

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING LLC,

Petitioner

v.

ALIGN TECHNOLOGY INC.,
Patent Owner

IPR2025-00816
U.S. Patent No. 11,369,456

**Supplemental Declaration of Dr. Sumit Yadav
in Support of Petition for *Inter Partes* Review of U.S. Patent No. 11,369,456**

I. Introduction

1. I, Dr. Sumit Yadav, submit this declaration to state my opinions on the matters described below.

2. In preparing this declaration, I reviewed and am familiar with the following additional documents:

<u>Exhibit No.</u>	<u>Description</u>
1041	Aldo Giancotti, et al., <i>Early Treatment of Anterior Crossbite with an Essix-Based Appliance</i> , Journal of Clinical Orthodontics, Vol. 38, No. 3 (2004)
1042	Benson H. Wong, <i>Invisalign A to Z</i> , American Journal of Orthodontics and Dentofacial Orthopedics, Vol. 121 (2002)

II. Level of Ordinary Skill

A. Typographical Correction

3. I determined that as a result of a typographical error, an omission existed in the following sentence from ¶24 of my initial declaration (Ex-1003): “This team would have included members with an advanced degree related to dentistry (e.g., BDS, MDS, DDS, DMD) with experience in orthodontics, including 1-3 years of orthodontic training or equivalent experience.” Ex-1003, ¶24. That sentence in ¶24 of my initial declaration should read as follows, with the unintentionally omitted portion underlined: “This team would have included members with an advanced degree related to dentistry (e.g., BDS, MDS, DDS, DMD) with experience in

orthodontics, including 1-3 years of orthodontic training or equivalent experience, and experience using clear aligners.” I applied this level of skill in my analysis.

B. Experience with Clear Aligners and Related Digital Platforms

4. I understand Dr. Valley opined that Essix-type clear aligners were not used to move teeth “over multiple stages.” I disagree with Dr. Valley. In my opinion, a POSITA would have understood that Essix-type clear aligners were regularly used for multi-stage treatments for tooth movement. This is consistent with my experience using Essix-type clear aligners between 2003-2006, which includes instances where I used Essix-type clear aligners for tooth alignment in a treatment involving as many as 6 stages.

5. My experience using Essix-type clear aligners for multi-stage treatments is also consistent with contemporaneous literature, which describes similar use of Essix-type clear aligners. For example, *Early Treatment of Anterior Crossbite with an Essix-Based Appliance* describes the correction of a crossbite using a series of two Essix aligners. Ex-1041 at 1-3. *The Invisalign System* describes various types of tooth movement achieved with Essix appliances, including multiple stage treatments using modified or successive stages with Essix-type clear aligners. Ex-1016 at 26, 30-38 (describing various types of tooth movement achieved with Essix aligners), 30-32 (describing multi-stage treatments using Essix-type clear

aligners). And, *Invisalign A to Z* describes the known use of one or more Essix aligners for “correcting mild discrepancies in the alignment of teeth.” Ex-1042 at 4.

6. Prior to August 30, 2006, I was aware of clear aligner systems offered by Align, including the Invisalign system and its associated digital platforms, and understood their use in treating patients through publicly available literature and publications. From 2003 to 2006, my use of Essix aligners was consistent with my awareness and understanding of the use of Invisalign’s clear aligners, which was based on publicly available literature, publications, and my academic experience.

7. After August 30, 2006, I obtained experience using other types of clear aligners and associated digital platforms. I have supervised and treated approximately 1,500 patients using a variety of different clear aligner systems and associated digital platforms since 2006. In that time frame, I also continued to stay abreast of publicly available literature regarding treatment using clear aligner systems. My experiences after 2006 are consistent with my own experience with Essix aligners from 2003 to 2006, as well as my knowledge of literature in the field. That experience only reinforced my understanding of prior techniques, as the digital platforms for treatment planning with clear aligners merely automated the type of corrections that were previously done manually.

8. My research activities, familiarity with technical and clinical literature, and teaching relating to clear aligner systems in the years following 2006 further

inform my understanding of clear aligners systems and associated digital platforms in 2006. Through reviewing and engaging with peer-reviewed publications and technical disclosures over time, I developed an appreciation for those systems. In teaching these topics, I examined the historical development of clear aligner technology and compared earlier systems with later refinements, which has reinforced my understanding of the capabilities and constraints of clear aligners as they existed in 2006. This combination of research, literature knowledge, and instructional experience provides a reliable basis for my opinions regarding the state of clear aligner systems and how a POSITA would have understood their operation and limitations at the relevant time. Thus, my experience with clear aligners since 2006 does not alter, but rather is consistent with, the understanding I had as of August 30, 2006, regarding clear-aligner treatment planning.

III. Chishti-511's Path-Definition Stage Does Not Guarantee Collision-Free Treatment Paths

9. I understand that Dr. Valley opined that “because Chishti-511’s aligner calculation process uses collision-free treatment paths (identified during Chishti-511’s path determination process) as input for calculating aligner configurations, a POSITA would not have understood that a determination that an aligner is unacceptable includes the identification of a collision, and therefore, any recalculation of the treatment paths due to an unacceptable aligner would not be in

response to identifying a collision.” Ex-2013, ¶61. I disagree with Dr. Valley’s opinion for at least the reasons described below.

A. Collisions May Arise When Simulating Movement As a Result of Deviations from the Initial Tooth Path

10. In my opinion, a POSITA would have understood that Chishti-511 discloses a computational orthodontic system that first defines an idealized, collision-free course of tooth movement where teeth are moved “in the quickest fashion.” Ex-1004, 3:40-4:22; Fig. 1 (steps 140, 150). Chishti-511 does not teach that its path definition stage conclusively determines a collision-free tooth path. Rather, Chishti-511 teaches that deviations from an initial tooth path are expected and are addressed by simulating actual tooth movement using finite element analysis. Ex-1004, 5:7-6:37; Figs. 2-4. Accounting for physical interactions between teeth and aligners, the simulation evaluates how it expects a patient’s teeth to move if they were to use aligners designed based on the initial treatment plan. Ex-1004, 6:2-15, 6:23-32. Importantly, Chishti-511 recognizes that with simulated movement, teeth may move in unexpected ways from their idealized paths, such as moving “too slow,” “too far short of the desired end position,” “too far past the desired end position,” or “in a direction other than the desired direction.” Ex-1004, 7:37-51.

11. In my opinion, a POSITA would have understood that each of these circumstances may lead to collisions. A tooth that travels in a different direction may

travel into the path of another tooth. Similarly, a tooth traveling “too slow,” “too far short,” or “too far” may likewise intersect with the path of a different tooth, resulting in a collision. This is consistent with real world applications because teeth often move differently than a planned or idealized initial path or set of movements.

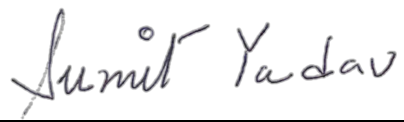
12. While Chishti-511’s system attempts to correct for the deviation identified during simulation by adjusting the aligners, Chishti-511 recognizes that there are limits to the adjustments that can be made. Ex-1004, 7:37-51 (for example noting that there is a “maximum” amount of adjustment that may done to an aligner). Chishti-511 also explains that if aligners are unacceptable, the process can relax constraints on the aligners. Ex-1004, 8:32-39; Fig. 6. Chishti-511 explains that its “constraints can include a maximum rate of displacement of a tooth, a maximum force on a tooth, and a desired end position of a tooth.” Ex-1004, 2:30-33, 8:33-53. A POSITA would have understood that changing these parameters likewise may result in different movements than in the idealized movement plan, resulting in collisions. Consequently, Chishti-511 explains that if aligners are still unacceptable after making adjustments to aligners (such as if teeth will collide during treatment), Chishti-511’s system “transfers control to a path definition process (such as step 150, FIG. 1) to redefine those parts of the treatment path having unacceptable aligners (step 630).” Ex-1004, 2:30-33, 8:32-39, 8:54-58, Fig. 6. Indeed, Chishti-511 acknowledges that aligners can be “unacceptable for a variety of reasons,” and a

POSITA would have understood this to include collisions. Ex-1004, 8:42-43. Chishti-511 explains that this “step can include both changing the increments of tooth motion, i.e., changing the segmentation, on the treatment path, changing the path followed by one or more teeth in the treatment path, or both.” Ex-1004, 8:58-61; Fig. 6.

IV. Conclusion

13. I declare 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, or both, under Section 1001 of Title 18 of the United States Code.

Dated: May 12th, 2026

By: 

Dr. Sumit Yadav