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13	FOR THE NORTHERN DISTRICT OF CALIFORNIA				
14	SAN JOSE DIVISION				
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16	Dental Monitoring SAS,	CASE NO. 5:22-CV-7335			
16 17	Dental Monitoring SAS,  Plaintiff,	CASE NO. 5:22-CV-7335  COMPLAINT FOR PATENT			
17	Plaintiff, v.	COMPLAINT FOR PATENT INFRINGEMENT			
17 18	Plaintiff,	COMPLAINT FOR PATENT			
17 18 19	Plaintiff, v. Align Technology, Inc.,	COMPLAINT FOR PATENT INFRINGEMENT			
17 18 19 20	Plaintiff, v. Align Technology, Inc.,	COMPLAINT FOR PATENT INFRINGEMENT			
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117 118 119 20 21 22 22 23 24 25	Plaintiff, v. Align Technology, Inc.,	COMPLAINT FOR PATENT INFRINGEMENT			

COMPLAINT CASE NO. 5:22-cv-7335

### INTRODUCTION

This case concerns Plaintiff Dental Monitoring SAS's ("Dental Monitoring") groundbreaking innovations in the remote dental health and treatment monitoring space. These remote-monitoring innovations minimize the number of trips to the dentist a patient must make, while providing orthodontists and dentists with the information they need on their patient's dental health. Dental Monitoring has invested close to \$150,000,000 developing its transformative, award-winning, AI-powered remote dental monitoring technologies—a massive investment for a company of Dental Monitoring's size. These industry-leading technologies reflect the contributions of hundreds of Dental Monitoring employees over the past half-decade. Dental Monitoring has protected its investment by developing a significant, home-grown, world-wide patent portfolio.

Defendant Align Technology, Inc. ("Align"), by contrast, initially failed to appreciate the need for sophisticated, remote dental monitoring, and it was caught flat-footed when COVID hit. Suddenly, patients were not comfortable going into orthodontists' offices or were not permitted to do so, and Align needed a way to allow orthodontists to monitor their patients' teeth. So, Align took shortcuts and infringed Dental Monitoring's pioneering patents. Dental Monitoring files this lawsuit to stop Align's ongoing infringement.

#### NATURE OF THE ACTION

- 1. This is a civil action for infringement of United States Patent Nos. 10,755,409 ("'409 patent"), 11,049,248 ("'248 patent"), and 11,109,945 ("'945 patent") (collectively, the "Patents-in-Suit"), which are generally directed to novel and innovative methods of acquiring and analyzing a patient's dentition and aligner images for dental treatment purposes, under the patent laws of the United States, 35 U.S.C. § 1 et seq.
- 2. Dental Monitoring seeks judgment that Align has infringed, and continues to infringe, the Patents-in-Suit arising out of Align's commercialization of teledental services in the United

States prior to the expiration of the Patents-in-Suit.

### THE PARTIES

- 3. Dental Monitoring is a corporation organized and existing under the laws of France with its principal place of business at 75 Rue de Tocqueville, 75017, Paris, France.
- 4. On information and belief, Align is a United States corporation organized and existing under the laws of the State of Delaware with its global headquarters in Tempe, Arizona, and its West Coast regional headquarters at 2820 Orchard Parkway, San Jose, California 95134.

### **JURISDICTION AND VENUE**

- 5. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, for infringement of the Patents-in-Suit.
- 6. The Court has subject matter jurisdiction over the matters pleaded herein under 28 U.S.C. §§ 1331 and 1338(a).
- 7. On information and belief, Align is a corporation organized and existing under the laws of the State of Delaware, with its historical global headquarters and current regional headquarters in San Jose, California, and acts of infringement have occurred within this district. Accordingly, this Court has personal jurisdiction over Align.
- 8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Align's regional and historic global headquarters is in San Jose, California, and Align has committed acts of infringement in the district, including by providing infringing services and products to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users in the district. Additionally, on information and belief, significant research, design, and testing efforts have occurred at Align's San Jose headquarters.

### FACTUAL BACKGROUND

# A. Dental Monitoring's Pioneering Technologies

- 9. Dental Monitoring is a pioneer and the technological leader in remote monitoring orthodontics, as well as visual and AI-powered orthodontics. Founded in 2014, Dental Monitoring set out to revolutionize the dental care industry. Specifically, Dental Monitoring sought to synchronize the delivery of care with the need for care, to eliminate many of the time-consuming, costly, and unnecessary trips to the dentist that plague the industry. Dental Monitoring sought to achieve this by having patients self-photograph their mouths with their smartphones in the comfort of their own homes (or anywhere else) and then, using proprietary and customized artificial intelligence ("AI") technology, accurately analyze those images—to assist the dental professionals, especially during orthodontic treatment, in tracking treatment progress by following tooth movement, and identify well over 100 gingival or dental issues, as well as orthodontic-related clinical or treatment issues, such as patient compliance, occlusion problems, or failures with orthodontic equipment (e.g., ill-fitting aligners or broken braces). Using Dental Monitoring's technologies, a patient can seamlessly interface remotely with their dentist and only come into the office if it is truly necessary.
- 10. These technological breakthroughs were the direct result of Dental Monitoring's consistent prioritization of and investment in research and development. Dental Monitoring employs a team of over 130 developers, scientists, dentists, technicians, and orthodontists focused on designing, testing, validating, and training its AI and visual recognition technology. This has resulted in the custom and novel AI-related technologies found at the core of Dental Monitoring's approach. Dental Monitoring also relies heavily on its database of over 500 million patient photographs, many of which are hand-curated by staff and partners. Since its inception less than a decade ago, Dental Monitoring has invested more than \$150,000,000 to create the remote monitoring

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orthodontic market, with a significant portion of the spending dedicated to R&D relating to these technologies. This investment, which is massive proportional to its overall budget, reflects Dental Monitoring's relentless focus on technological improvements and commitment to R&D and product design.

11. Dental Monitoring's successes have garnered international recognition. Cellerant Consulting Group recognized Dental Monitoring as a winner of the 2022 Best of Class Technology See The Standout Dental Technologies of 2022, Cellerant Consulting Group, Award. https://www.cellerantconsulting.com/best-of-class-technology-2022 (last accessed November 17, 2022). The award is presented at the American Dental Association's Annual Meeting and given to "innovative products that set a standard of quality in their respective categories" and "has been acknowledged as the most prestigious and coveted award that a dental manufacturer can receive." Origin Class Award, Cellerant Consulting See Best Group, https://www.cellerantconsulting.com/about-best-of-class (last accessed November 17, 2022). Similarly, the Health Care Technology Report recognized Dental Monitoring as one of the top 50 companies on its list of Top 100 Healthcare Technology Companies of 2022. See The Top 100 Healthcare Technology Companies of 2022, The Healthcare Technology Report (Aug. 3, 2022) https://thehealthcaretechnologyreport.com/the-top-100-healthcare-technology-companies-of-2022/ (last accessed November 17, 2022). Describing Dental Monitoring, the report said:

The Paris-based company is still the only provider in the world of AI-based remote monitoring of orthodontic appliances, and its proprietary program has built the largest visual orthodontic database in the world while alerting dental professionals to a wide variety of oral events.

The story of how DentalMonitoring changed the landscape of digital dentistry is one characterized by breakthroughs and rapid successes. After being founded in 2014 by veterans of the industry who sought a better way to design and manage orthodontic and dental devices, the company Dental [Monitoring] launched its major platform as well as at-home scanning device ScanBox and advanced simulator program

Vision. Last year, the company announced that it was the first dental software company in history to reach a \$1 billion valuation following a \$150 million round of growth financing. *Id*.

12. A leading online dentistry website, dentistry.co.uk, has called Dental Monitoring's services and products the "wonderful everyday solution for modern orthodontics." *See* Guy Deeming, *Dental Monitoring – the 'wonderful everyday solution for modern orthodontics'*, Dentistry Online (Nov. 11, 2020, 7:06), <a href="https://dentistry.co.uk/2020/11/11/dental-monitoring-wonderful-everyday-solution-modern-orthodontics/">https://dentistry.co.uk/2020/11/11/dental-monitoring-wonderful-everyday-solution-modern-orthodontics/</a> (last accessed November 17, 2022). Quoting an orthodontist, the website states:

We operate an appointment on demand system. Dental Monitoring calls it OWN: Only When Needed. So we do not see patients in a line of treatments for routine reviews. But only see them in-practice when we need to see them and to put our hands in their mouths.

For that reason we've significantly reduced the number of routine reviews on an annual basis.

This has saved us a huge amount of time.

The combination of those two things has saved us tens and tens of hours a month and hundreds and hundreds of hours a year from our existing diary. It allows us to grow, which allows us to work in a more calm and more measured manner with those physical appointments, which still have to happen. *Id.* 

13. Another leading dentistry website, Top Doctors UK, describes Dental Monitoring's service and product as "a newly modernized and innovative way to treat and monitor patient dental treatment remotely through the incorporation of a smartphone application." *See* Dana Bondoc, *Dental monitoring: what is it and what are the benefits?*, Top Doctors United Kingdom (Dec. 27, 2021), <a href="https://www.topdoctors.co.uk/medical-articles/dental-monitoring-what-is-it-and-what-are-the-benefits">https://www.topdoctors.co.uk/medical-articles/dental-monitoring-what-is-it-and-what-are-the-benefits</a> (last accessed November 17, 2022). It further states that:

Dental monitoring was developed in France and its purpose was to develop an artificial intelligence (AI) to identify not only various different dental structures and diseases such as cavities, gingivitis, and gum recession, but also to track dental movement with the overall objective being to help doctors remotely monitor patients undergoing

an Invisalign procedure . . . .

The main benefit of dental monitoring is that it allows both the doctor and patient to avoid any unnecessary appointment. All Invisalign patients can use the dental monitoring application to upload their dental photos on a weekly basis.

This dental monitoring app lets the patients know if they can change to the next aligner or not. It picks up poor wear issues and actually sends them an automatic message without asking [the orthodontist] to approve.

Dental monitoring can also detect a slight unseating of the aligner for the lower left second premolar. *Id*.

14. Proof of Dental Monitoring's success in improving dental care can also be found in its investors—specifically, the significant percentage of whom are dentists and orthodontists. After seeing Dental Monitoring's groundbreaking technologies in action, and appreciating its potential to help patients and care providers, more than 100 dentists and orthodontists have invested in the company, totaling millions of dollars. Dental Monitoring's employees are also significant shareholders in the company, further reflecting its value among the people who know it best.

#### **B.** The Patents-in-Suit

- 15. Dental Monitoring's research and development work has also led to a robust patent portfolio—more than 200 pending and issued patents filed throughout the world, including the Patents-in-Suit.
- 16. On August 25, 2020, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '409 patent, titled "Method for Analyzing an Image of a Dental Arch," naming Philippe Salah, Thomas Pellissard, Guillaume Ghyselinck, and Laurent Debraux as inventors. A true and correct copy of the '409 patent is attached hereto as Exhibit A.
- 17. Dental Monitoring owns the entire right, title, and interest in and to the '409 patent, including the right to sue and recover damages, including damages for past infringement.
  - 18. On June 29, 2021, the USPTO duly and legally issued the '248 patent, titled "Method

for Analyzing an Image of a Dental Arch," naming Philippe Salah, Thomas Pellissard, Guillaume Ghyselinck, and Laurent Debraux as inventors. A true and correct copy of the '248 patent is attached hereto as Exhibit B.

- 19. Dental Monitoring owns the entire right, title, and interest in and to the '248 patent, including the right to sue and recover damages, including damages for past infringement.
- 20. On September 7, 2021, the USPTO duly and legally issued the '945 patent, titled "Method of Evaluating an Orthodontic Aligner," naming Philippe Salah, Thomas Pellissard, Guillaume Ghyselinck, and Laurent Debraux as inventors. A true and correct copy of the '945 patent is attached hereto as Exhibit C.
- 21. Dental Monitoring owns the entire right, title, and interest in and to the '945 patent, including the right to sue and recover damages, including damages for past infringement.
- treatment. More specifically, the claims of these patents addressed an "ongoing need for a method simplifying the analysis of" dentition, aligner, and other related images used to provide dental treatment to patients, *e.g.*, orthodontic treatment using aligners. *See*, *e.g.*, '409 patent, 1:16–19, 3:60–63, 4:21–27. The claims solved that ongoing need by, for instance, reciting new and improved methods that employ neural networks and deep learning devices to acquire and analyze such images in a manner that is "particularly reliable" for dental treatment. *See*, *e.g.*, *id.* at 18:56–61, 28:44–48.
- 23. Furthermore, the neural networks and deep learning devices employed in the claims of the '409 and '248 patents are specifically trained for the purpose of analyzing these types of images used for dental treatment. *See, e.g.*, '409 patent, 3:13–17. As the patents explain, for example, the "invention provides a method that is particularly effective for creating a learning base" that is used to train the deep learning devices and neural networks to perform the analysis and make an accurate assessment, which is vital to effective dental treatment. *See, e.g.*, *id.* at 13:62–63. These

neural networks and deep learning devices therefore were not known or conventional, and are used in a specific way for a specific purpose that was not known or conventional. The claims of the patents thus provide a specific advance with respect to this particular technology in this particular field.

- 24. In addition to these technological improvements, the claims of the '409 patent also provide a new and improved method of "embedded monitoring" for the virtual acquisition of dentition, aligner, and other related images such that the process meets certain virtual acquisition conditions—which ultimately is necessary for effective dental treatment. *See, e.g.*, '409 patent, 23:46–24:8, 25:13–20. For instance, by specifically determining whether the quality or another characteristic of an acquired image (*e.g.*, "opening of the mouth" or "wearing of a dental appliance") meets a particular "setpoint" for such an image, requiring adjustments if that "setpoint" is not met, and "guid[ing]" a patient to make the correct adjustments, the claims of the '409 patent "considerably speed up the execution" of this method "while making this assessment particularly reliable." *Id.* at 27:16–22, 28:44–48, 32:13–33. The claims of the '409 patent therefore provide yet another specific technological advance in virtually acquiring and analyzing dentition, aligner, and other related images for the purposes of dental treatment.
- 25. Still further, the claims of the '945 patent also are directed to inventions relating to dental treatment. More specifically, the claims of the '945 patent provide a specifically improved method for evaluating the shape of an orthodontic aligner worn by a patient, and the inventions recited in the claims make it "considerably easier to evaluate the suitability of the aligner for the treatment, while at the same time making th[e] evaluation particularly reliable." *See*, *e.g.*, '945 patent, 2:23–31. The invention of these claims solved several problems that existed in the prior art, including the "need to travel" to an orthodontist to assess the progress of aligner treatment and the need for accurate remote assessment of aligner treatment. *Id.* at 1:53–59. The claims of the '945

patent therefore provide a specific technological advance in virtually acquiring and analyzing dentition, aligner, and other related images for the purposes of dental treatment.

# C. Align's Late Reaction and Efforts to Catch Up

- AI technology. By contrast, the dominant market players ignored the nascent market shift, and they continued to rely on the outdated approach of send-everyone-to-the-dentist's-office. All of that changed in March 2020, when COVID wracked the world. Suddenly, patients were afraid to go into the office, and dentists and orthodontics only wanted patients to come in if it was actually necessary. The need for remote monitoring exploded overnight.
- 27. One such company caught flat-footed was Align. Despite its tens of thousands of employees, billions of dollars of annual revenue, and its position as the dominant market leader in the clear-aligner space with its eponymous "Invsalign" aligners, Align had no meaningful AI-technology product for remote monitoring of patients' dental treatment (*e.g.*, aligner treatment) as of March 2020. This posed a significant risk to Align: if Invisalign patients were afraid to go into their care provider's office or were restricted from doing so, those care providers could not readily ensure that the aligners were working properly, nor could they make course adjustments based on observed tooth movement patterns.
- 28. To shortcut its development process, Align did not play by the rules. Instead, while purporting to discuss potential future business relationships, corporate executives at Align held repeated meetings with Dental Monitoring executives, extracted information by assessing and piloting the Dental Monitoring processes, gained a greater understanding of Dental Monitoring's processes and technologies, and ultimately, copied Dental Monitoring's approaches. These executives did so despite express reminders by Dental Monitoring's executives that its technological approaches and solutions were protected by a robust, world-wide patent portfolio, which included

the Patents-In-Suit. Moreover, on information and belief, Align searched for and reviewed Dental Monitoring's patent portfolio as a result of these meetings. If Align did not do so, Align was willfully blind to Dental Monitoring's patent portfolio, particularly given Dental Monitoring's express statements about its patent portfolio and Align's decision to copy Dental Monitoring's approach. Accordingly, Align's infringement of the Patents-In-Suit has been willful.

### D. Align's Infringing Products and Services

- 29. Given Dental Monitoring's robust patent portfolio and that Align followed Dental Monitoring's approach, it is no surprise that Align's new offerings infringe multiple of Dental Monitoring's patents.
- 30. Align offers a product that it calls the Invisalign system, which "is used for straightening teeth with a series of custom-made aligners for each patient." *See* Align Technology Solutions, <a href="https://www.aligntech.com/solutions">https://www.aligntech.com/solutions</a> (last accessed November 17, 2022). Invisalign "is prescribed to patients through Invisalign-trained orthodontists or general practitioner dentists." *Id.* As part of the process for designing an aligner, Invisalign creates a 3D model of a patient's teeth. *See* Invisalign, <a href="https://www.invisalign.com/invisalign-digital-experience">https://www.invisalign.com/invisalign-digital-experience</a> (last accessed November 17, 2022).
- 31. In March 2020, Align launched its Invisalign Virtual Care platform that "help[s] Invisalign doctors connect with patients remotely through the My Invisalign App to monitor treatment progress, and ensure continuity of care of patients during Invisalign treatment." *See* Virtual Care AI Press Release, <a href="https://investor.aligntech.com/news-releases/news-releases/details/align-technologys-next-generation-invisalign-virtual-care-ai">https://investor.aligntech.com/news-releases/news-releases/details/align-technologys-next-generation-invisalign-virtual-care-ai</a> (last accessed November 17, 2022).
- 32. According to Align, its aligner treatment requires a patient to progress through different aligners over the course of the treatment, its length depending on the treatment. *See*

Invisalign Treatment, <a href="https://www.invisalign.com/provider/treatment-solutions/invisalign-treatment">https://www.invisalign.com/provider/treatment-solutions/invisalign-treatment</a> (last accessed November 17, 2022). Whenever a patient has an aligner change, Align's Virtual Care platform requires the patient to take photos of their exposed teeth—some with the aligner on, and others with the aligner off—and submit them to their doctor through the "My Invisalign" app. See Align Virtual Care Patient Guide, <a href="https://sndortho.com/wpcontent/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf">https://sndortho.com/wpcontent/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf</a> (last accessed November 17, 2022).

- 33. In Fall 2022, Align announced the launch of its Invisalign Virtual Care AI platform, which "helps doctors remotely monitor Invisalign treatment progress based on their own preapproved clinical settings and AI-assisted algorithms for Automatic Assessment calibrated to each doctor's ClinCheck treatment features." Virtual Care ΑI Press Release, https://investor.aligntech.com/news-releases/news-release-details/align-technologys-nextgeneration-invisalign-virtual-care-ai (last accessed November 17, 2022). According to Align, the Invisalign Virtual Care AI platform "builds on" the existing Virtual Care platform and includes at least three new AI-assisted features. Id.
- 34. One new feature of the Invisalign Virtual Care AI platform is called "AI-assisted Automatic Assessment," and it measures and highlights the size of aligner spaces based on a doctor's settings. *Id.* This feature allows the doctor to quickly learn, on a tooth-by-tooth basis, whether any particular tooth does not fit correctly in the aligner or any tooth is not moving correctly. *Id.* The algorithms of the product help to determine aligner fit and whether patients should proceed to the next aligner in their treatment plan. *Id.* The Invisalign Virtual Care AI platform "incorporates attributes from the approved treatment plan into the assessment, such as tooth type, size, shape, etc." *Id.* A second new feature is "AI-assisted Photo Capture," which assists the patient in taking the required photos for their doctor. *Id.* A third new feature is "AI-assisted Automated Notification," which notifies patients about whether they should "advance to the next tray if their treatment is

track." Id.

deliver a streamlined experience." Id.

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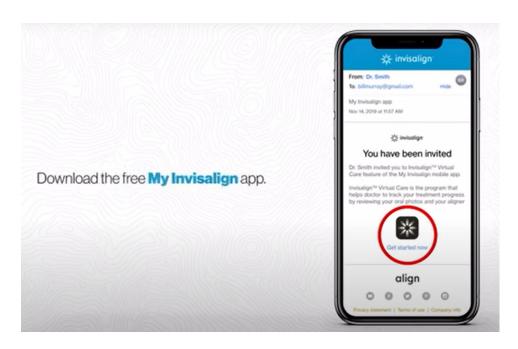
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Align has quoted doctors stating that the "new AI-assisted algorithms in Invisalign 35. Virtual Care AI" "elevated the remote monitoring experience," "provide[d] . . . objective measurement of aligner spaces, the single most important indicator of Invisalign treatment tracking in my practice," and "help[ed] determine aligner fit and advise patients to advance to the next aligner tray or stay on their current tray for longer to ensure the desired movements take effect." Id. Align has also stated that "Invisalign Virtual Care AI is another great example of how we are using digital

technology to connect doctors and their patients to facilitate even greater continuity of care and

tracking well, or to stay on their current aligner or to contact their doctor if their treatment is off

- 36. On information and belief, and based on material from Align's website, a patient is required to download an app on the patient's phone or similar device ("Align App") in order to use the Invisalign Virtual Care AI platform. On information and belief, the Align App provides a communication interface between each of (a) the patient and (b) the doctor's office and/or a server that Align operates ("Align Server"). The Align App and Align Server, in combination, instruct and guide the patient during the process of taking videos and images of the patient's teeth and aligner. On information and belief, the Align App transmits the images to the Align Server for analysis using a neural network or deep learning device.
- 37. For instance, the Invisalign Virtual Care AI platform requires a patient to download the Align App as an initial step.



Invisalign Virtual Care Guide, <a href="https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s">https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s</a> (last accessed November 17, 2022); see also Invisalign Virtual Care Guide, <a href="https://sndortho.com/wp-content/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf">https://sndortho.com/wp-content/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf</a> (last accessed November 17, 2022) at 1.

38. When capturing the images of their teeth, a patient may use an Invisalign cheek retractor to expose their teeth. Even if the patient does not have a retractor, the patient "may use two spoons as a temporary alternative" with their doctor's guidance.





Invisalign Virtual Care Guide, <a href="https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s">https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s</a> (last accessed November 17, 2022); see also Invisalign Virtual Care Guide, <a href="https://sndortho.com/wp-content/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf">https://sndortho.com/wp-content/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf</a> (last accessed November 17, 2022) at 2.

39. Furthermore, the Align App and/or patient must capture various images of the

patient's teeth with the aligner on and off, with their bite open or closed, and in certain positions.



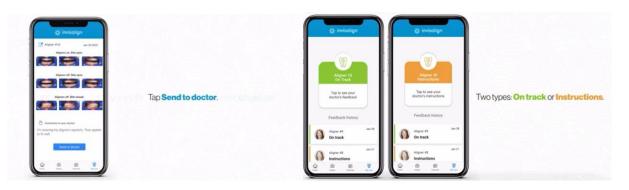
Invisalign Virtual Care Guide, https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s (last accessed November 17, 2022); see also Invisalign Virtual Care Guide, https://sndortho.com/wpcontent/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf (last accessed November 17, 2022) at 2.

40. The Invisalign Virtual Care AI platform guides a patient through the process of capturing images of their teeth and aligner. The Invisalign Virtual Care AI platform, for instance, instructs the patient to "come a bit closer" or "move back a bit" if the position of the dental arch is either too close or too far from an optimal position or distance.



See Invisalign Virtual Care Guide, https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s (last accessed November 17, 2022).

41. After capturing the images discussed above, the Align App and/or patient sends the images for analysis.



Invisalign Virtual Care Guide, <a href="https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s">https://www.youtube.com/watch?v=eYJONRcdTMM&t=43s</a> (last accessed November 17, 2022); see also Invisalign Virtual Care Guide, <a href="https://sndortho.com/wp-content/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf">https://sndortho.com/wp-content/uploads/2020/05/Virtual\_Care\_Patient\_Guide.pdf</a> (last accessed November 17, 2022) at 3.

42. On information and belief, the Invisalign Virtual Care AI platform uses a neural network or deep learning device to analyze the images that are sent by the Align App and/or patient. On information and belief, the Invisalign Virtual Care AI platform also makes comparisons between the images and the 3D model of the patient's dental arches that was created at the outset of the patient's treatment. Those assessments are then sent to the doctor for review, and the doctor can either accept or reject the assessment. The Invisalign Virtual Care AI platform also uses the doctor's notification settings to provide the two types of feedback shown above: "on track," which means that the patient's "new smile" is progressing according to the treatment plan and that they should continue wearing the aligners as directed, or "instructions," which means that the doctor or Virtual Care AI product itself has provided additional guidance or instructions. Virtual Care 3.0, https://assets.ctfassets.net/y75jnaifzz4q/2ftarI3dbbplLEuklKVKLY/42209bec5a97465a512232956 517934e/MKT-0007526 Rev D-

E Instructions for use Virtual Care AI Tech Model Patient 1 .pdf (last accessed November 17, 2022).

43. On information and belief, any neural network or deep learning device for analyzing dentition, aligner, and other related images must be trained based on a set of images. On information

and belief, this training is necessary to accurately analyze the images submitted by the Align App and/or patient as discussed above. On information and belief, the learning base for the neural network or deep learning device used in the Invisalign Virtual Care AI platform comprises at least 1,000 such images used for this training.

### **CLAIMS FOR PATENT INFRINGEMENT**

44. The allegations provided below are exemplary and without prejudice to Dental Monitoring's infringement contentions provided pursuant to the Court's scheduling order and local rules.

## **COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,755,409**

- 45. Dental Monitoring incorporates by reference the allegations set forth in paragraphs 1 through 44 as though fully set forth herein.
- 46. On information and belief, the use of Align's devices and services, such as the Invisalign Virtual Care AI platform and any apparatus used therewith (collectively, the "Align Accused Products and Services"), meets all claim limitations of at least claim 1 of the '409 patent. For example, the Align Accused Products and Services are used for "[a] method for acquiring an image of a dental arch of a patient." *Supra* ¶¶ 31–41. In addition, as part of acquiring an image of the patient's dental arches, the Align Accused Products and Services comprise (a) "activation of an image acquisition apparatus so as to acquire an image, called 'analysis image,' of said arch" (*supra* ¶¶ 36–40); (b) "analysis of the analysis image by means of a deep learning device trained by means of a learning base" (*supra* ¶¶ 41–43); (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" (*supra* ¶¶ 39–41); (d) "comparison of said image attribute value with a setpoint" (*supra* ¶¶ 39–41); and (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" (*supra* ¶¶ 39–41). The Align Accused Products and Services are non-limiting examples identified based on publicly available information, and Dental Monitoring reserves the right to identify additional infringing activities, products, and services on the basis of information obtained, for example, during discovery.

- 47. On information and belief, Align has directly infringed and continues to directly infringe one or more claims of the '409 patent by using (both commercially and in testing) the Align Accused Products and Services in the United States in violation of 35 U.S.C. § 271(a).
- 48. On information and belief, Align has directly infringed and continues to directly infringe one or more claims of the '409 patent by using, jointly with patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, the Align Accused Products and Services in violation of 35 U.S.C. § 271(a). Align conditions the purported benefits of the Align Accused Products and Services, such as the benefits mentioned above, on patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users performing method steps recited in one or more claims of the '409 patent. *Supra* ¶¶ 30–35.
- 49. On information and belief, Align also has induced and continues to induce the infringement of the '409 patent by others, including by providing the Align Accused Products and Services to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, instructing them to use the products and services in an infringing manner, and knowing that such use of the Align Accused Products and Services constitutes infringement of one or more claims of the '409 patent, in violation of 35 U.S.C. § 271(b). *Supra* ¶¶ 28, 31–41.
  - 50. On information and belief, Align also has contributed and continues to contribute to

the infringement of the '409 patent by others, including by providing the Align Accused Products and Services to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, knowing that the Align Accused Products and Services are especially made for use in infringing one or more claims of the '409 patent, and are without substantial noninfringing uses, in violation of 35 U.S.C. § 271(c). *Supra* ¶¶ 28, 31–41.

- On information and belief, Align has, additionally or alternatively, infringed one or more claims of the '409 patent by importing into the United States and/or using in the United States a product made by a process claimed in the '409 patent, in violation of 35 U.S.C. § 271(g). For example, on information and belief, the Align Accused Products and Services create an information message. On information and belief, these information messages are created according to a process claimed in the '409 patent. On information and belief, the information messages created according to a process claimed in the '409 patent are not materially changed by subsequent processes and are a significant and essential component of the Align Accused Products and Services. *Supra* ¶ 36–41.
- 52. On information and belief, before the filing of the Complaint and no later than that date, Align was aware of the existence of the '409 patent, at least, through its communications with Dental Monitoring. Align therefore has knowledge of the '409 patent and that its activities infringe the '409 patent.
- 53. Align's deliberate and willful infringement has damaged and continues to damage Dental Monitoring in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Dental Monitoring would have made but for Align's acts of infringement.
- 54. Align's deliberate and willful infringement has damaged and continues to damage Dental Monitoring in a manner for which damages are inadequate.
- 55. Unless and until Align is enjoined from infringing the '409 patent, Dental Monitoring will suffer substantial and irreparable harm for which there is no remedy at law.

#### COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,049,248

- 56. Dental Monitoring incorporates by reference the allegations set forth in paragraphs 1 through 55 as though fully set forth herein.
- 57. On information and belief, the use of the Align Accused Products and Services meets all limitations of at least claim 15 of the '248 patent. For example, the Align Accused Products and Services are used for "[a] method for assessing the shape of an orthodontic aligner." *Supra* ¶ 31–43. In addition, the Align Accused Products and Services comprise (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" (*supra* ¶ 31–32, 36–39); and (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" (*supra* ¶ 34–35, 41–43). The Align Accused Products and Services are non-limiting examples identified based on publicly available information, and Dental Monitoring reserves the right to identify additional infringing activities, products, and services on the basis of information obtained, for example, during discovery.
- 58. On information and belief, Align has directly infringed and continues to directly infringe one or more claims of the '248 patent by using (both commercially and in testing) the Align Accused Products and Services in the United States in violation of 35 U.S.C. § 271(a).
- 59. On information and belief, Align has directly infringed and continues to directly infringe one or more claims of the '248 patent by using, jointly with patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, the Align Accused Products and Services in violation of 35 U.S.C. § 271(a). Align conditions the purported benefits of the Align Accused

Products and Services, such as the benefits mentioned above, on patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users performing method steps recited in one or more claims of the '248 patent. *Supra* ¶¶ 30–35.

- 60. On information and belief, Align also has induced and continued to induce the infringement of the '248 patent by others, including by providing the Align Accused Products and Services to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, instructing them to use the products and services in an infringing manner, and knowing that such use of the Align Accused Products and Services constitutes infringement of one or more claims of the '248 patent, in violation of 35 U.S.C. § 271(b). *Supra* ¶¶ 28, 31–41.
- 61. On information and belief, Align also has contributed and continues to contribute to the infringement of the '248 patent by others, including by providing the Align Accused Products and Services to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, knowing that the Align Accused Products and Services are especially made for use in infringing one or more claims of the '248 patent, and are without substantial noninfringing uses, in violation of 35 U.S.C. § 271(c). *Supra* ¶ 28, 31–41.
- 62. On information and belief, Align has, additionally or alternatively, infringed one or more claims of the '248 patent by importing into the United States and/or using in the United States a product made by a process claimed in the '248 patent, in violation of 35 U.S.C. § 271(g). For example, on information and belief, the Align Accused Products and Services create an image attribute value. On information and belief, these image attribute values are created according to a process claimed in the '248 patent. On information and belief, the image attribute values created according to a process claimed in the '248 patent are not materially changed by subsequent processes and are a significant and essential component of the Align Accused Products and Services. *Supra* ¶¶ 36–41.

- 63. On information and belief, before the filing of the Complaint and no later than that date, Align was aware of the existence of the '248 patent, at least, through its communications with Dental Monitoring. Align therefore has knowledge of the '248 patent and that its activities infringe the '248 patent.
- 64. Align's deliberate and willful infringement has damaged and continues to damage Dental Monitoring in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Dental Monitoring would have made but for Align's acts of infringement.
- 65. Align's deliberate and willful infringement has damaged and continues to damage Dental Monitoring in a manner for which damages are inadequate.
- 66. Unless and until Align is enjoined from infringing the '248 patent, Dental Monitoring will suffer substantial and irreparable harm for which there is no remedy at law.

### COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,109,945

- 67. Dental Monitoring incorporates by reference the allegations set forth in paragraphs 1 through 66 as though fully set forth herein.
- On information and belief, the use of the Align Accused Products and Services meets all limitations of at least claim 1 of the '945 patent. For example, the Align Accused Products and Services are used for "[a] method for evaluating the shape of an orthodontic aligner worn by a patient." *Supra* ¶ 31–43. In addition, the Align Accused Products and Services comprise (a) "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" (*supra* ¶ 36–40); (b) "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)" (supra ¶¶ 30, 39–42); (c) "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" (supra ¶¶ 30, 39–42); and (d) "comparison of the interior and exterior tooth outlines, so as to determine at least one score according to said comparison" (supra ¶¶ 34, 39–42). The Align Accused Products and Services are non-limiting examples identified based on publicly available information, and Dental Monitoring reserves the right to identify additional infringing activities, products, and services on the basis of information obtained, for example, during discovery.

- 69. On information and belief, Align has directly infringed and continues to directly infringe one or more claims of the '945 patent by using (both commercially and in testing) the Align Accused Products and Services in the United States in violation of 35 U.S.C. § 271(a).
- 70. On information and belief, Align has directly infringed and continues to directly infringe one or more claims of the '945 patent by using, jointly with patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, the Align Accused Products and Services in violation of 35 U.S.C. § 271(a). Align conditions the purported benefits of the Align Accused Products and Services, such as the benefits mentioned above, on patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users performing method steps recited in one or more claims of the '945 patent. *Supra* ¶¶ 30–35.
- 71. On information and belief, Align also has induced and continues to induce the infringement of the '945 patent by others, including by providing the Align Accused Products and Services to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, instructing them to use the products and services in an infringing manner, and knowing that such use of the Align Accused Products and Services constitutes infringement of one or more claims of the

'945 patent, in violation of 35 U.S.C. § 271(b). *Supra* ¶¶ 28, 31–41.

- 72. On information and belief, Align also has contributed and continued to contribute to the infringement of the '945 patent by others, including by providing the Align Accused Products and Services to patients, dentists, orthodontists, clinics, healthcare professionals, and/or other end users, knowing that the Align Accused Products and Services are especially made for use in infringing one or more claims of the '945 patent, and are without substantial noninfringing uses, in violation of 35 U.S.C. § 271(c). *Supra* ¶ 28, 31–41.
- 73. On information and belief, Align has, additionally or alternatively, infringed one or more claims of the '945 patent by importing into the United States and/or using in the United States a product made by the process claimed in the '945 patent, in violation of 35 U.S.C. § 271(g). For example, on information and belief, the Align Accused Products and Services create images of patients' dental arches. On information and belief, these images are created according to the processes claimed in the '945 patent. On information and belief, the images created according to the claimed process in '945 patent are not materially changed by subsequent processes and are a significant and essential component of the Align Accused Products and Services. *Supra* ¶¶ 30, 36–41.
- 74. On information and belief, before the filing of the Complaint and no later than that date, Align was aware of the existence of the '945 patent, at least, through its communications with Dental Monitoring. Align therefore has knowledge of the '945 patent and that its activities infringe the '945 patent.
- 75. Align's deliberate and willful infringement has damaged and continues to damage Dental Monitoring in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Dental Monitoring would have made but for Align's acts of infringement.
  - 76. Align's deliberate and willful infringement has damaged and continues to damage

Dental Monitoring in a manner for which damages are inadequate.

77. Unless and until Align is enjoined from infringing the '945 patent, Dental Monitoring will suffer substantial and irreparable harm for which there is no remedy at law.

#### **JURY DEMAND**

78. Dental Monitoring demands a jury trial as to all issues that are triable by a jury in this action.

#### PRAYER FOR RELIEF

WHEREFORE, Dental Monitoring respectfully prays for relief against Align as follows:

- (a) For judgment that Align has infringed and continues to infringe one or more claims of the '409 patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (g);
- (b) For judgment that Align has infringed and continues to infringe one or more claims of the '248 patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (g);
- (c) For judgment that Align has infringed and continues to directly infringe one or more claims of the '945 patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (g);
- (d) For an order preliminarily enjoining Align's infringing acts;
- (e) For an order permanently enjoining Align's infringing acts;
- (f) For an accounting of all damages sustained by Dental Monitoring as a result of Align's infringing activities;
- (g) For actual damages in an amount according to proof, and in any event no less than a reasonable royalty, together with prejudgment interest;
- (h) For enhanced damages, including because Align was aware of Dental Monitoring's patent portfolio and because Align copied Dental Monitoring's technical approaches;
- (i) For an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 or as

1			otherwise permitted	by law;
2		(j)	Costs and expenses;	
3			-	
4		(k)	Award Dental Monidamages, attorneys'	toring its prejudgment interest and post judgment interest on i fees, and costs; and
5		(1)	For such other and for	urther relief that the Court deems just and proper.
6				
7	Dated:	Nove	ember 18, 2022	Respectfully submitted,
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