

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALIGN TECHNOLOGY, INC.,

Petitioner,

v.

DENTAL MONITORING SAS,

Patent Owner.

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Case No. IPR2024-00052

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

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**DECLARATION OF DR. BUDI KUSNOTO IN SUPPORT OF PATENT  
OWNER'S PRELIMINARY RESPONSE**

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## EXHIBIT LIST

| Exhibit Number | Description                                                                                                                                                                                   |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2005           | Curriculum Vitae of Budi Kusnoto, D.D.S., M.S.                                                                                                                                                |
| 2007           | Rui Zhao et al., Changing Clear Aligners Every 10 Days or 14 Days? A Randomised Controlled Trial, 39(1) Australasian Orthodontic J. 1 (2023)                                                  |
| 2022           | Timothy T. Wheeler, Orthodontic Clear Aligner Treatment, 23(1) Seminars in Orthodontics 83 (2017)                                                                                             |
| 2023           | Emilia Taneva, Budi Kusnoto, Carla A. Evans, Chapter 9: 3D Scanning, Imaging, and Printing in Orthodontics, Issues in Contemporary Orthodontics (Farid Bourzgui 2015)                         |
| 2024           | Orhan Tuncay et al., Effectiveness of a Compliance Indicator for Clear Aligners, 43(4) J. Clin. Orthod. 263 (2009)                                                                            |
| 2025           | Silvia Caruso, Sara Caruso, et al., A Knowledge-Based Algorithm for Automatic Monitoring of Orthodontic Treatment: The Dental Monitoring System. Two Cases, 21(5) Sensors (Basel) 1856 (2021) |
| 2026           | Barry J. Glaser, “The Insider’s Guide to Invisalign Treatment,” (3L Publishing, 2017)                                                                                                         |

1. I have been retained by counsel for Dental Monitoring SAS as an expert witness in the above-captioned proceeding. I have been asked to provide my opinions relating to the state of the art described in U.S. Patent No. 11,049,248 (“the ’248 Patent”) (EX1001). The following is my written declaration on this issue.

## **I. BACKGROUND**

### **A. Education and Industry Experience**

2. My qualifications are summarized below and are presented in more detail in my professional CV (EX2005), which is attached as Appendix A to this declaration.

3. Additionally, the following overview of my background pertains to my qualifications for providing expert testimony in this matter.

4. I have worked as a practicing clinician, researcher, and academic in orthodontics for twenty-five years. I have extensive experience with dental monitoring technology in clinical, patient care, and research settings.

5. In 1998, I obtained my Master’s degree in oral sciences and a specialty certificate in orthodontics from the University of Illinois at Chicago (“UIC”). I completed my fellowship at the University of Illinois at Chicago Craniofacial Center in 1999. I previously obtained my Bachelor’s degree in Computer Science Engineering from the Computer Science Institute in Indonesia in 1993. I later obtained my D.D.S. from the University of Indonesia in 1994.

6. I am currently a tenured Professor of orthodontics, Program and Clinical Director as well as Coordinator of the Digital Imaging Laboratory in the Department of Orthodontics at UIC. I also run a private orthodontic clinic, and am a consultant in several group practices.

7. As part of my work in the Department of Orthodontics at UIC, I have been deeply involved in the implementation of digital technology for dental treatment purposes. I am also actively involved in research and teaching on the subject of orthodontic diagnosis, treatment, and planning, as well as biomechanics. More specifically, I am actively involved in research relating to (a) the management of craniofacial patients and orthognathic cases; and (b) orthodontic diagnosis, treatment planning, and treatment, including through the use and implementation of 3D imaging technology, teledentistry, artificial intelligence, and machine learning. I am actively involved in benchmark, evidence-based, and translational research in these areas. My knowledge on the growth and development of the human craniofacial complex is complementary to my research and teaching in the field of orthodontic diagnosis, treatment planning, and treatment.

8. My orthodontics work has been published in numerous peer-reviewed journals. *See, e.g.,* Fernandes, E.C. et al., “The 100 Most-Cited Articles in Orthodontic Journals in the Last 20 Years,” *Am. J. Orthod. Dentofac. Orthop.* (2021). I am also an active member in good standing of the American Association

of Orthodontists, Illinois Society of Orthodontist, Midwest Society of Orthodontist, Chicago Dental Society, and American Dental Association.

9. Below are examples of publications concerning my work with digital technology, remote dental monitoring, and artificial intelligence.

- Morris R, Hoyer L, Elnagar M, Atsawasuan P, Galang-Boquiren M, Caplin J, Viana G, Obrez A, Kusnoto B., “Accuracy of Dental Monitoring™ 3D Digital Dental Models Using Photo and Video Mode,” American Journal of Orthodontics and Dentofacial Orthopedics, 156(3), 420–428.
- Elnagar MH, Aranovich S, Kusnoto B., “Digital Workflow for Combined Orthodontics and Orthognathic Surgery,” Oral and Maxillofacial Surgery Clinics of North America, 32(1), 1–14 (2019).
- Talaat S, Kaboudan A, Talaat W, Kusnoto B, Sanchez F, Elnagar MH, Bourauel C., “Improving the accuracy of publicly available search engines in recognizing and classifying dental visual assets using convolutional neural networks,” International journal of computerized dentistry, 23(3), 211–218 (2020).
- Masoud AI, Alwadei FH, Alwadei AH, Lin EY, Viana MGC, Kusnoto B, Evans CA., “Developing pediatric three-dimensional upper airway normative values using fixed and interactive thresholds,” Oral Radiol. 36(1); 89–99 (2020).
- Talaat S, Kaboudan A, Talaat W, Kusnoto B, Sanchez F, Elnagar MH, Ghoneima A., “The validity of an artificial intelligence application for assessment of orthodontic treatment need from clinical images,” Seminars in Orthodontics, 27(2), 164–171 (2021).
- Bulatova G, Kusnoto B, Viana G, Tsay TP, Avenetti DM, Sanchez F., “Assessment of automatic cephalometric landmark identification using artificial intelligence,” Orthodontics and Craniofacial Research, 24(S2), 37–42 (2021).
- Makki A, Elnagar MH, Sanchez F, Caplin J, Viana G, Kusnoto B., “Assessment of Handicapping Labio-Lingual Deviation index scoring

methods and their effect on orthodontic treatment coverage by Medicaid,” Journal of Public Health Dentistry (2022).

10. I also have had the opportunity to work with Dental Monitoring products, including products that employ artificial intelligence and machine learning for dental treatment, aligner treatment, teledentistry, and other purposes.

11. For at least these reasons, and based on the additional education and experience set forth in my CV, I believe I am qualified to provide the opinions in this declaration.

### **B. Compensation**

12. My hourly rate for my work on this matter is \$100. Payment of my compensation is being made in full to the Foundation for Modern Bioprogressive Orthodontics. My compensation does not depend in any way on the outcome of this matter or the particular testimony or opinions that I express.

### **C. Materials and Other Information Considered**

13. My opinions are based on my years of education, research, and experience, as well as my investigation and study of relevant materials. In forming my opinions, I have considered the materials I identify in this declaration, those listed in the Petition, and the exhibits thereto.

14. In particular, in forming my opinions, I have considered the Petition (Paper 2) and the declaration of Dr. Foroosh (EX1002). I do not address every argument or reference discussed in the Petition or by Dr. Foroosh, because I am informed that, if

the proceedings are instituted, I will be able to submit a further declaration responding to other arguments and references made by Petitioner or Dr. Foroosh. In doing so, I may rely upon the materials identified in this declaration and those listed in the Petition, its attachments and/or additional materials. I may also consider additional documents and information, including documents that may not yet have been provided to me or that I have not yet identified for myself.

15. My analysis of the materials in this investigation is ongoing and I will continue to review any new material as it is provided to me. This declaration represents only those opinions I have formed to date on the issues addressed in this declaration. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.

## **II. ALIGNER TREATMENT**

16. As of July 2017, use of clear aligners was an increasingly popular class of orthodontic treatment for tooth alignment. *See, e.g.*, EX2022 (Timothy T. Wheeler, *Orthodontic Clear Aligner Treatment*, 23(1) Seminars in Orthodontics 83 (2017)) at 83–89. At the time, aligners were known to be designed to progressively move teeth into positions desired by a dentist, orthodontist, or other dental professional. *See, e.g., id.* Set forth below is a summary of conventional aligner treatment as of July 2017.

## **A. Diagnosis**

17. As of July 2017, aligner treatment generally began with a patient attending an in-person consultation with an orthodontist for an initial clinical examination to establish a proper diagnosis as to the patient's suitability for aligner treatment.<sup>1</sup> This examination typically was conducted and obtained either by visual inspection and/or using in-office scanning technology.

18. If the orthodontist determined that the patient was suitable for aligner treatment, and if the patient chose to move forward with that treatment, the orthodontist would then conduct scans of the patient's starting dentition. These in-office scans were typically conducted on specialized machines employing various scanning technologies that generated digital three-dimensional models of a patient's dentition, and were conducted by an orthodontist or a specially trained technician. *See EX2023 (Emilia Taneva, Budi Kusnoto, Carla A. Evans, Chapter 9: 3D*

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<sup>1</sup> Most aligner treatment was, and still is, provided by orthodontists. Some general practice dentists (sometimes referred to as doctors) were also trained to provide clear aligner treatment to their patients. In this declaration, I have generally referred to treatment as provided by orthodontists, but this should be understood to encompass the aligner treatment provided by any dental professional trained to provide such treatment.

*Scanning, Imaging, and Printing in Orthodontics, Issues in Contemporary Orthodontics* (Farid Bourzgui 2015)) at 147–80; *see also* EX1001 at 27:26–33 (“Conventionally, at the start of an orthodontic treatment, the orthodontist determines the positioning of the teeth that he or she wants to obtain at a so-called ‘set-up’ instant of the treatment. The set-up may be defined by means of an imprint or from a three-dimensional scan of the teeth of the patient. The orthodontist then has manufactured, or manufactures, accordingly, an orthodontic appliance suited to this treatment.”).

19. Based on these initial scans, a sequence of aligners would be designed and fabricated by one of several third-party companies, such as Petitioner. *See* EX1001 at 27:35–43 (“An aligner conventionally takes the form of a removeable single-piece appliance, conventionally made of a transparent polymer material, which comprises a channel conformed for several teeth of an arch, generally all the teeth of an arch, to be able to be housed therein. . . . At the start of treatment, the shapes that the different aligners have to take at different moments of the treatment are conventionally determined, then the set of corresponding aligners is manufactured. At predetermined instants, the patient changes the aligners.”).

## **B. Treatment**

20. As of July 2017, aligner treatment typically involved three general categories of steps: (1) a patient wearing a series of aligners according to the

treatment plan of their orthodontist; (2) assessing the progress of that treatment, including aligner fit, at regular intervals; and (3) adjusting the treatment plan as necessary.

### **1. Wearing the Aligners**

21. Once the patient received their set of aligners, they would be required to wear their aligner until they were instructed to change from one aligner to the next to continue shifting their teeth according to the orthodontist's treatment plan. *See id.* Orthodontists typically instructed patients to change aligners every one to two weeks. *See, e.g.,* EX2007 (Rui Zhao et al., *Changing Clear Aligners Every 10 Days or 14 Days? A Randomised Controlled Trial*, 39(1) *Australasian Orthodontic J.* 1 (2023)) at 1. The timing could, however, change depending on the nature of a patient's dentition, their compliance with treatment protocols, and the fit of their aligners on their teeth. EX2024 (Orhan Tuncay et al., *Effectiveness of a Compliance Indicator for Clear Aligners*, 43(4) *J. Clin. Orthod.* 263 (2009)) at 263 ("Patient compliance is crucial in orthodontic treatment involving removeable appliances."). In a clinically optimal setting, patients would be instructed to change aligners as soon as their current aligner became "passive"—that is, the patient's dentition had shifted sufficiently such that the current aligner was no longer applying any force to the patient's dentition.

22. As of July 2017, the most common orthodontist-prescribed interval for each aligner was one week. The typical one-week period for wearing a particular aligner was selected primarily because patients were found to be most compliant under a treatment regime with weekly aligner changes, even though one week (or seven days) might not necessarily be the clinically optimal amount of time a patient should wear each aligner. *See, e.g.,* EX2025 (Silvia Caruso, Sara Caruso, et al., *A Knowledge-Based Algorithm for Automatic Monitoring of Orthodontic Treatment: The Dental Monitoring System. Two Cases*, 21(5) *Sensors* (Basel) 1856 (2021)) at 10 (“The choice to change aligners every 7 days in an adult patient is strongly related to compliance[.]”). For instance, a patient’s aligner might become passive in five days (before the one-week mark), but the patient would unnecessarily wait the few extra days to change their aligner at the one-week mark.

## **2. Assessing the Aligner Treatment**

23. As of July 2017, effective conventional aligner treatment required frequent and regular in-person orthodontic examinations. Regular in-person examinations were necessary because aligners were changed frequently, rates of progress varied from person to person, and treatments varied in complexity depending on the specific starting and desired dentition for each patient. *See, e.g.,* EX1001 at 17:39–43 (“It is desirable for each to regularly check his or her dentition, particularly in order to check that the position of his or her teeth is not changing for the worse. In

an orthodontic treatment, this change for the worse may in particular lead to the treatment being modified.”).

24. In addition, as of July 2017, conventional in-person aligner treatment examinations were performed every 10 weeks or so by an orthodontist. These in-person examinations did not involve quantitative measurements concerning aligner fit, nor did they involve making any quantitative measurements of separations between the aligner and the dental arch on a tooth-by-tooth basis.

25. Instead, conventional in-person aligner treatment examinations as of July 2017 involved two primary qualitative and subjective assessments at a patient’s examination. First, orthodontists would visually inspect the current state of dentition and compare that state to the anticipated dentition expected at that point in the aligner treatment. *See* EX1001 at 27:55–59 (“At regular intervals, the patient goes to the orthodontist for a visual inspection, notable to check whether the displacement of the teeth confirms to the expectations and whether the aligner worn by the patient is still suited to the treatment.”). In other words, if a patient was on week 10 of their treatment, an orthodontist would make a visual comparison between the dentition observed on the patient and a visual rendering of expected dentition at week 10 for that patient. *See id.* If the actual dentition deviated from the expected dentition, the orthodontist would examine the areas of deviation and assess what issues were causing dentition to progress differently than expected. These subjective visual

inspections performed by orthodontists were susceptible to inconsistency and inaccuracy, for example, due to level of experience, length of the appointment, speed of review, number of patients seen, fatigue, etc.

26. Second, orthodontists assessed the aligner treatment. Typical issues that might be identified during the assessment included problems with aligner fit, tooth attachments, or dentition complications. *See, e.g.*, EX2026 (Barry J. Glaser, “The Insider’s Guide to Invisalign Treatment,” (3L Publishing, 2017)) at 39–40, 275–76 (discussing various treatment features to be monitored at each visit); EX1006 (“Invisalign Clinical Monitoring Guide” (2003)) (discussing monitoring by the orthodontist of aligner fit, dentition, and attachments). In addition, aligners might be too tight, over correct, or move a tooth in an unintended direction (*i.e.*, non-tracking) such that the movement would be detrimental to the patient. For example, if the aligner moves the tooth in the wrong direction, a patient could suffer from side-effects such as periodontal defects (potentially severe gum complications) or fenestration of gingival recession (exposure of the tooth root due to bone loss).

27. Generally, a patient was asked to try on their current aligner, and each aligner was visually and manually examined for large gaps between the aligner and the teeth. These gaps are referred to as aligner “unseats.” Using their hands, the orthodontist would manually examine the aligner for potential rocking (that is, movement of one part of the aligner off of a patient’s teeth when pressure is applied

to another part of the aligner). A similar examination was then conducted using the next aligner in a patient's sequence.

### **3. Adjusting the Treatment Plan**

28. When an orthodontist identified significant issues with dentition progression or with aligner fit at the in-person examinations, the orthodontist typically instructed patients to pause their aligner sequencing. The orthodontist would then re-image the patient's bite, which was conventionally conducted using in-office LiDAR (Light Detection and Ranging) scanning technology. Using these new scans, the orthodontist would then order a refined aligner sequence, which was intended to correct issues identified with dentition and/or aligner fit, and discard the old aligners. Fabrication and shipping of refined aligners typically would delay treatment by at least two, and often three, weeks. *See, e.g.,* EX1001 at 27:60–67 (“If the orthodontist diagnoses an unsuitability to the treatment, he or she takes a new imprint of the teeth, or, in an equivalent manner, a new three-dimensional scan of the teeth, then orders a new series of aligners configured accordingly. It is considered that, on average, the number of aligners finally manufactured is approximately 45, instead of 20 aligners conventionally provided at the start of the treatment.”).

29. Alternatively, where an orthodontist identified unseats that were not so significant as to require refined aligners, the orthodontist might prescribe “chewies,”

small rubber shapes to be chewed on in specific locations in the mouth, which could reduce unseats.

### **III. THE '248 PATENT**

#### **A. The Effective Filing Date of the '248 Patent**

30. I understand that the priority date credited to an alleged invention is relevant to an analysis of the validity or patentability of that alleged invention at least because it determines which art is prior art to the alleged invention.

31. I understand that the '248 Patent was filed as U.S. Application No. 16/030,137 on July 9, 2018, claiming priority to French Patent Application No. FR1756956, filed July 21, 2017. I understand that neither Petitioner nor Dr. Foroosh disputes that this is the priority date of the '248 Patent. Pet. 12; EX1002 ¶26.

#### **B. Person of Ordinary Skill in the Art With Respect To The '248 Patent**

32. I understand that, in the context of a validity or patentability analysis, the person of ordinary skill in the art ("POSA") is a hypothetical person who looks to the prior art at the time of the invention and without the benefit of hindsight. I understand that the POSA is presumed to have knowledge of all references that are sufficiently related to one another and to the pertinent art, and to have knowledge of all arts reasonably pertinent to the particular problem that the claimed invention addresses.

33. Here, I have been asked to assume that a POSA as of July 21, 2017 would have had a bachelor's degree or higher in computer science, bioinformatics, or a related engineering discipline, and several years of work experience relating to the development of machine learning or artificial intelligence models or algorithms. A POSA would have also worked as part of a multi-disciplinary team, which would have included individuals familiar with medical imaging, dental imaging, dentistry, and/or orthodontics.

34. I understand that Petitioner has contended that a POSA as of July 21, 2017 would typically have an advanced degree, such as a Masters' Degree or Ph.D. in computer science or a related field, with at least two years of work in computer vision, image analysis, medical imaging, or related areas. A POSA could have less education but significant professional experience in one or more of these fields. A POSA could be a member of an interdisciplinary team including persons with backgrounds such as electrical engineering, computer science, optical imaging, and dentistry or orthodontics, and could call upon the knowledge of other team members as appropriate.

35. I do not understand these definitions to be significantly different. Regardless, my opinions contained herein are not impacted by any differences because I am a member of a multi-disciplinary/interdisciplinary team under either definition.

### **C. The Invention of the '248 Patent**

36. The '248 Patent discloses methods of “assessing the shape of an orthodontic aligner” for purposes of aligner treatment. *See, e.g.*, EX1001 at 32:6–23, *see also, e.g., id.* at 28:34–38 (The invention “considerably simplify[ies] the assessment of the good suitability of the aligner to the treatment, while making the assessment particularly reliable.”), 30:60–62 (“The suitability of the aligner can be assessed in the context of an orthodontic treatment (separation [*i.e.*, space between the aligner and the teeth] compatible or not with the orthodontic treatment).”).

37. The '248 Patent includes two independent claims. Independent claim 1 requires “more than 1 week after the start of the treatment with the aligner,” “acquisition [using a cellphone] of at least one image at least partially representing the aligner” as worn by a patient. *Id.* at 32:6–23. The claim further requires that the image is “a photograph, or an image extracted from a film.” *Id.* In addition, the claim requires “analysis of the analysis image by means of a deep learning device, trained by means of a learning base, so as to determine a value for at least one tooth attribute of an ‘analysis tooth zone’ representing, at least partially, a tooth on said analysis image, the tooth attribute relating to a separation between the tooth represented by the analysis tooth zone, and the aligner represented on the analysis image.” *Id.*

38. Independent claim 15 requires “more than 1 week after the start of the treatment with the aligner,” the “acquisition of at least one image at least partially representing the aligner in a service position in which it is worn by a patient.” *Id.* at 34:43–57. The claim further requires that the analysis image is “a photograph, or an image extracted from a film.” *Id.* In addition, the claim requires “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.” *Id.*

39. The methods claimed in the '248 Patent provide for ongoing, accurate, and remote assessment of aligner fit in between in-office orthodontist check-ins. *Id.* at 31:30–36. Because the claimed methods are not dependent on in-person assessments, which typically occurred only every 10 weeks, it is my opinion that they provide several improvements over conventional aligner treatment methods that were available in July 2017.

40. First, with the conventional aligner treatment methods available as of July 2017, a patient could progress through multiple ill-fitting aligners before fit-issues were discovered, and by the time those issues were discovered at an orthodontist's office, refined aligners might be necessary and aligner fit issues may have worsened—ultimately adding delay and expense to the treatment. The '248

Patent claims, however, provide for accurate and remote assessment of aligner treatment in between in-person orthodontist visits and thereby earlier detection of aligner fit issues. This can in some cases fix the issues and avoid the need for refined aligners or, in other cases, accelerate the process of determining that such refined aligners are necessary. *See, e.g.*, EX1001 at 31:37–47 (“The invention also relates to a method for adapting an orthodontic treatment, a method in which a method for assessing the shape of an orthodontic aligner according to the invention is implemented, then, as a function of the result of said assessment, a new aligner is manufactured. . . .”).

41. Second, in July 2017, orthodontists typically instructed patients to change aligners every one to two weeks. EX2007 (Zhao et al., Changing Clear Aligners Every 10 Days or 14 Days? A Randomised Controlled Trial, 39(1)) at 1. By providing for accurate and remote assessment of aligner treatment in between in-person orthodontist visits, the ’248 Patent methods allow orthodontists to custom tailor aligner intervals to a particular patient’s needs. For example, if a patient exhibits slower dentition progression, with aligner treatment employing remote monitoring, an orthodontist can prescribe a longer aligner change interval. *See, e.g.*, EX1001 at 31:37–47 (“The invention also relates to a method for adapting an orthodontic treatment, a method in which a method for assessing the shape of an orthodontic aligner according to the invention is implemented, then, as a function of

the result of said assessment, . . . the patient is counseled, for example for him or her to improve the conditions of use of his or her orthodontic aligner, in particular the positioning and/or the time bands when it should be worn and/or the maintenance of his or her orthodontic aligner, in order to optimize the treatment.”). Alternatively, if aligners become passive on a particular patient very quickly, remote monitoring can allow for shorter intervals, making overall treatment progress more efficiently. The ’248 Patent claims also allow orthodontists to detect treatment deviations and to intervene before treatment complications. For example, if the aligner moves the tooth in the wrong direction, a patient could suffer from side-effects such as periodontal defects (potentially severe gum complications) or fenestration of gingival recession (exposure of the tooth root due to bone loss). The ’248 Patent claims thus provide for a more personalized and dynamic form of treatment than conventional treatment methods that existed as of July 2017.

42. Third, the ’248 Patent methods can provide for reliable and quantitative assessment of aligner fit on a tooth-by-tooth basis, which could not be performed by orthodontists during in-person visits. As described in, for example, Invisalign Clinical Monitoring Guide (EX1006), in 2017, during in-person check-ins, an orthodontist would conventionally conduct a qualitative visual or manual examination of a patient’s aligner fit. Unlike the prior art treatment methods, however, the ’248 Patent discloses quantitatively measuring separations to a degree

of precision that an orthodontist did not—and could not—previously achieve with his or her naked eye (e.g., spaces less than 1 mm). Indeed, at the time, no technology or tools existed that allowed an orthodontist to perform such a measurement.

#### **IV. THE INVISALIGN CLINICAL MONITORING GUIDE**

43. The Invisalign Clinical Monitoring Guide (“Invisalign,” EX1006) describes the practice of in-person aligner treatment that was conventional as of July 2017. It was published by Petitioner “to help the Invisalign practitioner successfully monitor Invisalign treatments and address issues that may arise between receipt of Aligners from [Petitioner] to the completion of treatment.” EX1006 at i. “To prevent issues from occurring,” Invisalign teaches orthodontists to “perform certain steps at every appointment.” *Id.* at ii. It is clear that Invisalign is concerned with in person treatment because it recommends that orthodontists have their “patient[s] arrive with the previous stage Aligner and the current Aligner.” *Id.* This is consistent with my discussion above, that during an in-office appointment, a patient was generally asked to try on their aligner, and it was visually and manually examined for large gaps between the aligner and the teeth.

44. Invisalign notes that a separation between the teeth and the aligner of greater than 1 mm can be considered a general aligner fit issue, but a separation less than that is a “natural deflection that should occur so the Aligner can move the tooth.” *Id.* Invisalign does not, however, disclose any method to accurately measure

separation, even during an in-office appointment. Consistent with my experience providing aligner treatment in July 2017, a POSA would have understood Invisalign to suggest only that an orthodontist perform a qualitative visual or manual in-person approximation of the aligner fit. This method is subjective, and as noted above, it can produce inconsistent and inaccurate results due to factors including, the level of experience, length of the appointment, speed of the review, number of patients seen, and fatigue. In my experience, an orthodontist in July 2017 could not reliably and consistently distinguish in-person between, for example, separations of 0.9 mm (on track treatment) and 1.1 mm (off track treatment) based on the visual examination taught in Invisalign. For this reason, Invisalign suggests that, in the case of a separation that *appears* to be less than 1 mm, the orthodontist should simply continue to monitor aligner fit. *Id.*

45. Invisalign does not teach or suggest any method for remote assessment of aligner fit that could be performed in between in-office orthodontist check-ups, and I am not aware of any product that Petitioner offered in 2017 that could have been used to remotely assess aligner treatment progress. Although Invisalign includes certain photos, a POSA would have understood that these photos were simply examples of what an orthodontist might observe during an in-person appointment. EX1006 at 1. There is no suggestion in Invisalign that those images

were taken remotely, for example, using a cellphone, or that such images could be used for the remote assessment of aligner treatment.

46. Finally, a POSA would have understood the teaching in Invisalign to submit high quality records, including photos, to refer to the need to collect accurate information to design and manufacture the aligners. EX1006 at iii. As I explained above, if the patient chose to move forward with aligner treatment, the orthodontist would conduct scans of the patient's starting dentition, and based on these initial scans, a sequence of aligners would be designed and fabricated. The PVS impressions and photos discussed in Invisalign were an alternative to such scans that could also be used to design and manufacture aligners.

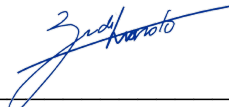
47. For all of these reasons, unlike the '248 Patent, in my opinion, Invisalign does not suggest acquisition of images showing an aligner as worn by a patient for the purposes of assessing aligner treatment or any method for remote assessment of aligner fit in between in-office orthodontist check-ins, and Invisalign does not disclose any method or tool for making any quantitative measurements of separations between the aligner and the dental arch.

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I, Budi Kusnoto, do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, under Section 1001 of Title 18 of the United States Code.

Executed January 30, 2024, in Chicago, Illinois.

 1-30-2024  
\_\_\_\_\_  
Dr. Budi Kusnoto