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-7335-WHA **DECLARATION OF MAUREEN VALLEY, D.M.D., M.P.H., M.S.**

I, Maureen Valley, hereby declare the following:

I. INTRODUCTION

1. My name is Maureen Valley, D.M.D., M.P.H., M.S. I have been retained on behalf of Align Technology, Inc. ("Align" or "Defendant"). I understand that Dental Monitoring SAS ("Dental Monitoring" or "Plaintiff") has asserted that Align infringes certain claims of U.S. Patent Nos. 10,755,409 (the "'409 patent") and 11,049,248 (the "'248 patent"). I understand that, of these asserted claims, each party has selected one claim for an upcoming "patent showdown" procedure where the parties will make certain arguments related to the validity and infringement of these two claims. I understand that Align has selected claim 12 of the '409 patent, and Dental Monitoring has selected claim 14 of the '248 patent. I have been asked by counsel for Align to offer my opinions as an expert witness regarding the state of the art related to these two patent claims.

2. I am over 18 years of age. I have personal knowledge of the facts stated in this declaration and have formed opinions based on my review of materials available to me. I could and would testify competently to such facts and opinions if asked. I am qualified to provide opinions on what an ordinarily skilled dentist or orthodontist in 2017 would have known and understood with respect to treatment involving aligners, including but not limited to treatment involving teledentistry and the use of photographs as part of orthodontic treatment.

II. QUALIFICATIONS AND BACKGROUND

A. Education and experience

3. My curriculum vitae was attached to my expert report as Exhibit A in this matter. It is accurate and lists many of my qualifications, some of which I summarize below.

4. In 1987, I earned a Bachelor of Arts Degree in Biology from the University of California, Santa Barbara. In 1992, I also earned a Doctor of Medicine in Dentistry Degree from Harvard School of Dental Medicine and a Master of Public Health Degree from Harvard School of Public Health. Additionally, in 1994, I earned a Master of Science and a Certificate in Orthodontics from Northwestern University School of Dentistry.

5. Since 1999, I have maintained my current dental license from the California Board of Dental Examiners. I have been a practicing dental professional since 1987, and a practicing orthodontist since 1994. I am currently an orthodontist for an orthodontic/pediatric/oral surgery dental service organization called Kids Care Dental and Orthodontics in Lodi, California. In my career, I have been involved in the treatment and care of approximately 10,000 patients, including approximately 2500 patients using aligners.

6. For over twenty years, including during and beyond the 2017 period that I discuss in this declaration, I was a member of numerous professional organizations, including the California Association of Orthodontists, the California Dental Association, the American Association of Orthodontists, and the American Dental Association.

7. I was a faculty member and taught a variety of university courses at the Harvard School of Dental Medicine and the University of the Pacific Arthur A. Dugoni School of Dentistry. I also have experience as an educational consultant where I created course content for Align Technology presentations, and as a speaker where I taught Invisalign® certification and advanced courses for dentists and orthodontists, both nationally and internationally. I have received honors and awards, including the Arthur A. Dugoni School of Dentistry, Faculty Recognition Award.

8. In the last four years, I have offered expert testimony by deposition in the following cases: IPR2019-00132, IPR2019-00134, IPR2019-00148, IPR2019-00153, IPR2019-00154,

IPR2019-00155, and IPR2019-00156.

B. Materials considered

9. In forming the opinions that I express in this declaration, I have relied on my education and more than thirty years of experience in the field of dentistry and orthodontics. I have further considered the materials cited or referenced in this declaration. I provided a list of the materials I considered in Exhibit B to my expert report in this matter, and I have referenced certain materials directly in this declaration. The publicly available articles and materials that I considered would have been available to professionals in the field of dentistry and orthodontics. In analyzing practices and techniques used in the field, I felt comfortable reviewing these materials to gain additional knowledge beyond my own as a practicing health care professional, and relying on these materials as accurate.

10. As a healthcare professional, I also feel comfortable relying on my own experience, including interactions with patients and other dental professionals to gain an understanding of dental practices and techniques. Although my experience in the field is sufficient for me to reach the opinions I express in this declaration, the listed materials further inform my understanding and contain the type of facts and data on which I would expect a dentist and orthodontist to reliably reach the opinions I include in this declaration.

C. Retention and compensation

11. I am being compensated for my work in this case at a rate of $550 per hour (or $650 per hour for testimony) plus expenses, which is my customary rate for consulting and expert work. My compensation is in no way tied to the outcome of this case or to the content of this declaration.

III. OPINIONS

A. Before 2017, It Was Well Known and Routine Practice in Orthodontics and Dentistry to Capture and Use Photographs of Teeth, Assess Such Photographs to Obtain Better, Usable Photographs (If Needed), and Assess Aligner Fit by Analyzing Such Photographs

12. In my opinion, by 2017, both in terms of dentists' education, experience, and the available literature, taking usable pictures of teeth (with and without aligners) including, if

necessary, guiding a person to take better quality or more usable pictures, and using those pictures to visually assess aligner fit and treatment progress, were common practice and part of the standard of care. These have been well-known, general concepts in the field for years.

1. The Standard of Care in the Industry and the Evolution of the Use of Photography in Dentistry and Teledentistry

13. Using media like photographs is a natural way to support dental and orthodontic care, and thus obtaining, analyzing, and using good-quality photographs has long been part of the standard of care and practice. Because photography is a well-known medium, dentists, dental assistants, and even patients have taken and adjusted photographs for use in dental care.

14. Even as a dental student in 1987-1992 and an orthodontic resident in 1992-1994, I took required courses in dental photography. We were taught to take a series of standard photographs of patients (the same that we still take today), both extraoral (exterior of the face) and intraoral (interior of the mouth) for initial, progress, and final records. After graduation, I attended digital dental photography continuing education courses. These courses taught camera and accessory (e.g., cheek and lip retractor) usage, and correct dental photo composition. Similarly, dental and orthodontic assistants have also been educated in dental photography, and in most all practices, with the clinician's oversight and instruction, have been responsible for taking the patient's photographs. In my dental practice, I am also aware that similar collegiate and clinical courses continued during 2017 and even today, providing instruction on the concepts of using a camera and accessories to take and assess dental photographs.

15. The orthodontic profession has taught that along with radiographs, these photographs were an essential part of diagnostic records and were considered part of the standard of care for patients undergoing orthodontic treatment. The American Board of Orthodontics and the American Association of Orthodontists, among those who set the standard of orthodontic care, publish guidelines for how to take these essential orthodontic photographs. For example, the American Board of Orthodontics posts information on its website related to extraoral and intraoral photographs, including instruction on distances and angles, using cheek retractors, and using good-

quality lighting.[1] This information teaches clinicians examples of good-quality and well composed images, as well as examples of poor-quality images.[2] The literature in 2017 and earlier reinforced that taking clinical photographs of teeth was a well-known part of dental practice. Shadi Samawi, *Clinical Digital Photography in Orthodontics: Professional Photographic Records in Daily Practice,* 18 JORDAN DENTAL JOURNAL 20, 25-31 (2012) ("Samawi") (describing clinical photography technique, including standardized angles of intraoral and extraoral photographs).

16. While dental photographs were previously taken using more traditional film cameras, eventually smaller, less expensive, and easier-to-use digital cameras were incorporated to execute on the existing idea within the profession of using photographs as part of dental care. Samawi at 21-22. With the evolution of digital photography and the abandonment of film cameras with their labor-intensive and expensive film development into bulky slides or hardcopy photographs requiring physical storage, dentists were able to take an unlimited number of photographic records and easily store them in a patient's digital chart. The advent of personal smartphones and tablets with camera capabilities (such as iPhones in 2007 and iPads in 2010) furthered this trend. In 2012, Payne's study found "a high level of smartphone ownership and usage among medical students and junior doctors." Karl Frederick Braekkan Payne et al., *Smartphone and medical related App use among medical students and junior doctors in the United Kingdom (UK): a regional survey,* 12 BMC MEDICAL INFORMATICS AND DECISION MAKING 1 (2012) ("Payne"). Dental practitioners in 2016 noted that "[t]he use of photographs in dentistry has increased rapidly over recent years and it has become an integral part of routine dental practice." M. Estai et al., *Remote dental screening by dental therapists,* BRITISH DENTAL ASSOCIATION 11, 12 (2016) ("Estai").

17. The use of photographs in dentistry was especially relevant to the development of teledentistry, "a combination of telecommunications and dentistry involving the exchange of

[1] https://ntiiiby.americanboardortho.com/orthodontists/become-certified/clinical-exam/mail-in-cre-submission-procedure/case-record-preparation/photograph-requirements/.

[2] https://ntiiiby.americanboardortho.com/media/2gndyap0/example-photo-montage.pdf and https://ntiiiby.americanboardortho.com/media/krgfhpdg/example-photos-radiographs.pdf.

an image," "analysis of the analysis image by means of a deep learning device trained by means of a learning base," "determination … of a value for an image attribute," "comparison of said image attribute value with a setpoint," and "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," in order 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." '409 patent, claim 1. I also understand that claim 12 specifies the method as claimed in claim 1, "in which the information message is sent by the acquisition apparatus." '409 patent, claim 12.

34. In my opinion, based on my experience and confirmed by review of publicly available literature from the relevant time, as of 2017, with the sole exception of using a deep learning device to carry out image analysis, the claimed method steps were all part of the standard of care. For example, dental professionals routinely guided patients to activate cameras to acquire images of their teeth. In turn, the dental professionals evaluated an image attribute (such as quality of the photo, or whether the correct teeth were captured), and compared the perceived image attribute with a setpoint (such as the professional's photo-taking guidance to the patient or published examples of the desired photos). The dental professional would communicate with patients by sending an information message to the patient regarding this comparison. If the image did not respect the setpoint (e.g., if the photo did not match the example), the dental professional would guide the patient to acquire a new image. Relevant to claim 12, as most patients would have used their smartphone cameras to capture images of their teeth in 2017, it would be a natural conclusion that the same device would also have conveyed any messages to the patient. Thus, in my opinion, claim 12 of the '409 patent simply takes the standard of care as practiced by dental professionals in 2017 and does it on a computer.