery is not complete in this matter. Align therefore has not yet completed its investigation, discovery, or analysis of matters relating to the invalidity of the Asserted Patents, including without limitation invalidity due to on-sale or public use statutory bars. In addition, Align's search for prior art is ongoing. Align reserves the right to amend, modify, and supplement, without prejudice, these Contentions as additional information is discovered or otherwise identified or appreciated, including testimony provided about the scope and content of the claimed inventions or the state of the prior art. Additionally, because third-party discovery is not yet complete, Align reserves the right to present additional items of prior art located during the course of such discovery or further investigation, and to assert contentions of invalidity to the extent that such discovery or investigation yields information forming the basis for such contentions of invalidity. For example, Align may issue subpoenas in the course of discovery to third parties believed to have knowledge, documentation, and/or corroborating evidence concerning some of the prior art listed below and/or additional prior art. These third parties may include, without limitation, the authors, inventors, developers, designers, or assignees of the references and systems listed in these disclosures.

The accompanying invalidity claim charts contain specific examples of prior art references, patents, knowledge, inventions, uses, sales, methods, and/or systems that included and/or disclosed, either expressly or inherently, each limitation of certain claims and/or examples of prior art references and systems in view of which a person of ordinary skill in the art would have considered each limitation and the claimed combination of such limitations obvious. Align has endeavored to identify relevant portions and/or features of the identified prior art. The identified prior art, however, may contain additional descriptions of, or alternative support for, the claim limitations. Align may rely on uncited portions or features of the identified prior art, other documents, and expert testimony to provide context or to aid in understanding the identified prior art. Where Align cites to a particular figure in a reference, the citation should be understood to encompass the caption and description of the figure and any text relating to the figure. Similarly, where Align cites to particular text referring to a figure, the citation should be understood to include the figure and caption as well.

Align further may rely on inventor admissions concerning the scope of the claim(s) and prior art relevant to the claim(s) that are found in: the Asserted Patents, the prosecution history of the Asserted Patents and/or related patents and patent applications; any deposition testimony of any inventor of the Asserted Patents and/or related patents and applications; any previous trial testimony of any inventor of the Asserted Patents and related patents and/or applications; and any papers filed or any evidence produced or submitted by Plaintiff or its affiliates in connection with these litigations, or any other litigation, related to the Asserted Patents and/or any related patents and applications.

Prior art not included in these Contentions, whether known or not known to Align, may become relevant. In particular, Align is currently unaware of the extent, if any, to which Plaintiff will contend that limitations of the claims are not disclosed in the prior art identified by Align. Align reserves the right to identify additional references that would render obvious the allegedly missing limitation(s) of the disclosed device or method. Discovery is ongoing, and Align has not yet completed its search for and analysis of relevant prior art. Thus, Align reserves the right to revise, amend, and/or supplement the information provided herein, including identifying, charting, and relying on additional references, should Align's further search and analysis yield additional information or references, consistent with the Patent Local Rules and the Federal Rules of Civil Procedure.

Prior art patents or publications included in these Contentions may be related (*e.g.*, as a divisional, continuation, continuation-in-part, parent, child, or other relation or claim of priority) to earlier or later filed patents or publications, may have counterparts filed in other jurisdictions, or may incorporate (or be incorporated by) other patents or publications by reference. The listed patents or publications are intended to be representative of these other patents or publications, to the extent they exist. Accordingly, Align reserves the right to modify, amend, and/or supplement these Contentions with these related patents or publications, as well as other prior art references, upon further investigation.

II. BACKGROUND

A. The Asserted Patents

TABLE 1	
Asserted Patent	**Claims Asserted by Plaintiff**
U.S. 10,755,409	1-7 and 11-15
U.S. 11,049,248	1-8 and 12-16
U.S. 11,109,945	1-2 and 4-6

B. Priority Date of the Asserted Patents

The Asserted Patents are subject to the America Invents Act ("AIA"). Through its Infringement Contentions and in response to Align's Interrogatory No. 2, Plaintiff has asserted that the claims of the '409 and '248 patents are entitled to a priority date "at least as early as" July 21, 2017, and the '945 patent is entitled to a priority date "at least as early as" June 9, 2017. Though Plaintiff uses the phrase "at least as early as," the dates Plaintiff has identified are the earliest possible priority dates for these AIA patents based on their corresponding foreign priority applications. Plaintiff, however, has failed to identify any support for the Asserted Claims in those corresponding foreign priority applications. Nonetheless, for purposes of these Contentions, Align has assumed and applied the priority dates Plaintiff has identified, although Align reserves the right to challenge the alleged priority dates of the Asserted Patents.

The Asserted Patents are not entitled to their alleged priority dates for at least the following reasons. The specifications of the '409 and '248 patent and the corresponding foreign priority applications, FR 17 56947 and FR 17 56956, respectively, do not provide sufficient support for the claimed "analysis…by means of a deep learning device." *See, e.g.*, *infra*, Sections IV.A and V (addressing lack of disclosure). Those priority applications also fail to include FIG. 18 and the corresponding disclosure from the '409 and '248 patents and thus lack support for at least the claimed "historical tooth zones." *See, e.g.*, '409 patent at 21:28-31 (describing "historical tooth models" resembling "analysis zone" in FIG. 18); '248 patent at 21:18-21 (same); '409 patent at 32:46 (claiming "historical tooth zones"); '248 patent at 32:51-54 (same). Further, the specification of the '945 patent and the corresponding priority application, FR 17 55187, do not provide sufficient

support for the claimed "determination, by means of image processing software." *See, e.g.*, *infra*, Sections IV.A and IV (addressing lack of disclosure).

Align reserves the right to further supplement these arguments to challenge the alleged priority dates of the Asserted Patents.

III. INVALIDITY OF THE PATENTS-IN-SUIT UNDER 35 U.S.C. § 103

Pursuant to Patent L.R. 3-3 and 3-4, Align identifies herein prior art patents, publications, disclosures, products/devices/systems, knowledge, and uses that render obvious the Asserted Patents under 35 U.S.C. § 103. Align reserves the right to rely on other references disclosed or incorporated by reference in these Contentions, in the prior art identified below, in the Asserted Patents or any related patents, in the file histories of the Asserted Patents or any related patents, and in the attached exhibits.

Align's Contentions as to how each identified prior art reference anticipates and/or renders obvious the claims of the Asserted Patents are set forth in claim chart form as attached in Exhibits A, B, and C. Align also has set forth the obviousness of the Asserted Claims of the '409 patent in the Petition for *Inter Partes* Review in IPR2023-01369 (Align-DM_0012348-Align-DM_0012434) ("'409 IPR"), including the Declaration of Dr. Hassan Foroosh (Align-DM_0012465-Align-DM_0012594) ("'409 IPR Foroosh Decl."), and the accompanying exhibits (Align-DM_0012435-Align-DM_0014241), all of which are incorporated by reference here in their entirety. Align's claim charts may disclose multiple theories of invalidity in a single chart, including anticipation and/or one or more combinations of prior art that render the Asserted Claims obvious.

Additionally, persons of ordinary skill in the art generally read a prior art reference as a whole and in the context of other publications and literature. Numerous prior art references, including those identified herein, cited on the face of the Asserted Patents, and in the attached exhibits, reflect common knowledge and the state, scope, and content of the prior art before the priority date of the Asserted Patents. Align may rely on such references and on expert testimony to demonstrate the general state of the art at the time of the alleged inventions and what one of ordinary skill in the art would have understood at a time prior to the date of the alleged inventions, and to provide

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background and context pertinent to the teachings in, and interpretation of, the prior art referenced by the attached claim charts.

In general, a claimed invention is invalid due to obviousness "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art." 35 U.S.C. § 103; *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art at the time of invention; and (4) objective evidence of nonobviousness." *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 877 (Fed. Cir. 1993); *see Graham*, 383 U.S. at 17-18. The U.S. Supreme Court decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) reaffirmed *Graham*, but further held that a claimed invention can be obvious even if there is no explicit teaching, suggestion, or motivation for combining the prior art to produce that invention.

To the extent that any claim is not anticipated pursuant to 35 U.S.C. § 102, Align contends that any purported differences are such that the claimed subject matter as a whole would have been obvious to one skilled in the art at the time of the alleged invention, in view of the state of the art and knowledge of those skilled in the art under 35 U.S.C. § 103. Each claim would have been obvious in view of each reference cited in Exhibits A, B, and C and the '409 IPR Petition either alone or combined with the knowledge that was possessed by one of ordinary skill in the art. Additionally, each claim would have been obvious to one of ordinary skill in the art in view of the combination of any one of the prior art references identified in Exhibits A, B, and C and the '409 IPR Petition with one or more of the other references identified in the Tables below.

A. References

Align has identified a non-exhaustive list of one or more potential combinations that would render each of the claims obvious in the claim charts identified by exhibit number in the Tables below and the attached claim chart exhibits. Specifically, Align contends that the following

references anticipate or render obvious the claims (alone, or in combination with other references as set forth in detail in each claim chart):

TABLE 3

Short Name	Patent or Publication Number	Country of Origin	Issue or Publication Date	Production Number	Claim Chart Exhibit
Salah	W.O. 2016/066651	United States	5/6/2016	Align-DM_0013975 - Align-DM_0014055 (French publication); Align-DM_0013794 - Align-DM_0013875 (English translation)	A
Carrier	U.S. 2021/0068923	United States	3/11/2021	Align-DM_0013689 - Align-DM_0013727	A
Carrier Provisional	App. No. 62/417,985	United States	Filed 11/4/2016	Align-DM_0013728 - Align-DM_0013792	A
Maninis	Non-Patent Literature	United States	5/2/2017	Align-DM_0013793	A, B
Liao	U.S. 2017/0337682	United States	11/23/2017	Align-DM_0014286 - Align-DM_0014326	A, B
Frey	Non-Patent Literature	United States	5/4/2017	Align-DM_0014242 - Align-DM_0014285	B, C
Kim	U.S. 2017/0281313	United States	10/5/2017	Align-DM_0014327 - Align-DM_0014359	B, C
Invisalign Practice Guide	Non-Patent Literature	United States	8/8/2003	Align-DM_0010924 - Align-DM_0010975	C

Additionally, Align relies on evidence of public use based on dental practice as it was publicly known and applied (used) as of 2017 before the priority dates of the Asserted Patents. Align reserves the right to introduce further testimony by dental practitioners who will confirm that certain claim limitations were a standard of care prior to the alleged priority dates. For example, Align expects that such testimony will show that, before the alleged priority date and as part of the standard of care, dental practitioners treated patients remotely by performing a visual assessment of aligner fit based on sent to them by patients of their teeth (with or without aligners on) or via videoconferencing applications.

1. **Salah**

Salah is entitled "Method for Monitoring Dentition" and names five inventors, matching four of the inventors listed on the Asserted Patents. However, Salah was published on May 6, 2016, more than one year before the earliest claimed priority date of each of the Asserted Patents. Salah is prior art under 35 U.S.C. §102(a)(1). As Salah was published in French (Align-DM_0013975-Align-DM_0014055), a certified translation has been submitted as Align-DM_0013794-Align-DM_0013875.

Salah discloses methods for monitoring patients' teeth, such as during orthodontic treatment. Salah at Abstract, 1:12-22, 8:10-18. Salah also discloses methods of obtaining 2D images of patient teeth, comparing those teeth to a 3D model, and using those comparisons to update the model and measure treatment progress. *Id.* at 1:26-2:19, 46:15-19, Fig. 1. Salah's analysis can include using contour detection on an acquired image to aid mapping to a reference model, and Salah discloses that this contour detection can be performed using deep learning. *Id.*at 34:11-14, 36:14.[1] These 2D images may be obtained by a patient or relative using a device such as a cell phone, which may also perform the evaluation process. *Id.* at 2:21-27, 31:4-7. Salah also discloses that the image acquisition apparatus can guide the user to obtain appropriate images, including giving feedback on image acceptability and camera positioning. *Id.* at 27:21-28:10; '409 IPR Foroosh Decl., ¶¶45-46.

2. **Carrier and Carrier Provisional**

Carrier is entitled "Methods and Apparatuses for Dental Images." Carrier was filed on November 18, 2020, and published on March 11, 2021. Carrier claims priority to Application No. 16/827,594, filed March 23, 2020, and Application No. 15/803,718, filed November 3, 2017, as well as to Provisional Patent Application No. 62/417,985 ("Carrier Provisional"), which was filed November 4, 2016. Each application in Carrier's priority chain was co-pending with the previous application and claimed priority to each earlier application in the chain, and each non-provisional application shares a common specification. The Carrier Provisional provides § 112 support for at least one claim of Carrier. The chart below illustrates exemplary support in the Carrier Provisional

[1] Salah uses the term "deepleraning," which a POSA would have recognized to be a typographical error meant to refer to "deep learning." *Id*.; '409 IPR Foroosh Decl., ¶101.

for claim 1 of Carrier. Exhibit A-2 provides parallel citations to both the Carrier Provisional and Carrier, demonstrating that all matter relied on is found in both references. Accordingly, under *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015), Carrier is available as prior art under 35 U.S.C. §102(a)(2) as of November 4, 2016.

Carrier	Carrier Provisional
1. A computer-implemented method comprising:	¶18.
providing a mobile application on a mobile device associated with a patient, the mobile application configuring a user interface for display on the mobile device;	¶¶54-55, 73-75, 94-95, Figs. 5A, 8.
guiding the patient through the user interface to take a first plurality of photos of teeth of the patient, the first plurality of photos corresponding to a first plurality of predetermined views of the teeth, wherein guiding the patient to take the first plurality of photos comprises showing a first plurality of overlays over the teeth in accordance with the first plurality of predetermined views;	¶¶36, 61, 73-75, 85, Figs. 4A-5A, 8, 10.
guiding the patient through the user interface to take a second plurality of photos of the teeth, the second plurality of photos corresponding to a second plurality of predetermined views of their teeth, wherein guiding the patient to take the second plurality of photos comprises showing a second plurality of overlays over the teeth in accordance with the second plurality of predetermined views; and	¶¶36, 61, 73-75, 85, Figs. 4A-5A, 8, 10.
transmitting the first plurality of photos and the second plurality of photos so the first plurality of photos and the second plurality of photos can be evaluated for medical treatment.	¶86, Fig. 8.

Carrier teaches methods to obtain images of patients' teeth for therapeutic use, including images obtained by a mobile phone. Carrier Provisional at Abstract, ¶7; Carrier at Abstract, ¶8. The device provides guidance to users to help take high-quality images, including providing an overlay such as an image or outline of teeth that a user may use to align the imaging apparatus. Carrier Provisional at ¶¶54-55; Carrier at ¶¶99-100. The device can assess alignment by measuring distance between teeth and the overlay by performing edge detection on teeth and performing image

recognition to ensure required teeth are visible. Carrier Provisional at ¶¶63, 81; Carrier at ¶¶108, 128.

3. **Maninis**

Kevis-Kokitsi Maninis et al. published "Convolutional Oriented Boundaries: From Image Segmentation to High-Level Tasks" ("Maninis," Align-DM_0013793-Align-DM_0013793) no later than May 2, 2017, on arXiv.org. See '409 IPR Foroosh Decl. at ¶¶62-67; Align-DM_0013793-Align-DM_0013793, 1; Align-DM_0014222-Align-DM_0014225 (arXiv.org publication policies); Align-DM_0014226-Align-DM_0014227 (document unchanged); Align-DM_0014233-Align-DM_0014234 (same); Align-DM_0014228-Align-DM_0014229 (dissemination by authors); Align-DM_0014230-Align-DM_0014232 (direct download link); Align-DM_0014221-Align-DM_0014221 (earlier version with same material disclosure). Maninis is prior art under 35 U.S.C. §102(a)(1).

Maninis discloses methods for image classification and contour detection using a Convolutional Neural Network (CNN). Maninis, Abstract. Maninis teaches a "deep learning architecture" that produces significant improvements over state-of-the-art techniques. *Id.* at 3, 8-9. Maninis uses a neural network trained on precisely annotated images to detect contours defining regions containing objects based on detected probabilities for contour locations. *Id.* at 3-4, 5-6, 13, Fig. 2. Maninis also demonstrates the ability to label the specific object contained within each identified region, again improving over the state of the art. *Id.* at 11-12, Tables 4-7, Fig. 16; '409 IPR Foroosh Decl., ¶68.

4. **Liao**

Liao is entitled "Method and System for Image Registration Using An Intelligent Artificial Agent." Liao was filed on May 4, 2017 and published on November 23, 2017. Liao is prior art under 35 U.S.C. §102(a)(2).

Liao discloses methods for registration of medical images using an intelligent artificial agent that employs a deep neural network (DNN). Liao (Align-DM_0014286-Align-DM_0014326) at Abstract. The artificial intelligent agent learns registration tasks from a training dataset and achieves improved registration results as more data are used for training. *Id.* ¶¶5, 39. The intelligent artificial

agent is trained to more closely mimic how humans perform image registration as a process of sequential actions of object recognition and manipulation. *Id.* ¶¶ 39, 53, 100. For example, Liao demonstrates the ability to recognize and segment objects (e.g., anatomical structures) within an image. *Id.* ¶53, 105.

5. **Frey**

Frey is entitled "DIY Dental Monitoring Solution" and was published online on The Ortho Cosmos blog at least by May 4, 2017, according to a copy of the article accessed by the Internet Archive. *See* Frey (Align-DM_0014242-Align-DM_0014285). Frey is prior art under 35 U.S.C. §102(a)(1).

Frey discloses a method for practitioners to set up a teleorthodontics system to remotely monitor their patients' orthodontic progress. *Id.* at 18. Frey provides instructions regarding the type of recorded content that patients should capture for review by their practitioner, such as videos with teeth apart and aligners in, biting down with aligners removed, and teeth apart and aligners out. *Id.* at 19. The recorded content along with other information provided is submitted to the practitioner through an online form. *Id.* at 21-23. Frey further discloses that practitioners can follow up with patients, for example by email or text, regarding the submissions. *Id.* at 25-26.

6. **Kim**

Kim is entitled "Method and System for Providing Remote Teeth Alignment Services and Computer-Readable Medium on Which the Method is Recorded." Kim was filed on April 5, 2016 and published on October 5, 2017. Kim is prior art under 35 U.S.C. §102(a)(2).

Kim describes remote dental monitoring for assessing whether an additional or modified aligner is needed based on teeth alignment report information. Kim (Align-DM_0014327-Align-DM_0014359) at ¶¶ Abstract, 19, 20. Teeth alignment report information includes an image of aligner being worn by the patient that is captured using a smartphone. *Id.* ¶¶ 19, 66, 81. Upon determining that an additional or modified aligner is needed, Kim sends clear aligner manufacturing information to a clear aligner manufacturer terminal. *Id.* ¶¶ 20, 67. A clear aligner manufacturer then manufactures the requested aligner based on the received clear aligner manufacturing information. *Id.* ¶ 67.

7. **Invisalign Practice Guide**

Align published the "Invisalign Clinical Monitoring Guide" on August 8, 2003 (Align-DM_0010924-Align-DM_0010975) ("Invisalign Practice Guide"). The Invisalign Practice Guide is prior art under 35 U.S.C. §102(a)(1).

Align provided the Invisalign Practice Guide to practitioners to provide instructions regarding how to monitor their patients' Invisalign treatments and address issues that may arise between each stage of aligner treatment. Invisalign Practice Guide, 2. One of the tips provided instructs practitioners to provide specific comments for individual teeth. *Id.* at 5. For example, the Invisalign Practice Guide instructs practitioners to provide a score to individual teeth in the form of a size (mm) and direction of movement. *Id*.

B. Motivations to Combine

Those of ordinary skill in the art at the time of the alleged invention of the Asserted Patents would have been motivated to modify or combine the prior art references set forth herein at least because: (a) the references in general deal with the same or related subject matter; (b) one of ordinary skill in the art would have been motivated by the problem that the inventor was attempting to solve, or with other problems that would have been faced in reaching a solution, and would have looked to references that concerned similar issues or taught how to overcome the problems faced; (c) the combinations were obvious to try and would have operated in their known and expected way; (d) the combinations were within the technical skill and understanding of a person of ordinary skill in the art; (e) the combinations would have been motivated by the developments in technology; and (f) the combinations reflect various design choices that would have been known to one of ordinary skill in the art and within that person's technical capability to implement (*i.e.*, technically feasible).

Align has set forth exemplary motivations to combine the references identified above in its claim charts attached to these Contentions. *See* Ex. A, B, and C. Align has further set forth motivations to combine in the '409 IPR. *See*, *e.g.*, '409 IPR Petition at 18-24; '409 IPR Foroosh Decl. ¶¶77-87.

Moreover, by the alleged priority dates of the Asserted Patents, computer technology had progressed such that there was a general trend across industries toward applying deep learning

techniques in a variety of different contexts and applications, including computer vision, natural language processing, bioinformatics, camera and smartphone technologies, web searches, content filtering, e-commerce recommendations, and healthcare. *See, e.g.*, LeCun et al., "Deep learning," Nature, Vol. 521 at 436 (May 28, 2015); *see also* Yu, Machine Leaning for Dental Image Analysis (2016), https://arxiv.org/ftp/arxiv/papers/1611/1611.09958.pdf; *KSR*, 550 U.S. at 417 (explaining "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one") A POSA would have been well aware of this trend and would have found it obvious to apply deep learning techniques to the analyses of dental images, providing further motivation for the combinations set forth in Align's claim charts attached to these contentions. *See* Ex. A, B, and C.

The various motivations described above provide a basis for combining or modifying references, as detailed below, to render each of the claims obvious. In addition, the Court can consider the inferences and creative steps a person of ordinary skill in the art would employ in making such combinations. *See KSR*, 550 U.S. at 418 ("[A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ").

C. Secondary Considerations

Align served an interrogatory asking Dental Monitoring to identify each alleged secondary consideration of nonobviousness upon which Dental Monitoring relies, describe its basis for nexus, and identify all supporting facts, persons knowledgeable, and documents concerning such secondary considerations. Align's Interrogatory No. 6 to Dental Monitoring. In response, Dental Monitoring refused to substantively respond to Align's interrogatory or identify any secondary consideration upon which it intends to rely. It is Align's position that Dental Monitoring has therefore waived reliance on secondary considerations to rebut any argument of obviousness.

In any event, Align has set forth why there are no secondary considerations of nonobviousness in response to Dental Monitoring's Interrogatory No. 8, which is incorporated by reference here in their entirety. In particular, for example, Dental Monitoring's claimed inventions produced no unexpected results, received no praise, did not solve long-felt but unsolved needs, and did not overcome skepticism of experts. For example, Dental Monitoring's monitoring solution did

not produce unexpected results or satisfy unsolved needs because "smartphones already provide[d] [the] capability" to monitor orthodontic progress "without the need for additional software." *See* S. Frey, "DIY Dental Monitoring Solution," The Ortho Cosmos (Apr. 29, 2017), accessible at https://web.archive.org/web/20170504155213/http:/theorthocosmos.com/blog as accessed by the Internet Archive on May 4, 2017 (describing how to implement Dental Monitoring's remote monitoring in a few DIY steps). Additionally, Dental Monitoring's claimed invention did not face expert skepticism as it is simply routine. Taking pictures of teeth has long been a common part of dental practice, with doctors and patients commonly using pictures to assist in delivering orthodontic care. *See, e.g.*, Dkt. 53-3, Invisalign Clinical Guide at 4, 15. Similarly, assessing the shape of an aligner was part of the standard of care that dentists have delivered for many years. *See, e.g.*, Dkt. 53-2, Invisalign Instructions at 3; Dkt. 53-3, Invisalign Clinical Guide at 3, 5, 7-16 (discussing assessment of aligners worn by patient); see also *id*. at 17-36 (discussing tooth-specific movements). Align's U.S. Patent Publication No. 2021/0068923, which has a priority date of November 4, 2016, also predates the '409 patent. Further, to the extent Dental Monitoring seeks to argue that a nexus exists between evidence of secondary considerations and the claimed invention, Dental Monitoring has failed to make such a showing.

Align reserves the right to respond if Dental Monitoring attempts to identify any secondary considerations at a later date.

IV. INVALIDITY OF THE CLAIMS UNDER 35 U.S.C. § 101 FOR BEING DIRECTED TO PATENT-INELIGIBLE SUBJECT MATTER

Claims 1-7 and 11-15 of the '409 patent, claims 1-8 and 12-16 of the '248 patent, and claims 1-2 and 4-6 of the '945 patent (all Asserted Claims) are invalid under 35 U.S.C. § 101 and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). At their core, DM's patents are about taking pictures of teeth and assessing the shape of clear aligners—basic concepts that dentists and their patients have been applying since long before the Asserted Patents. While the patents reference common technology like cameras connected to computers (often a cell phone) and undefined concepts like "deep learning," referencing vague or generic technology does not transform these abstract ideas into patentable subject matter. The claims of the Asserted Patents present classic examples of abstract, patent-ineligible subject matter, failing at both steps of the *Alice* test.

The Asserted Patents fail at *Alice* step one because, even viewed in the most charitable light, they claim quintessentially abstract, patent-ineligible concepts of guiding a camera operator to take an image of teeth ('409 patent) and assessing the shape of orthodontic aligners ('248 and '945 patents). *Alice*, 573 U.S. at 218-21. Notably, the patents *admit* that patients and orthodontists routinely carried out these activities. At most, the claimed methods apply these abstract ideas using generic camera-enabled computers performing generic computer functions to collect, analyze, and present information. Indeed, this Court already has recognized that "[p]racticing each step of the claimed methods of the patents-in-suit . . . leads only to abstract information." Dkt. 49 at 5.

The Asserted Patents also fail at *Alice* step two because the remainder of the claim elements, whether considered alone or as an ordered combination, do not comprise any inventive concept that transforms the claimed subject matter into something patent eligible. *Alice*, 573 U.S. at 221-26. At most, the claimed methods recite elements such as a "deep learning device" or "image processing software," but they do so only generically, without explaining how it works or claiming any specific technological improvement. Rather, the patents admit that claimed methods simply incorporate prior art implementations of these elements that were well-understood, routine, and conventional.

Further, although DM touts in its complaint that it possesses unique software, AI processes, and databases of photographs (*e.g.*, Dkt. 1 ("Compl.") ¶¶ 9, 11), the Asserted Patents do not describe or claim any of this. Rather, the claimed methods seek to preempt all implementations of these abstract ideas, triggering the very concern that drives the § 101 inquiry. *Alice*, 573 U.S. at 216.

A. Factual Background

Since the advent of metal braces, dentists have been using routine practices to check the fit of a patient's braces as the patient's teeth move. Sometimes the dentist's practices included visual inspection of the shape of the braces on the patient's teeth, or taking pictures to aid in the dentist's assessment.

Align has long been an innovator in the dentistry field. Most notably, over 25 years ago, Align introduced its Invisalign system that uses clear plastic aligners for correcting misalignment of teeth, rather than conventional metal braces. Align also provides guidance and instructions for doctors to properly use Invisalign, including instructions on how to visually inspect a patient's

aligner to ensure it fits properly to move the patient's teeth. *See, e.g.*, Align-DM_0010910-23, Invisalign aligners instructions for use ("Invisalign Instructions") at Align-DM_0010914 ("At each appointment . . . [c]heck for appropriate aligner stage and their fit"); Align-DM_0010924-75, Invisalign Clinical Monitoring Guide (August 8, 2003) ("Invisalign Clinical Guide") at Align-DM_0010926 ("Have patients arrive with the previous stage Aligner and the current Aligner, so you can evaluate any fit concerns that may arise. . . . At each appointment, review . . . [t]hat the current Aligner is a good fit . . . ."), Align-DM_0010928 ("Monitoring and detailing are critical."), Align-DM_0010930-39 (identifying fit issues based on visual inspection). These materials also recommend that doctors take good-quality pictures and impressions of patients' teeth. Invisalign Clinical Guide at Align-DM_0010927 and Align-DM_0010938. And for years, Align has offered a website and mobile applications to help patients and doctors use the Invisalign system.

For its part, Plaintiff DM piggybacks off of dental companies that manufacture aligners by offering what DM calls "remote monitoring orthodontics." Compl. ¶ 9.

DM alleges infringement of "at least" claim 1 of the '409 patent, claim 15 of the '248 patent, and claim 1 of the '945 patent. *Id*. ¶¶ 46, 57, 68. The Asserted Patents relate to common and standard dentistry practices, namely taking an accurate picture of a patient's mouth ('409 patent) and assessing the shape of an orthodontic aligner ('248 and '945 patents). DM alleges that it can dress-up those common dentistry concepts with artificial intelligence ("AI") (*see, e.g.*, *id*. ¶¶ 9, 11, 33-43), but neither DM's complaint nor the Asserted Patents explain what "AI" means in this context or set forth any specific software implementation of it. Rather, DM purports to hold its so-called AI technology as "proprietary." *See, e.g.*, *id.* ¶¶ 9, 11.

Asserted claim 1 of the '409 patent, for example, recites:

> A method for acquiring an image of a dental arch of a patient, said method comprising the following steps:
>
> a′) activation of an image acquisition apparatus so as to acquire an image, called "analysis image", of said arch;
>
> b′) analysis of the analysis image by means of a deep learning device trained by means of a learning base;

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c′) determination, for the analysis image, as a function of the results of the analysis in the preceding step, of a value for an image attribute;

d′) comparison of said image attribute value with a setpoint;

e′) sending of an information message as a function of said comparison, the information message being related to the quality of the image acquired or to the position of the acquisition apparatus in relation to said arch or to the setting of the acquisition apparatus or to the opening of the mouth or to the wearing of a dental appliance, or to a combination thereof,

to check whether the analysis image respects the setpoint and, if it does not respect the setpoint, to guide the operator in order for him or her to acquire a new analysis image.

Asserted claim 15 of the ’248 patent, for example, recites:

A method for assessing the shape of an orthodontic aligner, said method comprising the following steps:

a″) more than 1 week after the start of the treatment with the aligner, acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient, called “analysis image” the analysis image being a photograph, or an image extracted from a film;

b″) analysis of the analysis image by means of a deep learning device, trained by means of a learning base, so as to determine a value for an image attribute of the analysis image, the image attribute relating to a separation between at least one tooth represented on the analysis image, and the aligner represented on said analysis image.

Asserted claim 1 of the ’945 patent, for example, recites:

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

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

at least one updated image referred to as “aligner image”, at least partially representing the aligner in a service position in which it is worn by said teeth; and at least one updated image referred to as “dentition image”, identical to or different from the aligner image, representing said teeth,

> 2) if the dentition image is different from the aligner image, conversion of the dentition image so that it represents said teeth as seen under the acquisition conditions used during the acquisition of the aligner image in step 1);
>
> 3) determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively;
>
> 4) comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison.

Like any other picture, the images discussed in the Asserted Patents start with a camera, which the patents generally call an "image acquisition apparatus." '409 patent at 8:57-63; '248 patent at 8:47-53; '945 patent at 5:61-64. And for these patents, essentially any camera-enabled device will do. For example, the Asserted Patents explain that the "image acquisition apparatus" is "preferably chosen from a cellphone, a so-called 'connected' camera, a so-called 'smart' watch, a tablet or a personal computer, fixed or portable, comprising an image acquisition system such as a webcam or a camera." '409 patent at 8:57-63; '248 patent at 8:47-53 (same); '945 patent at 3:42-55, 5:61-64 (similar).

The Asserted Patents, in fact, admit that the use of camera-enabled devices was well-known in the orthodontic field. For example, all three patents refer extensively to the prior art International Application No. PCT/EP2015/074896, published as WO 2016/066651A1 ("WO '651"), and the '409 and '248 patents expressly incorporate by reference this application into their specifications. '409 patent at 7:50-54; *see also id.* at 2:42-47, 3:4-10; '248 patent at 7:38-42; *see also id.* at 2:42-47, 3:4-10; '945 patent at 7:6-42, 9:7-8.[2] WO '651, in turn, describes prior art methods for remotely "monitoring the position . . . [of the] teeth of a patient" and "track[ing] the evolution of an orthodontic treatment . . . to minimize the appointments of the patients with their orthodontists." Align-DM_0011057-121 at 1:2-3, 44:19-23. In these methods, a patient (or other user) would periodically use an "image acquisition apparatus" such as a "mobile phone" (or other camera-

[2] Because WO '651 is published in French (Align-DM_0010976-1056), Align refers to an English translation (Align-DM_0011057-121) that DM submitted to the U.S. Patent and Trademark Office (USPTO) during the prosecution of the corresponding national stage application, U.S. Application No. 15/522,520. WO '651 is incorporated by reference into at least the '409 and '248 patents.

enabled devices) to acquire images of the patient's dental arch. *Id.* at 23:27-32, 24:15-20, 45:21-25. As WO '651 explains, the apparatus may itself provide feedback to guide the patient in acquiring the images:

> The user may be guided by written and/or voice messages for the acquisition. For example, the personal appliance may announce "take a photo from the front", emit a signal to inform the user that the photo is acceptable or that, on the contrary, he or she must take another photo, announce "take a photo from the right", preferably by displaying an arrow to orient the user, etc. The end of the acquisition process may also be announced by the apparatus. The apparatus may also assist in the positioning, for example by visual messages (for example by displaying arrows), and/or audible messages (like a succession of beeps whose frequency increases as the positioning of the apparatus improves), and/or written and/or voice messages ("higher", "lower", etc.).

Id. at 26:20-28. The acquired images are then analyzed or processed by a generic computer using "image processing software" to develop a reference model of the patient's teeth that is compared to an initial reference model "to determine the movement of teeth." *Id.* at 2:9-16, 32:28-33:2.

The '409 patent claims essentially the same method described in WO '651 for guiding someone to take a picture of a patient's teeth, but purports to incorporate a generic "deep learning device." *E.g.*, '409 patent at abstract, claim 1. For example, the only independent claim (claim 1) recites a method under which an operator (i.e., a patient) of an "image acquisition apparatus" (e.g., a phone) "acquire[s] an image" (i.e., takes a picture) that is "analy[zed] . . . by means of a deep learning device" to "determine[e] . . . a value for an image attribute." *Id.* The "image attribute value" is "compar[ed] . . . with a setpoint." *Id.* And if the "setpoint" is not respected, an "information message" (e.g., a pop-up message) is sent to help "guide the operator in order for him . . . to acquire a new analysis image" (i.e., take a better picture). *Id*. According to the '409 patent, the operator may "make a mistake in the acquisition of the updated images" and thus the information message may be sent, for example, to instruct the operator to adjust "the position of the acquisition apparatus" (i.e., move the phone), adjust a "setting of the acquisition apparatus" (e.g., increase the brightness of the phone), or remind the operator to "open your mouth" or "wear your appliance" while acquiring the image. *Id.* at 25:34-39, 26:50-67. Notably, the claimed method does not require any new or specific

implementation of the "analysis," "determination," and "comparison" steps, or the "deep learning device." In fact, the claimed method does not even explain how the "deep learning device" works.

At most, the '409 patent describes the "deep learning device" in generic terms as "preferably a neural network [that] is trained with [a] learning base." A "neural network" is a system modeled after the human brain that uses sample databases to train a computer to "learn" and ultimately perform certain tasks. The '409 patent contains minimal description of "neural networks," explaining that the referenced "'neural network' or 'artificial neural network' is a set of algorithms well known to a person skilled in the art." *Id.* at 16:13-16. In other words, the patent admits that neural networks that can be used in the claimed methods were well known and in the prior art.

The patent further provides a description that is at best generic and circular: "the deep learning device is preferably trained by a learning process called 'deep learning,'" where "[b]y presenting, as input for the deep learning device, historical images (images+descriptions), the deep learning device progressively learns to recognize patterns on an image." '409 patent at 16:44-50; '248 patent at 16:36-43 (same). That is, the patent generally explains that the deep learning device can use pictures of teeth to recognize patterns in other pictures of teeth. And though the patent identifies a laundry list of known neural networks, it states that this list is "not limiting" and does not suggest that "deep learning device" used in the claimed methods has any specific implementation. '409 patent at 16:17-42.

The '248 patent is directed to methods for "assessing the shape of an orthodontic aligner" based on the separation between the teeth and aligner. '248 patent at abstract, claims 1 and 15. At the outset, the patent acknowledges that "[t]his assesment [wa]s conventionally performed by an orthodontist" based on images transmitted by a patient. *Id*. at 1:11-15, claim 15. Independent claim 15, which DM asserts in the complaint, specifies the "acquisition" of an image of "the aligner in a service position in which it is worn by a patient" (i.e., a patient taking a picture of teeth while wearing an aligner) followed by the "analysis" of this image using a generic "deep learning device" to "determine a value for an image attribute . . . relating to [the] separation between at least one tooth . . . and the aligner" (i.e., use "deep learning" to measure the distance between a tooth and the aligner). *Id.* at claim 15. Claim 1, the other independent claim of the '248 patent, recites a similar method but

specifies that the determination and comparison are done with respect to a "tooth attribute" and additionally requires that the analysis image be acquired by a "cell phone." *Id.* at claim 1. Again, the claimed methods do not require any specific implementation of the "analysis" step or the "deep learning device." *See id.* The '248 patent further describes the "deep learning device" in the same generic fashion as the '409 patent. *Compare* '248 patent at 16:5-36, *with* '409 patent at 16:13-42.

The '945 patent is similarly directed to methods for "evaluating the shape of an orthodontic aligner," a process the patent acknowledges was conventionally carried out by an orthodontist based on a "visual inspection." '945 patent at 1:41-45, claim 1. Claim 1, the only independent claim, specifies the "acquisition" of an "aligner image" of the "aligner in a service position" (again, taking a picture of teeth while wearing an aligner) and a "dentition image . . . representing said teeth" (i.e., a picture of the teeth without the aligner). *Id.* at claim 1. The claimed method proceeds to use generic "image processing software" to "determin[e]" and "compar[e]" "interior and exterior tooth outlines" and to further "determin[e]" a "score according to said comparison." *Id.*

Here, again, the claimed method does not require any new or specific implementation of "image processing software." Rather, the patent acknowledges that "[a] person skilled in the art knows how to process an image in order to isolate [tooth] outline," and that "[t]his processing for example involves the well-known application of masks or filters, which come with image processing software." *Id.* at 10:22-27. The '945 patent also lists "known and preferred methods" of image processing operations and discloses that "[t]ooth outline determination can be optimized by following the teachings of [the prior art application] PCT/EP2015/074900," which was published as WO2016066654A ("WO '654"). *Id.* at 10:28-11:34.[3]

B. Patent Eligibility Under 35 U.S.C. § 101

Under the Supreme Court's *Alice* decision, a patent claim covers ineligible subject matter if (1) the claim is directed to an abstract idea, and (2) the claim elements, considered individually and as an ordered combination, do not add an "inventive concept" to that abstract idea. *Alice*, 573 U.S. at 217. At *Alice* step one, the court considers whether a claim is directed to a patent-ineligible

[3] WO '651, noted above, also describes the processing of images to determine and compare the "edges" or "outline of [] teeth." Align-DM_0011057-121 at 16:30-31, 18:16-17, 21:14-24, 32:20-22, 38:26-39:8.

concept, such as an abstract idea. *Id.* This inquiry looks at "the focus of the claims" and "their character as a whole." *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353-54 (Fed. Cir. 2016) (citation omitted). While the "claim language" is key, the specification may be useful in understanding the problem facing the inventor and how the patent characterizes the invention. *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 766-67 (Fed. Cir. 2019).

If a claim is directed to an abstract idea, *Alice* step two considers the particular claim elements "both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." 573 U.S. at 217 (citation omitted). "To save a patent at step two, an inventive concept must be evident in the claims." *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1338 (Fed. Cir. 2017). The Supreme Court has described this second step as the "search for an 'inventive concept'—i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Alice*, 573 U.S. at 217-18 (citation omitted, alteration in original). A patent claim does not amount to more than the ineligible concept if it simply relies on computer elements and functions that are "'well-understood, routine, conventional activit[ies]' previously known to the industry." *Id.* at 225 (citation omitted). In this regard, "the relevant inquiry is not whether the claimed invention as a whole is unconventional or non-routine" but rather whether there is "an 'inventive concept' . . . that is 'sufficient to ensure that the patent in practice amounts to *significantly* more than a patent upon the [ineligible concept] itself.'" *BSG Tech LLC v. Buyseasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018) (citations omitted, alterations in original, emphasis added).

C. The Claims of the Asserted Patents Are Abstract Under *Alice* Step One

DM alleges infringement of "at least" claims 1-7 and 11-15 of the '409 patent, claims 1-8 and 12-16 of the '248 patent, and claims 1-2 and 4-6 of the '945 patent. Plaintiff's Infringement Contentions at 1. "Procedurally, it is not necessary for a district court to address each claim of the patents-in-suit," and the "*Alice* analysis may instead focus on representative claims." *People.ai*, 575

F. Supp. 3d at 1199.[4] That is, the Court "may select representative claims where the other claims recited in the patent are substantially similar and linked to the same abstract idea, and the patentee does not present any meaningful argument for the distinctive significance of any claim limitations not found in the representative claim." *Id*. Here, for purposes of the *Alice* analysis, the independent claims of the Asserted Patents, i.e., claim 1 of the '409 patent, claims 1 and 15 of the '248 patent, and claim 1 of the '945 patent—which include the only claims discussed in detail in the complaint—are representative. Align thus primarily focuses on the independent claims, while addressing as necessary the dependent claims.

As discussed below, the claims of the Asserted Patents are directed to abstract ideas that are implemented using generic computer-based elements, like cameras and phones. Humans have long adjusted cameras to figure out how to get the best angle on a shot, and dentists assessing patients' teeth and orthodontic appliances have long been part of the standard of care. Adding a computer or "deep learning device" does not make these ideas any less abstract.

1. The Claims of the Asserted Patents Are Directed to Abstract Ideas.

The claims of the Asserted Patents are directed to the abstract ideas of guiding a camera operator to capture an image or assessing the shape of an orthodontic aligner by collecting, analyzing, and presenting information. To determine whether a patent claim is directed to an abstract idea, courts often "compare the claims at issue to those claims already found to be directed to an abstract idea in previous cases." *SmileDirectClub, LLC v. Candid Care Co.*, 505 F. Supp. 3d 340, 349 (D. Del. 2020) (citation omitted). Relevant here, the Federal Circuit has explained that "collecting information, including when limited to particular content" is within the realm of abstract ideas. *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1094 (Fed. Cir. 2016) (quoting *Elec. Power*, 830 F.3d at 1353 (collecting cases)). The Federal Circuit also has "treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category." *Elec. Power*, 830 F.3d at 1354. "[M]erely presenting the results of abstract processes of collecting and analyzing information,

[4] In *Alice*, for example, the Supreme Court ruled on the validity of 208 claims in four patents based on an analysis of two claims. 573 U.S. at 224.

without more (such as identifying a particular tool for presentation), [also] is abstract as an ancillary part of such collection and analysis." *Id*. Moreover, a combination of these abstract ideas that does not identify any allegedly inventive technology for performing the steps is itself an abstract idea. *Id*. As an example, in *FairWarning*, the Federal Circuit found that method claims for collecting and analyzing information to detect misuse of protected health information and notifying a user when misuse is detected were directed to an abstract idea. 839 F.3d at 1094-95.

District courts also have applied these principles to find that claims similar to the claims here were directed to abstract ideas. For example, in *SmileDirectClub*, the court concluded under *Alice* step one that the claims at issue were directed to the abstract idea of "teleorthodontics" or "having patients arrange for and receive dental aligners without ever seeing a dentist or orthodontist in person." *SmileDirectClub*, 505 F. Supp. 3d at 346-49. Similarly, in *Becton*, the court found that the claims at issue were directed to the abstract idea of remote supervision of pharmacy functions. *Becton, Dickinson & Co. v. Baxter Int'l, Inc.*, 127 F. Supp. 3d 687, 692-93 (W.D. Tex. 2015). As will sound familiar, the claims there recited steps such as "[t]he 'capturing' of an image, 'implementing' verification software, 'transmitting' the image, and 'providing' an indication that the process has been verified," but the court explained that those were "merely steps in the supervision and verification process" and that the "claims do not present a concept or idea that is any more concrete than supervision and verification." *Id.*

(i) <u>The '409 patent relates to the abstract idea of guiding a camera.</u>

Here, the claimed methods of the '409 patent relate to the abstract idea of collecting, analyzing, and presenting information to guide a camera operator to take a picture of teeth. *E.g.*, '409 patent at claim 1. This is a familiar concept to anyone who has ever operated a digital camera by looking at the image on the viewscreen to ensure that it captures the desired location or focus.

Nor is this concept new to orthodontic treatment. As the '409 patent acknowledges, in conventional orthodontic assessments, patients would capture images of their dental arch and transmit the images to an orthodontist for assessment. *Id*. at 1:11-15. It is beyond dispute that taking pictures of teeth has long been a common part of dental practice, with doctors and patients commonly using pictures to assist in delivering orthodontic care. *See, e.g.*, Invisalign Clinical Guide at Align-

DM_0010927 and Align-DM_0010938. WO '651, which is part of the admitted prior art of the '409 patent, goes even further and describes known methods whereby patients would use an "image acquisition apparatus" such as a "mobile phone" (or other camera-enabled device) to acquire images of their dental arch (Align-DM_0011057-121 at 23:27-32, 24:15-20, 45:21-25), and the images would be processed and analyzed to "track the evolution of an orthodontic treatment" (*id.* at 1:2-3, 44:19-23). WO '651 even explains that as part of this process, the image acquisition apparatus may guide the patient in acquiring the images by providing visual or audible messages that, for example, inform the patient whether the image is "acceptable" or if the "positioning" of the apparatus needs to be adjusted. *Id.* at 26:20-28.

Independent claim 1 of the '409 patent recites this same method of "acquir[ing]" and "analy[zing]" an image to "send[] . . . an information message" to "guide the operator . . . to acquire a new analysis image," though it adds the use of a generic "deep learning device." '409 patent at claim 1. The claimed steps, however, merely reflect the collection, analysis, and presentation of information, which courts have consistently found to be abstract. *See, e.g.*, *F45 Training Pty Ltd. v. Body Fit Training USA Inc.*, No. 20-CV-1194, 2021 WL 2779130, at *9-10 (D. Del. July 2, 2021) ("Collecting and analyzing information, displaying results, and storing data are all abstract ideas, individually and in combination."); *see also USC IP P'ship, L.P. v. Meta Platforms, Inc.*, No. 2022–1397, 2023 WL 5606977, at *3 (Fed. Cir. Aug. 30, 2023) ("[T]he claimed concept of collecting and using intent data is not a technical solution to a technical problem."). Even viewed collectively, these steps do not present a concept or idea that is any more concrete than generating information to guide a camera operator to take a picture of teeth. Indeed, as this Court already has recognized, the claimed method "is not directed to the acquired images themselves, or to the acquisition of such images, but to the sending of an information message." Dkt. 49 at 4. Thus "practicing each step of the claimed method[] . . . leads only to abstract information." *Id.* at 5.

(ii) The '248 and '945 patents relate to the abstract concept of assessing or evaluating an orthodontic aligner's shape.

Similarly, the claimed methods of the '248 and '945 patents are directed to the abstract idea of collecting and analyzing information to "assess[]" or "evaluat[e] the shape of an orthodontic aligner." '248 patent at claims 1, 15; '945 patent at claim 1. The patents admit that this was

conventionally done by an orthodontist through a "visual inspection" of a patient's teeth and the aligner (*e.g.*, '945 patent at 1:43-45), either during an in-person visit (*id.*) or by viewing of images of the patient's dental arch that the patient sends to the orthodontist (*e.g.*, '248 patent at 1:11-15). Like taking pictures, assessing the shape of an aligner was part of the standard of care that dentists have delivered for many years. *See, e.g.*, Align-DM_0010910-23, Invisalign Instructions at Align-DM_0010914; Align-DM_0010924-75, Invisalign Clinical Guide at Align-DM_0010926, Align-DM_0010928 and Align-DM_0010930-939 (discussing assessment of aligners worn by patient); *see also id*. at Align-DM_0010940-959 (discussing tooth-specific movements). Although claimed methods purport to do this through computer-based methods reciting steps of "acquir[ing]" and "analy[zing]" images of an aligner to provide a "score" (*e.g.*, '945 patent at claim 1) or a value for a "tooth attribute" or "image attribute" (*e.g.*, '248 patent at claims 1, 15), these steps again at most reflect the abstract concepts of collecting, analyzing, and presenting information—something that dentists did for years before DM even existed. *See F45 Training*, 2021 WL 2779130, at *9-10; *USC IP*, 2023 WL 5606977, at *3. Here too, this Court has aptly recognized that the claimed methods of the '248 and '945 patents at most "result in the generation of abstract information—'a value for an image attribute' or 'score'—for 'assessing' or 'evaluating' an aligner." Dkt. 49 at 4; *see also id*. at 5 ("Practicing each step of the claimed methods of the patents-in-suit, however, leads only to abstract information . . . .").

(iii) The dependent claims do not change the result.

DM does not assert or address any of the dependent claims of the Asserted Patents, and the Court therefore need not consider them. Even so, they are substantially similar to the corresponding independent claims and linked to the same abstract ideas of guiding a camera operator to capture an image or assessing the shape of an orthodontic aligner. *See People.ai*, 575 F. Supp. 3d at 1198. The dependent claims, at most, set forth additional steps reflecting the collection, analysis, and presentation of information in furtherance of these abstract ideas:

- *Identifying and assigning values to tooth attributes and image attributes*: '409 patent at claims 2-4, 6-7, 13-14; '248 patent at claims 3, 6, 7, 14;

- *Assessing an aligner by using tooth attributes, image attributes, or measured distances*: '248 patent at claims 2, 3, 7, 8, 14, 16; '945 patent at claims 2, 5-6;
- *Creating a "learning base" that includes a certain number of images of teeth, dental arches, or aligners*: '409 patent at claims 3, 5, 7; '248 patent at claims 7, 8, 14;
- *Updating a "learning base" with updated images of teeth, dental arches, or aligners*: '248 patent at claim 14;
- *Training a "deep learning device" with the "learning base"*: '409 patent at claims 3, 7; '248 patent at claims 7, 8, 14;
- *Using a "neural network" as the "deep learning device"*: '409 patent at claim 15; '248 patent at claim 13;
- *Reconciling "aligner images" and "dentition images"*: '945 patent at claim 4; and
- *Using a cellphone or other generic device to capture images or to present information*: '409 patent at claims 11, 12; '248 patent at claim 12; '945 patent at claim 2.

Therefore, the claims of the Asserted Patents are directed to abstract ideas under *Alice* step one.

2. The Claims of the Asserted Patents Are Not Directed to Any Specific Improvements in Computer Functionality or Other Technology.

Although the Asserted Patents reference the use of computer-based elements in the claimed methods, this does not salvage the claimed methods. It is well established that the use of generic computers to perform a well-known method or abstract idea is insufficient to render claims patent eligible. *See, e.g.*, *Versata Dev. Grp. v. SAP Am., Inc.*, 793 F.3d 1306, 1335 (Fed. Cir. 2015) ("Courts have examined claims that required the use of a computer and still found that the underlying, patent-ineligible invention could be performed via pen and paper or in a person's mind."); *F45 Training*, 2021 WL 2779130, at *9-10 (claims that "have long been practiced by[] humans without computers" are not patentable simply because computers are used); *Bot M8*, 465 F. Supp. 3d at 1025 ("Generic computer parts and functions do not become patentable every time they enter a new field.").

Nor is it sufficient to say that the claimed methods do something "better" than how people alone can do it: "[a]n improved result, without more stated in the claim does not 'confer eligibility

to an otherwise abstract idea.'" *Bot M8*, 465 F. Supp. 3d at 1020 (citation omitted). Rather, "the *claim itself* must 'sufficiently capture the inventors' asserted technical contribution to the prior art by reciting *how* the solution specifically improves the function of prior art." *Id.* (quoting *Koninklijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143, 1150-51 (Fed. Cir. 2019) (emphasis in original)). This does not mean that a computer cannot be part of an invention. But a patent owner seeking to show that its claims are patentable must claim and describe *improvements in how* computers operate, rather than merely the use of existing computers as tools to implement abstract ideas. *Elec. Power*, 830 F.3d at 1354; *Free Stream Media Corp. v. Alphonso Inc.*, 996 F.3d 1355, 1363 (Fed. Cir. 2021); *F45 Training*, 2021 WL 2779130, at *9-10.

Here, the claims of the Asserted Patents do not specify any improvements in computer functionality or other technology, but instead enlist generic computer elements to implement the abstract ideas of guiding a camera operator to take an image of teeth or assessing aligner shape. For example, the claimed methods recite steps of taking one or more pictures. '409 patent at claim 1 ("activation of an image acquisition apparatus so as to acquire an image"); '248 patent at claims 1, 15 ("acquisition of at least one image"); '945 patent at claim 1 ("acquisition of at least one two-dimensional image"). But as the patents admit, this is done using a generic camera-enabled computer such as "a cellphone, a so-called 'connected' camera, a so-called 'smart' watch, a tablet or a personal computer, fixed or portable, comprising an image acquisition system such as a webcam or a camera." '409 patent at 8:57-63; *see also id*. at 11:33-46, 12:57-64; '248 patent at 8:47-53, 11:22-35, 12:47-54; '945 patent at 3:42-55, 5:61-64.

Even when the claims of the Asserted Patents specify the analysis or processing of images, they do so using generic computer elements such as a "deep learning device" or "image processing software," which the patents do not address with any specificity, let alone "the 'specificity required to transform [the] claim from one claiming only a result to one claiming a way of achieving it' to avoid ineligibility." *Free Stream*, 996 F.3d at 1363 (citation omitted). For example, the claims of the '409 and '248 patents simply recite the analysis of an image "by means of a deep learning device" that is "trained by means of a learning base." *E.g.*, '409 patent at claim 1; '248 patent at claims 1, 15. But neither patent provides details regarding the specific implementation of the "deep learning

device" to be used. At most, the '409 and '248 patents provide generic descriptions that the "deep learning device" may be a "neural network," which they acknowledge to be a "set of algorithms well known to a person skilled in the art." '409 patent at 16:13-16; '248 patent at 16:5- 8 (same). And as a further tacit acknowledgement that they do not set forth any improvements in computer technology, the '409 and '248 patents point to pre-existing tools like GoogleNet (2015), Microsoft ResNet (2015), and other models "specializing in the location and detection of objects in an image." '409 patent at 16:17-42; '248 patent at 16:9-35 (same). At bottom, the claims simply include computer elements described in purely functional terms, which does not constitute an improvement in computer functionality. *USC IP*, 2023 WL 5606977, at *3 ("[T]he claims herein are not directed to improvements in computer functionality, for the claims only recite high-level functional language such as 'processing the confirmed intent' with no limitation as to how 'processing' steps are performed.") (quotations omitted).

Merely dressing up a claim by referencing technology like "deep learning" does not transform something unpatentable into something patentable. *See, e.g.*, *Enco Sys., Inc. v. DaVincia, LLC*, 845 F. App'x 953, 957-58 (Fed. Cir. 2021) (nonprecedential) (finding claim patent ineligible under § 101 where required training of model was described by referencing prior art software); *Angel Techs. Grp. LLC v. Facebook Inc.*, No. 21-CV-8459, 2022 WL 3093232, *4 (C.D. Cal. 2022) (finding claim patent ineligible under § 101 because it required use of "artificial intelligence" "to locate images matching characteristics of a subset of image data," noting that the claim "provide[d] no details on how to implement these algorithms, how they [would] work, or how Plaintiff improved upon it" and that "all [the] claim discloses about artificial intelligence is that it will be used which is the very essence of an abstract idea"); *Hyper Search, LLC v. Facebook, Inc.*, No. 17-CV-1387, 2018 WL 6617143, at *10 (D. Del. Dec. 17, 2018) (finding "claims reciting neural networks to be unpatentable for failing to recite more than an abstract idea" and holding that limiting an abstract idea to a "'particular technological environment' does not transform an abstract idea into a patent-eligible invention").

Similarly, the claimed methods of the '945 patent recite the use of generic "image processing software" to determine tooth outlines and does not specify any particular implementation of such

software that would amount to an improvement in computer technology. *E.g.*, '945 patent at claim 1. To the contrary, the patent acknowledges that a "[a] person skilled in the art knows how to process an image in order to isolate an outline" and that "[t]his processing for example involves the well-known application of masks or filters, which come with image processing software." *Id.* at 10:22-27.

The Asserted Patents do not even purport to claim improvements in aligners, cameras, computers, or other technological elements, which underscores the abstractness of the claimed methods. *See, e.g.*, *SmileDirectClub*, 505 F. Supp. 3d at 343 (reasoning that the patent at issue "does not describe how to make an intraoral scanner, aligners, or three-dimensional representations of teeth" and "does not purport to teach any advances in machinery, equipment, devices, or computer technology"). At bottom, *nothing* is improved, except for the simple convenience of using generic computer elements to do what patients and dentists have long done. Therefore, the claims of the Asserted Patents are not directed to improvements in computer functionality or other technology that salvage them from abstractness.

D. The Claims of the Asserted Patents Fail *Alice* Step Two

Because the claims of the Asserted Patents are directed to abstract ideas, the inquiry turns to *Alice* step two, which asks whether the claim elements, considered individually and as an ordered combination, add an inventive concept to the abstract ideas. *See Elec. Power*, 830 F.3d at 1353. "Stating an abstract idea while adding the words 'apply it with a computer'" does not transform an abstract idea into a patent eligible invention. *Alice*, 573 U.S. at 223. Rather, the claim must supply additional features that are more than just well-understood, routine, or conventional activity to transform an abstract idea into a patent-eligible invention. *Ultramercial, Inc. v. Hulu*, *LLC*, 772 F.3d 709, 715 (Fed. Cir. 2014); *BSG*, 899 F.3d at 1290-91. Here, to the extent the claimed methods recite additional features, the Asserted Patents admit that these features were well understood, routine, and conventional.

For example, the claims of the '409 and '248 patents recite the use of a "deep learning device." *E.g.*, '409 patent at claim 1; '248 patent at claims 1, 15. The patents, however, admit that this was a well-understood, routine, and conventional feature. According to the '409 and '248

patents, the "deep learning device" is "preferably a neural network [that] is trained with the learning base," and they acknowledge that "[a] 'neural network' or 'artificial neural network' is a set of algorithms well known to a person skilled in the art." '409 patent at 16:13-16; '248 patent at 16:5-8. The patents also generically list existing neural networks to choose from, including neural networks "specializing in the location and detection of objects in an image" ('409 patent at 16:17-42;'248 patent at 16:5-35), demonstrating that, at most, the claims simply use well-known computer components to make more convenient existing processes for taking pictures, such as that set forth in the admitted prior art WO '651 application. '409 patent at 2:42-43, 3:9-10, 7:9-33, 7:50-54, 8:55-56, 9:37-39, Figs. 11-16; *see also* '248 patent at 2:42-47, 3:9-10, 7:9-24, 7:38-42, 8:43-46, 9:28-30, Figs. 11-16; '945 patent at 7:6-42. As explained above, however, courts routinely invalidate patents that merely reference artificial intelligence without tying specific improvements to the claimed invention, and nothing in the Asserted Patents warrants a different result here.

Similarly, the claimed methods of the '945 patent recite the use of "image processing software" to determine "interior and exterior tooth outlines." *E.g.*, '945 patent at claim 1. The patent, however, admits that the use of image processing software to perform edge detection was well-understood, routine, and conventional. Indeed, the '945 patent recognizes that "[a] person skilled in the art knows how to process an image in order to isolate an outline," that "[t]his processing for example involves the *well-known application of masks or filters, which come with image processing software*," and that "[s]uch processing operations for example make it possible to detect the regions of greatest contrast." *Id.* at 10:22-27 (emphasis added). The patent goes on to list "known and preferred methods" of image processing operations (*id*. at 10:28-11:32) and states that "[t]ooth outline determination can be optimized by following the teachings of [prior art] PCT/EP2015/074900" (*id*. at 11:33-34).

Further, to the extent the claims of the Asserted Patents recite elements such as "deep learning," "neural networks," and "image processing software," "the claims recite those conventional elements"—whether viewed individually or as an ordered combination—"at too high a level of generality to constitute an inventive concept." *See, e.g.*, *Evolutionary Intel. LLC v. Sprint Nextel Corp.*, 677 F. App'x 679, 680 (Fed. Cir. 2017). These elements are "purely functional 'black

box[es]'" that the specifications indicate can be carried out in many different ways. *USC IP*, 2023 WL 5606977, at *3. And to be sure, the inventive concept must be set forth in the claims themselves. *Two-Way Media*, 874 F.3d at 1338; *see also id*. at 1339 ("Neither the protocol nor the selection signals are claimed, precluding their contribution to the inventive concept determination."). But neither the claims nor the patent specifications indicate how taking a picture of teeth or assessing the shape of an orthodontic aligner is improved through the use of generic, pre-existing computer elements such as "a deep learning device" ('409 patent at claim 1; '248 patent at claims 1, 15) or "image processing software" ('945 patent at claim 1). *E.g.*, *Hawk Tech. Sys., LLC v. Castle Retail, LLC*, 60 F.4th 1349, 1358-59 (Fed. Cir. 2023).

Nor do the claim elements add an inventive concept when considered as an ordered combination. At best, the claimed steps are organized conventionally to carry out the task of taking a picture or assessing aligner shape using generic computer components. Because the "steps are organized in a completely conventional way," they "fail to describe a 'specific, discrete implementation of the abstract idea' sufficient to qualify for eligibility under § 101." *Two-Way Media*, 874 F.3d at 1341 (citation omitted); *see also Hawk Tech. Sys.*, 60 F.4th at 1359 (finding a lack of inventiveness in a claimed ordered combination because that merely recited an abstract idea performed on generic computer components); *Contour IP Holding, LLC v. GoPro, Inc.*, No. 17-CV-04738, 2022 WL 658553, *7 (N.D. Cal. 2022) ("[T]his combination does nothing new that is above and beyond the idea itself").

In short, as the Asserted Patents admit, the elements implemented by the claims—whether considered individually or as an order combination—were well understood, routine, and conventional. They cannot, and do not, transform the claimed abstract ideas into patent-eligible subject matter. The claimed methods therefore fail both *Alice* steps one and two, and are invalid under § 101.

E. The Claims of the Asserted Patents Epitomize *Alice's* Concern over Preemption

The Supreme Court has explained that the concern driving the exclusion of abstract ideas from patent-eligible subject matter is one of preemption. *Alice*, 573 U.S. at 216. While all patents at some level reflect laws of nature, natural phenomena, or abstract ideas, monopolizing an abstract

idea with a patent would impede innovation and inhibit further discovery, "thereby thwarting the primary object of the patent laws." *Id.*; *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012). That is precisely what the claims of the Asserted Patents attempt to do—they monopolize the abstract ideas of guiding an operator to capture an image or assessing aligner shape while seeking to preempt all ways of doing so. Indeed, although DM's complaint touts unique software, AI processes, and databases of photographs that it holds as "proprietary" (*see, e.g.*, Compl. ¶¶ 9, 11), the Asserted Patents do not describe any of this, nor are the claims limited to any specific implementation of this technology. This is precisely the kind of overbroad, abstract claiming that the patent-eligibility analysis under § 101 is designed to redress.

V. INVALIDITY OF THE CLAIMS UNDER 35 U.S.C. § 112 FOR LACK OF WRITTEN DESCRIPTION AND/OR ENABLEMENT

The specifications of the Asserted Patents do not provide adequate written description to support the full asserted scope of the Asserted Claims, as best as that scope can be understood. 35 U.S.C. § 112(a) requires that the specification contain "a written description of the invention." To fulfill the written description requirement, the specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citation omitted); *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (patent must provide written-description support to show inventor had possession of full scope of claims); *ICU Med., Inc. v. Alaris Med. Sys.*, Inc., 558 F.3d 1368, 1376-78 (Fed. Cir. 2009) (same); *Rivera v. ITC*, 857 F.3d 1315, 1321 (Fed. Cir. 2017) (same). To satisfy the written description requirement, "the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)). The Asserted Claims do not meet that requirement.

Additionally, to the extent the Asserted Claims are not found to be obvious, the specifications of the Asserted Patents do not enable the full asserted scope of the Asserted Claims, as best as that scope can be understood. Section 112(a) requires the specification to describe "the manner and

process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains … to make and use the [invention].” The enablement requirement is separate from and in addition to the written description requirement. *Ariad*, 598 F.3d at 1344. This “requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (citation omitted); *see Wyeth & Cordis Corp. v. Abbott Labb'ys*, 720 F.3d 1380 (Fed. Cir. 2013). “If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 611 (2023). The Asserted Patents do not meet that requirement.

The Asserted Patents fail to satisfy the written-description requirement and, to the extent they are not found to be obvious, further fail to satisfy the enablement requirements due to at least the following claim language or limitations:

1. Claim 1 of the ’409 patent, claims 1 and 15 of the ’248 patent and all dependent claims lack written description and enablement support for their full asserted scope to the extent they reference “analysis of the analysis image by means of a deep learning device[,] trained by means of a learning base.”

- The ’409 and ’248 patents do not demonstrate possession of the full asserted scope of the Asserted Claims in light of this limitation. In particular, the specifications do not clearly allow skilled artisans to recognize that the inventors possessed the full scope of the claimed analysis of an analysis image, specifying only that it is carried out by some generic “deep learning device.” The patent specifications fail to provide any particular algorithm for carrying out the analysis step, much less a disclosure that would support any and all ways of performing the analysis step. The specifications further provide no description of a “deep learning device,” other than high-level functional description of what the inventors intend the device to do. *See, e.g.*, ’409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15,

24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55.[5] The specifications indicate that there are many non-limiting options for types of "deep learning devices" one could use to carry out these functions. *See, e.g.*, '409 patent at 16:15-43, 32:3-4. The specifications also list a variety of non-limiting image attributes that can be assessed in the claimed method. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. In addition, to the extent the specifications describe aspects of training a "deep learning device" with a learning base, the descriptions are partial (e.g., instructing to use at least a certain number of images) and high-level. *See, e.g.*, '409 patent at 1:33-40, 2:4-3:18, 4:1-6, 13:59-14:2, 16:44-50, 17:4-6, 19:23-27. Even then, the patents convey that these are only some of the possible ways to create a learning base. *See, e.g.*, '409 patent at 7:44-48, 16:6-12. The patents generally assert that the "deep learning device" gets more accurate the more models or images are used to train it ('409 patent at 19:25-27), but neither the specifications nor the claims place a limit on the number of images to use to build the learning base. For at least these reasons, this limitation is not adequately described.

- To the extent the Asserted Claims are not found to be obvious, the '409 and '248 patents also do not enable skilled artisans to practice the full asserted claim scope in light of this limitation. In particular, the patents do not provide sufficient information to enable skilled artisans to practice the full scope of the claims including this limitation without undue experimentation. The patent specifications fail to provide any particular algorithm for carrying out the analysis step, much less a disclosure that would guide a skilled artisan to practice the claimed analysis without undue experimentation. The specifications further provide no description of a "deep learning device," other than high-level functional description of what the inventors intend the device to do. *See, e.g.*, '409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15, 24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55. The specifications indicate that there are many non-limiting options for

[5] Corresponding citations appear in the '248 patent.

types of "deep learning devices" one could use to carry out these functions. *See, e.g.*, '409 patent at 16:15-43, 32:3-4. The specifications also list a variety of non-limiting image attributes that can be assessed in the claimed method. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. In addition, to the extent the specifications describe aspects of training a "deep learning device" with a learning base, the descriptions are partial (e.g., instructing to use at least a certain number of images) and high-level. *See, e.g.*, '409 patent at 1:33-40, 2:4-3:18, 4:1-6, 13:59-14:2, 16:44-50, 17:4-6, 19:23-27. Even then, the patents convey that these are only some of the possible ways to create a learning base. *See, e.g.*, '409 patent at 7:44-48, 16:6-12. The patents generally assert that the "deep learning device" gets more accurate the more models or images are used to train it ('409 patent at 19:25-27), but neither the specifications nor the claims place a limit on the number of images to use to build the learning base. For at least these reasons, this limitation is not enabled.

2. Claims 3 and 7 of the '409 patent, claims 7, 8, and 14 of the '248 patent and all dependent claims lack written description and enablement support for their full asserted scope to the extent they reference "creation of a learning base."[6]

- The '409 and '248 patents do not demonstrate possession of the full asserted scope of the Asserted Claims in light of this limitation. In particular, the specifications do not clearly allow skilled artisans to recognize that the inventors possessed the full scope of the claimed training of at least one deep learning device by means of a

[6] The specific limitations are "creation of a learning base comprising more than 1000 images of dental arches, or 'historical images', each historical image comprising one or more zones each representing a tooth, or 'historical tooth zones', to each of which, for said tooth attribute, a tooth attribute value is assigned" ('409 claim 3); "creation of a learning base comprising more than 1000 images of dental arches, or 'historical images', each historical image comprising an attribute value for at least one image attribute, or 'image attribute value'" ('409 claim 7); "creation of a learning base comprising more than 1000 images of dental arches, or 'historical images', each historical image representing an aligner worn by a 'historical' patient and comprising one or more zones each representing a tooth, or 'historical tooth zones', to each of which, for the at least one tooth attribute relating to a separation between the tooth represented by the historical tooth zone considered, and the aligner represented, a tooth attribute value is assigned" ('248 claims 7 and 14); and "creation of a learning base comprising more than 1000 images of dental arches, or 'historical images', each historical image comprising an attribute value for at least one image attribute, or 'image attribute value', the image attribute relating to a separation between the tooth or teeth and the aligner represented on the historical image" ('248 claim 8).

learning base. The specifications provide no description of a "deep learning device," other than high-level functional description of what the inventors intend the device to do. *See, e.g.*, '409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15, 24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55. The specifications indicate that there are many non-limiting options for types of "deep learning devices" one could use to carry out these functions. *See, e.g.*, '409 patent at 16:15-43, 32:3-4. The specifications also list a variety of non-limiting image attributes that can be assessed in the claimed method, which would impact how the "deep learning device" would need to be trained. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. In addition, to the extent the specifications describe aspects of training a "deep learning device" with a learning base, the descriptions are partial (e.g., instructing to use at least a certain number of images) and high-level. *See, e.g.*, '409 patent at 1:33-40, 2:4-3:18, 4:1-6, 13:59-14:2, 16:44-50, 17:4-6, 19:23-27. Even then, the patents convey that these are only some of the possible ways to create a learning base. *See, e.g.*, '409 patent at 7:44-48, 16:6-12. The patents generally assert that the "deep learning device" gets more accurate the more models or images are used to train it ('409 patent at 19:25-27), but neither the specifications nor the claims place a limit on the number of images to use to build the learning base. For at least these reasons, this limitation is not adequately described.

- To the extent the Asserted Claims are not found to be obvious, the '409 and '248 patents do not enable skilled artisans to practice the full asserted claim scope in light of this limitation. In particular, the patents do not provide sufficient information to enable skilled artisans to practice the full scope of the claims including this limitation without undue experimentation. The specifications provide no description of a "deep learning device," other than high-level functional description of what the inventors intend the device to do. *See, e.g.*, '409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15, 24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55. The specifications indicate that there are many non-limiting options for

types of "deep learning devices" one could use to carry out these functions. *See, e.g.*, '409 patent at 16:15-43, 32:3-4. The specifications also list a variety of non-limiting image attributes that can be assessed in the claimed method, which would impact how the "deep learning device" would need to be trained. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. In addition, to the extent the specifications describe aspects of training a "deep learning device" with a learning base, the descriptions are partial (e.g., instructing to use at least a certain number of images) and high-level. *See, e.g.*, '409 patent at 1:33-40, 2:4-3:18, 4:1-6, 13:59-14:2, 16:44-50, 17:4-6, 19:23-27. Even then, the patents convey that these are only some of the possible ways to create a learning base. *See, e.g.*, '409 patent at 7:44-48, 16:6-12. The patents generally assert that the "deep learning device" gets more accurate the more models or images are used to train it ('409 patent at 19:25-27), but neither the specifications nor the claims place a limit on the number of images to use to build the learning base. For at least these reasons, this limitation is not enabled.

3. Claims 1 and 3 of the '409 patent, claim 1 of the '248 patent, and all dependent claims lack written description and enablement support for their full asserted scope to the extent they reference "determination, for the analysis image, as a function of the results of the analysis in the preceding step, of a value for an image attribute" / "determination, as a function of said probability, … of the attribute value of said tooth" / "so as to determine a value for at least one tooth attribute of an 'analysis tooth zone' representing, at least partially, a tooth on said analysis image."

- The '409 and '248 patents do not demonstrate possession of the full asserted scope of the Asserted Claims in light of this limitation. In particular, the specifications do not clearly allow skilled artisans to recognize that the inventors possessed the full scope of the claimed determination of values for image and/or tooth attributes. The specifications list a variety of non-limiting image attributes that can be assessed. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. However, the specifications provide no information as to *how* values are to be determined for image attributes and tooth attributes. For at least these reasons, this limitation is not adequately described.

- To the extent the Asserted Claims are not found to be obvious, the '409 and '248 patents do not enable skilled artisans to practice the full asserted claim scope in light of this limitation. In particular, the patents do not provide sufficient information to enable skilled artisans to practice the full scope of the claims including this limitation without undue experimentation. The specifications list a variety of non-limiting image attributes that can be assessed. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. However, the specifications provide skilled artisans no information as to *how* values are to be determined for image attributes and tooth attributes. For at least these reasons, this limitation is not enabled.

4. Claims 3 and 7 of the '409 patent, claims 7, 8, and 14 of the '248 patent, and all dependent claims lack written description and enablement support for their full asserted scope to the extent they reference "submission of the analysis image to the deep learning device for it to determine [, for said analysis image,] at least one probability relating to [: the presence, at a location in said analysis image, of a zone representing, at least partially, a tooth, or 'analysis tooth zone', the attribute value of the tooth represented on said analysis tooth zone / said image attribute value / : the presence, in a location of said analysis image, of an analysis tooth zone; and the attribute value of the tooth represented on said analysis tooth zone]."

- The '409 and '248 patents do not demonstrate possession of the full asserted scope of the Asserted Claims in light of this limitation. In particular, the specifications do not clearly allow skilled artisans to recognize that the inventors possessed the full scope of this limitation. The specifications provide no description of a "deep learning device," other than high-level functional description of what the inventors intend the device to do. *See, e.g.*, '409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15, 24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55. The specifications indicate that there are many non-limiting options for types of "deep learning devices" one could use to carry out these functions. *See, e.g.*, '409 patent at 16:15-43, 32:3-4. The specifications also list a variety of non-limiting image attributes that can be assessed in the claimed method. *See, e.g.*, '409 patent at 3:38-

4:32, 32:3-4. In addition, to the extent the specifications describe aspects of training a "deep learning device" with a learning base, the descriptions are partial (e.g., instructing to use at least a certain number of images) and high-level. *See, e.g.*, '409 patent at 1:33-40, 2:4-3:18, 4:1-6, 13:59-14:2, 16:44-50, 17:4-6, 19:23-27. Even then, the patents convey that these are only some of the possible ways to create a learning base. *See, e.g.*, '409 patent at 7:44-48, 16:6-12. The patents generally assert that the "deep learning device" gets more accurate the more models or images are used to train it ('409 patent at 19:25-27), but neither the specifications nor the claims place a limit on the number of images to use to build the learning base. For at least these reasons, this limitation is not adequately described.

- To the extent the Asserted Claims are not found to be obvious, the '409 and '248 patents do not enable skilled artisans to practice the full asserted claim scope in light of this limitation. In particular, the patents do not provide sufficient information to enable skilled artisans to practice the full scope of the claims including this limitation without undue experimentation. The specifications provide no description of a "deep learning device," other than high-level functional description of what the inventors intend the device to do. *See, e.g.*, '409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15, 24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55. The specifications indicate that there are many non-limiting options for types of "deep learning devices" one could use to carry out these functions. *See, e.g.*, '409 patent at 16:15-43, 32:3-4. The specifications also list a variety of non-limiting image attributes that can be assessed in the claimed method. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. In addition, to the extent the specifications describe aspects of training a "deep learning device" with a learning base, the descriptions are partial (e.g., instructing to use at least a certain number of images) and high-level. *See, e.g.*, '409 patent at 1:33-40, 2:4-3:18, 4:1-6, 13:59-14:2, 16:44-50, 17:4-6, 19:23-27. Even then, the patents convey that these are only some of the possible ways to create a learning base. *See, e.g.*, '409 patent at 7:44-48, 16:6-12. The patents generally

assert that the "deep learning device" gets more accurate the more models or images are used to train it ('409 patent at 19:25-27), but neither the specifications nor the claims place a limit on the number of images to use to build the learning base. For at least these reasons, this limitation is not enabled.

5. Claim 6 of the '409 patent and all dependent claims lack written description and enablement support for their full asserted scope to the extent they reference "in the step b'), all said analysis tooth zones are identified, and at least one tooth attribute value is determined for each analysis tooth zone, and, in the step c'), the value for the image attribute is determined as a function of said tooth attribute values."

- The '409 and '248 patents do not demonstrate possession of the full asserted scope of the Asserted Claims in light of this limitation. In particular, the specifications do not clearly allow skilled artisans to recognize that the inventors possessed the full scope of the claimed determination of values for image and/or tooth attributes. The specifications list a variety of non-limiting image attributes that can be assessed. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. However, the specifications provide no information as to *how* values are to be determined for image attributes and tooth attributes. For at least these reasons, this limitation is not adequately described.
- To the extent the Asserted Claims are not found to be obvious, the '409 and '248 patents do not enable skilled artisans to practice the full asserted claim scope in light of this limitation. In particular, the patents do not provide sufficient information to enable skilled artisans to practice the full scope of the claims including this limitation without undue experimentation. The specifications list a variety of non-limiting image attributes that can be assessed. *See, e.g.*, '409 patent at 3:38-4:32, 32:3-4. However, the specifications provide skilled artisans no information as to *how* values are to be determined for image attributes and tooth attributes. For at least these reasons, this limitation is not enabled.

6. Claim 5 of the '248 patent and all dependent claims lack written description and enablement support (to the extent this claim is not obvious) for their full asserted scope to the extent they reference "as a function of the result of said assessment, a new aligner is manufactured."

- The '248 patent does not demonstrate possession of or enable the full asserted scope of the Asserted Claims in light of this limitation. In particular, the patent provides no guidance whatsoever related to the manufacturing of aligners, let alone sufficient guidance to guide a skilled artisan to practice the claimed invention of manufacturing an aligner with the results of the claimed assessment without undue experimentation. For at least this reason, this limitation is not enabled and lacks adequate written description.

7. Claim 1 of the '945 patent and all dependent claims lack written description and enablement support for their full asserted scope to the extent they reference "determination, by means of image processing software, for each of a plurality of teeth represented on the dentition and aligner images, of interior and exterior tooth outlines representing the outline of the free end of said tooth on the dentition and aligner images, respectively."

- The '945 patent does not demonstrate possession of the full asserted scope of the Asserted Claims in light of this limitation. In particular, the specification does not clearly allow skilled artisans to recognize that the inventors possessed the full scope of the claimed determination of interior and exterior tooth outlines. The patent specification fails to provide any particular algorithm for carrying out the analysis step, much less a disclosure that would support any and all ways of performing the analysis step. Instead, the specification simply states that image processing software can be used to determine tooth outlines and that the process "involves the well-known application of masks and filters," followed by a non-limiting laundry list of possible image processing software. '945 patent at 10:19-11:32. For at least these reasons, this limitation is not adequately described.
- To the extent the Asserted Claims are not found to be obvious, the '945 patent does not enable skilled artisans to practice the full asserted claim scope in light of this

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limitation. In particular, the patent does not provide sufficient information to enable skilled artisans to practice the full scope of the claims including this limitation without undue experimentation. The patent specification fails to provide any particular algorithm for carrying out the analysis step, much less a disclosure that would guide a skilled artisan to practice the claimed analysis without undue experimentation. Instead, the specification simply states that image processing software can be used to determine tooth outlines and that the process "involves the well-known application of masks and filters," followed by a non-limiting laundry list of possible image processing software. '945 patent at 10:19-11:32. For at least these reasons, this limitation is not enabled.

To the extent the Court permits Plaintiff to amend or supplement its Infringement Contentions at a later time, Align reserves the right to modify or supplement its Contentions regarding invalidity under 35 U.S.C. § 112 for lack of written description and/or enablement to respond to any claim scope alleged or implied by such contentions.

VI. INVALIDITY OF THE CLAIMS UNDER 35 U.S.C. § 112 FOR INDEFINITENESS

Claims 1-7 and 11-15 of the '409 patent, claims 1-8 and 12-16 of the '248 patent, and claims 1, 2, and 4-6 of the '945 patent (i.e., all Asserted Claims) are invalid as indefinite.[7]

The Asserted Claims are indefinite because they invoke means-plus-function claiming under 35 U.S.C. § 112(f) but are not supported by any corresponding structure disclosed in the specification. Section 112(f) "allows a patentee to express a claim limitation as 'a means or step for performing a specified function without the recital of structure, material, or acts in support thereof,' and the section provides that claim limitations expressed in this manner 'shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.'" *Robert Bosch, LLC v. Snap-On Inc.*, 769 F.3d 1094, 1097 (Fed. Cir. 2014). "The use of the term 'means' triggers a rebuttable presumption that § 112, ¶ 6 governs the construction of the claim term." *Id*. And although there is reversed rebuttable presumption that a claim lacking the term "means"

[7] Defendant notes that its charting of a prior art reference for a claim or limitation that Defendant contends is invalid for lack of definiteness in no way represents an admission or concession that the scope of the claim or limitation is definite or ascertainable.

does not invoke § 112(f), this presumption can be overcome "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Id*. (quotation omitted); *see also id*. at 1099 (to analyze whether the presumption is overcome, "we ask if the claim language, read in light of the specification, recites sufficiently definite structure to avoid § 112, ¶ 6."); *see also Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (presumption overcome "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function."). "The question is whether the claim language names particular structures or, instead, refers only to a general category of whatever may perform specified functions." *Bosch*, 769 F.3d at 1099.

The rebuttable presumption that the means-plus-function statute does not apply to a patient claim lacking the word "means" is not strong. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). "Generic terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke § 112, para. 6." *Id*. at 1350 (quotation omitted).

At least the following terms from the Asserted Claims are means-plus-function terms under § 112(f):

- "analysis of the analysis image by means of a deep learning device[,] trained by means of a learning base" ('409 patent at claim 1; '248 patent at claims 1, 15); and
- "determination, by means of image processing software…of interior and exterior tooth outlines" ('945 patent at claim 1).

Even assuming that the phrase "means of" (as opposed to "means *for*") in the terms above does not *per se* invoke § 112(f) and that there is a rebuttable presumption that it is not invoked, that presumption is overcome here. *See Bosch*, 769 F.3d at 1098-99. As noted, this presumption against invoking § 112(f) is *not* a strong one. *Williamson*, 792 F.3d at 1349. Here, in each instance, the claim language refers to a generic function that is performed "by means of" a generic computer device or element. For example, the asserted claims of the '409 and '248 patents refer to a generic "deep

learning device" that performs some generic "analysis," and similarly the asserted claims of the '945 patent refer to some generic "image processing software" that performs some generic "determination," without identifying any particular structure that carries out those functions or even how they are carried out. The phrases "deep learning device" and "image processing software" do not connote a particular structure and are akin to the various nonce words and phrases that courts have found to invoke means-plus-punction claiming. *Williamson*, 792 F.3d at 1350 ("Generic terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke § 112, para. 6.").

The specifications of the Asserted Patents similarly do not impart any structural significance to these terms and merely describe them in terms of their generic functions. The claims merely recite nonce words and phrases such as "deep learning device" and "image processing software" that are described as performing certain claimed functions, such as "analysis of an analysis image" "and determin[ing]…tooth outlines." *See, e.g.*, '409 patent at 1:24-25, 1:39-40, 1:51-2:3, 3:14-18, 4:5-6, 8:41-50, 13:64-65, 24:14-15, 24:46-47, 24:66-25: 4, 28:27-29, 29:24-25, 29:54-55 (describing "deep learning device" in purely functional terms), 16:13-50 (describing non-limiting examples of neural networks);[8] '945 patent at 10:22-27 (describing simply that image processing software comes with certain functions, such as application of masks or filters). In fact, the phrase "image processing software" is used only once in the '945 patent specification, and in that context the specification simply identifies certain functions of image processing software and a laundry list of generic methods. '945 patent at 10:22-11:32. Thus, specifications of the Asserted Patent support the conclusion that the claim language invokes §112(f). *Id*. at 1351.

A claim term that invokes § 112(f) is indefinite "[i]f there is no structure in the specification corresponding to the means-plus-function limitation in the claims." *Bosch*, 769 F.3d at 1101; *see also Aristocrat*, 521 F.3d at 1331; *Williamson*, 792 F.3d at 1351. "In cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, [the

[8] Corresponding citations appear in the '248 patent.

Federal Circuit] has consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor." *Aristocrat*, 521 F.3d at 1333; *see also id*. ("[S]imply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to 'the corresponding structure, material, or acts' that perform the function, as required by section 112 paragraph 6.").

The specifications of the Asserted Patents provide no discussion of the structure of the claimed "deep learning device," and "image processing software," let alone an adequate disclosure of structure that comports with § 112(f). *See, e.g.*, *Williamson*, 792 F.3d at 1352 ("Even if the specification discloses corresponding structure, the disclosure must be 'adequate' corresponding structure to achieve the claimed function."). Rather, the specifications only identify generic computer devices and elements. Nowhere do they describe *how* the claimed deep learning device and image processing software actually carry out the claimed functions. *See, e.g.*, *id*. at 1100 ("Contrary to what Bosch contends, the specification does not teach how the 'program recognition device' receives and processes signals"). And to the extent the specifications list possible programs that constitute neural networks or carry out "image processing," or otherwise reference what a POSA would have known to do (e.g., '409 patent at 16:13-42; '945 patent at 10:22-11:32), it is well established that "merely listing examples of possible structures is insufficient to avoid invocation of § 112, ¶ 6." *Id*. at 1101; *see also Williamson*, 792 F.3d at 1351 ("[T]he fact that one of skill in the art could program a computer to perform the recited functions cannot create structure where none is otherwise disclosed."); *Aristocrat Techs. Aus. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1334-37 (Fed. Cir. 2008) (similar).

For at least these reasons, the Asserted Claims are indefinite under § 112(f). But even to the extent that the Asserted Claims do not invoke § 112(f), they are nonetheless indefinite under § 112(b). Section 112(b) requires that a patent claim "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." Claim terms that fail to inform those skilled in the art "with reasonable certainty . . . about the scope of the invention" fail the definiteness requirement of § 112(b). *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Here, neither the Asserted Claims nor the patent specifications provide any guidance to determine

with reasonable certainty the scope of the claims to the extent they refer to a generic "deep learning device" that carries out some generic "analysis" or a generic "image processing software" that carries out some generic "determination."

Further still, the claims are invalid as indefinite under § 112(b) for at least the reasons described below:

1. Claim 1 of the '409 patent and all dependent claims are indefinite due to the claim language referencing "comparison of said image attribute value with a setpoint." The '409 patent fails to inform those skilled in the art with reasonable certainty about the scope of the above term because it is not clear what constitutes a "setpoint," and the skilled artisan would not know from reading the '409 patent whether a setpoint is being used as a comparator.

2. Claim 1 of the '409 patent and all dependent claims are indefinite due to the claim language referencing "check[ing] whether the analysis image respects the setpoint and, if it does not respect the setpoint, to guide the operator in order for him or her to acquire a new analysis image" The '409 patent fails to inform those skilled in the art with reasonable certainty about the scope of the above term because it is not clear what constitutes a "setpoint," and the skilled artisan would not know from reading the '409 patent whether a setpoint is being used as a comparator.

3. Claim 5 of the '409 patent and all dependent claims are indefinite due to the claim language referencing "[t]he method as claimed in claim 3, in which, in the step 1) or 1'), a learning base is created comprising more than 10 000 historical images." The '409 patent fails to inform those skilled in the art with reasonable certainty about the scope of the above term because there is no step 1') in any claim from which claim 5 depends. Therefore, the referenced step "1')" lacks antecedent basis, and the scope of claim 5 is not reasonably certain.

4. Claims 2, 3, and 16 of the '248 patent and all dependent claims are indefinite due to the claim language referencing "suitability." The '248 patent fails to inform those skilled in the art with reasonable certainty about the scope of the above term because a skilled artisan would not know the meaning of "suitability" in the context of the claims, including how to assess whether an aligner is "suitable" based on the claimed tooth attribute(s). For example, what may be suitable to one dental practitioner may not be suitable to another dental practitioner.

5. Claim 1 of the '945 patent and all dependent claims are indefinite due to the claim language referencing "updated image." Step 1) of claim 1 recites the "acquisition of at least one two-dimensional image … referred to as 'updated image'," as well as "at least one updated image referred to as 'aligner image'" and "at least one updated image referred to as 'dentition image.'" The '945 patent, however, fails to inform those skilled in the art with reasonable certainty about the scope of the above term because it is unclear based on the claim language whether the claim requires one, two, or even three updated images. For example, the lead-in clause of step 1) refers to acquiring at least one "updated image," but it is unclear whether this is in addition to the acquisition of at least one "aligner image" and at least one "dentition image," which are recited later in step 1) and also referred to as "updated image[s]."

VII. DOCUMENT PRODUCTION

A. Patent L.R. 3-4(a)

Pursuant to Patent L.R. 3-4(a), Align states that it has produced source code showing the operation of accused features of the accused products. Additionally, Align has produced technical documents that show the operation of the accused products, such as Align-DM_0000310–Align-DM_0000320; Align-DM_0000321–Align-DM_0000331; Align-DM_0003121-Align-DM_0003264; Align-DM_0003265-Align-DM_0003409; Align-DM_0011984-Align-DM_0012154; Align-DM_0003985–Align-DM_0004099.

B. Patent L.R. 3-4(b)

Pursuant to Patent L.R. 3-4(b), Align states that copies of printed public prior art are being produced concurrently with service of these Contentions. *See* Align-DM_0013689-Align-DM_0013875; Align-DM_0013975-Align-DM_0014055; Align-DM_0014242-Align-DM_0014359; Align-DM_0003713-Align-DM_0003720; Align-DM_0010924-Align-DM_0010975; Align-DM_0014360-Align-DM_0014430.

C. Patent L.R. 3-4(c)

Patent L.R. 3-4(c) requires production of "[a]ll agreements that the party opposing infringement contends are comparable to a license that would result from a hypothetical reasonable royalty negotiation." Discovery regarding this topic is deferred in light of the parties' stipulation

that discovery relating to remedies will be reserved until after the patent showdown process. Dkt. 74.

D. Patent L.R. 3-4(d)

Patent L.R. 3-4(d) requires production of "[d]ocuments sufficient to show the sales, revenue, cost, and profits for accused instrumentalities identified pursuant to Patent L.R. 3-1(b) for any period of alleged infringement." Discovery regarding this topic is deferred in light of the parties' stipulation that discovery relating to remedies will be reserved until after the patent showdown process. Dkt. 74.

E. L.R. 3-4(e)

Patent L.R. 3-4(e) requires production of "[a]ll agreements that may be used to support the party denying infringement's damages case." Discovery regarding this topic is deferred in light of the parties' stipulation that discovery relating to remedies will be reserved until after the patent showdown process. Dkt. 74.

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of September, 2023, a true and correct copy of the foregoing document, DEFENDANT'S PATENT LOCAL RULE 3-3 AND 3-4 INITIAL INVALIDITY CONTENTIONS AND DISCLOSURES, was served by email on Plaintiff's counsel of record.

/s/ Hari Santhanam
Hari Santhanam

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