IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

ALIGN TECHNOLOGY, INC., Plaintiff and Counterclaim Defendant, v. 3SHAPE A/S and 3SHAPE TRIOS A/S Defendants and Counterclaimants.	C.A. No. 6:20-cv-00979-ADA **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Align Technology, Inc. ("Align") demands a trial by jury on all issues so triable and, for its complaint against Defendants 3Shape A/S and 3Shape Trios A/S (collectively, "3Shape"), alleges as follows:

THE PARTIES

1. Align is a Delaware corporation incorporated in April 1997, with its principal place of business in San Jose, California.

2. 3Shape A/S is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.

3. 3Shape Trios A/S is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.

4. 3Shape makes, uses, sells, and offers for sale in the United States and/or imports into the United States the TRIOS, TRIOS 3, and TRIOS 4 scanners and software products that embody systems and/or methods for intraoral scanning for dental applications.

JURISDICTION AND VENUE

5. This lawsuit is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Defendants in that they have, directly or through agents and/or intermediaries, committed acts within Texas giving rise to this action and/or have established minimum contacts with Texas such that the exercise of jurisdiction would not offend traditional notions of fair play and justice.

8. On information and belief, Defendants regularly conduct business in Texas, and purposefully avail themselves of the privileges of conducting business in Texas. In particular, on information and belief, Defendants, directly and/or through their agents and/or intermediaries, make, use, import, offer for sale, sell, and/or advertise their products and affiliated services in Texas. Defendants have placed, and continue to place, infringing products into the stream of commerce, via an established distribution channel, with the knowledge and/or understanding that such products are sold in the United States including in Texas and specifically including this District.

9. On information and belief, Defendants have derived substantial revenue from their infringing activity occurring with the State of Texas and within this District and/or should reasonably expect their actions to have consequences in Texas. In addition, Defendants have knowingly induced, and continue to knowingly induce, infringement within this District by advertising, marketing, offering for sale and/or selling devices containing infringing functionality within this District to at least resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users, and by providing instructions, user manuals, advertising

and/or marketing materials that facilitate, direct or encourage the use of infringing functionality with knowledge thereof.

10. Defendants have committed patent infringement in Texas that has led to foreseeable harm and injury to Align.

11. Additionally, Defendants are subject to jurisdiction in the United Sates, and specifically in Texas, pursuant to FED. R. CIV. P. 4(k)(2). Defendants have contacts with the United States that include, *inter alia*, advertising, offering to sell, and/or selling their products and software throughout the United Sates, including Texas and this District.

12. Venue is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, as foreign corporations, 3Shape A/S and 3Shape Trios A/S may be sued in any judicial district.

BACKGROUND

13. Align is a global medical device company with industry leading innovative products such as iTero intraoral scanners and OrthoCAD software that help dental and orthodontic professionals deliver effective, innovative dental and orthodontic options to their patients.

14. Align's iTero intraoral scanners scan and provide, in conjunction with Align's OrthoCAD software, 3D imaging of an intraoral surface, such as the teeth and gums, without drying and powdering the intraoral surface (as older technology required), resulting in a digital impression. Align's iTero intraoral scanners and the software that works in conjunction with the scanners thus eliminate the need for traditional teeth impressions typically taken with an elastomeric or other material.

15. The digital impression captured by Align's iTero intraoral scanners, when teamed with Align's OrthoCAD software, can be used in a variety of dental and orthodontic applications, such as, for example, modeling the occlusion between the patient's teeth and processing images that

are capable of describing relationships between the various parts of the skeletal, dental and soft tissue elements of the craniofacial complex.

16. Align's iTero intraoral scanner and OrthoCAD digital software constitute a proprietary system and method for treating, among other things, malocclusion, misalignment, and/or chipped or missing teeth. Align's high-precision, high speed intraoral scanner and related software allow for the creation of a variety of orthodontic and dental devices including, but not limited to, crowns, bridges, bracket templates, aligners, and implants. Each dental device is custom-manufactured for each patient using computer-aided design techniques and sophisticated computer graphic interfaces to communicate with the patient's dental or orthodontic professional in the planning and implementation of the customized treatment program.

17. Align's iTero intraoral scanner and OrthoCAD software, developed by Align over many years and at great expense and effort, represent a breakthrough in the manufacturing principle of "mass customization" and a vast improvement over conventional methods for treating, among other things, chipped or missing teeth, misalignment of teeth, and malocclusion. Additionally, the iTero intraoral scanner and OrthoCAD software provide a "chair-side" platform for live viewing of the digital impression as it is being built on the display screen during scanning, for accessing valuable digital diagnosis and treatment tools, and for enhancing accuracy of records, treatment efficiency, and the overall patient experience. The innovations embodied in Align's iTero intraoral scanner and OrthoCAD software are protected by numerous United States and foreign patents, including the patents at issue in this case.

18. 3Shape designs, develops, manufactures, and markets the TRIOS, TRIOS 3, and TRIOS 4 scanners, as well as the related Dental System software products that include software modules including, but not limited to, the Implant Studio, Ortho System, Ortho Analyzer, Ortho Planner, Appliance Designer, and Ortho Control Patent (hereinafter "Dental System software

products"). Moreover, 3Shape is involved in the sale and/or importation into the United States of intraoral scanners, digital models, and digital data and Dental System software products for dental and orthodontic applications including, but not limited to, crowns, bridges, bracket templates, aligners, and implants. 3Shape's intraoral scanners, digital and physical models generated from digital data using 3Shape software, and 3Shape's software products for dental and orthodontic applications described above embody and/or use the patented apparatuses, systems, and methods at issue.

19. 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners, as well as 3Shape's related Dental System software products (collectively, the Accused Products), directly compete with the Align's iTero scanners and OrthoCad software. On information and belief, 3Shape developed, made, and sold its intraoral scanners and software with the intent to directly compete with Align's intraoral scanners and software. Before introducing its products, 3Shape was aware of the structure, design, and operation of Align's patented intraoral scanners and software, including but not limited to intraoral scanners and software developed by Cadent Holdings, Inc. ("Cadent"), which Align acquired on April 29, 2011. Moreover, 3Shape has previously entered into agreements with Align that provided 3Shape with significant access to Align's patented technologies.

20. On information and belief, 3Shape developed, made, and sold its infringing TRIOS, TRIOS 3, and TRIOS 4 scanners and related infringing Dental System software products despite having knowledge of the Align patents at issue (i) based, at a minimum, on its knowledge of the Align intraoral scanners and software being covered by numerous patents including the patents at issue through its prior business dealings with Align, including those with Cadent, whereby 3Shape acquired specific and detailed knowledge from Align regarding the structure, function, operation, and commercial benefits of the Align products and the patent protection afforded to certain structures, functions, and operations of the patented Align technology; (ii) by virtue of 3Shape's patent prosecution activities wherein Align's certain of patents at issue and/or family members were

cited as prior art, including but not limited to U.S. Patent Nos. 9,101,433, 10,728,519, 10,750,151, and 10,750,152, or related family members; and/or (iii) by virtue of 3Shape's U.S. Food and Drug Administration Section 510(k) premarket notification of intent to market the accused products, which identifies 3Shape's accused products as substantially equivalent to Align's patent-practicing products.

THE ASSERTED COLOR SCANNING PATENTS

21. U.S. Patent No. 9,101,433 ("'433 Patent"), U.S. Patent No. 10,728,519 ("'519 Patent"), U.S. Patent No. 10,750,151 ("'151 Patent"), and U.S. Patent No. 10,750,152 ("'152 Patent") disclose methods and systems for obtaining a color scan of a patient's dentition. These patents are attached as **Exhibits 1-4** to this Complaint.

22. A common problem in obtaining a three-dimensional color scan of the intraoral cavity is the difficulty in associating position information obtained using a three-dimensional scanning method with color information obtained using a two-dimensional scanning method. The two-dimensional color information and three-dimensional depth information will commonly be mismatched. Existing methods required covering the intraoral cavity surface with a layer of opaque material before taking the three-dimensional image, and then removing the layer and manually re-aligning the camera to capture a two-dimensional color image of the same area.

23. The '433, '519, '151, and '152 patents address this problem by disclosing inventions that provide relatively simple and effective ways for mapping two-dimensional color information onto a three-dimensional surface model. Specifically, the inventions provide devices and methods for obtaining a numerical entity that represents the color and surface topology of an object. This allows dentists to more easily obtain a color three-dimensional image for use in carrying out procedures in the dental cavity, such as prosthesis color matching and orthodontics.

24. The '519, '151, and '152 patents are continuations of the '433 patent, which has previously been the subject of an *inter partes* review filed by (*inter alia*) 3Shape A/S in the Patent and Trademark Office. In a Final Written Decision issued on June 6, 2019, the Patent Trial and Appeal Board upheld as valid claims 12 and 14 of the '433 patent. 3*Shape A/S v. Align Technology Inc.*, IPR No. 2019-00163, "Decision, Inter Partes Review," at 33-42 (June 9, 2020).

25. The '433, '519, '151, and '152 patents are also continuations of U.S. Patent No. 8,363,228 ("'228 Patent"), U.S. Patent No. 8,451,456 ("'456 Patent"), and U.S. Patent No. 8,675,207 ("'207 Patent"), which have previously been the subject of an International Trade Commission ("ITC") investigation related to 3Shape's color scanners. The '433 patent was also a subject of that investigation. After an extensive investigation, the ITC confirmed the Initial Decision of the ALJ and found that 3Shape's TRIOS 3 and associated Ortho and Dental System software infringed the '228 Patent, the '456 Patent, and the '207 Patent. *In re Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091, "Commission Opinion," at 37-44 (Dec. 19, 2020).[1] While the recently-issued '519, '151, and '152 patents differ in certain details from the '228, '456, and '207 patents, the differences in claim language do not meaningfully change the infringement analysis with respect to 3Shape's infringing activities.

26. The '433 Patent was issued by the United States Patent and Trademark Office ("USPTO") on August 11, 2015. The '519 Patent was validly issued by the USPTO on July 28, 2020. The '151 and '152 patents were validly issued by the USPTO on August 18, 2020.

27. The prior art that 3Shape has relied upon in previous challenges to the validity of the '433 patent in the USPTO was presented to the USPTO in the prosecution of the '519, '151,

[1] All citations in this Complaint to decisions by the ITC refer to the public versions of the ITC opinions. This Complaint does not rely on confidential information contained in the sealed version of the opinions.

and '152 patents and is cited on the face of those patents. The USPTO issued the patents over the prior art cited by 3Shape.

THE ASSERTED SELECTIVE RESCANNING PATENTS

28. U.S. Patent No. 10,945,609 ("'609 Patent") and US Patent No. 10,791,936 ("'936 Patent") disclose systems and methods for improving the 3D virtual model of a patient's teeth by allowing the user to remove and replace deficient portions of the 3D virtual model. These patents are attached as **Exhibits 5-6** to this Complaint.

29. A common problem in obtaining accurate 3D virtual models of the intraoral cavity is that portions of the patient's teeth may be partially obstructed by agents such as blood, saliva, soft tissue, or debris. In the presence of such obstructions, the 3D virtual model of the intraoral cavity may not accurately represent the structure of the patient's teeth. As a result, various dental or orthodontic applications that rely on the 3D virtual model (such as crowns or aligners) may not fit properly.

30. The '609 and '936 patents address this problem by disclosing inventions that allow the user, after cleaning the patient's mouth, to digitally erase just the obscured portion of the 3D virtual model, re-scan that portion of the intraoral cavity, and update the 3D virtual model with the new, unobscured portion. This improvement allows dentists to more easily obtain an accurate 3D virtual model of the patient's teeth, free of any obstructions that might erode the usefulness of the model.

31. The '609 and '936 patents are both continuations of U.S. Patent No. 9,299,192 ("'192 Patent"), which has previously been the subject of an International Trade Commission ("ITC") investigation related to 3Shape's scanners. After an extensive investigation, the presiding Administrative Law Judge found that 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners and associated Dental System software infringed the '192 Patent. *In re Certain Dental and Orthodontic*

Scanners and Software, Inv. No. 337-TA-1144, "Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond," at 197-217 (April 30, 2020).

32. The '936 patent was issued by the USPTO on October 6, 2020. The '609 patent issued on March 16, 2021. In the prosecution of these patents, Align presented the USPTO with the prior art that 3Shape has relied upon in previous challenges to the validity of the '192 Patent, both in the ITC proceeding and in a subsequent IPR, as well as the PTAB's decision in the '192 Patent IPR. The USPTO issued the patents over the prior art cited by 3Shape.

THE ASSERTED HOLE-CLOSING TECHNOLOGY PATENT

33. U.S. Patent No. 10,709,527 ("'527 Patent") describes and claims systems and methods for obtaining a 3D virtual model of an intraoral cavity in which a 3D virtual model generated from a first set of 3D data is missing a portion of the model and a second set of 3D data for the missing portion is generated and combined with the 3D virtual model. This patent is attached as **Exhibit 7** to this Complaint.

34. The '527 Patent overcomes a common problem in obtaining accurate 3D virtual models of the intraoral cavity, in which portions of the patient's teeth may be partially obstructed by soft tissue or foreign matter, causing the 3D model to be incomplete. The '527 Patent addresses that problem by collecting a first set of data to generate a 3D virtual model, determining the missing portion of the model, collecting a second set of data associated with the missing portion, and combining the second set of data with the model to generate a 3D virtual model with the missing portion filled in.

35. The '527 Patent claims priority to a U.S. patent application filed on February 8, 2006 and a U.S. provisional application filed on July 15, 2005. At that time, the field of intraoral scanning was in its infancy. The invention of the '527 patent represented a significant advancement in the art over methods and systems for creating 3D models that did not determine whether missing portions

existed and subsequently generate additional data to create a model that included the missing portion.

36. The '527 Patent was issued by the USPTO on July 14, 2020.

COUNT ONE – INFRINGEMENT OF THE '433 PATENT

37. Align incorporates by reference its allegations in Paragraphs 1-36 as if fully restated in this paragraph.

38. On August 11, 2015, the USPTO lawfully issued the '433 Patent, entitled "Method and Apparatus for Colour Imaging a Three-Dimensional Structure." Align is the sole owner of the '433 Patent and of all rights of recovery thereunder for past and future infringement.

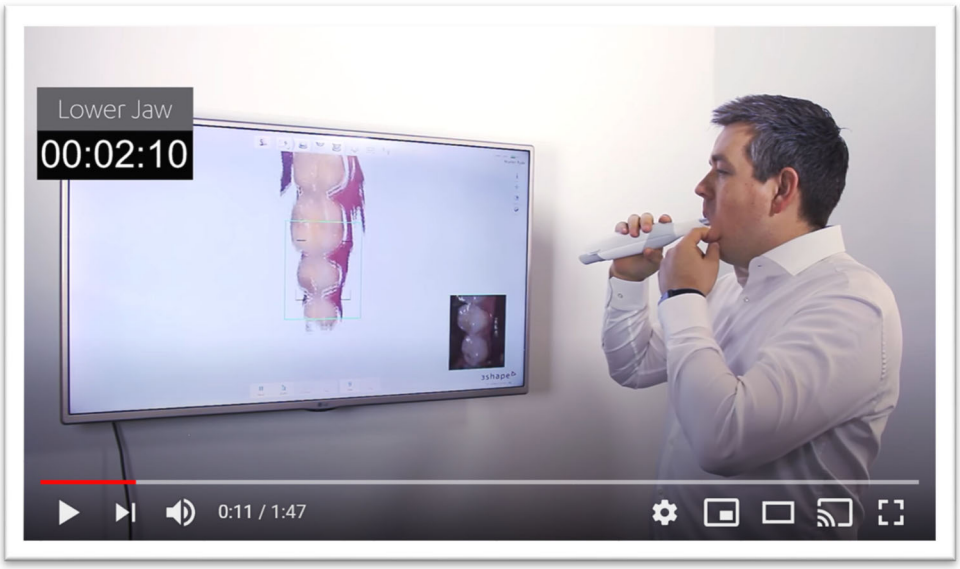
39. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '433 Patent by practicing the patented method in the United States and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '433 Patent.

40. By way of illustration only, 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners and associated Ortho and Dental System software meet each and every element of claim 1 of the '433 Patent.

41. The TRIOS, TRIOS 3, and TRIOS 4 scanners, used with associated Dental System software, provide for a system for determining the surface topology and associated color of at least a portion of a three-dimensional structure. That system comprises "an apparatus comprising an image gathering member to generate depth data of the structure portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction," as well as "one or more processors operably coupled to the apparatus, the one or more processors configured to cause the system to: [1] receive, from the apparatus, the depth data of the structure portion corresponding to

the two-dimensional reference array substantially orthogonal to the depth direction; [2] receive, from the apparatus, two-dimensional first image data of the structure portion associated with the two-dimensional reference array; [3] receive, from the apparatus, two-dimensional second image data of the structure portion associated with the two-dimensional reference array, the second image data being different from the first image data; [4] generate two-dimensional estimated image data based on the first image data and the second image data so as to account for when the first image data and the second image data were generated relative to when the depth data was generated so that the estimated image data corresponds to when the depth data was generated; and [5] map the estimated image data to the depth data for the two-dimensional reference array." '433 Patent, col. 26 ll. 19-49.

42. 3Shape's marketing materials illustrate how 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners, in conjunction with the related Dental System software products, satisfy all elements of claim 1 of the '433 Patent. By way of example only, the 3Shape marketing video, brochure, and marketing materials below show that 3Shape's TRIOS, TRIOS 3, and TRIOS 4 intraoral scanners and associated software contain the infringing functionality. The TRIOS, TRIOS 3, and TRIOS 4 scanners provide a system that maps two-dimensional color information onto a three-dimensional surface model to create a three-dimensional color model. On information and belief, the TRIOS, TRIOS 3, and TRIOS 4 scanners repeatedly generate two-dimensional color information of the intraoral cavity while collecting three-dimensional depth data and match the color information with the depth information.

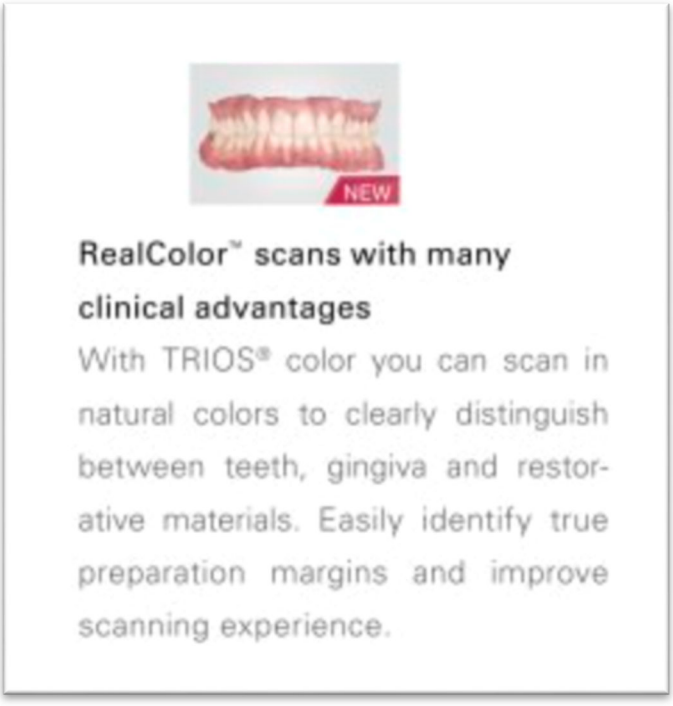


(*See, e.g.,* 3Shape TRIOS 3 Video (YouTube, available at: https://www.youtube.com/watch?v=C5jKnxEyrbU).)

(*See, e.g.,* 3Shape TRIOS Digital Impression Solution Brochure (Medical Expo website, available at https://pdf.medicalexpo.com/pdf/3shape/trios/71366-100299.html).)

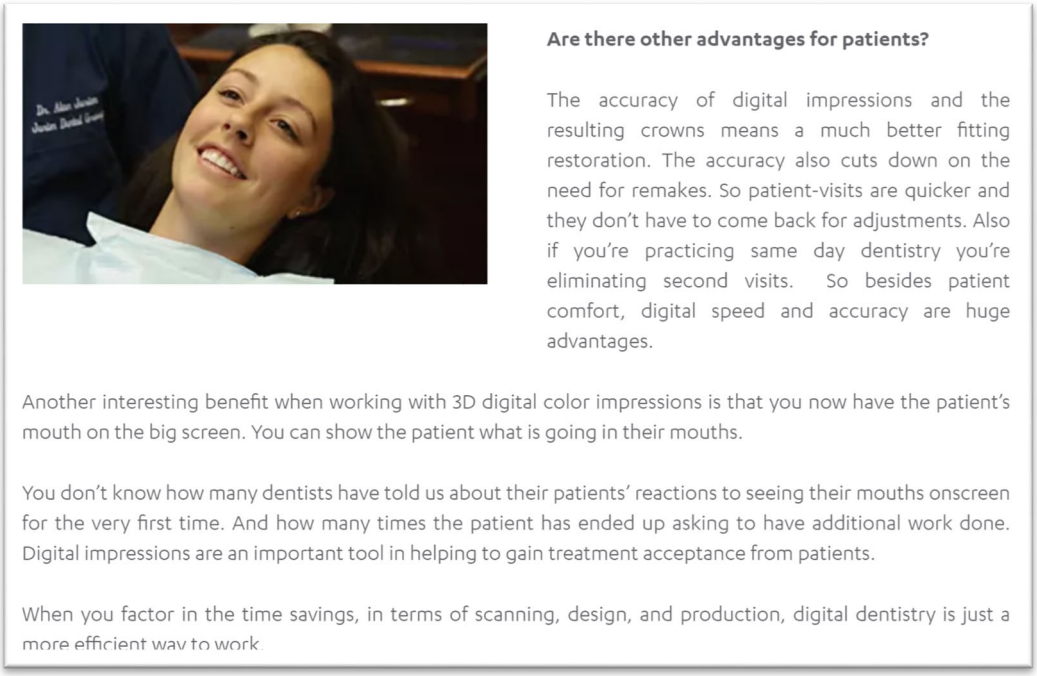

SCAN IN COLOR
3shape
NEW
Up to 1000 3D pictures for true geometries
Combining hundreds or thousands of 3D pictures to create the final 3D digital impression based on real data rather than interpolated artificial surfaces.
Scanning has never been easier
Easily move along the teeth as the scanner captures the impression in real time. No need to hold the scanner at a specific distance or angle for focus.
Autoclaveable tip with anti-mist heater
Achieve optimal hygiene and meet clinical requirements. The integrated anti-mist heater automatically ensures an optimal temperature for undistorted and crystal clear scanning.

(*Id.*)


NEW
RealColor™ scans with many clinical advantages
With TRIOS® color you can scan in natural colors to clearly distinguish between teeth, gingiva and restorative materials. Easily identify true preparation margins and improve scanning experience.

(*Id.*)

(*Id.*)



Are there other advantages for patients?

The accuracy of digital impressions and the resulting crowns means a much better fitting restoration. The accuracy also cuts down on the need for remakes. So patient-visits are quicker and they don't have to come back for adjustments. Also if you're practicing same day dentistry you're eliminating second visits. So besides patient comfort, digital speed and accuracy are huge advantages.

Another interesting benefit when working with 3D digital color impressions is that you now have the patient's mouth on the big screen. You can show the patient what is going in their mouths.

You don't know how many dentists have told us about their patients' reactions to seeing their mouths onscreen for the very first time. And how many times the patient has ended up asking to have additional work done. Digital impressions are an important tool in helping to gain treatment acceptance from patients.

When you factor in the time savings, in terms of scanning, design, and production, digital dentistry is just a more efficient way to work.

(*See, e.g.,* Interview with 3Shape founder, Tais Clausen (3Shape website, available at https://www.3shape.com/en/news/2015/why-your-patients-love-digital-technology.)

43. 3Shape has directly infringed the '433 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '433 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

44. Additionally, 3Shape has actively induced infringement of the '433 Patent under 35 U.S.C. § 271(b). 3Shape possesses knowledge of and is aware of the '433 patent by virtue of, at a minimum, the filing of the Complaint in *Align Technology, Inc. v. 3Shape A/S*, Case 1:17-cv-01649-LPS (D. Del.) (filed on Nov. 14, 2017), and, on information and belief, had prior knowledge of the '433 patent by virtue of the prior business dealings between 3Shape and Align and other facts described above. 3Shape induced, with specific intent, infringement of the '433 Patent by its customers. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

45. 3Shape also has been and is now contributing to the infringement of one or more claims of the '433 Patent, either literally or under the doctrine of equivalents.

46. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '433 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products is especially made and/or especially adapted for use in infringement of the '433 Patent.

3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '433 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

47. 3Shape has willfully infringed the '433 Patent. On information and belief, at least as of the date upon which it learned of the '433 Patent (which was no later than November 14, 2017), 3Shape has known of the '433 Patent, and after acquiring that knowledge, 3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

48. 3Shape's acts of infringement have injured Align.

49. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

COUNT TWO – INFRINGEMENT OF THE '519 PATENT

50. Align incorporates by reference its allegations in Paragraphs 1-49 as if fully restated in this paragraph.

51. On July 28, 2020, the USPTO lawfully issued the '519 Patent, entitled "Method and Apparatus for Colour Imaging a Three-Dimensional Structure." Align is the sole owner of the '519 Patent and of all rights of recovery thereunder for past and future infringement.

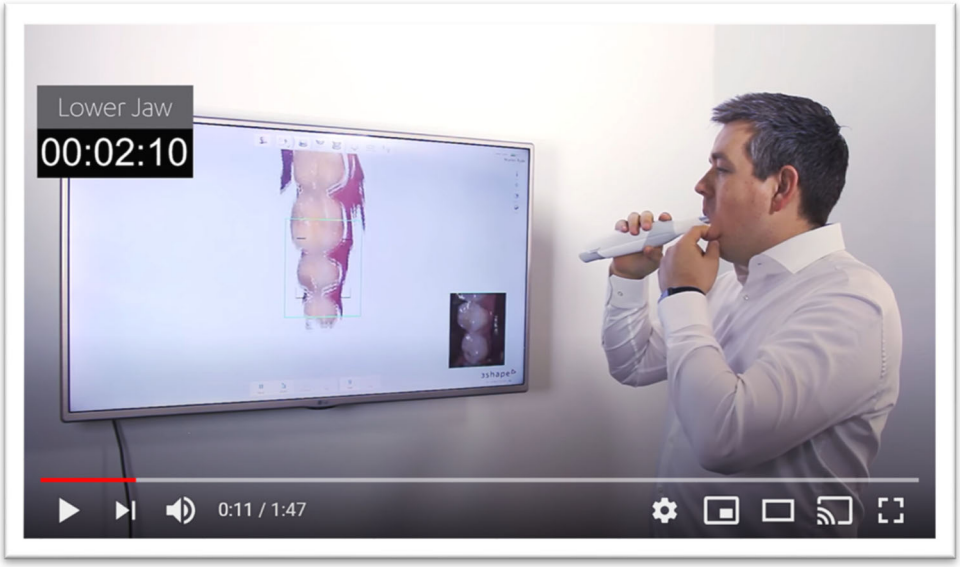
52. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '519 Patent by practicing the patented method and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '519 Patent.

53. By way of illustration only, 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners and associated Dental System software products meet each and every element of claim 1 of the '519 Patent.

54. The TRIOS, TRIOS 3, and TRIOS 4 scanners, used with associated Dental System software, provides for a system for determining the surface topology and associated color of at least a portion of a three-dimensional structure. That system comprises "a hand-held device comprising: [1] a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction; [2] an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; [3] an illumination unit configured to transmit a first array of incident light along a path towards the three-dimensional structure; and [4] a detector configured to measure intensity of each of a plurality of returned light that returns along the path and from the three-dimensional structure," as well as "a processor operably coupled to the hand-

held device and configured to associate the depth data with the two-dimensional color image data." '519 Patent, col. 26 l. 62 – col. 27 l. 15.

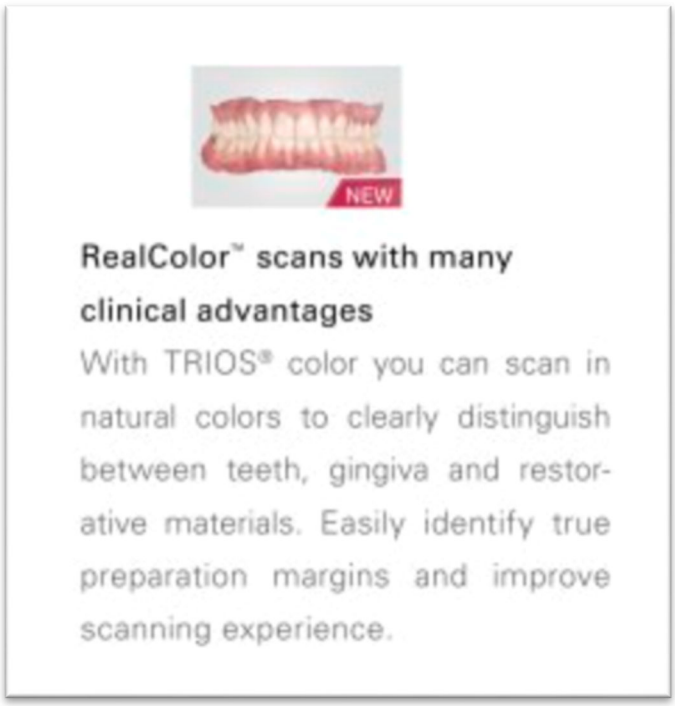
55. 3Shape's marketing materials illustrate how 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners, in conjunction with the related Dental System software products, satisfy all elements of claim 1 of the '519 Patent. By way of example only, the 3Shape marketing video, brochure, and marketing materials below show that 3Shape's TRIOS, TRIOS 3, and TRIOS 4 intraoral scanners and associated software contain the infringing functionality. The TRIOS, TRIOS 3, and TRIOS 4 scanners are handheld devices that generate three-dimensional scans of the intraoral cavity and associated two-dimensional color images. On information and belief, the TRIOS, TRIOS 3, and TRIOS 4 scanners generate the data using a light that reflects off the intraoral cavity.



(*See, e.g.,* 3Shape TRIOS 3 Video (YouTube, available at: https://www.youtube.com/watch?v=C5jKnxEyrbU).)

(*See, e.g.,* 3Shape TRIOS Digital Impression Solution Brochure (Medical Expo website, available at https://pdf.medicalexpo.com/pdf/3shape/trios/71366-100299.html).)

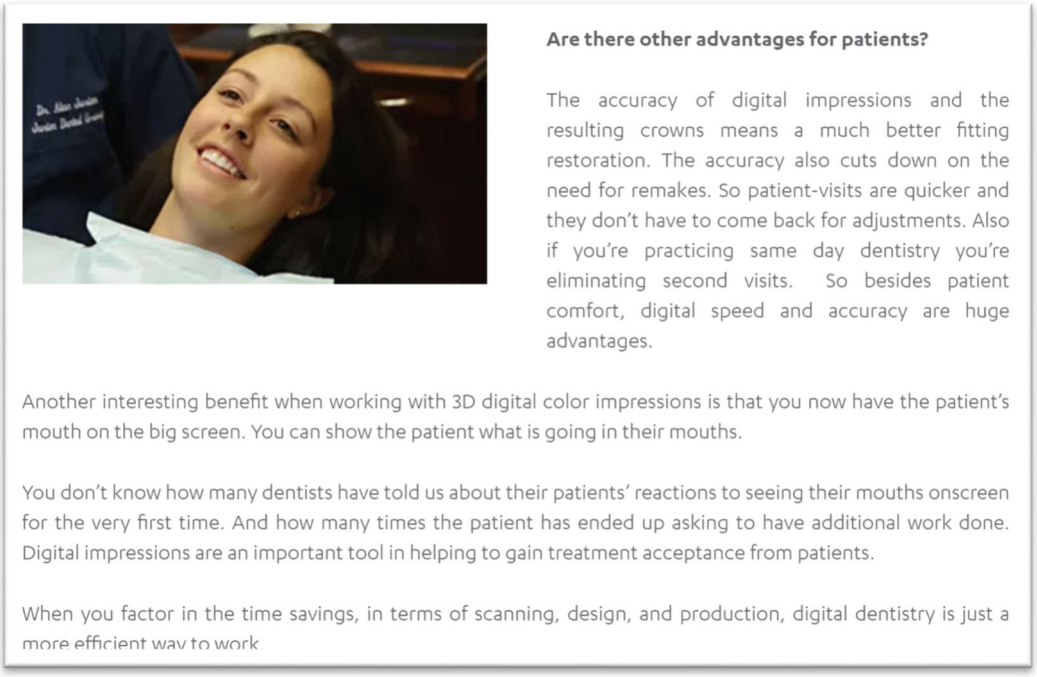
(*Id.*)


NEW
RealColor™ scans with many clinical advantages
With TRIOS® color you can scan in natural colors to clearly distinguish between teeth, gingiva and restorative materials. Easily identify true preparation margins and improve scanning experience.

(*Id.*)


Complete digital workflows
3Shape TRIOS® is not just about impression-taking. TRIOS® realizes full digital workflows opening new clinical possibilities and business opportunities - starting from the patient's visit in the clinic and ending with completed treatment.
1. Order creation
2. Scanning
3. Clinical validation
4. Send digital impression
5. CAD design
6. Preview design
7. Manufacturing
8. Seat restoration

(*Id.*)



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You don't know how many dentists have told us about their patients' reactions to seeing their mouths onscreen for the very first time. And how many times the patient has ended up asking to have additional work done. Digital impressions are an important tool in helping to gain treatment acceptance from patients.

When you factor in the time savings, in terms of scanning, design, and production, digital dentistry is just a more efficient way to work.

(*See, e.g.,* Interview with 3Shape founder, Tais Clausen (3Shape website, available at https://www.3shape.com/en/news/2015/why-your-patients-love-digital-technology.)

56. The publicly filed decision of the International Trade Commission in *In re Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091 (Dec. 19, 2020), further confirms that 3Shape's intraoral scanners, when used in conjunction with the associated Dental System software, satisfy the elements of the '519 Patent. That decision found that "TRIOS 'associates' the depth data and the color data[.]" *Id.* at 51. This finding, and the other findings in the ITC opinion, confirm that 3Shape's scanners infringe at least claim 1 of the '519 Patent.

57. 3Shape has directly infringed the '519 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '519 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

58. Additionally, 3Shape has actively induced infringement of the '519 Patent under 35 U.S.C. § 271(b). On information and belief, at least as of the date upon which it learned of the '519

Patent (which was no later than the date this Complaint was served), 3Shape induced, with specific intent, infringement of the '519 Patent by its customers. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

59. 3Shape also has been and is now contributing to the infringement of one or more claims of the '519 Patent, either literally or under the doctrine of equivalents.

60. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '519 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products is especially made and/or especially adapted for use in infringement of the '519 Patent. 3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '519 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists,

orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

61. 3Shape has willfully infringed the '519 Patent. On information and belief, at least as of the date upon which it learned of the '519 Patent (which was no later than the date this Complaint was served), 3Shape has known of the '519 Patent, and after acquiring that knowledge, 3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

62. 3Shape's acts of infringement have injured Align.

63. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

COUNT THREE – INFRINGEMENT OF THE '151 PATENT

64. Align incorporates by reference its allegations in Paragraphs 1-63 as if fully restated in this paragraph.

65. On August 18, 2020, the United States Patent and Trademark Office lawfully issued the '151 Patent, entitled "Method and Apparatus for Colour Imaging a Three-Dimensional Structure." Align is the sole owner of the '151 Patent and of all rights of recovery thereunder for past and future infringement.

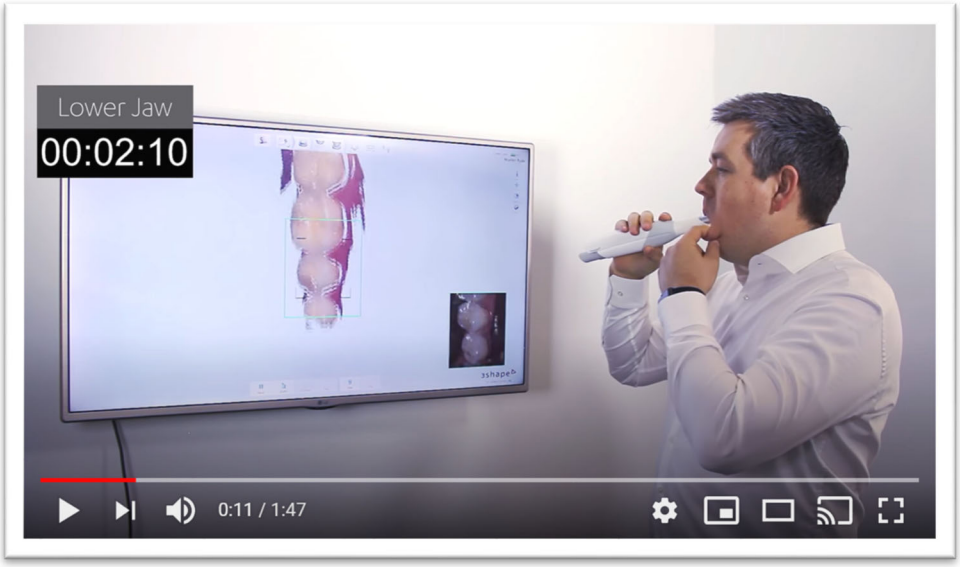
66. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '151 Patent by practicing the patented method and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '151 Patent.

67. By way of illustration only, 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners and associated Dental System software products meet each and every element of claim 18 of the '151 Patent.

68. The TRIOS, TRIOS 3, and TRIOS 4 scanners, used with associated Dental System software, provides for a "system for determining surface topology and associated color of an intraoral structure." That system comprises "a handheld device comprising [1] a probe, [2] focusing optics configured to scan a focal plane of the handheld imaging device over a range of depths, [3] a white light illuminator, and [4] an image sensor configured to capture depth image data over the range of depths and color image data of the intraoral structure, wherein incident light beams from the white light illuminator and returned light beams from the intraoral structure pass through the focusing optics," as well as "one or more processors operably coupled to the handheld imaging device, the one or more processors configured to cause the system to [1] generate depth data of the intraoral structure using the depth image data from the handheld imaging device, [2] generate color data of the intraoral structure using the color image data from the handheld imaging device, and [3] provide a color three-dimensional numerical entity based on the depth data and the color data." '151 Patent, col. 28 ll. 17-37.

69. 3Shape's marketing materials illustrate how 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners, in conjunction with the related Dental System software products, satisfy all elements of claim 18 of the '151 Patent. By way of example only, the 3Shape marketing video, brochure, and marketing materials below show that 3Shape's TRIOS, TRIOS 3, and TRIOS 4 intraoral scanners and associated software contain the infringing functionality. The TRIOS, TRIOS 3, and TRIOS 4 scanners provide a method for generating a color three-dimensional model of the intraoral cavity. On information and belief, the TRIOS, TRIOS 3, and TRIOS 4 scanners include a handheld device

that generates two-dimensional color information using an image sensor that senses the white light reflected off the intraoral cavity at a range of depths from the object.

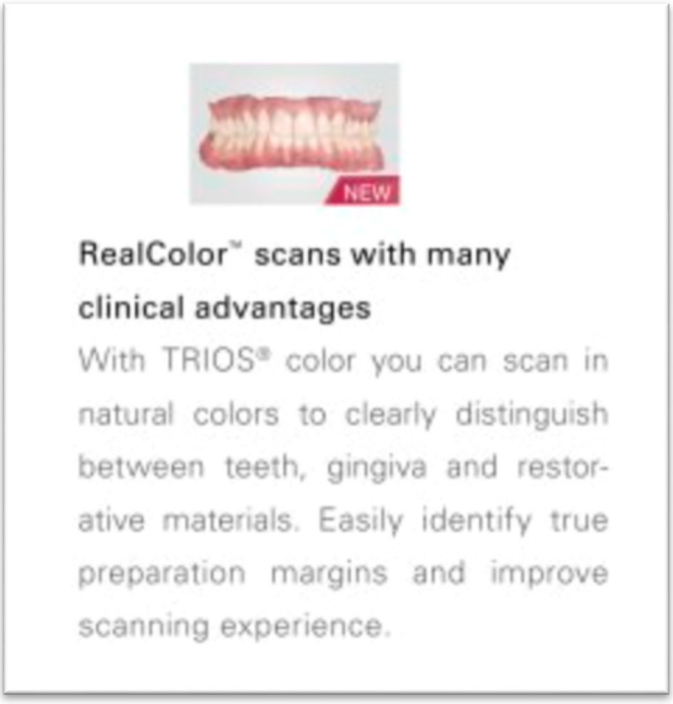


(*See, e.g.*, 3Shape TRIOS 3 Video (YouTube, available at: https://www.youtube.com/watch?v=C5jKnxEyrbU).)

(*See, e.g.*, 3Shape TRIOS Digital Impression Solution Brochure (Medical Expo website, available at https://pdf.medicalexpo.com/pdf/3shape/trios/71366-100299.html).)


SCAN IN COLOR
3shape
NEW
Up to 1000 3D pictures for true geometries
Combining hundreds or thousands of 3D pictures to create the final 3D digital impression based on real data rather than interpolated artificial surfaces.
Scanning has never been easier
Easily move along the teeth as the scanner captures the impression in real time. No need to hold the scanner at a specific distance or angle for focus.
Autoclaveable tip with anti-mist heater
Achieve optimal hygiene and meet clinical requirements. The integrated anti-mist heater automatically ensures an optimal temperature for undistorted and crystal clear scanning.

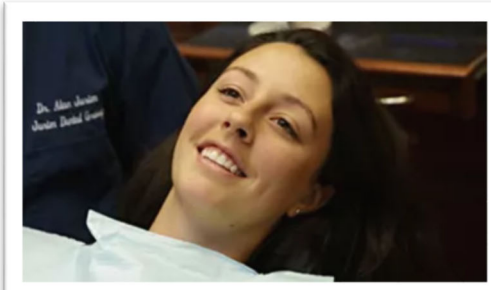
(*Id.*)


NEW
RealColor™ scans with many clinical advantages
With TRIOS® color you can scan in natural colors to clearly distinguish between teeth, gingiva and restorative materials. Easily identify true preparation margins and improve scanning experience.

(*Id.*)


Complete digital workflows
3Shape TRIOS® is not just about impression-taking. TRIOS® realizes full digital workflows opening new clinical possibilities and business opportunities - starting from the patient's visit in the clinic and ending with completed treatment.
1. Order creation
2. Scanning
3. Clinical validation
4. Send digital impression
5. CAD design
6. Preview design
7. Manufacturing
8. Seat restoration

(*Id.*)



Are there other advantages for patients?

The accuracy of digital impressions and the resulting crowns means a much better fitting restoration. The accuracy also cuts down on the need for remakes. So patient-visits are quicker and they don't have to come back for adjustments. Also if you're practicing same day dentistry you're eliminating second visits. So besides patient comfort, digital speed and accuracy are huge advantages.

Another interesting benefit when working with 3D digital color impressions is that you now have the patient's mouth on the big screen. You can show the patient what is going in their mouths.

You don't know how many dentists have told us about their patients' reactions to seeing their mouths onscreen for the very first time. And how many times the patient has ended up asking to have additional work done. Digital impressions are an important tool in helping to gain treatment acceptance from patients.

When you factor in the time savings, in terms of scanning, design, and production, digital dentistry is just a more efficient way to work.

(*See, e.g.*, Interview with 3Shape founder, Tais Clausen (3Shape website, available at https://www.3shape.com/en/news/2015/why-your-patients-love-digital-technology.)

70. The publicly filed decision of the International Trade Commission in *In re Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091 (Dec. 19, 2020), further confirms that 3Shape's intraoral scanners, when used in conjunction with the associated Dental System software, satisfy the elements of the '151 Patent. That decision found that "TRIOS 'associates' the depth data and the color data[.]" *Id.* at 51. This finding, and the other findings in the ITC opinion, confirm that 3Shape's scanners infringe at least claim 18 of the '151 Patent.

71. 3Shape has directly infringed the '151 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '151 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

72. Additionally, 3Shape has actively induced infringement of the '151 Patent under 35 U.S.C. § 271(b). On information and belief, at least as of the date upon which it learned of the '151

Patent (which was no later than the date this Complaint was served), 3Shape induced, with specific intent, infringement of the '151 Patent by its customers. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

73. 3Shape also has been and is now contributing to the infringement of one or more claims of the '151 Patent, either literally or under the doctrine of equivalents.

74. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '151 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products is especially made and/or especially adapted for use in infringement of the '151 Patent. 3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '151 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists,

orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

75. 3Shape has willfully infringed the '151 Patent. On information and belief, at least as of the date upon which it learned of the '151 Patent (which was no later than the date this Complaint was served), 3Shape has known of the '151 Patent, and after acquiring that knowledge, 3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

76. 3Shape's acts of infringement have injured Align.

77. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

COUNT FOUR – INFRINGEMENT OF THE '152 PATENT

78. Align incorporates by reference its allegations in Paragraphs 1-77 as if fully restated in this paragraph.

79. On August 18, 2020, the United States Patent and Trademark Office lawfully issued the '152 Patent, entitled "Method and Apparatus for Structure Imaging a Three-Dimensional Structure." Align is the sole owner of the '152 Patent and of all rights of recovery thereunder for past and future infringement.

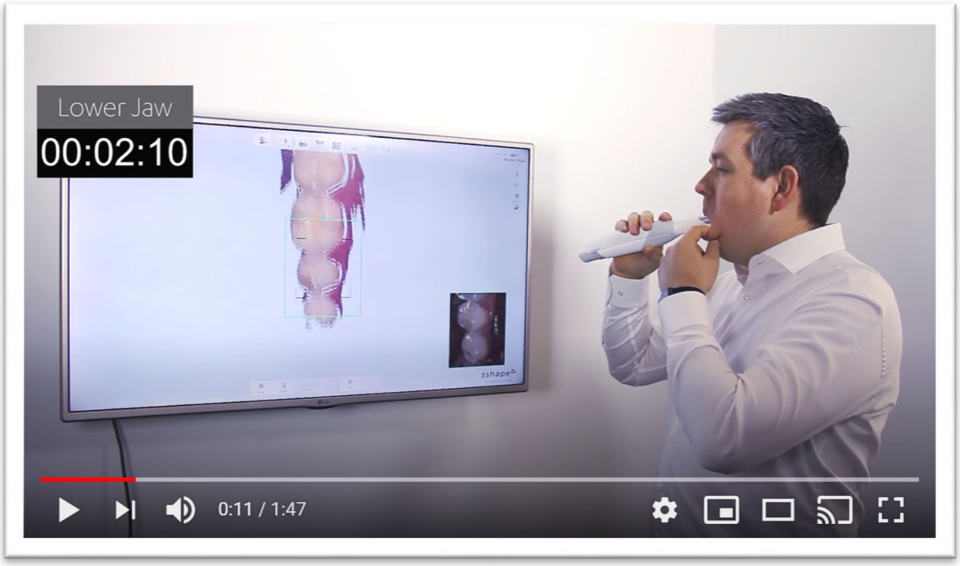
80. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '152 Patent by practicing the patented method and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '151 Patent.

81. By way of illustration only, 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners and associated Dental System software products meet each and every element of claim 1 of the '152 Patent.

82. The TRIOS, TRIOS 3, and TRIOS 4 scanners, used with associated Dental System software, constitute a "system for generating a 3D model of an intraoral structure portion." That system comprises "a hand-held imaging device comprising [1] a probe, [2] focusing optics configured to scan a focal plane of the hand-held imaging device over a range of depths, [3] an illuminator, and [4] an image sensor configured to capture image data over the range of depths of the intraoral structure portion, wherein light from the illuminator passes through the focusing optics to the intraoral structure portion and light from the intraoral structure portion passes through the focusing optics to the image sensor and wherein the image data includes first image data captured in response to illuminating the intraoral structure portion with light from the illuminator," as well as "one or more processors operably coupled to the hand-held imaging device, the one or more processors configured to cause the system to: [1] generate depth data of the intraoral structure portion using the first image data from the hand-held imaging device; [2] generate color data of the intraoral structure portion using the first image data from the hand-held imaging device; and [3] provide, using one or more processors, a three-dimensional numerical entity based on the depth data and the color data." '152 Patent, col. 26 l. 58 – col. 27 l. 15.

83. 3Shape's marketing materials illustrate how 3Shape's TRIOS, TRIOS 3, and TRIOS 4 scanners, in conjunction with the related Dental System software products, satisfy all elements of claim 1 of the '152 Patent. By way of example only, the 3Shape marketing video, brochure, and marketing materials below show that 3Shape's TRIOS, TRIOS 3, and TRIOS 4 intraoral scanners and associated software contain the infringing functionality. The TRIOS, TRIOS 3, and TRIOS 4 scanners are a system for generating a color three-dimensional model of the intraoral cavity.

Specifically, the TRIOS, TRIOS 3, and TRIOS 4 scanners include a handheld device that, on information and belief, generates two-dimensional color information using an image sensor that senses the light reflected off the intraoral cavity at a range of depths from the object.



(*See, e.g.*, 3Shape TRIOS 3 Video (YouTube, available at: https://www.youtube.com/watch?v=C5jKnxEyrbU).)

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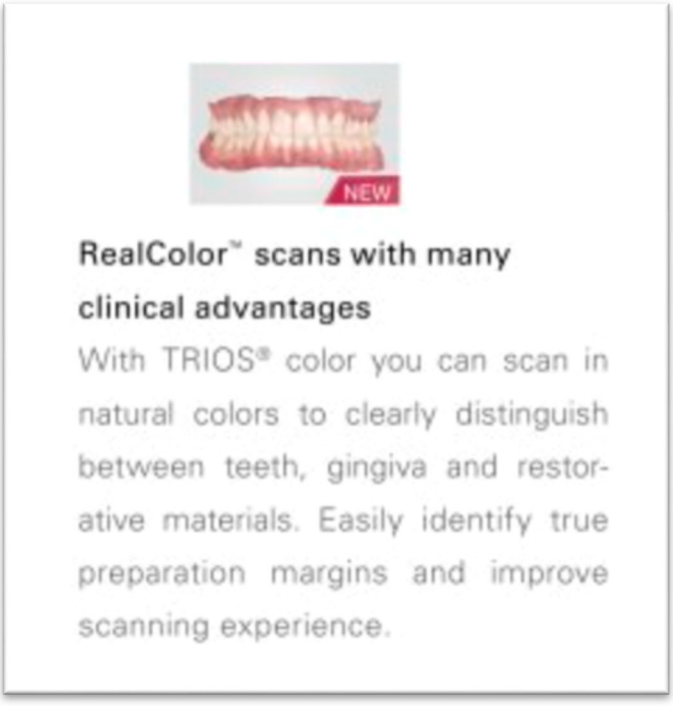
Scanning has never been easier
Easily move along the teeth as the scanner captures the impression in real time. No need to hold the scanner at a specific distance or angle for focus.
Autoclaveable tip with anti-mist heater
Achieve optimal hygiene and meet clinical requirements. The integrated anti-mist heater automatically ensures an optimal temperature for undistorted and crystal clear scanning.

(*Id.*)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(*Id.*)


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3Shape TRIOS® is not just about impression-taking. TRIOS® realizes full digital workflows opening new clinical possibilities and business opportunities - starting from the patient's visit in the clinic and ending with completed treatment.
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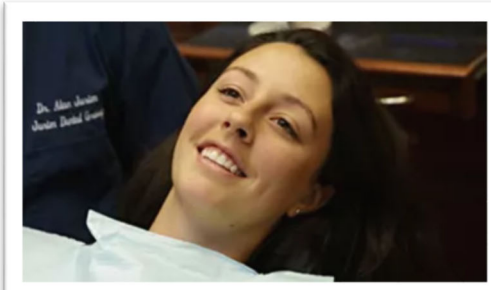
2. Scanning
3. Clinical validation
4. Send digital impression
5. CAD design
6. Preview design
7. Manufacturing
8. Seat restoration

(*Id.*)



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The accuracy of digital impressions and the resulting crowns means a much better fitting restoration. The accuracy also cuts down on the need for remakes. So patient-visits are quicker and they don't have to come back for adjustments. Also if you're practicing same day dentistry you're eliminating second visits. So besides patient comfort, digital speed and accuracy are huge advantages.

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When you factor in the time savings, in terms of scanning, design, and production, digital dentistry is just a more efficient way to work.

(*See, e.g.*, Interview with 3Shape founder, Tais Clausen (3Shape website, available at https://www.3shape.com/en/news/2015/why-your-patients-love-digital-technology.)

84. The publicly filed decision of the International Trade Commission in *In re Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091 (Dec. 19, 2020), further confirms that 3Shape's intraoral scanners, when used in conjunction with the associated Dental System software, satisfy the elements of the '152 Patent. That decision found that "TRIOS 'associates' the depth data and the color data[.]" *Id.* at 51. This finding, and the other findings in the ITC opinion, confirm that 3Shape's scanners infringe at least claim 1 of the '152 Patent.

85. 3Shape has directly infringed the '152 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '152 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

86. Additionally, 3Shape has actively induced infringement of the '152 Patent under 35 U.S.C. § 271(b). On information and belief, at least as of the date upon which it learned of the '152

Patent (which was no later than the date this Complaint was served), 3Shape induced, with specific intent, infringement of the '152 Patent by its customers. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

87. 3Shape also has been and is now contributing to the infringement of one or more claims of the '152 Patent, either literally or under the doctrine of equivalents.

88. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '152 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products is especially made and/or especially adapted for use in infringement of the '152 Patent. 3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '152 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists,

orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

89. 3Shape has willfully infringed the '152 Patent. On information and belief, at least as of the date upon which it learned of the '152 Patent (which was no later than the date this Complaint was served), 3Shape has known of the '152 Patent, and after acquiring that knowledge, 3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

90. 3Shape's acts of infringement have injured Align.

91. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

COUNT FIVE – INFRINGEMENT OF THE '609 PATENT

92. Align incorporates by reference its allegations in Paragraphs 1-91 as if fully restated in this paragraph.

93. On March 16, 2021, the USPTO lawfully issued the '609 Patent, entitled "Systems and Methods for Accounting for Changes in Surface Topology When Scanning a Patient's Teeth." Align is the sole owner of the '609 Patent and of all rights of recovery thereunder for past and future infringement.

94. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '609 Patent by practicing the patented method and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '609 Patent.

95. By way of illustration only, 3Shape's TRIOS scanner and associated Dental System software products meet each and every element of claim 12 of the '609 Patent.

96. The TRIOS scanner and associated Dental System software products constitute a "system for accounting for changes in surface topology when scanning a patient's teeth for a dental procedure." That system comprises "an intraoral scanner" as well as "a computer readable medium including instructions that when executed by a computer system, causes the computer system to: [1] receive first scan data of a first surface portion and a second surface portion of the patient's intraoral cavity from the hand-held intraoral scanner, the first surface portion having a first surface topology, the first scan data associated with a first plurality of captured images of the patient's intraoral cavity; [2] display a first model of the patient's intraoral cavity, wherein the first model of the patient's intraoral cavity is based on the received first scan data of the patient's teeth and comprises surface data representative of the first surface portion and the second surface portion; [3] receive user input, via the displayed first model, demarcating the surface data representative of the first surface portion and the surface data representative of the second surface portion; [4] receive second scan data of the patient's intraoral cavity from the hand-held intraoral scanner, the second scan data including surface data of the first surface portion, the second scan data associated with a second plurality of captured images of the patient's intraoral cavity; [5] update the first model by modifying only at least a portion of the surface data representative of the first surface portion according to the user input using at least a portion of the second scan data of the patient's intraoral cavity including the first surface portion; and [6] output the updated first model of the patient's teeth with the at least the portion of the surface data updated using the received second scan data." '609 Patent, col. 31 ln. 36 – col. 32 ln. 3.

97. 3Shape's marketing materials illustrate how 3Shape's TRIOS scanner, in conjunction with the related Dental System software products, satisfies all elements of claim 12 of the '609

Patent. By way of example only, 3Shape's video entitled "TRIOS® – Scan Strategy – Bite,"[2] shows that 3Shape's TRIOS intraoral scanner and associated software contains the infringing functionality. The TRIOS scanner is used to generate a first virtual model of the intraoral cavity, and that model is shown on the user's display. Users are advised to "avoid bubbles of saliva being scanned onto the occlusal surface," as "thick saliva and air bubbles will result in incorrect scanning of the molar surface." If the user "should accidentally scan one or more of these aforementioned artifacts," they can use the Dental System software products to "simply trim away the artifacts." Then, after the user cleans the patient's teeth, they can use the TRIOS scanner to "re-scan that area." The software then modifies the first 3D intraoral scan data by replacing the deficient portion of the original scan with the second 3D intraoral scan data.

98. The publicly filed initial determination of the International Trade Commission in *In re Certain Dental and Orthodontic Scanners and Software,* Inv. No. 337-TA-1144 (April 30, 2020), confirms that 3Shape's intraoral scanners, when used in conjunction with the Dental System software (including specifically 3Shape's TRIM tool), satisfy the elements of the '609 Patent. That decision found that "TRIOS displays an image of the first virtual model," which is "displayed on the computer screen connected to the TRIOS scanner." *Id.* at 198-99. That "first virtual model generated from this 3D scan data may have some area that the user does not like, and the user can erase that area using the TRIM tool." *Id.* at 200. 3Shape's "technical documents describe deleting the marked area from the model and, after trimming, the user can continue scanning on the rest of the model." *Id.* at 197-98. Thus, "a user of the TRIM tool identifies and removes an inaccuracy in the first virtual model and then replaces that portion by rescanning in order to end up with a unified or modified whole virtual model." *Id.* at 197. These findings, and the other findings in the ITC opinion, confirm that 3Shape's scanners infringe at least claim 17 of the '609 Patent.

[2] Available at https://www.youtube.com/watch?v=hIP1CbFnFPU.

99. 3Shape has directly infringed the '609 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '609 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

100. Additionally, 3Shape has actively induced infringement of the '609 Patent under 35 U.S.C. § 271(b). On information and belief, at least as of the date upon which it learned of the '609 Patent (which was no later than the date this Complaint was served), 3Shape induced, with specific intent, infringement of the '609 Patent by its customers. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

101. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '609 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products, or a component thereof, is especially made and/or especially adapted for use in infringement of the '609 Patent. 3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products, or a component thereof, is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to,

resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '609 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

102. 3Shape has willfully infringed the '609 Patent. On information and belief, at least as of the date upon which it learned of the '609 Patent (which was no later than the date this Complaint was served), 3Shape has known of the '609 Patent, and after acquiring that knowledge, 3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

103. 3Shape's acts of infringement have injured Align.

104. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

COUNT SIX – INFRINGEMENT OF THE '936 PATENT

105. Align incorporates by reference its allegations in Paragraphs 1-104 as if fully restated in this paragraph.

106. On October 6, 2020, the USPTO lawfully issued the '936 Patent, entitled "Methods and Systems for Creating and Interacting With Three Dimensional Virtual Models." Align is the sole owner of the '936 Patent and of all rights of recovery thereunder for past and future infringement.

107. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '936 Patent by practicing the patented method and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '936 Patent.

108. By way of illustration only, 3Shape's TRIOS scanner and associated Dental System software products meet every element of claim 1 of the '936 Patent.

109. 3Shape's TRIOS Scanner, in conjunction with the associated Dental System software products, constitute a "system for scanning a patient's teeth for a dental procedure." That system comprises "a hand-held intraoral scanner," as well as "a computer readable medium including instructions that when executed by a computer system, cause the computer system to: [1] receive first scan data of the patient's teeth from the hand-held intraoral scanner; [2] display, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth; [3] receive user input defining a portion of the model to be removed; [4] remove, from the displayed model, a removed surface portion of the model to be removed according to the user input; [5] receive second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity; [6] replace at least a portion of the removed surface portion of the model using the receive second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity; and [7] output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the received second scan data." '936 Patent col. 30, ln 24-50.

110. 3Shape's marketing materials illustrate how 3Shape's TRIOS scanner, in conjunction with the related Dental System software products, satisfies all elements of claim 1 of the '936 Patent.

By way of example only, 3Shape's video entitled "TRIOS® – Scan Strategy – Bite[3] shows that 3Shape's TRIOS intraoral scanner and associated software contains the infringing functionality. The TRIOS scanner is used to generate a first virtual model of the intraoral cavity, and that model is shown on the user's display. Users are advised to "avoid bubbles of saliva being scanned onto the occlusal surface," as "thick saliva and air bubbles will result in incorrect scanning of the molar surface." If the user "should accidentally scan one or more of these aforementioned artifacts," they can use the Dental System software products to "simply trim away the artifacts." Then, after the user cleans the patient's teeth, they can use the TRIOS scanner to "re-scan that area." The software then modifies the first 3D intraoral scan data by replacing the deficient portion of the original scan with the second 3D intraoral scan data.

111. The publicly filed initial determination of the International Trade Commission in *In re Certain Dental and Orthodontic Scanners and Software,* Inv. No. 337-TA-1144 (April 30, 2020), confirms that 3Shape's intraoral scanners, when used in conjunction with the Dental System software (including specifically 3Shape's TRIM tool), satisfy the elements of the '936 Patent. That decision found that "TRIOS displays an image of the first virtual model," which is "displayed on the computer screen connected to the TRIOS scanner." *Id.* at 198-99. That "first virtual model generated from this 3D scan data may have some area that the user does not like, and the user can erase that area using the TRIM tool." *Id.* at 200. 3Shape's "technical documents describe deleting the marked area from the model and, after trimming, the user can continue scanning on the rest of the model." *Id.* at 197-98. Thus, "a user of the TRIM tool identifies and removes an inaccuracy in the first virtual model and then replaces that portion by rescanning in order to end up with a unified or modified whole virtual model." *Id.* at 197. These findings, and the other findings in the ITC opinion, confirm that 3Shape's scanners infringe at least claim 1 of the '936 Patent.

[3] Available at https://www.youtube.com/watch?v=hIP1CbFnFPU.

112. 3Shape has directly infringed the '936 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '936 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

113. Additionally, 3Shape has actively induced infringement of the '936 Patent under 35 U.S.C. § 271(b). On information and belief, at least as of the date upon which it learned of the '936 Patent (which was no later than the date this Complaint was served), 3Shape induced, with specific intent, infringement of the '936 Patent by its customers. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

114. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '936 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products, or a component thereof, is especially made and/or especially adapted for use in infringement of the '936 Patent. 3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products, or a component thereof, is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to,

resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '936 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

115. 3Shape has willfully infringed the '936 Patent. On information and belief, at least as of the date upon which it learned of the '936 Patent (which was no later than the date this Complaint was served), 3Shape has known of the '936 Patent, and after acquiring that knowledge, 3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

116. 3Shape's acts of infringement have injured Align.

117. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

COUNT SEVEN - INFRINGEMENT OF THE '527 PATENT

118. Align incorporates by reference its allegations in Paragraphs 1-117 as if fully restated in this paragraph.

119. On July 14, 2020, the USPTO lawfully issued the '527 Patent, entitled "Method of Manipulating a Dental Virtual Model, Method for Creating Physical Entities Based on a Dental Virtual Model Thus Manipulated, and Dental Models Thus Created." Align is the sole owner of the '527 Patent and of all rights of recovery thereunder for past and future infringement.

120. 3Shape has directly, literally under 35 U.S.C. § 271(a), and/or equivalently under the doctrine of equivalents, infringed the '527 Patent by practicing the patented method and by making, using, selling, offering for sale, and/or importing into the United States, without authority, the Accused Products. The Accused Products meet each and every element of one or more claims of the '527 Patent.

121. By way of illustration only, 3Shape's TRIOS scanner and associated Dental System software products meet each and every element of claim 12 of the '527 Patent.

122. The TRIOS scanner and associated Dental System software products constitute a "system for scanning obstructed intraoral structures of a patient." That system comprises "a hand-held intraoral scanner . . . configured to focus light onto an intraoral structure" as well as "a computer having instructions that, when executed, cause the system to: [1] scan, using the hand-held intraoral scanner, the intraoral structure of a patient to generate first 3D data of the surface of the intraoral structure of the patient; [2] generate a 3D virtual model of the intraoral structure of the patient based on the first 3D data; [3] determine a missing portion of the 3D virtual model that are missing a portion of the intraoral structure of the patient; [4] generate second 3D data representing the intraoral structure of the missing portion of the 3D virtual model; [5] combine the second 3D data with the 3D virtual model such that the 3D virtual model includes a representation of the intraoral structure in place of the missing portion." '527 Patent, col. 14, ln. 41-63.

123. 3Shape's marketing materials illustrate how 3Shape's TRIOS scanner, in conjunction with the related Dental System software products, satisfies all elements of claim 12 of the '527 Patent. By way of example only, 3Shape's video entitled "TRIOS® - Postprocessing,"[4] shows that 3Shape's TRIOS intraoral scanner and associated software contains the infringing functionality. The TRIOS scanner is used to generate a first virtual model of the intraoral cavity, and that model is

[4] Available at https://www.youtube.com/watch?v=haxhHFKi0II.

previewed on the user's display. Before the 3D virtual model is finalized, it goes through a post-processing procedure. In the post-processing step, the system employs "more advanced algorithms" on the collected 3D data to "bring out more detail" in the model. This is advantageous to ensure that the "lab will always have the maximum level of detail to work on." On information and belief, the post-processing step optimize the 3D virtual model and closes holes within the model. The post-processing step may be manually started by the user. However, every 3D model is "automatically processed during the sending procedure." 3Shape's post-processing step is particularly critical to be able to place a margin line. *Cf.* '527 patent, col. 6, ln. 47-50 ("A computer-based method for manipulating a virtual dental model, particularly useful for defining a finish line (also referred to herein as 'margin line'), according to the invention is illustrated in FIG. 1.").

124. 3Shape has directly infringed the '527 Patent, including by making, selling, offering for sale in the United States, and importing into the United States products that contain the system disclosed in the '527 Patent. Further, 3Shape uses the patented system, and practices the patented method, as it tests its infringing product prior to marketing and selling the product.

125. Additionally, 3Shape has actively induced infringement of the '527 Patent under 35 U.S.C. § 271(b). On information and belief, at least as of the date upon which it learned of the '527 Patent (which was no later than the date this Complaint was served), 3Shape induced, with specific intent, infringement of the '527 Patent by its customers. 3Shape specifically intends for its customers, including dentists and orthodontists, to infringe the '527 patent by using 3Shape's TRIOS scanner, in conjunction with the related Dental System software products. 3Shape encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and/or technical materials to its customers.

126. 3Shape has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '527 Patent by selling or offering to sell the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products within the United States and/or by importing the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products into the United States, with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or associated Dental System software products, or a component thereof, is especially made and/or especially adapted for use in infringement of the '527 Patent. 3Shape has contributed to the infringement by others with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products is a material part of the patented invention, and with knowledge that the infringing technology in the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products, or a component thereof, is not a staple article of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products and components thereof do not have any substantial non-infringing uses. 3Shape has such knowledge at least because the claimed features of the '527 Patent are used by other including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the TRIOS, TRIOS 3, TRIOS 4, and/or the associated Dental System software products.

127. 3Shape has willfully infringed the '527 Patent. On information and belief, at least as of the date upon which it learned of the '527 Patent (which was no later than the date this Complaint was served), 3Shape has known of the '527 Patent, and after acquiring that knowledge,

3Shape has continued to infringe the patent through conduct that 3Shape knew or should have known amounted to infringement of the patent.

128. 3Shape's acts of infringement have injured Align.

129. 3Shape's wrongful conduct has caused Align to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and importing the patented inventions. On information and belief, 3Shape will continue these infringing acts unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Align respectfully requests that this Court:

a. enter a judgment that Align is the owner of all right, title, and interest in and to the patents-in-suit, together with all the rights of recovery under such patents for past and future infringement thereof;

b. enter a judgment that 3Shape has infringed each of the asserted patents;

c. enter a judgment that the patents-in-suit are valid and enforceable;

d. permanently enjoin 3Shape, their parents, subsidiaries, affiliates, agents, servants, employees, attorneys, representatives, successors and assigns, and all others in active concert or participation with them from infringing the asserted patents;

e. order an award of damages to Align in an amount adequate to compensate Align for 3Shape's infringement, said damages to be no less than a reasonable royalty;

f. enter a judgment that the infringement was willful and treble damages pursuant to 35 U.S.C. § 284;

g. order an accounting to determine the damages to be awarded to Align as a result of 3Shape's infringement, including an accounting for infringing sales not presented at trial and award additional damages for any such infringing sales;

h. assess pre-judgment and post judgment interest and costs against 3Shape, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

i. render a finding that this case is "exceptional" and award to Align its costs, expenses and reasonable attorneys' fees, as provided by 35 U.S.C. § 285; and

j. grant such other and further relief as the Court may deem proper and just.

DEMAND FOR A JURY TRIAL

Align hereby respectfully requests a trial by jury of all issues so triable, pursuant to FED. R. CIV. P. 38.

Dated: April 26, 2021

By: */s/ Faye E. Paul*

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