

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

In the Matter of:

**CERTAIN DIGITAL MODELS, DIGITAL
DATA, AND TREATMENT PLANS
FOR USE IN MAKING INCREMENTAL
DENTAL POSITIONING ADJUSTMENT
APPLIANCES, THE APPLIANCES MADE
THEREFROM, AND METHODS OF
MAKING THE SAME**

Inv. No. 337-TA-_____

**COMPLAINT UNDER SECTION 337
OF THE TARIFF ACT OF 1930, AS AMENDED**

Complainant:

**ALIGN TECHNOLOGY, INC.
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Proposed Respondents:

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Ex. W	Certified copies of the assignments for U.S. Patent Application nos. 09/686,190 (abandoned), 09/169,276 (abandoned) and provisional application no. 60/050,342, the parent applications to U.S. Patent No. 7,134,874
Ex. X	Certified copy of the assignment for U.S. Patent No. 6,450,807, the parent application of U.S. Patent No. 8,070,487

APPENDICES

Appendix No.	Description
App. A	Certified copy of U.S. Patent No. 6,217,325
App. B	Certified copy of U.S. Patent No. 6,471,511
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App. L	Certified copy of the prosecution history of U.S. Patent No. 6,705,863
App. M	Certified copy of the prosecution history of the reexamination of U.S. Patent No. 6,705,863
App. N	Certified copy of the prosecution history of U.S. Patent No. 6,722,880
App. O	Certified copy of the prosecution history of the reexamination of U.S. Patent No. 6,722,880
App. P	Certified copy of the prosecution history of U.S. Patent No. 7,134,874
App. Q	Certified copy of the prosecution history of U.S. Patent No. 8,070,487
App. R	Each referenced document mentioned in the '325, '511, '666, '863, '880, '874, and '487 patent prosecution histories

I. INTRODUCTION

1. Complainant Align Technology, Inc. (“Align”) files this Complaint for violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”) and respectfully requests that the United States International Trade Commission (“ITC”) commence an investigation and impose relief to remedy the unlawful importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation, by the owner, importer or consignee of articles covered by valid and enforceable United States patents owned by Align.

2. The proposed respondents in this investigation are ClearCorrect, Inc., ClearCorrect Operating, LLC, and ClearCorrect Holdings, LLC (collectively, “ClearCorrect USA”), ClearCorrect Pakistan (Private), Ltd. (“ClearCorrect Pakistan”), and those acting in concert with them (collectively with ClearCorrect USA and ClearCorrect Pakistan, “Respondents”).

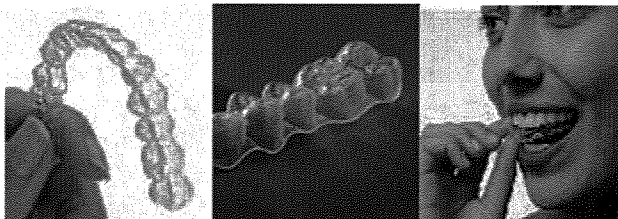
3. ClearCorrect Pakistan is engaged in unlawful and unfair acts of competition in violation of Section 337 by selling for importation and importing certain digital models, digital data or treatment plans that infringe or are made, produced, or processed by means of a process covered by valid claims of each of the following United States Letters Patent: (i) U.S. Patent No. 6,217,325 (“the ‘325 patent”); (ii) U.S. Patent No. 6,705,863 (“the ‘863 patent”); (iii) U.S. Patent No. 6,626,666 (“the ‘666 patent”) and (iv) U.S. Patent No. 8,070,487 (“the ‘487 patent”).

4. ClearCorrect USA is engaging in unlawful and unfair acts of competition in violation of Section 337 by making and selling in the United States certain digital models, digital data or treatment plans and certain incremental dental positioning adjustment appliances that

infringe or are made, produced, or processed by means of a process covered by valid claims of each of the following United States Letters Patent: (i) the '325 patent; (ii) the '863 patent; (iii) the '666 patent; (iv) U.S. Patent No. 6,471,511 ("the '511 patent"); (v) U.S. Patent No. 6,722,880 ("the '880 patent"); (vi) U.S. Patent No. 7,134,874 ("the '874 patent"); and (vii) the '487 patent. ClearCorrect Pakistan induces and/or contributes to ClearCorrect USA's direct infringement by making, selling for importation, and importing into the United States certain digital models for use in fabricating incremental positioning adjustment appliances with knowledge of those patents and the specific intent to induce ClearCorrect USA to infringe the patents or contribute to the infringement.

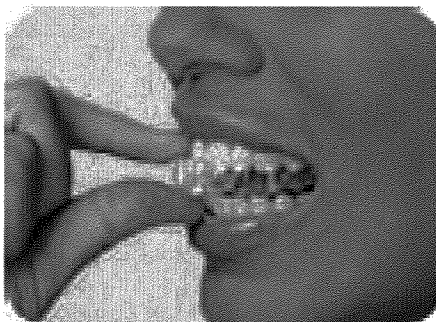
5. An industry as required by 19 U.S.C. § 1337(a)(2) and (3) exists in the United States relating to the articles protected by these patents.

6. Align designs, develops, manufactures and markets high-technology, custom-manufactured orthodontic devices. Align's "Invisalign System" is a proprietary method for treating crooked and misaligned teeth using a series of clear, removable "aligners," custom-manufactured for each patient using computer-aided design techniques and sophisticated computer graphic interfaces to communicate with the patient's dental professional in the planning and implementation of the customized treatment program. Examples of Invisalign® aligners (taken from Align's website) are pictured below:



7. The Invisalign System, developed by Align over many years and at great expense and effort, represents a breakthrough in the manufacturing principle of “mass customization” and a vast improvement over conventional methods for treating misalignment of teeth, or malocclusion. The innovations embodied in the Invisalign System are protected by numerous United States and foreign patents. The Invisalign System has garnered dozens of awards and accolades in its fourteen-year history. Among the awards Align has received are the 2002 Medical Design Excellence Award and the 2001 Stereolithography Excellence Award. The Invisalign System has been enthusiastically adopted by over one million patients and 30,000 dental professionals world-wide.

8. ClearCorrect was founded in 2007 by dentist Willis Pumphrey (“Pumphrey”). To the best of Align’s knowledge, ClearCorrect is the only US company other than Align that makes and sells a series of customized aligners based on digital treatment planning for use in straightening teeth. An example of a ClearCorrect aligner is shown below:



9. ClearCorrect is not the first knockoff of the Invisalign system. In 2005, the founder, and former chairman and CEO of Align founded OrthoClear. OrthoClear manufactured clear aligners designed by a team in Lahore, Pakistan, some of whom had been formerly employed by Align when Align had a Pakistan facility. Among others, Dr. Nadeem Arif, Mudassar Rathore, Dr. Waqas Wahab and Dr. Asim Waheed were key employees of OrthoClear.

10. In 2006, Align sued OrthoClear in federal district court and petitioned the ITC pursuant to Section 337 alleging infringement of various U.S. patents and misappropriation of trade secrets. As a result of Align's claims, the defendants/respondents entered into a settlement and consent order prohibiting OrthoClear or its employees, including Rathore, Arif, Wahab, and Waheed, from selling products using Align technology. Thereafter, OrthoClear ceased to operate in the United States or Pakistan.

11. ClearCorrect USA appears to have grown out of the demise of OrthoClear. Pumphrey has stated that he had 400 patients using the OrthoClear system at the time of OrthoClear ceased operations, and he set up manufacturing in Houston to fill the gap. According to Pumphrey, "[n]ecessity was the mother of invention." Declaration of Dr. Eric Kuo ("Kuo Decl."), Ex. A, attached hereto, Ex. 19 at 2; Ex. 20 at ALIGN0000059. In 2008, ClearCorrect began expanding and accepting cases from other dentists and orthodontists. . On February 6, 2009, the United States Food and Drug Administration cleared ClearCorrect USA's marketing of aligners based on ClearCorrect USA's Premarket Notification 510(k) Summary. That Summary represented that ClearCorrect's "technology is essentially identical to that used by a number of sequential alignment systems, including the predicates [Invisalign/Align System and Align Technology.]" Ex. A (Kuo Decl.), Ex. 21 at ALIGN0000014.

12. At some point, ClearCorrect USA began working with ClearCorrect Pakistan. ClearCorrect USA states that it had no role in forming ClearCorrect Pakistan other than “contemporaneous negotiations with the principals of what ultimately became ClearCorrect Pakistan (Private), Ltd. for the provision of services as a third party vendor.” ClearCorrect USA describes “ClearCorrect Pakistan (Private), Ltd.” as simply “a convenient name for the new entity,” not evidence of any financial or corporate relationship between the two. Ex. A (Kuo Decl.), Ex. 26 at 7.

13. In fact, ClearCorrect Pakistan is managed by former OrthoClear employees Mudassar Rathore, Dr. Nadeem Arif, Dr. Asim Waheed, and Dr. Waqas Wahab. *Id.* at 6.

14. Align seeks an order directing ClearCorrect USA to cease and desist from (1) importing digital models, digital data, or treatment plans for use in fabricating incremental positioning adjustment appliances or, (2) marketing or selling, offering for sale, offering sales or technical support related to, or using incremental positioning adjustment appliances that were made, produced, or processed by means that are covered by, or that infringe or induce infringement of, one or more claims of the Align patents described herein.

15. Align seeks an order directing ClearCorrect Pakistan to cease and desist from selling for importation, importing, marketing or selling, offering for sale, offering sales or technical support related to, or using, digital models, digital data or treatment plans for use in fabricating incremental positioning adjustment appliances that were made, produced, or processed by means that are covered by, or that infringe or induce infringement of, one or more claims of the Align patents described herein.

II. THE PARTIES

A. The Complainant

16. Align is a Delaware corporation incorporated in April 1997, with its principal place of business in San Jose, California. Align designs, develops, manufactures, and markets the Invisalign System, a proprietary method for treating malocclusion. Align received United States Food and Drug Administration ("FDA") clearance to market the Invisalign System in 1998.

B. The Respondents

17. ClearCorrect Operating, LLC is a Texas corporation with its principal places of business in Houston, Texas. On information and belief, ClearCorrect Operating, LLC designs, develops, manufactures, and markets orthodontic products and is involved in the importation into the United States, or sale for importation into the United States of digital models, digital data and/or treatment plans for use in fabricating incremental positioning adjustment appliances, and the manufacture, offer for sale and sale within the United States of incremental positioning adjustment appliances made using those digital models, digital data or treatment plans. These digital models, digital data and treatment plans and the incremental positioning adjustment appliances are generated using the patented processes at issue here. Ex. A (Kuo Decl.), Exs. 21, 22, 25, 27 and 28.

18. On information and belief, ClearCorrect Pakistan (Private), Ltd. is a business organization, form unknown, with its principal places of business in Lahore, Pakistan. On information and belief, ClearCorrect Pakistan is responsible for the services necessary to design digital models, digital data or treatment plans used in fabricating ClearCorrect aligners in Texas.

Ex. A (Kuo Decl.), Ex. 23 at 13–14. ClearCorrect Pakistan electronically transmits those models to ClearCorrect USA.

III. THE PRODUCTS AT ISSUE

A. Description of the Products at Issue

19. A typical orthodontic aligner patient's teeth are treated with a series of custom-manufactured, wearable, thin, clear, plastic, removable aligners. The aligners are manufactured to correspond to a precise planned orthodontic treatment developed by the aligner manufacturer that implements a prescription, instructions and preferences prepared for the individual patient by dental professionals. Each aligner covers a patient's teeth and is nearly invisible when worn. Aligners are commonly worn in pairs, over the upper and lower dental arches. After a period of use, the patient replaces the aligner with the next aligner in the series. This process is repeated until the treatment is complete.

20. The products at issue in this investigation are certain incremental dental positioning adjustment appliances, or orthodontic aligners, and the digital models, digital data or treatment plans used to manufacture those appliances. ClearCorrect USA manufactures the appliances using digital models, digital data or treatment plans generated by ClearCorrect Pakistan using Align's patented technology and imported by ClearCorrect USA.

B. Background Information on the Products and Processes at Issue

1. Conventional Treatment of Malocclusion

21. Conventionally, dental professionals have treated malocclusion primarily with metal archwires and brackets, commonly referred to as braces. Occasionally, dental professionals attempt to improve treatment aesthetics by using ceramic, tooth-colored brackets or

by bonding brackets on the inside, or lingual surfaces, of the patient's teeth. Dental professionals also augment braces with elastics, metal bands, headgear and other ancillary devices.

22. The average conventional treatment takes approximately 12 to 24 months to complete and requires many hours of direct dental professional involvement, or "chair time." To initiate conventional treatment, a dental professional will diagnose a patient's condition and create an appropriate treatment plan. In a subsequent visit, the dental professional will bond brackets to the patient's teeth with cement and attach an archwire to the brackets. Thereafter, by tightening or otherwise adjusting the braces approximately every six weeks, the dental professional is able to exert sufficient force on the patient's teeth to achieve desired tooth movement. Because of the length of time between visits, the dental professional must tighten the braces to a degree sufficient to achieve sustained tooth movement during the interval. In a final visit, the dental professional removes each bracket and residual cement from the patient's teeth.

23. Although braces are generally effective in correcting a wide range of malocclusions, they are subject to many limitations and disadvantages. Conventional orthodontic treatment is associated with:

(a) Unattractive appearance. Braces call attention to the patient's condition and treatment. In addition, braces trap food, which can further compromise appearance, and the bonding of brackets to teeth can cause permanent markings on the teeth. Braces can also result in permanent discoloration of teeth. Many adults associate braces with adolescence.

(b) Oral discomfort. Braces are sharp and bulky and can abrade and irritate the interior surfaces of the mouth. The tightening or adjustment of braces results in root and gum soreness and discomfort, especially in the days immediately following an orthodontic visit.

(c) Poor oral hygiene. Braces compromise oral hygiene by making it more difficult to brush and floss; moreover, as noted, braces trap food. These problems can result in tooth decay and periodontal damage.

(d) Inability to project treatment. Historically, dental professionals have not had a means to accurately model the movement of teeth over a course of treatment. Accordingly, dental professionals must rely on intuition and judgment to plan and project treatment. As a result, they cannot be precise about either the final tooth arrangement or the direction or distance of expected tooth movement between patient visits. This reactive process, which lacks predictability may result in unwanted tooth movements and can limit the dental professional's ability to estimate the duration of treatment.

(e) Physical demands on dental professional. The manipulation of wires and brackets requires sustained manual dexterity and visual acuity, and may place other physical burdens on the dental professional. The iterative nature of the process also requires the dental professional to regularly meet with the patient.

(f) Root resorption. The sustained high levels of force associated with conventional treatment can result in root resorption, which is a shortening of tooth roots. This shortening can have substantial adverse periodontal consequences for the patient.

(g) Emergencies. At times, braces need to be repaired or replaced on an emergency basis, causing often significant inconvenience to both the patient and the dental professional.

(h) Diet. Braces can be inadvertently removed or broken if a patient eats hard foods like nuts or apples. When this happens, enamel of the tooth may be removed with the bracket and the patient will have to schedule an appointment for a new bracket, wire and ligatures to be attached. There are also foods the patient must avoid (e.g., gum, caramel or taffy).

24. As a result of these and other limitations, less than one percent of adults in the United States with malocclusion elect traditional orthodontic treatment.

2. The Innovative Invisalign System

25. The Invisalign System was conceived, designed and developed to overcome the problems associated with conventional orthodontic treatment. The Invisalign System treatment process is comprised of several phases, the principal steps of which are:

(a) Orthodontic diagnosis and transmission of treatment data to Align. Prior to the commencement of treatment, typically in an initial patient visit, the dental professional determines whether Invisalign is an appropriate treatment option for the patient. The dental professional then obtains various data regarding the patient's case, typically including an intra-oral scan or a physical impression of the lower and upper archforms and photographs, dental x-rays and bite registration. Ex. A (Kuo Decl.) ¶ 3 and Ex. 3. The dental professional then prepares a case submission kit that includes the initial patient treatment data package described

above and a treatment planning form, or prescription (i.e., lab instructions). The dental professional sends the complete case submission kit to Align.

(b) Preparation of three-dimensional computer models of the patient's initial malocclusion. Upon receipt of the case submission kit, Align disinfects the impressions and inventories the materials submitted in the kit. In some cases, the materials submitted may include an intra-oral scan of a patient's dentition or other digital images. Align then creates a customer order in its "enterprise resource planning" software system, digitally scans all physical patient records submitted with the kit, and creates an electronic case file to manage the transmission of all patient data within Align's process. Align then uses the intra-oral scans or impressions and sophisticated digital scanning technology (e.g., Computed Tomography or CAT scan) to create a three-dimensional, digital or "virtual" model of the patient's existing dentition. Ex. A (Kuo Decl.) ¶ 4 and Ex. 4.

(c) Preparation of computer-simulated final stage. Once the initial digital model is created, Align's technicians, assisted by proprietary materials embodying Align's protocols, tolerances and know-how and utilizing Align's internal "ToothShaper™" and "Treat™" software, (1) segment the digital model into individually manipulable teeth (Ex. A (Kuo Decl.), Ex. 5); (2) define various positional parameters of the individual teeth so that their movement can be accurately described and modeled (Ex. A (Kuo Decl.), Ex. 6); (3) detail the model to correct scan and segmentation anomalies; (4) establish the proper relationship (occlusion) between the upper and lower jaw images; (5) develop a digital model of the patient's teeth in the final tooth arrangement based on the dental professional's prescription (Ex. A (Kuo Decl.), Ex. 7) and various protocols established by Align; (6) identify, create and store digital

models of appropriate intermediate incremental steps, or “stages” from the existing initial stage to the proposed, final stage (Ex. A (Kuo Decl.), Ex. 8). This “staging” is accomplished by Align’s highly-trained technicians using proprietary and confidential software that accurately identifies, measures and calculates the desired movement of the teeth and that further embodies and accommodates specific treatment methodologies, protocols, tolerances and constraints developed by Align in the course of successfully processing over a million patients’ treatments. Ex. A (Kuo Decl.) ¶ 5. Finally, the technician initiates and completes a quality control process to ensure that the completed case meets Align’s quality standards. *Id.*

(d) Review and modification of the proposed treatment by the dental professional. At the outset of treatment, digital images of the proposed treatment plan are provided to the dental professional, who views the images (and related data) using Align’s proprietary viewing software client called ClinCheck®. Ex. A (Kuo Decl.) ¶ 6. Align’s ClinCheck software allows the dental professional to view the treatment images from various preset views and/or to freely manipulate the angle, rotation and magnification of the view of that image. The dental professional may also view an animation from case commencement through completion. *Id.* At this point, the dental professional may ask questions about or request modifications to the treatment plan by an interactive communication protocol between Align and the dental professional. *Id.* Once satisfied with the proposal, the dental professional approves the case (sometimes after review with the patient of the ClinCheck software images), thus retaining ultimate control over the patient’s treatment. Ex. A (Kuo Decl.) ¶ 6 and Exs. 10–12.

(e) Construction of molds corresponding to each stage of treatment. Then, using computer assisted manufacturing techniques, Align uses the digital data from each

stage to construct a series of physical models of the patient's teeth corresponding to each intermediate and final stage of treatment. Ex. A (Kuo Decl.) ¶ 7 and Exs. 13–15.

(f) Manufacture of aligners and shipment to the dental professional.

These physical models, in turn, are used as reference molds to thermo-form sheets of clear resilient medical-grade polymer material over the molds to create the aligners. Ex. A (Kuo Decl.) ¶ 7 and Exs. 15, 17–18. The formed plastic aligners are marked, trimmed, removed from the molds, polished, cleaned and shipped to the dental professional and given to the patient to wear. *Id.* Each aligner gradually moves the patient's teeth into the proper position for the next aligner in the series. *Id.* Each aligner in the sequence is replaced by a subsequent one until the treatment is complete. For most product configurations, Align fabricates all aligners of the treatment plan prior to a patient wearing any of the aligners. For other product configurations, aligners are produced in batches. Furthermore, the dental professional has the option to order additional aligners if they are needed to improve the treatment outcome (e.g., if the treatment goes off track, or if treatment detailing is needed). The option exists for the dental professional to intervene as needed to modify the treatment plan throughout the course of treatment, based on the actual results accomplished. Ex. A (Kuo Decl.) ¶ 7.

(g) The use of attachments and IPR. In certain cases, dental

professionals may use Invisalign in conjunction with treatment-specific attachment devices bonded to the patient's teeth. These attachment devices may be positioned in the digital models of different stages of the treatments and are used to increase the force applied to a tooth or teeth in circumstances where the aligners alone may have difficulty in effecting the desired movement. Ex. A (Kuo Decl.) ¶ 5. In certain cases, Align provides an aligner-like template to the dental

professionals to aid in the placement and bonding of attachments to the patient's teeth. Also, in cases where extractions or interproximal reduction ("IPR") are prescribed by the dental professional or recommended according to Align's proprietary and confidential protocols, the treatment plan has the flexibility to allow for and accommodate these techniques.

26. The Invisalign System remedies many of the problems associated with conventional orthodontic treatment. The primary benefits of the Invisalign System are:

- (a) Excellent aesthetics. Aligners are nearly invisible when worn, significantly reducing the aesthetic concerns associated with conventional braces.
- (b) Comfort. By replacing the six-week adjustment cycle of traditional braces with shorter stages of approximately two-weeks, aligners move teeth more gently than conventional braces. Also, aligners are thin, smooth and low in profile. As a result, aligners are substantially more comfortable and less abrasive than conventional braces.
- (c) Improved oral hygiene. Patients remove aligners for tasks that are difficult with conventional braces, such as eating, brushing and flossing. This feature reduces the incidence of tooth decay and periodontal damage during treatment when compared to conventional braces.
- (d) Potentially reduced root resorption. Align believes that controlling force and shortening treatment time has the potential to reduce the incidence of root resorption.
- (e) Reduced incidence of emergencies. Typically, a lost or broken aligner is simply replaced with the next aligner in the series, minimizing inconvenience to both patient and dental professional.

(f) Reduced visits to dental professional. The entire treatment is digitally planned and approved at the outset of treatment by the doctor. Once approved, Align typically provides all of the aligners to the dental professional before treatment begins. The dental professional can provide some or all of the aligners to the patient to reduce the required patient visits.

(g) No dietary restrictions. The aligner should be removed when eating and drinking. With the aligners removed, the patient can eat without restriction.

IV. THE PATENTS-IN-SUIT

27. Align's breakthrough technologies enjoy significant intellectual property protections, including 245 issued United States patents and 171 issued foreign patents. Each of the patents described below is, to the best of Align's knowledge, information and belief, directly infringed by either the digital models, digital data or treatment plans produced by ClearCorrect Pakistan or the aligners manufactured by ClearCorrect USA and indirectly infringed by ClearCorrect Pakistan's provision of digital models to ClearCorrect USA.

28. The inventions embodied in Align's patents were developed at considerable effort and expense, primarily using Align resources and personnel. Each patent was issued to Align by the United States Patent and Trademark Office in recognition of Align's rights in the inventions covered therein. In each instance, the named inventors on the patent, having developed the invention under Align's direction and using Align's support and resources, validly assigned all of their rights, title and interests in those inventions to Align.

29. The asserted Align patents teach novel methods of straightening teeth. Instead of brackets, archwires, and other conventional orthodontic appliances, the new technology uses a

series of custom-molded aligners, or incremental dental position adjustment appliances. In Align's commercial embodiment of the inventions, the aligners are made of clear, strong, medical-grade plastic that is virtually invisible when worn. Ex. A (Kuo Decl.) ¶ 7.

30. The aligners have cavities for the teeth and are configured so that when the aligner is first placed in the mouth certain teeth will not immediately conform perfectly to the geometries of the cavities in the aligner, but will be anchored sufficiently on the teeth for desired forces to be applied. This may include additional forces introduced through the use of attachment devices. Each aligner, however, is pliant enough to accommodate the teeth and applies resilient force on the teeth to move them to fit the geometries of the cavities. Each aligner corresponds to one stage or segment of an orthodontic treatment plan for straightening the patient's teeth. The patient wears each aligner until the teeth have been adequately repositioned to the tooth arrangement corresponding to the aligner cavities in that aligner, before replacing the currently worn one it with the next in the series until the desired tooth position is achieved.

31. Because every patient's teeth and bite are unique and each aligner in the series corresponds to a different tooth arrangement, each aligner must be custom manufactured for the individual patient and stage of treatment. Fabrication of unique aligners on a commercially viable scale, therefore, presents significant obstacles. Some aspects of the patented inventions are addressed to the use of computer technology to overcome these obstacles. Using the patented technology, Align has become one of the largest manufacturers of mass-customized products in the world.

32. Unlike traditional brackets and wires, which generally apply force across the entire set of teeth at the same time, with aligners the application of force to individual teeth can be controlled to occur at particular stages in the treatment plan. Thus, the treatment plan can be designed so that at each stage only certain teeth move while others stay in place. This results in a more targeted and efficient force delivery system. Teeth that are not selected to move during a given stage can function as anchors to keep the aligner in place as it applies resilient force to the teeth selected to move. Some aspects of the patented inventions involve the use of computer technology and three-dimensional imaging to assist in the development of a treatment plan that determines for each aligner which teeth to move and how they should move.

B. The '325 Patent

1. Identification of the Patent and Ownership by Align

33. U.S. Patent No. 6,217,325 ("the '325 patent") (Appendix A) issued to Align as assignee on April 17, 2002, and is entitled "Method and System for Incrementally Moving Teeth." The inventors are Muhammed Chishti, Apostolos Leros, Brian Freyburger, Kelsey Wirth, and Richard Ridgley. A reexamination certificate for the '325 patent, Request No. 90/007,645, issued on January 15, 2008.

34. The '325 patent is a divisional of application No. 08/947,080 ("the '080 application"), filed Oct. 8, 1997, which issued as U.S. Patent No. 5,975,893 ("the '893 patent"). The '325 and '893 patents claim priority from provisional application number 60/050,342 filed June 20, 1997 ("the '342 provisional"). As explained further below, many of the patents-in-suit claim priority from the '342 provisional and are continuations or continuations in part of the '893

patent. The entire right, title and interest of the inventors in the '325 patent subject matter was assigned to Align (*see* copy of assignment at Ex. S).

35. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '325 patent and its reexamination (Appendices H and I) and four copies of each referenced document mentioned in the '325 patent prosecution history, together with a collection of all references mention in all asserted patents' prosecution history in order to avoid duplication. (Appendix R).

2. Non-Technical Description of the Patented Invention

36. The '325 patent teaches methods for facilitating tooth repositioning treatment and fabricating tooth repositioning appliances. In one embodiment, a visual image is presented that is based on an initial digital data set representing an initial tooth arrangement. The visual image is manipulated to reposition individual teeth. A final digital data set representing the repositioned teeth is generated. A plurality of intermediate digital data sets representing successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement is produced. A plurality of successive tooth repositioning appliances are made, at least some of which relate to some of the produced digital data sets.

37. In another embodiment, a digital data set representing a modified tooth arrangement is provided, and a fabrication machine produces a positive model of the arrangement. A polymeric shell dental appliance is produced as a negative of the positive model and is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement.

38. Other embodiments similar to these two embodiments are also disclosed.

C. The '511 Patent

1. Identification of the Patent and Ownership by Align

39. U.S. Patent No. 6,471,511 ("the '511 patent") (Appendix B) issued to Align as assignee on October 29, 2002, and is entitled "Defining Tooth-Moving Appliances Computationally." The inventors are Muhammad Chishti, Elena L. Pavlovskaja, Gregory P. Bala, and Brian Freyburger. Prior to issuance, the entire right, title and interest of the inventors in the '511 patent were assigned to Align (*see* copy of assignment at Ex. T).

40. The '511 patent is a continuation-in-part of PCT/US98/12861 ("the PCT application"), which is a continuation-in-part of the '893 patent.

41. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '511 patent (Appendix J) and four copies of each referenced document mentioned in the '511 patent prosecution history (Appendix R).

2. Non-Technical Description of the Patented Invention

42. The inventions disclosed and claimed in the '511 patent relate to, among other things, a computer-implemented orthodontic treatment plan. The path of each tooth from its initial to its final position is segmented and the tooth's motion in each segment is evaluated to stay within limits of acceptable linear and rotational translation. Aligners for each treatment segment are generated.

D. The '666 Patent

1. Identification of the Patent and Ownership by Align

43. U.S. Patent No. 6,626,666 ("the '666 patent") (Appendix C) issued to Align as assignee on September 30, 2003, and is entitled "Method and System for Incrementally Moving Teeth." The inventors are Muhammad Chishti, Apostolos Leros, Brian Freyburger, Kelsey Wirth, and Richard Ridgley.

44. The '666 patent is a continuation of the '325 patent. The entire right, title and interest of the inventors to the subject matter of the '666 patent was assigned to Align (*see* copy of assignment at Ex. S).

45. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '666 patent (Appendix K) and four copies of each referenced document mentioned in the '666 patent prosecution history (Appendix R).

2. Non-Technical Description of the Patented Invention

46. The inventions disclosed and claimed in the '666 patent relate to methods for producing a plurality of digital data sets representing tooth arrangements. An initial digital data set representing an initial tooth arrangement is provided to a computer system. Boundaries about at least some of the individual teeth are defined on a visual image provided by the computer system. At least some of the tooth boundaries are moved relative to the other teeth to produce a final data set. A plurality of successive digital data sets are produced and represent successive tooth arrangements progressing from the initial to the final tooth arrangement.

E. The '863 Patent

1. Identification of the Patent and Ownership by Align

47. U.S. Patent No. 6,705,863 ("the '863 patent") (Appendix D) issued to Align as assignee on March 16, 2004, and is entitled "Attachment Devices and Methods for a Dental Appliance." The inventors are Loc X. Phan, Muhammad Chishti, and Ross J. Miller. Prior to issuance, the entire right, title and interest of the inventors in the '863 patent were assigned to Align (*see* copy of assignment at Ex. U). A reexamination certificate for the '863 patent, Request No. 90/007607, issued on January 8, 2008.

48. The '863 patent is a continuation in part of application number 09/454,278, which issued as U.S. Patent No. 6,309,215 and claims priority from provisional application numbers 60/110,881 and 60/110,189. It also is a continuation in part of application number 09/466,353, which issued as U.S. Patent No. 6,398,548 ("the '548 patent") and claims priority from the PCT application. It is also a continuation in part of the '511 patent.

49. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '863 patent and its reexamination (Appendices L and M) and four copies of each referenced document mentioned in the '863 patent prosecution history (Appendix R).

2. Non-Technical Description of the Patented Invention

50. The '863 patent relates to a method for producing digital models for use in fabricating incremental dental positioning appliances. A digital model of a patient's dentition is provided and a plurality of modified digital models are produced so that they can be used in

fabricating successive incremental dental positioning appliances. A digital model of an attachment device is positioned on at least some of the plurality of modified digital models.

F. The '880 Patent

1. Identification of the Patent and Ownership by Align

51. U.S. Patent No. 6,722,880 ("the '880 patent") (Appendix E) issued to Align as assignee on April 20, 2004 and is entitled "Method and System for Incrementally Moving Teeth." The inventors are Muhammad Chishti and Kelsey Wirth. Prior to issuance, the entire right, title and interest of the inventors in the '880 patent were assigned to Align (*see* copy of assignment at Ex. V). Reexamination Request No. 90/007,797 terminated due to the denial of the petition for reexamination.

52. The '880 patent is a continuation of the '548 patent.

53. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '880 patent and its terminated reexamination (Appendices N and O). Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by four copies of each referenced document mentioned in the '880 patent prosecution history (Appendix R).

2. Non-Technical Description of the Patented Invention

54. The '880 patent teaches methods of using digital data sets representing tooth arrangements to fabricate aligners. Specifically, the invention is directed to fabricating a predetermined series of aligners by obtaining a digital data set representing an initial tooth arrangement, obtaining a repositioned tooth arrangement based on the initial tooth arrangement,

obtaining a series of digital data sets representing a series of successive tooth arrangements and fabricating the aligners based on the digital data sets.

G. The '874 Patent

1. Identification of the Patent and Ownership by Align

55. U.S. Patent No. 7,134,874 ("the '874 patent") (Appendix F) issued to Align as assignee on November 14, 2006, and is entitled "Computer Automated Development of an Orthodontic Treatment Plan and Appliance." The inventors are Muhammad Chishti, Brian Freyburger, Kelsey Wirth, Andrew Beers, Huafeng Wen, Phillips Alexander Benton, Timothy Jones, and Ross Miller.

56. The '874 patent is a continuation of application no. 09/686,190 filed on October 10, 2000 and later abandoned ("the '190 application"), which was a continuation of application no. 09/169,276 ("the '276 application"), filed on October 8, 1998 and later abandoned, which was a continuation-in-part of the PCT application. Prior to issuance of the '874 patent, the entire right, title and interest of the inventors to the '874 patent's subject matter were assigned to Align (*see* copy of assignments at Ex. W).

57. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '874 patent (Appendix P) and four copies of each referenced document mentioned in the '874 patent prosecution history (Appendix R).

2. Non-Technical Description of the Patented Invention

58. The '874 patent relates to computer-implemented methods of creating treatment plans. The computer uses an initial digital data set ("IDDS") representing the teeth at their initial

positions, which data set is generated by scanning the patient's teeth or a model of the patient's teeth. A set of intermediate tooth positions is generated, and then a plurality of successive appliances shaped to reposition the teeth toward the final positions is generated. The plurality of appliances is generated before the patient wears any of the said plurality of appliances.

H. The '487 Patent

1. Identification of the Patent and Ownership by Align

59. U.S. Patent No. 8,070,487 ("the '487 patent") (Appendix G) issued to Align as assignee on December 6, 2011, and is entitled "System and Method for Positioning Teeth." The inventors are Muhammad Chishti, and Andrew Beers.

60. The '487 patent is a continuation of application no. 10/788,510 filed on February 27, 2004, which issued as U.S. Patent No. 7,331,783, which is a continuation of application no. 10/133,155 filed on April 26, 2002, which issued as U.S. Patent No. 6,786,721. U.S. Patent No. 6,786,721 is a continuation of application no. 09/169,036, filed on October 8, 1998, which issued as U.S. Patent No. 6,450,807. U.S. Patent No. 6,450,807 is a continuation in part of the PCT application. Prior to issuance of the '487 patent, the entire right, title and interest of the inventors to the '487 patent's subject matter was assigned to Align (*see* copy of assignment at Ex. X).

61. Pursuant to Commission Rules 210.12(c), the original of this Complaint is accompanied by a certified copy and three additional copies of the prosecution history of the '487 patent (Appendix Q) and four copies of each referenced document mentioned in the '487 patent prosecution history (Appendix R).

2. Non-Technical Description of the Patented Invention

62. The '487 patent relates to computer-implemented methods of creating orthodontic treatment plans. The computer uses an IDDS representing the teeth at their initial positions, which data set is generated by scanning the patient's teeth or a model of the patient's teeth. A set of intermediate tooth arrangements is generated, and then a plurality of successive appliances shaped to reposition the teeth toward the final positions is generated. A plurality of the intermediate tooth arrangements is generated before the patient wears any of the said plurality of appliances.

I. Foreign Counterparts to the Patents

63. Submitted herewith as Exhibit B is a list of each issued foreign patent and pending foreign patent application corresponding to the asserted patents. Other than the items listed in Exhibit B, there are no foreign patents or patent applications corresponding to the asserted patents that have been issued, abandoned, denied, or remain pending.

V. LICENSES

64. Align does not license any third parties to practice the patented inventions referenced herein.

VI. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS

A. Overview of ClearCorrect's Knockoff System

65. Like the Invisalign System, the ClearCorrect System uses a series of clear, polymer aligners which contain cavities to receive and move teeth by applying resilient force on them. As explained by ClearCorrect, "(e)ach aligner you put on, moves your teeth a little bit at a time, until eventually you get straight teeth." Ex. A (Kuo Decl.), Ex. 22.

66. Like Align, ClearCorrect USA receives molds of a patient's initial tooth arrangement from dental professionals. ClearCorrect USA scans the molds to create digital files. Once stored digitally, ClearCorrect USA or ClearCorrect Pakistan uses the input of the dental professional and three-dimensional modeling tools to reposition the teeth to the desired state of normal occlusion. Ex. A (Kuo Decl.), Ex. 23 at 13.

67. ClearCorrect USA sends the dental professional a three dimensional digital model of a "treatment setup" that shows the projected end result of the treatment, or the projected state of normal or ideal occlusion to be achieved through orthodontic treatment. Once satisfied with the end result, the dental professional accepts the case. Ex. A (Kuo Decl.), Exs. 27 and 28.

68. ClearCorrect USA or ClearCorrect Pakistan plots the entire anticipated movement from the initial malocclusion to normal or ideal occlusion. ClearCorrect contends that it or ClearCorrect Pakistan make the projections needed for three-dimensional digital models in sets of four, with each set called a "phase." Ex. A (Kuo Decl.), Ex. 23 at 14.

69. In cases in which ClearCorrect Pakistan makes the three-dimensional digital models, ClearCorrect Pakistan electronically transmits the digital models, digital data or treatment plan for a phase back to ClearCorrect USA for fabrication of molds and aligners. ClearCorrect USA then manufactures the aligners for that phase and ships the aligners to the dental professional. Ex. A (Kuo Decl.), Exs. 30-34 and Ex. 23 at 2-3.

70. Like Align, ClearCorrect USA manufactures its aligners by thermo-forming plastic over positive models representing the successive tooth arrangements desired for the

patient. Each aligner corresponds to a specific tooth arrangement representing one stage in the overall treatment plan. Ex. A (Kuo Decl.), Ex. 23 at 15.

71. ClearCorrect also utilizes attachments in its treatment. Those attachments are affixed to a patient's teeth. Given the appearance of the molds, it appears that ClearCorrect uses digital models of the attachments. Ex. A (Kuo Decl.) ¶ 24 and Ex. 38.

B. Patent Infringement

1. The '325 Patent

72. Respondents import into the United States, sell for importation into the United States, or sell within the United States after importation digital data, digital models or treatment plans for use in fabricating incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by at least claim 31 and 32 of the '325 patent.

73. Respondent ClearCorrect Pakistan, through its import into the United States and sale for importation into the United States of digital data, digital models, or treatment plans induces Respondent ClearCorrect USA's infringement of at least claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38 and 39 of the '325 patent through sales of incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by those claims. ClearCorrect Pakistan induces such infringement by importing or selling for importation the digital data, digital models, or treatment plans with knowledge of the '325 patent and specific intent to induce ClearCorrect USA to infringe that patent.

74. Photographs of ClearCorrect appliances used in the ClearCorrect System according to the method claimed in the '325 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

75. A claim chart that applies exemplary claims 1–3, 11, 13, 14, 21, 30–35, 38 and 39 of the '325 patent to the ClearCorrect System is attached as Exhibit C.

76. The claim chart attached as Exhibit C is based in part on the Declaration of Dr. Eric Kuo.

2. The '511 Patent

77. Respondent ClearCorrect Pakistan, through its import into the United States, sale for importation into the United States of digital data, digital models, or treatment plans induces Respondent ClearCorrect USA's infringement of at least claim 1 of the '511 patent through sales of incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by those claims. ClearCorrect Pakistan induces such infringement by importing or selling for importation the digital data, digital models, or treatment plans with knowledge of the '511 patent and specific intent to induce ClearCorrect USA to infringe that patent.

78. Photographs of ClearCorrect appliances used in the ClearCorrect System according to the method claimed in the '511 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

79. A claim chart that applies exemplary claim 1 of the '511 patent to the ClearCorrect System is attached as Exhibit D.

80. The claim chart attached as Exhibit D is based in part on the Declaration of Dr. Eric Kuo.

3. The '666 Patent

81. Respondents import into the United States, sell for importation into the United States, or sell within the United States after importation digital data, digital models or treatment plans for use in fabricating incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by at least claims 1, 3, 7, and 9 of the '666 patent.

82. Photographs of ClearCorrect appliances used according to the method claimed in the '666 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

83. A claim chart that applies exemplary claims 1, 3, 7, and 9 of the '666 patent to the ClearCorrect System is attached as Exhibit E.

84. The claim chart attached as Exhibit E is based in part on the Declaration of Dr. Eric Kuo.

4. The '863 Patent

85. Respondents import into the United States, sell for importation into the United States, or sell within the United States after importation digital data, digital models or treatment plans for use in fabricating incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by at least claims 1 and 4–8 of the '863 patent.

86. Photographs of ClearCorrect appliances used and fabricated according to the methods claimed in the '863 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

87. A claim chart that applies exemplary claims 1 and 4–8 of the '863 patent to the ClearCorrect product and System are attached as Exhibit F.

88. The claim charts attached as Exhibit F are based in part on the Declaration of Dr. Eric Kuo.

5. The '880 Patent

89. Respondent ClearCorrect Pakistan, through its import into the United States and sale for importation into the United States of digital data, digital models, or treatment plans induces Respondent ClearCorrect USA's infringement of at least claims 1 and 3 of the '880 patent through sales of incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by those claims. ClearCorrect Pakistan induces such infringement by importing or selling for importation the digital data, digital models, or treatment plans with knowledge of the '880 patent and specific intent to induce ClearCorrect USA to infringe that patent.

90. Photographs of ClearCorrect appliances used and fabricated according to the methods claimed in the '880 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

91. A claim chart that applies exemplary claims 1 and 3 of the '880 patent to the ClearCorrect product and system are attached as Exhibit G.

92. The claim charts attached as Exhibit G are based in part on the Declaration of Dr. Eric Kuo.

6. The '874 Patent

93. Respondent ClearCorrect Pakistan, through its import into the United States and sale for importation into the United States of digital data, digital models, or treatment plans induces Respondent ClearCorrect USA's infringement of at least claims 1, 2, 38, 39, 41, and 62 of the '874 patent through sales of incremental dental position adjustment appliances that are made, produced, processed, or by means of, a process covered by those claims. ClearCorrect Pakistan induces such infringement by importing or selling for importation the digital data, digital models, or treatment plans with knowledge of the '874 patent and specific intent to induce ClearCorrect USA to infringe that patent.

94. Photographs of ClearCorrect appliances fabricated according to the methods claimed in the '874 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

95. A claim chart that applies exemplary claims 1, 2, 38, 39, 41, and 62 of the '874 patent to the ClearCorrect product are attached as Exhibit H.

96. The claim charts attached as Exhibit H are based in part on the Declaration of Dr. Eric Kuo.

7. The '487 Patent

97. Respondents import into the United States, sell for importation into the United States, or sell within the United States after importation orthodontic treatment plans, digital data or digital models for use in fabricating incremental dental position adjustment appliances that infringe at least claims 7-9, and that are made, produced, processed, or by means of, a process covered by at least claims 1, 3 and 5 of the '487 patent.

98. Photographs of ClearCorrect appliances fabricated using the orthodontic treatment plans claimed in the '487 patent are attached as Exhibits 31 and 35 to Exhibit A (Kuo Decl.).

99. A claim chart that applies exemplary claims 1, 3, 5, 7, 8, and 9 of the '487 patent to the ClearCorrect product are attached as Exhibit I.

100. The claim charts attached as Exhibit I are based in part on the Declaration of Dr. Eric Kuo.

VII. SPECIFIC INSTANCES OF SALE AND IMPORTATION

101. On or about April 2009, ClearCorrect began the national rollout of its orthodontic aligners in the United States. In a publication on its website from April 30, 2009, ClearCorrect claimed it

was founded by dentists to serve the dental and orthodontic industry by providing a superior and more affordable clear aligner system. The highly sophisticated ClearCorrect treatment delivery system and corresponding aligner products are based on years of research and clinical experience. Cutting-edge technological advances and advanced treatment expertise, coupled with comprehensive marketing and sales support, make ClearCorrect the premier clear aligner solution of choice for informed dentists and patients. The company's modern, needs-based approach for serving doctors and patients has earned it a leadership position within the dental industry.

Ex. A (Kuo Decl.), Ex. 40 (ClearCorrect, Inc. Begins National Rollout of its FDA-Cleared Transparent Orthodontic Aligners and Hands-On Certification Workshop, April 30, 2009).

102. In the same press release, ClearCorrect claimed a series of "key differences and advantages" over Align, including "Better Treatment control," "Easier to diagnose and shorter learning curve," "ClearCorrect was developed by leading dentists and orthodontic professionals," "Lower Fees," "No Midcourse correction fees," "No refinement fees," "Treatment products

include initial retention,” “More affordable for both dentists and more importantly, the patients,” “Better training,” and “Responsive customer service.” *Id.*

103. On August 24, 2011, ClearCorrect issued a press release reporting that it had been

ranked as the *fastest-growing health company in America* by Inc. magazine. The manufacturer of orthodontic clear aligners *placed first among companies in the health industry* on the prestigious Inc. 500 list, published in the September 2011 issue of Inc. magazine. ClearCorrect's *3-year growth rate of 8,625%* also ranked as *17th fastest-growing company overall* out of thousands of applicants.

Ex. A (Kuo Decl.), Ex. 41 (ClearCorrect Press Release: ClearCorrect Ranked as America's Fastest-Growing Health Company By Inc. Magazine) (emphases added). ClearCorrect has represented in related litigation that it uses an entity in Pakistan named ClearCorrect Pakistan (Private), Ltd. to perform its treatment planning operations (*i.e.*, plan, for each patient, the movement of their teeth from an initial occlusion to an ideal occlusion). ClearCorrect has also represented that it imports from ClearCorrect Pakistan data representing the output of ClearCorrect Pakistan's treatment planning operations (*i.e.*, ClearCorrect sends ClearCorrect Pakistan digital data representing a patient's initial tooth arrangement, and ClearCorrect Pakistan manipulates the locations of the teeth and returns a set of data or treatment plan representing the incremental, customized locations of that patient's teeth over time—which is then used to manufacture all of that patient's aligners). Ex. A (Kuo Decl.), Ex. 23.

104. Upon information and belief, ClearCorrect imports these articles electronically.

VIII. RELATED LITIGATION

105. Align has instituted civil litigation against ClearCorrect in the Southern District of Texas, Case No. 4:11-cv-00695, based in part on some of the acts of patent infringement asserted

in this Complaint. A copy of the Texas complaint is attached as Exhibit 1 to the Declaration of Len M. Hedge (“Hedge Decl.”), attached hereto as Exhibit J.

106. In response to discovery in the Texas action, ClearCorrect disclosed a partial listing of the 60+ employees of ClearCorrect Pakistan, many of whom operate the software it uses to perform treatment planning operations. Ex. A (Kuo Decl.), Ex. 26 at 2–5. While some of the names are incomplete, Align has been able to identify at least a dozen ClearCorrect Pakistan employees who are former employees of Align and/or a former entity known as OrthoClear. Align has an extensive litigation history against OrthoClear, which operated a facility in Pakistan that designed and manufactured clear aligners in violation of Align’s patents and trade secrets (and, in turn, sold those aligners in the United States). Align is the current owner of all of OrthoClear’s intellectual property.

107. In January 2005, Align petitioned the ITC, which instituted an action pursuant to Section 337 against OrthoClear based on acts of trade secret misappropriation and infringement of many of the same patents at issue here (*e.g.*, the ‘880 and ‘511 Patents)—including the usage by OrthoClear (in Pakistan) of infringing software to perform treatment planning operations. On October 13, 2006, Align and OrthoClear entered into a Consent Order whereby OrthoClear and its officers, directors, agents, servants, employees, successors, and assigns agreed (1) to not import articles infringing any of the patents-in-suit, and (2) to not sell, import, sell-after-importation, or aid/abet/encourage/participate in, or induce the sale for importation of the “articles.” Ex. J (Hedge Decl.), Ex. 2. “Articles” is defined as “the incremental dental positioning adjustment appliances manufactured by or for OrthoClear referenced in the

Complaint and any other articles manufactured in violation of the patents or trade secrets described therein.” *Id.*

108. In spite of this Consent Order and Align’s patents, former OrthoClear managers, directors, and operators are now accomplishing the same tasks (*i.e.*, using software to perform treatment planning operations, in violation of Align’s patents) under the auspices of a different entity, ClearCorrect Pakistan (Ex. A (Kuo Decl.), Ex. 26 at 2-5):

NAME	TITLE AT ORTHOCLEAR	TITLE AT CLEARCORRECT PAKISTAN
Dr. Nadeem Arif	Director of Quality Control	“Doctor” / Manager
Dr. Waqas Wahab	Manager of Dental Lab	“Doctor” / Manager
Mudassar Rathore	Director of Manufacturing Operations	Manager
Dr. Asim Waheed	Manager Training / Issue Control	“Doctor” / Manager
Mian Naeem	Operator	Operator (Resigned)
Imran Jameel	Operator	Operator
Muhammad Nasir	Operator	Operator
Hassan Raza	Operator	Operator
Muhammad Sohaif	Operator	QC/Operator
Zahid Riaz	Operator	Operator
Kashif Saleemi	Operator	Operator
Muhammad Ali Babar	Operator	Operator
Nazir Sultan	Operator	Operator
Anwar Javed	Operator	Operator
Muhammad Akram	Operator	Operator
Tariq Latif	Operator	Operator
Amjad Aziz	Operator	Operator

109. Contemporaneously with the filing of this action, Align is requesting the initiation of an ITC enforcement action to address the former OrthoClear employees' violation of the Consent Order via their work in managing, owning, operating, and/or working for ClearCorrect Pakistan in connection with its treatment planning operations for ClearCorrect.

IX. DOMESTIC INDUSTRY

110. Align constitutes a domestic industry under 19 U.S.C. § 1337(a).

111. As discussed above, Align's patents cover and relate to the Invisalign System, which encompasses proprietary software programs, sophisticated design parameters and tools, extensive know-how, advanced production processes, and, ultimately, customized aligners and computerized interfaces used to treat patients. Align's sole business is the development, design, manufacture, sale and marketing of the Invisalign System and its various elements as well as the various products of Cadent Holdings, Inc. which Align acquired in 2011.

112. In all, Align has spent over [REDACTED] on developing, implementing, maintaining, advertising, and upgrading its Invisalign clear aligner therapy system. Ex. K (Arola Decl.) ¶ 12.

B. Significant Investment in Plant, Equipment, Labor, and Capital

113. Align's headquarters and principal place of business is located in San Jose, California (the "California Facility"). The California Facility consists of two buildings that house Align in approximately 122,350 square feet of space. The lease on the California Facility extends until September 2017, at a monthly rent of approximately \$61,000. Ex. J (Hedge Decl.) ¶ 2.

114. The California Facility is home to Align's senior executive officers, as well as the marketing and sales, customer care, research and development, software engineering, and administrative functions of the company. *Id.* at ¶ 3. The California Facility contains a number of Align's main divisions, including Product Marketing, Corporate Marketing, Customer Relations, Product Development, Financial/Accounting, Investor Relations, and Accounts Payable. *Id.* Align's California Facility manages each of its non-US facilities. *Id.*

115. Align has invested millions of dollars furnishing its manufacturing facility in Juarez, Mexico with the equipment required to produce highly customized, highly precise, medical quality aligners in volume. As of the end of 2010, Align's total investments in equipment for its manufacturing facility were valued at more than \$40 million, representing more than 70 percent of Align's worldwide equipment investment. Ex. K (Arola Decl.) ¶ 4. All of the technology that is implemented in Juarez was developed in, or with the oversight of, Align's California Facility. *Id.*

116. Align employs over 2,500 employees, including approximately 1,775 in manufacturing and operations, 365 in sales and marketing (approximately 240 of which are in Align's North American Sales organization), 275 in Research & Development (most of whom are located in the United States), and 130 in general and administrative functions (most of whom are located in the United States). In total, Align has approximately 600 employees in the US. Ex. K (Arola Decl.) ¶ 5.

117. Align's U.S. employees have significant responsibility for designing, developing, operating, and maintaining the proprietary software programs and advanced manufacturing processes using the patented technologies and processes covered by this action. A significant

amount of Align's investment in labor and capital—exceeding [REDACTED]—has been devoted to the research and development of Align's Treat™ software. Ex. K (Arola Decl.) ¶ 6. This proprietary software, which has been developed, upgraded, and maintained on a continuing basis since the inception of Align, assists Align's technicians in preparing treatment plans for the planned movement of patients' teeth, including the processes embodied in the '863, '325, and '511 Patents.

118. As of December 2010, Align's total U.S.-burdened payroll exceeded \$46 million. *Id.* at ¶ 5.

119. Align's investment in its plants, equipment, and labor in the United States supports each of the patents asserted in this action. The substantial investment of millions of dollars Align has spent in developing, acquiring, and installing the technology and equipment that is utilized in its manufacturing facility is devoted solely to producing Align's custom aligners, which are created using the software and processes covered by the patents asserted here. *Id.* at ¶ 4.

C. Substantial Investment in the Exploitation of Align's Patented Technologies

120. Because Align's primary business is the development, design, manufacture, sale and marketing of the Invisalign System and its various elements, and because all of the patents-in-suit in this investigation pertain to the Invisalign System, most of Align's business activities constitute exploitation of the patents at issue. Align has spent over \$240 million in research and development of the Invisalign System. *Id.*

121. Align is practicing, in its operations in the United States and overseas, at least one claim of each of the patents asserted in this action. *See* Domestic Industry Charts attached as Exhibits L–R.

122. The Invisalign production process and the aligners that are produced result from the exploitation of Align's patented technologies in the United States, as well as overseas. Invisalign kits are distributed to dental professionals in the United States and returned to Align's Juarez facility. . There, technicians log in the Invisalign kits, disinfect the contents if necessary, prepare them for scanning, use sophisticated machinery to create CT scans of the impression and bite, and create computerized data files using the results of the CT scans and entered data. The process varies slightly if intra-oral scans are submitted. These data files are used by Align's technicians in Costa Rica to prepare a treatment plan, using a suite of software that was designed and initially developed by Align in the United States. The treatment plans are used to manufacture a series of positive molds of the patient's teeth using sophisticated stereolithography machines. The positive molds are used to fabricate the aligners in the Juarez facility. Ex. J (Hedge Decl.) ¶ 4.

123. Even where aspects of the patents in suit asserted herein are practiced by Align outside the United States (*e.g.*, in the Costa Rica facility), other aspects are practiced in the United States, and the non-U.S. activity is an integral part of, and directly supports and is supported by, the related activity in the United States, all of which is directed to the development, design, manufacturing, delivery and improvement of the Invisalign System. Ex. A (Kuo Decl.) ¶¶ 2–7; Ex. J (Hedge Decl.) ¶¶ 3–5; Ex. K (Arola Decl.) ¶¶ 4–12.

124. Align technicians in Costa Rica use computer software, designed and initially developed in California, to generate a malocclusion treatment plan. These treatment plans are made up of successive digital data sets, which reposition a patient's teeth from the initial tooth position to a final tooth position. This software includes Align's Treat application, which provides the technician with a software environment in which they can manipulate the individual teeth and produce successive digital data sets representing incremental movements. Ex. A (Kuo Decl.) ¶¶ 5 and 11. These data sets represent the actual progression of the patient's teeth over the treatment process (from malocclusion to the target occlusion), and are required to complete the manufacturing process (*i.e.*, they are used to create physical molds, which are used to create the aligners). *Id.* at ¶¶ 7 and 11.

125. Align has spent over [REDACTED] developing and maintaining this suite of software (most of which has taken place in California), which is critical to its ability to effectively produce its custom-made aligners. Ex. K (Arola Decl.) ¶ 6. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] Ex. J
(Hedge Decl.) ¶ 4.

126. In using Align's proprietary computer software to (1) separate individual teeth from a model of the initial tooth arrangement, (2) create digital data sets made up of tooth locations throughout treatment, as they move from malocclusion towards a normal or ideal occlusion, (3) generate a treatment plan made up of those successive digital data sets, and (4) generate a specific tooth path for each tooth (and through the subsequent use all of the above

data to fabricate customized aligners) Align's technicians practice an embodiment of every patent at issue:

- In Align's embodiment of claim 31 of the '325 patent, Align technicians use Align's proprietary software to generate a treatment plan made up of digital data sets corresponding to the locations of the patient's teeth over the course of treatment. The technicians do so by providing an initial digital data set representing that patient's initial tooth arrangement (created by Align's scanning equipment and technology), and manipulating that digital data set in a visual environment provided by Align's Treat software. The technicians reposition the individual teeth to move them from a state to malocclusion to a final state of normal or ideal occlusion. Once the technicians have produced a digital data set representing the positions of the teeth in the final tooth arrangement, they then use the same Align software to produce a plurality of intermediate digital data sets progressing from the initial tooth arrangement to the final tooth arrangement. These digital data sets are then used by Align to create models of the patient's teeth at each stage of treatment. Align's employees then use these models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. Ex. A (Kuo Decl.) ¶¶ 3–11.
- In Align's embodiment of claim 1 of the '511 patent, Align technicians use proprietary Align software to generate a treatment plan made up of digital data sets corresponding to the desired locations of the patient's teeth over the course of treatment. The technicians use Align software, and a digital data set representing that patient's initial tooth arrangement, to select and move individual teeth. The technicians reposition the

individual teeth to move them from a state to malocclusion to a state of normal or ideal occlusion, or a desired final tooth arrangement. The software is able to calculate a tooth path for the motion of individual teeth from their initial position to a final position, and segment the movements into segments so that each tooth's motion stays within threshold limits of movement. The digital data sets that are created by the operation of Align's software are then used to create physical models of the patient's teeth at the different stages of treatment. Align's employees then use these physical models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. *Id.*

- In Align's embodiment of claim 1 of the '863 patent, Align technicians use proprietary Align software to generate a treatment plan made up of digital data sets corresponding to the locations of the patient's teeth over the course of treatment. The technicians do so by using an initial digital data set representing that patient's initial tooth arrangement (created by Align's scanning equipment and technology), and manipulating that digital data set in a visual environment provided by Align's Treat software. In some cases, the technician and/or the Align software may determine that the patient's treatment requires the use of an "attachment device" which assists the custom aligner in moving the tooth in certain ways (*e.g.*, rotating the tooth). The technician and/or the Align software will create a digital model of the physical attachment device, which is positioned on at least some of the digital models representing the patient's tooth arrangements throughout the treatment process. The resulting digital model—which now includes the attachment device—corresponds to the device the orthodontist or dentist will place on the patient's tooth. These digital data sets (at least some of which include digital representations of

the attachment devices) are then used by Align to create physical models of the patient's teeth at each stage of treatment. Align's employees then use these models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. If an attachment is used throughout the treatment process, at least one of these aligners will contain a receptacle to accept an attachment device. *Id.*

- In Align's embodiment of claim 1 of the '880 patent, Align technicians use Align's proprietary software to generate a treatment plan made up of digital data sets corresponding to the locations of the patient's teeth over the course of treatment. The technicians do so by using an initial digital data set representing that patient's initial tooth arrangement (created by Align's scanning equipment and technology), and manipulating that digital data set in a visual environment provided by Align's Treat software. These digital data sets are then used by Align to create a physical model of the patient's teeth at each stage of treatment. Align's employees then use these models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. *Id.*
- In Align's embodiment of claim 2 of the '874 patent, Align technicians use Align's proprietary software to generate a treatment plan made up of digital data sets corresponding to the locations of the patient's teeth over the course of treatment. The technicians do so by using an initial digital data set representing that patient's initial tooth arrangement (created by Align's scanning equipment and technology), and manipulating that digital data set in a visual environment provided by Align's Treat software. Align

creates this initial digital data set by scanning the patient's teeth or by scanning a physical replica created of the patient's teeth. The technicians reposition the individual teeth to move them from a state to malocclusion to a state of normal or ideal occlusion, or desired final tooth arrangement. Once the technicians have produced a digital data set representing the positions of the teeth in the final stage, they then use the same Align software to produce intermediate digital data sets progressing from the initial tooth arrangement towards the final tooth arrangement. These digital data sets are then used by Align to create physical models of the patient's teeth at each stage of treatment. Align's employees then use these models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. Align performs all of these actions, and generates the patient's appliances, typically before the patient has worn any of these appliances in order to reposition their teeth. *Id.*

- In Align's embodiment of claim 1 of the '666 patent, Align technicians use proprietary Align software to generate a treatment plan made up of digital data sets corresponding to the locations of the patient's teeth over the course of treatment. The technicians use Align software, and a digital data set representing that patient's initial tooth arrangement, to select and move individual teeth. The technicians reposition the individual teeth to move them from a state to malocclusion to a state of normal or ideal occlusion, or a desired final tooth arrangement. The technician is able to use the software to identify and move individual teeth by defining boundaries around individual teeth using the visual image presented by the software. The technician is able to move these teeth to create digital data sets representing successive tooth arrangements as the patient proceeds throughout treatment. The digital data sets that are created by the operation of Align's

software are then used to create physical models of the patient's teeth at the different stages of treatment. Align's employees then use these models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. *Id.*

- In Align's embodiment of claim 7 of the '487 patent, Align's technicians use proprietary software to generate an orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances. The technicians use the Align software to generate treatment plans that include a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth. The technicians use the Align software to generate at least some of the intermediate tooth arrangements to represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement. The digital data sets that are created by the operation of Align's software are then used to create physical models of the patient's teeth at the different stages of treatment. Align's employees then use these models to create the aligners, using Align's technology and manufacturing equipment that was developed and/or purchased in the United States. *Id.*

127. Almost all of the software and know how needed to practice these claims was developed in the United States.

128. At its California facility, Align maintains identical versions of the software tools and technical manuals and treatment protocols used in Costa Rica, and Align personnel located in California regularly provide technical support and guidance to the Align technicians in Costa

Rica, as well as manufacturing personnel in Juarez. Ex. J (Hedge Decl.) ¶ 5. In providing this support, Align personnel in California are practicing the very patented methods that are at issue in this proceeding. Indeed, both the Costa Rica and Juarez facilities are managed by personnel located in the United States. *Id.* at ¶ 3.

129. Align has invested tens of millions of dollars to develop the manufacturing capacity and software necessary to manufacture highly customized, highly precise, medical quality aligners in volume. Since 2005, Align has spent over [REDACTED] in the US to develop and upgrade its suite of confidential and proprietary software—including over [REDACTED] million in 2009, [REDACTED] million in 2010, and [REDACTED] million in 2011. Align currently employs over [REDACTED] software developers in the US who are engaged in developing and upgrading this software. As a result of these investments, approximately 1.7 million patients worldwide (as of Q4 2011), of which approximately 75% are in the United States, have entered treatment with Invisalign, and Align has manufactured more than 80 million unique, custom aligners. Ex. K (Arola Decl.) ¶ 6.

130. The Invisalign System has been incorporated into the teaching curricula of the country's leading academic institutions, including the Harvard School of Dental Medicine, the Columbia University School of Dental and Oral Surgery, the New York University College of Dentistry, the University of the Pacific School of Dentistry, and the Department of Orthodontics at the University of Illinois at Chicago. *Id.* at ¶ 7.

131. Align directly supports the academic and research community with funding and grants for Invisalign-related scientific research. In 2005, Invisalign announced the establishment of the Align Technology Inc. Research Award Program, with an initial funding amount of up to \$500,000. This program invites Invisalign-related scientific research proposals from academic

and clinical dental research faculty, private practitioners, as well as residents and dental students. *Id.* at ¶ 8. In 2011, Align provided over \$165,000 in scientific research funding to three universities in North America and three universities internationally for one- and two-year projects seeking to better understand orthodontic treatment with clear aligners. *Id.* To date, Align has sponsored more than \$1.5 million in direct university, clinical research and foundation grants. *Id.*

132. Align conducted private and university-based clinical studies across the United States prior to commercially releasing the Invisalign System and obtained section 510(k) pre-market approval to market Invisalign from the United States Food and Drug Administration in 1998. *Id.* at ¶ 9. Since that time, Align has continued to invest in research and development of the Invisalign System, including launching new clinical studies to expand applicability and determine specific Aligner properties. As a result of these clinical studies, the range of applicability demonstrated by Invisalign has expanded significantly. Align has also invested over [REDACTED] in the U.S. to train and certify dental professionals in the use of the Invisalign System. Align has trained and certified over [REDACTED] doctors in the US since commencing its training and certification program. *Id.* at ¶ 10. The training is conducted by Align employees and associated dental professionals. A team of Align personnel in the United States are devoted to developing and implementing the training and certification of dental professionals. *Id.*

133. Align has spent a significant amount of money to establish itself in the United States marketplace and to create a United States market for its high-technology, custom-manufactured orthodontic products. Align is the only company in the orthodontic industry today that devotes significant resources to creating consumer awareness and expanding the market for

orthodontic treatment through direct-to-consumer advertising. *Id.* at ¶ 11. In 2000 and 2001, Align launched its first national advertising campaigns, generating advertising-related expenses of almost \$40 million. *Id.* Align launched a new direct-to-consumer campaign involving television, radio, and print media in mid-2005, which was designed to emphasize orthodontic treatment benefits and drive more consumers to Align's orthodontists and general practitioner dentists. *Id.* Indeed, Align's U.S.-based advertising personnel are constantly evaluating and revising Align's marketing strategy, and over the last three years, Align has initiated several new advertising roll-outs in the U.S. targeting specific channels (*e.g.*, social media, television, Twitter, and Facebook) and demographics (*e.g.*, teenagers). *Id.* Since inception, Align has spent in excess of \$150 million on advertising and building awareness of the Invisalign product in the United States, including \$22.4 million in 2011, \$20.7 million in 2010, \$20.3 million in 2009, and \$23 million in 2008. *Id.*

X. RELIEF

134. By reason of the foregoing, Align requests that the United States International Trade Commission:

(a) institute an immediate investigation pursuant to Section 337, as amended, with respect to violations of that section based upon the importation into the United States or the sale within the United States of certain digital models, digital data and treatment plans that were made, produced or processed by means that are covered by, or that infringe or induce infringement of, one or more claims of the Align patents described herein;

(b) schedule and conduct a hearing on said unlawful acts and, following said hearing;

(c) issue permanent cease and desist orders prohibiting the proposed respondents from selling for importation or importing any digital model, digital data, or treatment plan data files that were either (1) made, produced or processed by means that are covered by or (2) that infringe or induce infringement of one or more claims of the Align patents described herein;

(d) issue permanent cease and desist orders prohibiting the proposed respondents from using or selling any digital model, digital data, or treatment plans that were (1) imported into the United States and (2) made, produced or processed by means that are covered by one or more claims of the Align patents described herein;

(e) issue permanent cease and desist orders prohibiting the proposed respondents from using or selling any digital model, digital data, or treatment plans that were (1) imported into the United States and (2) infringe or induce infringement of one or more claims of the Align patents described herein;

(f) issue permanent cease and desist orders prohibiting the proposed respondents from making or selling any incremental digital positioning appliances made using digital models, digital data, or treatment plans that were (1) imported into the United States and (2) made, produced or processed by means that are covered by one or more claims of the Align patents described herein;

(g) issue permanent cease and desist orders prohibiting the proposed respondents from making or selling any incremental digital positioning appliances made using digital models, digital data, or treatment plans that (1) were imported into the United States and

(2) infringe or induce infringement of one or more claims of the Align patents described herein;

and

(h) issue such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and authority of the Commission.

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Respectfully submitted,



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