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

ALIGN TECHNOLOGY, INC., Plaintiff, v. CLEARCORRECT OPERATING, LLC, CLEARCORRECT HOLDINGS, INC., & INSTITUT STRAUMANN AG, Defendants	Case No. 6:24-cv-00187 **JURY TRIAL DEMANDED** **RELATED CASE**

COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

Align Technology, Inc. ("Align") files this Complaint against ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc. (collectively, "ClearCorrect"), and Institut Straumann AG ("Straumann") and alleges as follows:

NATURE OF THE ACTION

1. Align pioneered innovative systems for correcting malocclusion (or teeth and jaw misalignment) in patients as young as six years old, including teeth straightening, jaw advancement, and bite-correction. Over the past two decades, Align has enabled dental professionals to deliver malocclusion care to over 17 million patients with Align's acclaimed Invisalign® system. Through investments in research and development of over $2 billion, Align has developed and patented specialized tri-layer plastics, software, and end-to-end tools for digital dentistry.

2. Founded ten years after Align, ClearCorrect also sells malocclusion solutions. But unlike Align, ClearCorrect did not develop its technologies independently. By 2011, ClearCorrect's copying and ongoing infringement of Align's patents left Align no choice but to file suit. The resulting litigation spanned nearly a decade, two continents, and multiple courts. It

persisted even after a federal district court granted summary judgment that ClearCorrect had infringed one of Align's patents and after the U.S. International Trade Commission ruled in Align's favor on infringement. Facing the threat of a jury trial in the spring of 2019, ClearCorrect and Straumann Holding AG (the parent company of Straumann, which also owns ClearCorrect, DrSmile, and many other dental companies as wholly owned subsidiaries) agreed to a $51 million settlement with Align to end the litigation.

3. Post-settlement, however, ClearCorrect's misconduct continues. For example, ClearCorrect and Straumann have created and distributed advertising that misleads consumers into believing its copycat aligners are superior to Align's. In one advertisement, ClearCorrect and Straumann juxtapose an apparently unstained ClearCorrect aligner with a bright yellow stained Align aligner, after allegedly soaking both in mustard for 24 hours. But consumers do not typically soak aligners in mustard for 24 hours, let alone eat mustard for 24 hours straight, and staining is not a common problem with Align's aligners. Nonetheless, the advertisement falsely suggests that wearing Align's aligners will make one's teeth appear hideously discolored.

4. Moreover—and unknown to Align—ClearCorrect never abandoned its strategy of infringing Align's patents. Shortly after the 2019 settlement, Straumann acquired Bay Materials LLC ("Bay Materials"), a former Align supplier. The acquisition followed Bay Materials' 2018 release of a tri-layer plastic called "Zendura FLX." In 2020, ClearCorrect rebranded Zendura FLX as "ClearQuartz" and began using Zendura FLX in its aligners. ClearCorrect's tri-layer ClearQuartz aligners infringe multiple Align patents.

5. Nor did ClearCorrect stop with plastics. In 2020, after a Straumann entity hired a former Align senior software engineer, ClearCorrect introduced its new "ClearPilot" treatment planning software, which works in tandem with its "Cut and Stage" software. In advertisements for ClearPilot, ClearCorrect and Straumann tout advanced treatment planning features that Align developed and patented first. ClearCorrect's treatment planning software infringes multiple Align patents.

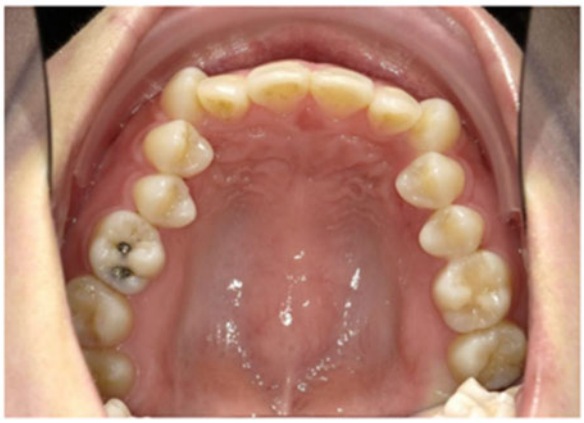
6. Beyond tri-layer plastics and treatment planning software, ClearCorrect and Straumann also have promoted digital dentistry tools like Align's. For example, they advertise an intraoral scanner system for scanning and rescanning patient teeth as an alternative to preparing a physical mold by biting into dental putty. That system infringes at least one Align patent.

7. ClearCorrect and Straumann are welcome to compete for sales of orthodontic treatments, but they must do so by accurately advertising their products and by developing and selling their own technology—not by disparaging and copying Align's. As prior litigation did not deter ClearCorrect and Straumann from violating Align's intellectual property rights, Align again files suit for just compensation and injunctive relief.

BACKGROUND

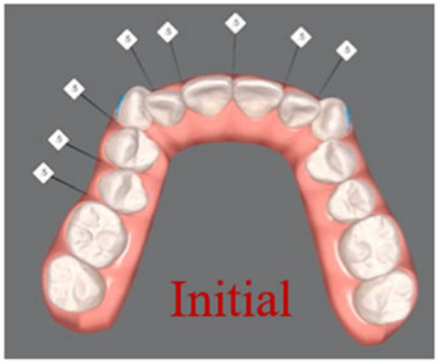
Align's Invisalign® System

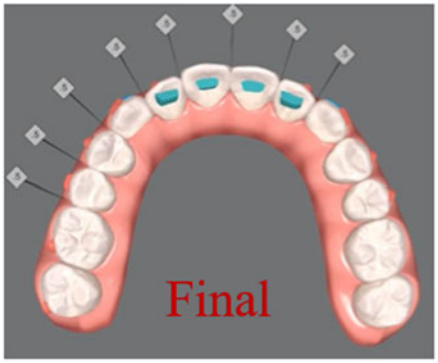
8. Align's Invisalign® system allows orthodontists and dentists (collectively "doctors") to treat the improper alignment of teeth and bites, or "malocclusion," using a series of custom-manufactured aligners. The Invisalign® system corrects malocclusion with clear trays that can be removed, allowing consumers to keep brushing, eating, and enjoying their lives as they normally would without the inconvenience and discomfort of traditional braces. When inserted, the Invisalign® tray applies a low constant force on precise parts of teeth that gradually and safely move the teeth into a desired position. The following images show an exemplary patient's teeth before and after treatment with Invisalign®:



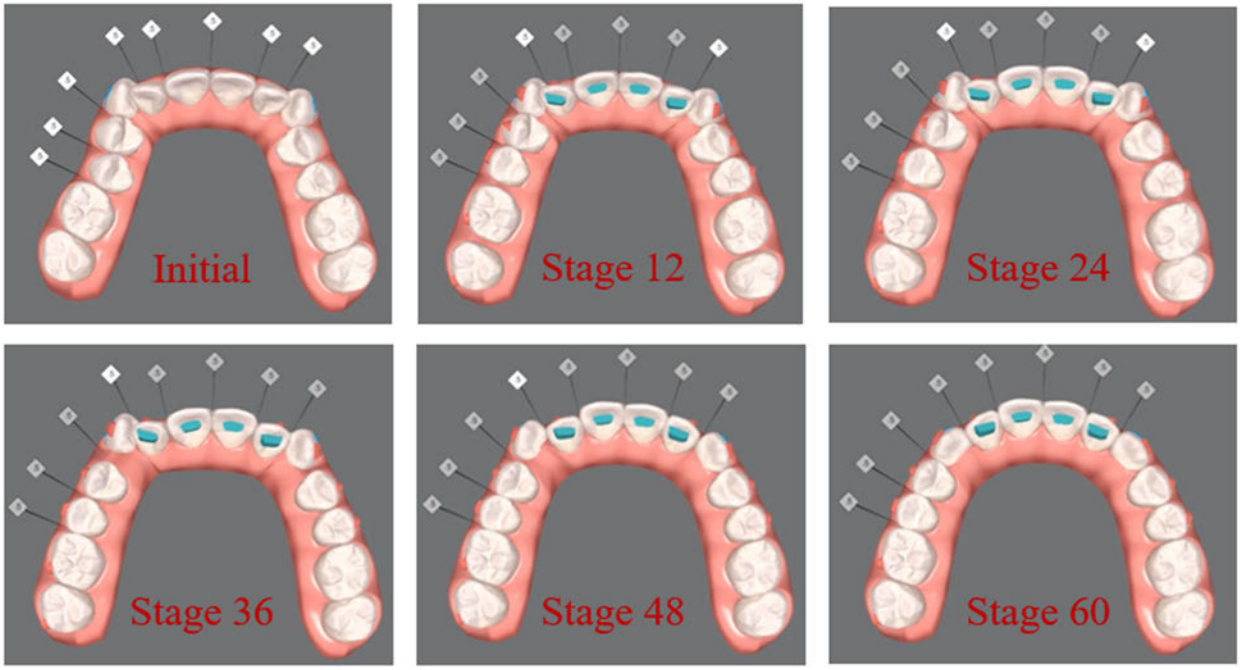
9. To obtain Invisalign® treatment, a patient meets with a doctor for an initial consultation. The treating doctor takes a scan or impression of a patient's teeth using an intraoral scanner like Align's iTero® device or with a material such as polyvinyl siloxane to obtain 3D profiles of the upper and lower tooth arch. The doctor then prescribes custom-manufactured Invisalign® aligners as appropriate.

10. Creating the aligners involves several steps. First, Align uses the 3D profiles to create a digital treatment plan based on the treating doctor's prescription, which includes intermediate and final positions of the teeth, specific aligner features to apply a desired force system on specific locations of a tooth for precise tooth movement, and other procedures to achieve the desired outcome. To do so, Align uses proprietary, state-of-the-art software based on its history of treating 17 million patients to identify and segment each of the patient's teeth. Taking into account the treating doctor's instructions and preferences, Align's software proposes the desired final positions. The following images depict digital representations of the teeth above in their initial (left) and desired final (right) positions:

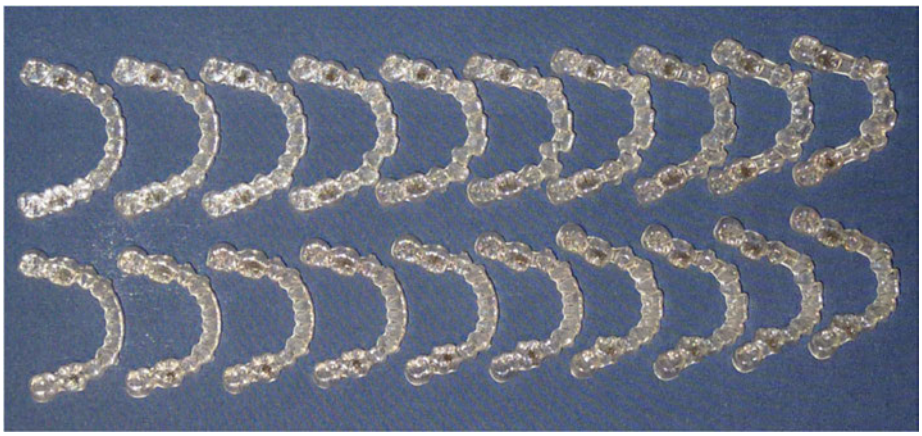




11. Based on the initial and final positions, Align then creates an individualized treatment plan for that patient using its specialized software. The software outputs intermediate steps, or "stages," reflecting planned, incremental movements by each tooth during treatment. Each stage may reflect movements (such as lateral movement, translation, tipping, rotation, etc.) down to less than 0.25 millimeter—smaller than the period at the end of this sentence. For example, several stages of a treatment plan for the above teeth are shown below:



12. After Align creates a treatment plan, Align provides that plan to the treating doctor for approval through its ClinCheck software. The doctor can modify the plan as they see fit. Once the doctor approves the treatment plan, Align manufactures the aligners. An exemplary set of aligners (every fifth stage) is shown below:



13. Since Align introduced its Invisalign® system in 1999, doctors have used it to treat more than 17 million patients suffering from malocclusion.

Align's Proprietary Invisalign® Technologies

14. Align's acclaimed Invisalign® system is the result of decades of research and development by Align. Align has invested over $2 billion in developing its Invisalign® system,

and its research and development expenses now exceed $250 million per year. Align also employs thousands of material scientists, biomechanical engineers, software engineers, doctors, and other research and development professionals in the U.S. and abroad.

15. Align's research and development has led to substantial improvements in its Invisalign® system. Align now makes most of its aligners from a proprietary, three-layer material called SmartTrack®, rather than a single-layer plastic. Its SmartStage® software can calculate treatment plans for complex malocclusions and design treatment plans for over 90% of malocclusions, including via advanced round-tripping and staggering approaches. And Align's Digital Platform—an end-to-end integrated solution for digital dentistry and orthodontics—integrates the iTero® intraoral scanners with its Invisalign® system so that doctors no longer need to take molds of their patients' teeth using impression kits to provide Invisalign® treatment. Instead, doctors now can scan their patients' teeth and then conveniently submit digital models of their patients' teeth to Align for treatment planning. These technologies are discussed in detail below.[1]

SmartTrack®: Align's Three-Layer Plastic Aligners

16. Treatment with clear aligner therapy requires use of the right material. The ideal material must be capable of applying a constant force to move the teeth, be durable enough for the patient's use for up to two weeks, and be clear. Align has spent years perfecting its proprietary aligner materials. At first, Align made its aligners from a single-layer plastic called PC30. To improve its aligners' performance, Align then switched to another plastic called EX30. Although its EX30 aligners were a success, Align began collaborating with Bayer MaterialScience AG in 2006 to develop even better, next-generation materials. After years of testing more than 260 different plastics, the collaboration led to a breakthrough: aligners made from a new, three-layer material called "SmartTrack®." This new material has two soft, polyurethane outer layers that touch a patient's gums, teeth, and lips, and a hard co-polyester

[1] The Invisalign System includes additional features, such as SmartForce attachments, that currently are beyond the scope of this case.

inner layer. Aligners made from the SmartTrack® material have superior elasticity, force retention, durability, comfort, and thermoformability, and they lead to better clinical outcomes than aligners made from EX30.

17. Around the same time that Align was developing its new, three-layer aligners, ClearCorrect was copying Align's clear aligner product. In 2008, ClearCorrect submitted a 510(k) Premarket notification to the FDA for its own aligners.[2] A 510(k) Premarket notification seeks FDA clearance to market a medical device that is substantially equivalent to an already-cleared "predicate device."[3] If the FDA agrees that the proposed and predicate devices are "substantially equivalent," it approves the applicant's marketing of the proposed device under the 510(k) regulatory pathway.[4] The abbreviated 510(k) pathway allows applicants to bypass the FDA's more onerous pre-market approval process, which requires clinical trials.[5] Based on ClearCorrect's characterization of its aligners as "essentially identical" to Align's predicate, patent-protected "Invisalign[®]/Align System," the FDA cleared ClearCorrect's aligners for sale.[6]

18. After Align switched to its three-layer, SmartTrack® aligners, ClearCorrect similarly pivoted to a three-layer product. On information and belief, ClearCorrect now manufactures its aligners using a three-layer ClearQuartz plastic.[7] ClearCorrect purchases the plastic for those aligners from Align's old supplier, Bay Materials, now a member of the Straumann Group.[8] On information and belief, ClearCorrect also conducts competitive

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[2] *See* Ex. 10.
[3] *Premarket Notification 510(k)*, FDA (October 3, 2022), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k.
[4] *Id.*
[5] *Id.*; *Premarket Approval (PMA)*, FDA (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.
[6] *See* Ex. 10 at 1-2, 4.
[7] DrSmile, which operates abroad, sells aligners made from the same, three-layer ClearQuartz plastic. *See technology*, DrSmile (2023), https://drsmile.co.uk/aligner/technology/.
[8] *See Aligner Material – FAQs*, ClearCorrect (May 3, 2023), https://support.clearcorrect.com/hc/en-us/articles/204800937-Aligner-Material-FAQs.

intelligence on Align, including studying its sales strategies for aligners.[9] As before, ClearCorrect secured regulatory approval for its new, three-layer aligners under the FDA's abbreviated 510(k) pathway by arguing substantially equivalence to Align's Invisalign® system.[10] ClearCorrect's three-layer aligners and their manufacture practice Align's U.S. Patent Nos. 10,973,613, 11,154,384, 11,648,090, and 11,648,091.

SmartStage®: Align's Innovative Treatment Planning Software

19. Since its founding in 1997, Align also has pioneered software for precisely staging when and how each patient's teeth should move during treatment with aligners. This process, also referred to as "treatment planning," dictates the shapes of the custom aligners necessary to treat each patient. Devising a treatment plan requires determining the speed, order, and trajectory along which each of a patient's teeth (usually thirty-two teeth) should move in three dimensions while also accounting for every other tooth's position and future movements. Getting speed right matters because, among other reasons, moving teeth too quickly can result in devitalization (tooth death), detachment, or additional problems. The planned order of movement must avoid collisions that would prevent proper, safe, and effective treatment. For example, some treatment plans require "staggering" teeth movement wherein one tooth moves only after another does so. And if determining trajectories for each tooth in relation to every other tooth was not complicated enough, some cases also require moving a first tooth out of the way of a second tooth before the first tooth proceeds to its final position through a process called "round-tripping."

20. Solving these problems with software required years of research and development by Align, including analyzing millions of Invisalign® treatments. In 2006, nearly a decade after its founding, Align filed for patent protection of critical advancements in treatment planning, including certain kinds of round-tripping and staggering. These advancements provided major benefits to patients. Among other things, they allowed doctors to treat complex malocclusion

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[9] *Bay Materials LLC v. 3M Company*, No. 21-cv-01610-RGA-JLH, Dkt. No. 92-3 at 239-244 (D. Del. Mar. 17, 2022).
[10] *See* Ex. 12 at 1, 4-5.

cases without resorting to conventional means of collision avoidance, such as filing down the sides of their patients' teeth (using a process known as interproximal reduction) or even removing teeth entirely. Align received patents covering these and other innovations, including its asserted U.S. Patent Nos. 8,038,444, 10,456,217, 10,524,879, and 11,369,456.

21. In this arena, too, ClearCorrect imitated Align. In 2005, the founder and former chairman and CEO of Align founded a company called OrthoClear, which manufactured clear aligners designed by former Align employees in Pakistan.[11] Pursuant to a global settlement with Align in 2006, OrthoClear ceased operations and transferred its intellectual property and customers' patients to Align.[12] Some of those former Align employees nevertheless proceeded to work for a company called ClearCorrect Pakistan, which for years supplied treatment plans to ClearCorrect in the United States.[13]

22. Just a few years later, Align sued ClearCorrect for patent infringement related to other treatment planning software.[14] It was only after the ITC found that ClearCorrect infringed Align's patents and a district court granted Align summary judgment of infringement that ClearCorrect settled with Align for $51 million.

23. Today, ClearCorrect's treatment planning software has similar features to Align's treatment planning software, including the ability to treatment plan with round-tripping and staggering. ClearCorrect advertises treatment planning with "round tripping" on its website,[15] and a video on its YouTube channel shows its ClearPilot software animating a treatment plan that includes staggering.[16] As shown in the below stills, the video depicts a red-circled tooth moving only after other blue- and green-circled teeth move:

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[11] *See, e.g.*, *Align Technology, Inc. v. Int'l Trade Com'n*, 771 F.3d 1317, 1319 (Fed. Cir. 2014).
[12] *Id.* at 1319–20.
[13] *See, e.g.*, *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-833 (Commission Opinion Apr. 10, 2014) at 5–6 (Terminated)
[14] *See Align Technology, Inc. v. ClearCorrect, Inc. et al.*, No. 11-cv-00695 (S.D. Tex.).
[15] *See Treatment Preferences*, ClearCorrect (Oct. 20, 2023), https://support.clearcorrect.com/hc/en-us/articles/4416586057495-Treatment-Preferences.
[16] *ClearPilot features: The Control is in Your Hands*, ClearCorrect (Jan. 25, 2021), https://www.youtube.com/watch?v=DYVS21zqH0c.

24. In a 510(k) Premarket notification to the FDA in 2022, ClearCorrect also admitted that "[t]he software used by technicians internal to ClearCorrect is . . . functionally equivalent to the software of the Primary Predicate [Align's Invisalign® system],"[17] which can treatment plan with both staggering and round-tripping.

Align's Intraoral Scanner Technology

25. In addition to pioneering three-layer aligners and advanced treatment planning, Align integrated its Invisalign® system with certain intraoral scanners. Align's iTero® intraoral scanner system, for example, lets doctors create 3D models of their patients' teeth and then electronically transmit those models to Align for use in treatment planning. Intraoral scanning is faster and more accurate than the conventional method of a doctor casting a patient's teeth. For example, it also allows for restorative scanning workflows that limit undesirable scan data due to changing clinical conditions. Additionally, it is more flexible: if the obtained scan data is imperfect or undesirable for any reason, the doctor can rescan part of a patient's mouth and

[17] Ex. 12 at 8.

integrate the new data into the existing scan before sending it to Align. Align's asserted U.S. Patent No. 10,791,936 covers scanning and rescanning workflows to limit imperfect or undesirable scan data.

26. As with Align's other technologies relating to its Invisalign® system, ClearCorrect and Straumann promote an infringing alternative, the Virtuo Vivo intraoral scanner system. ClearCorrect and Straumann advertise that system to doctors in this District and elsewhere in the U.S. for use in connection with treatment planning for ClearCorrect aligners.[18] Straumann even solicits orders for the Virtuo Vivo intraoral scanner system on its website.[19] Like Align's iTero® scanner system, the Virtuo Vivo intraoral scanner system also employs workflows involving scanning and rescanning to limit imperfect or undesirable scan data.

Align's Complimentary Technologies

27. Align's intraoral scanner, treatment planning, and aligner material technologies are more than the sum of their parts. Because aligners treat malocclusion by pushing, pulling, and turning teeth into alignment with the aligners' shapes, high-quality aligner treatment requires that (1) the aligners' shapes accurately and precisely define how and where a patient's teeth should move and (2) the aligners' mechanical properties safely and effectively move a patient's teeth to conform to those desired movements. Align's technologies interoperate to produce aligners satisfying these criteria.

28. Align's innovative scanner technology produces high-quality digital impressions necessary for accurately and precisely defining how and where a patient's teeth should move. Its iTero® Element scanner can capture 6,000 images per second, convert the scan into a digital model visible on a doctor's screen as the scan progresses, and complete a scan in as little as 60

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[18] *How to Submit a Case with a Virtuo Vivo Scanner Tutorial*, ClearCorrect (June 19, 2023), https://support.clearcorrect.com/hc/en-us/articles/4415474813463-How-to-Submit-a-Case-with-a-Virtuo-Vivo-Scanner-Tutorial; *Straumann Virtuo Vivo—Connection to ClearCorrect*, Straumann, https://www.straumann.com/content/dam/media-center/digital/en/training-and-education/intra-oral-scanners/virtuo-vivo/Virtuo%20Vivo%20Connectivity%20%E2%80%93%20Virtuo%20Vivo%20to%20ClearCorrect.pdf.

[19] *Yes, please contact me about this special Virtuo Vivo™ offer*, Straumann (2024), https://www.straumann.com/digital/us/en/home/equipment/io-scanners/virtuo-vivo.html.

seconds. If the doctor's scan is imperfect or undesirable for any reason, Align's technology allows the doctor to rescan part of a patient's mouth and integrate the new data into the existing scan. Align's scanning technology constitutes a significant improvement over conventional, putty-based methods of taking physical molds of patients' teeth.

29. But a high-quality digital impression of a patient's existing jaw is just the beginning of determining how and where a patient's teeth should move for safe and effective treatment. That determination requires calculating a treatment plan for moving a patient's teeth in the correct order, at the correct speeds, along the correct trajectories, and to the correct, desired final positions. Using the initial, high-quality digital impression discussed above, Align's innovative treatment planning technology does exactly that. It computes planned incremental teeth movements down to less than 0.25 millimeters and generates three-dimensional, digital models of intermediate positions reflecting the same. Align's treatment planning technology can even compute advanced treatment plans involving tooth staggering and round-tripping to avoid or reduce collisions between teeth during treatment.

30. Yet even a high-quality treatment plan does not guarantee high-quality treatment: the aligners used as part of a treatment plan must have the right mechanical properties to implement it. Aligners made from Align's advanced SmartTrack® material have the necessary properties for successful patient outcomes. For example, SmartTrack® has sufficient stiffness to apply forces to move teeth as defined by those three-dimensional digital models and does so better than earlier, single-layer materials. Each aligner made from SmartTrack® can move a patient's teeth further than aligners made by less resilient materials. The low, constant forces applied by SmartTrack® aligners also ensure that patients' teeth safely move through bone. Moreover, SmartTrack® provides precise control over whether and how a patient's teeth tip, rotate, extrude, intrude, and move laterally. SmartTrack® aligners can apply low, constant forces on specific parts of a patient's teeth because, unlike single layer aligners, SmartTrack® aligners will not significantly deform when fit to a patient's dentition. Finally, SmartTrack®'s

elastic properties allow patients to insert and remove their aligners comfortably. Align's SmartTrack® aligners therefore provide significant advantages over earlier aligners.

31. Lastly, Align—as the world's largest producer of 3D-printed, custom components—prints molds for each stage developed in the treatment plan and then thermoforms SmartTrack® over those molds to create Invisalign® aligners. Align has prepared aligners for over 17 million patients and has created hundreds of millions of aligners.

32. In sum, Align's advanced scanning and treatment planning technologies allow doctors to define how their patients' teeth should move, and its materials technologies ensure that those patients' teeth safely and effectively perform the defined movements. ClearCorrect and Straumann promote and sell their competing, interoperable technologies in an effort to reap the same benefits provided by Align's technologies.

Straumann and ClearCorrect's False Advertising

33. In addition to copying Align's technology, ClearCorrect and Straumann unfairly compete with Align by using false and misleading advertisements to promote ClearCorrect aligners.

34. For example, on its website, Straumann claims that "ClearCorrect aligners have been proven to be more stain-resistant than the leading aligner brand."[20] It then depicts ClearCorrect aligners alongside aligners bearing Align's trademarks, allegedly after immersing both aligners in coffee and mustard for 24 hours[21]:

[20] *Premier Aligner*, Straumann (2024) https://www.straumann.com/clearcorrect/en/doctors/clearcorrect-aligners.html.
[21] *Id.*

The stylized starburst in the images on the right above indicates that the aligners are Align's. Align's sunburst or starflower mark is registered as U.S. Trademark No. 5,290,579 and appears in U.S. Trademark No. 3,911,988.[22] Align uses the sunburst or starflower mark on its websites and marketing materials.[23]

35. ClearCorrect's website similarly asserts that "[t]he stain-resistance properties" of ClearCorrect's aligners have been "tested against the leading aligner brand," with ClearCorrect's "demonstrated to be more stain resistant."[24] It then provides similar comparison photos:[25]

On information and belief, these photos depict modified Align aligners. The references to the

[22] *See* Exs. 13, 14.
[23] *See, e.g.*, https://www.invisalign.com/.
[24] *ClearCorrect Aligners*, ClearCorrect (March 12, 2024) https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.
[25] *Id.*

"[l]eading [c]ompetitor" and the "leading aligner brand" also unmistakably refer to Align.[26]

36. By advertising misleading images of Align aligners after immersion in mustard and coffee for 24 hours, ClearCorrect and Straumann falsely imply that Invisalign aligners will appear unattractive and stained during normal use. But no reasonable consumer would submerse an aligner in coffee or mustard for 24 hours (or keep mustard or coffee in their mouth for the 22 hours a day that Invisalign® patients wear their aligners), and Align's aligner will not experience the severe staining depicted in ClearCorrect's and Straumann's advertising under normal conditions. To the contrary, Align's instructions for use encourage users to remove their aligners when eating or drinking.[27] ClearCorrect similarly admonishes its users to avoid "hot, sweet, or colored liquids."[28] ClearCorrect's and Straumann's advertisements therefore mislead consumers into believing that Align's aligners are aesthetically inferior and encourages them to select ClearCorrect's aligners instead, to Align's detriment.

37. ClearCorrect and Straumann's advertising misleads consumers to believe that ClearCorrect aligners are aesthetically more pleasing than Align aligners. On information and belief, these false statements drive consumers to select ClearCorrect aligners rather than Align aligners and thereby harm Align.

THE PARTIES

38. Align is a Delaware corporation with its principal place of business at 410 North Scottsdale Road, Suite 1300, Tempe, Arizona.

39. On information and belief, ClearCorrect Operating, LLC is a corporation organized and existing under the laws of Texas, with its principal place of business at 21 Cypress Blvd, Suite 1180, Round Rock, Texas.

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[26] *See Bay Materials, LLC v. 3M Company*, No. 21-cv-01610-RGA, Dkt. 14 at 5 (D. Del. Nov. 22, 2021) (Straumann Holding AG subsidiary Bay Materials referring to Align as having "the largest share of the clear aligner market").

[27] *Use and Care Instructions for Your Invisalign Aligners®*, Align, https://downloads.ctfassets.net/vh25xg5i1h5l/1dq4zXvkZn6neU1VRQ8Wq6/e23a371b1165d096c916dca72c32314b/US_147492_219608-Rev-A_IFU_Patient_NA_PDF.pdf.

[28] *Wear & Care*, ClearCorrect, https://support.clearcorrect.com/hc/article_attachments/360062137794/INV-0111-1.0_Wear__Care_Guide_Booklet_1.pdf.

40. On information and belief, ClearCorrect Holdings, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 21 Cypress Blvd Suite 1180, Round Rock, Texas.

41. On information and belief, Institut Straumann AG is a foreign corporation with its principal place of business at Peter Merian-Weg 12, 4052 Basel, Switzerland.

THE ASSERTED PATENTS

42. The Asserted Patents are U.S. Patent Nos. 10,973,613 (the "'613 patent"), 11,154,384 (the "'384 patent"), 11,648,090 (the "'090 patent"), 11,648,091 (the "'091 patent"), 8,038,444 (the "'444 patent"), 10,456,217 (the "'217 patent"), 10,524,879 (the "'879 patent"), 11,369,456 (the "'456 patent"), and 10,791,936 (the "'936 patent").

43. For each of the Asserted Patents, and to the extent necessary, Align complied with the provisions of 35 U.S.C. § 287 by, for example, selling its aligners and iTero intraoral scanner systems with packaging listing one or more of the Asserted Patents and/or referring consumers to its website, alignteсh.com/patents, which correlates its patents to its products.

The Materials Patents

44. The '613 patent, titled "Multilayer Dental Appliances and Related Methods and Systems," duly and legally issued on April 13, 2021, from U.S. Application No. 15/476,655 and names Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. Align is the owner of all right, title, and interest in and to the '613 patent. A true and correct copy of the '613 patent is attached hereto as Exhibit 1.

45. The '384 patent, titled "Multilayer Dental Appliances and Related Methods and Systems," duly and legally issued on October 26, 2021, from U.S. Patent Application No. 17/214,487 and names Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. Align is the owner of all right, title, and interest in and to the '384 patent. A true and correct copy of the '384 patent is attached hereto as Exhibit 2.

46. The '090 patent, titled "Multilayer Polymer Sheets," duly and legally issued on May 16, 2023, from U.S. Patent Application No. 17/858,825 and names Chunhua Li, Yan Chen,

Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. Align is the owner of all right, title, and interest in and to the ’090 patent. A true and correct copy of the ’090 patent is attached hereto as Exhibit 3.

47. The ’091 patent, titled “Multilayer Polymer Sheets,” duly and legally issued on May 16, 2023, from U.S. Patent Application No. 17/902,445 and names Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. Align is the owner of all right, title, and interest in and to the ’091 patent. A true and correct copy of the ’091 patent is attached hereto as Exhibit 4.

The Treatment Planning Patents

48. The ’444 patent, titled “Automated Treatment Staging for Teeth,” duly and legally issued on October 18, 2011, from U.S. Patent Application No. 11/848,172 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. Align is the owner of all right, title, and interest in and to the ’444 patent. A true and correct copy of the ’444 patent is attached hereto as Exhibit 5.

49. The ’217 patent, titled “Automated Treatment Staging for Teeth,” duly and legally issued on October 29, 2019, from U.S. Patent Application No. 15/834,608 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. Align is the owner of all right, title, and interest in and to the ’217 patent. A true and correct copy of the ’217 patent is attached hereto as Exhibit 6.

50. The ’879 patent, titled “Automated Treatment Staging for Teeth,” duly and legally issued on January 7, 2020, from U.S. Patent Application No. 15/834,649 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. Align is the owner of all right, title, and interest in and to the ’879 patent. A true and correct copy of the ’879 patent is attached hereto as Exhibit 7.

51. The ’456 patent, titled “Automated Treatment Staging for Teeth,” duly and legally issued on June 28, 2022, from U.S. Patent Application No. 16/723,706 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. Align is the owner of all

right, title, and interest in and to the ’456 patent. A true and correct copy of the ’456 patent is attached hereto as Exhibit 8.

The Scanner Patent

52. The ’936 patent, titled “Methods and Systems for Creating and Interacting with Three Dimensional Virtual Models,” duly and legally issued on October 6, 2020, from U.S. Patent Application No. 16/586,528 and names Avi Kopelman as the inventor. Align is the owner of all right, title, and interest in and to the ’936 patent. A true and correct copy of the ’936 patent is attached hereto as Exhibit 9.

JURISDICTION AND VENUE

53. This is a civil action for false advertising under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and for patent infringement under 35 U.S.C. §§ 1, *et seq.*

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

55. This Court has jurisdiction over claims arising under the laws of the State of Texas pursuant to 28 U.S.C. § 1367 because the state claims are so related to the claims over which this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 that they form part of the same case or controversy under Article III of the United States Constitution.

56. This Court has personal jurisdiction over Align’s claims against ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. for false advertising, unfair competition, civil conspiracy, and infringement of every asserted patent because: (1) ClearCorrect Operating, LLC is incorporated in Texas; (2) ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. are headquartered in Texas; and (3) on information and belief, ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. have availed themselves of Texas by regularly and continuously conducting business in this District and throughout Texas, including by committing, and continue to commit, acts of patent infringement in this District and throughout Texas. For example, on information and belief, ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. encourage the use of infringing intraoral scanners by dentists to collect data used to perform

infringing treatment planning methods, perform infringing treatment planning methods, use treatment plans made via the infringing methods, manufacture infringing aligners using infringing methods, and offer for sale and sell the infringing aligners, all at and/or from their headquarters in Round Rock, Texas.

57. The Court also has personal jurisdiction over Align's claims for false advertising, unfair competition, civil conspiracy, and patent infringement against Straumann. Straumann availed itself of Texas through its close contacts with Texas-based ClearCorrect, and its false and misleading advertisement of ClearCorrect aligners, manufacture and sale of those aligners, and inducement of consumers to submit intraoral scans, purchase, and use those aligners all relate to its contacts with ClearCorrect. The Court also has personal jurisdiction over Align's claims against Straumann for infringement of the Materials and Treatment Planning Patents (the '613, '384, '090, '091, '444, '217, '879, and '456 patents) because Straumann reached into Texas and caused ClearCorrect and others to directly infringe those patents there. On information and belief, Straumann: (1) induced and continues to induce ClearCorrect to infringe Align's patents, as explained in paragraphs 71-75, 77-79, 94-95, 97-99, 113-114, 116-118, 136-137, 139-141, 156-157, 159-161, 176-180, 195-199, and 213-217 of this Complaint; (2) aimed its inducement at Texas because that is where ClearCorrect is located; and (3) knew that its inducement would cause ClearCorrect to directly infringe Align's patents in Texas because, again, that is where ClearCorrect is located.

58. The Court also has personal jurisdiction over Align's claims for false advertising, unfair competition, civil conspiracy, and infringement of the Scanner Patent (the '936 patent) against ClearCorrect and Straumann because those claims arise from a common nucleus of operative facts with Align's claims for infringement of its other patents relating to three-layer plastics and treatment planning. As explained in paragraphs 33-37 of this complaint, Straumann's false advertisements unfairly encourage consumers to buy infringing ClearCorrect aligners rather than Align aligners. And as explained in paragraph 26 of this Complaint,

Straumann and ClearCorrect encourage doctors to use the Virtuo Vivo scanner system to submit scans to ClearCorrect for use in treatment planning for ClearCorrect aligners.

59. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because ClearCorrect Operating, LLC resides in this District and because both ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. have a regularly established place of business and, upon information and belief, have committed acts of infringement in this District. Venue also is proper because Straumann is a foreign corporation and therefore "may be sued in any judicial district." 28 U.S.C. § 1391(c).

COUNT 1

FALSE ADVERTISING UNDER THE LANHAM ACT

60. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

61. Straumann's and ClearCorrect's statements on their respective websites falsely represent the nature, characteristics, and qualities of Align's aligners in violation of 15 U.S.C. § 1125(a). Straumann's and ClearCorrect's advertisements depicting Align's product-stained mustard yellow are misleading as explained in above paragraphs 33-36. On information and belief, these advertisements either deceived or had the capacity to deceive a substantial segment of potential Align customers because they do not accurately reflect how Align's products will appear under normal and expected, everyday use by consumers. These statements were material in that they are likely to influence consumer purchasing decisions raising concerns about the aesthetic quality of Align's aligners and thereby driving consumers to ClearCorrect's competing aligners. Align has already suffered injury and damages due to, on information and belief, customers (doctors and patients) choosing ClearCorrect's aligners over Align's aligners due to these advertisements. On information and belief, Align will continue to suffer such injury and damages as a result of Straumann and ClearCorrect's false advertisements unless and until this Court grants equitable relief.

62. Furthermore, by advertising these images comparing Align's aligners with ClearCorrect's aligners, Straumann and ClearCorrect caused these misleading representations to be used in connection with goods and services in interstate commerce. For example, on information and belief, ClearCorrect's aligners are manufactured in Round Rock, Texas and sold nationwide, meaning they necessarily travel in interstate commerce.

63. On information and belief, Straumann's and ClearCorrect's false and misleading statements were willfully false and misleading. On information and belief Straumann and ClearCorrect submerged Align's aligners in mustard for 24 hours at 37 ºC and then advertised that result with intent to mislead consumers regarding whether and how much Align's aligners will stain during normal and expected use. On information and belief, Straumann and ClearCorrect knew that no consumer would submerge their aligners in mustard for 24 hours (let alone keep mustard in their mouth for the 22 hours a day that Invisalign® patients wear their aligners) and, as a corollary, knew that their mustard-stained aligners did not accurately depict the coloring of Align's aligners during normal and expected use.

COUNT 2

UNFAIR COMPETITION

64. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

65. Straumann and ClearCorrect's conduct is contrary to honest practice in industrial and commercial matters. Straumann and ClearCorrect engaged in false advertising as described in detail in above paragraphs 60-63. That false advertising interfered and continues to interfere with Align's ability to conduct business because, on information and belief, it unfairly leads consumers to select ClearCorrect's aligners over Align's aligners. Thus, Straumann and ClearCorrect's violation of the Lanham Act also constitutes unfair competition under Texas common law.

COUNT 3

CIVIL CONSPIRACY

66. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

67. Upon information and belief, Straumann and ClearCorrect are members of a civil conspiracy against Align. Their object was and is to drive consumers from Align to ClearCorrect via the false and misleading comparative advertisements discussed in the above paragraphs 33-37. They had a meeting of the minds on this object: as noted in paragraphs 34-35, above, both Straumann and ClearCorrect posted substantially the same false and misleading advertisements on their websites; and as noted in paragraphs 72-73, below, Straumann exercises control over ClearCorrect. Straumann and ClearCorrect also had the specific intent to and committed unlawful, overt acts of false advertising to further their object as discussed in the above paragraphs 33-37. And, as also discussed in those paragraphs, Straumann and ClearCorrect's false advertising injured Align. As such, Straumann and ClearCorrect are liable for the wrongful conduct for each member of the unlawful civil conspiracy as if it were their own.

COUNT 4

INFRINGEMENT OF U.S. PATENT NO. 10,973,613

68. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

69. On information and belief, ClearCorrect has been and is now directly infringing the '613 patent in this district and elsewhere, in violation of 35 U.S.C. §§ 271(a) and 271(g) at least by making aligners from ClearQuartz plastic and by offering them for sale and selling them to doctors. For example, on information and belief, ClearCorrect's manufacture, offering for sale, and sale of ClearQuartz aligners infringes at least claim 1 of the '613 patent.

70. On information and belief, ClearCorrect and Straumann have been and are now indirectly infringing the '613 patent in violation of 35 U.S.C. § 271(b), at least by inducing doctors and consumers to sell, offer for sale, and use ClearCorrect's ClearQuartz aligners made

according to the processes patented in the ’613 patent. For example, on information and belief, ClearCorrect and Straumann induce doctors to sell ClearCorrect’s ClearQuartz aligners to their patients by advertising those aligners to doctors.[29] On information and belief, ClearCorrect and Straumann also induce those doctors’ patients to use ClearCorrect’s ClearQuartz aligners via direct advertising to consumers of dental services.[30]

71. On information and belief, Straumann also has been and is now indirectly infringing the ’613 patent in violation of 35 U.S.C. § 271(b) by inducing ClearCorrect to practice the claimed methods of the ’613 patent by making aligners and by inducing ClearCorrect to offer for sale and sell those aligners to doctors.

72. On information and belief, Straumann controls ClearCorrect’s operations and therefore induces ClearCorrect to commit its infringing acts.[31] In August 2016, counsel for the Straumann Group in a patent case involving dental technology told a federal court that “Institut Straumann was the operating Swiss entity.”[32] A month later, Straumann stipulated that it “has certain oversight responsibilities for the Straumann Group, which includes all Straumann Holding wholly owned-subsidiaries selling Straumann products, including with respect to overseeing and directing the Straumann Group’s Executive Management Board[.]”[33] On information and belief, the Executive Management Board “is responsible for the [Straumann]

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[29] *See, e.g.*, *How to register as a ClearCorrect provider*, ClearCorrect (May 4, 2023), https://support.clearcorrect.com/hc/en-us/articles/115006554767-How-to-register-as-a-ClearCorrect-provider; *ClearCorrect: your partner in ortho.*, Straumann (2024), https://www.straumann.com/content/clearcorrect/us/en/website/doctors.html.

[30] *See, e.g.*, *Education and Resources for Patients*, ClearCorrect (Feb. 2, 2022), https://support.clearcorrect.com/hc/en-us/articles/115007996827-Education-and-Resources-for-Patients; *ClearCorrect®: Unlock the potential of your smile*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients.html.

[31] *See Straumann Group 2023 Annual Report*, Straumann (Feb. 27, 2024), https://www.straumann.com/content/dam/media-center/group/en/documents/annual-report/2023/Straumann_AR23.pdf at 131 (“The Group is managed through Institut Straumann AG”).

[32] *Zircore, LLC v. Straumann Manufacturing, Inc., et al.*, No. 15-cv-01557-JRG-RSP, Dkt. 139 (Aug. 29, 2016 Hearing Transcript) at 20:6 (E.D. Tex. Sept. 5, 2016).

[33] *Zircore, LLC v. Straumann Manufacturing, Inc., et al.*, No. 15-cv-01557-JRG-RSP, Dkt. 146, ¶ 2 (E.D. Tex. Sept. 15, 2016).

Group's overall business and day-to-day management,"[34] including ClearCorrect's day-to-day management.[35] Further, in 2017 ClearCorrect represented that Straumann Holding—and therefore Straumann—"was the company best positioned to integrate ClearCorrect into its existing business operations."[36]

73. Other evidence confirms Straumann's control over ClearCorrect and, as a corollary, its responsibility for ClearCorrect's infringement. First, on information and belief, Straumann hires employees on behalf of ClearCorrect. Its website has advertised open positions in Round Rock, Texas,[37] including for a "Medical Device Regulatory Affairs Specialist," reporting to the Head of Regulatory Affairs for ClearCorrect Operating, LLC. Second, on information and belief, Straumann has taken over ClearCorrect's former website, clearcorrect.com, which now redirects to straumann.com/clearcorrect/en/doctors.html.[38] Doctors now can even log in to ClearCorrect's doctor portal using "Straumann eShop credentials."[39] And third, on information and belief, Straumann controls ClearCorrect's CLEARCORRECT trademark. The federal government's Trademark Status and Document Retrieval system lists Straumann Holding AG as the registrant for U.S. Trademark Registration No. 6,160,693 for CLEARCORRECT, and as explained above, Straumann controls the Straumann Group, including Straumann Holding AG.

74. On information and belief, Straumann also induced and induces ClearCorrect to commit direct infringement by funneling doctors and consumers to ClearCorrect. Straumann

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[34] *Executive Management Board*, Straumann (2024), https://www.straumann.com/group/en/home/investors/corporate-governance/executive-management-board.html.
[35] *Group Structure*, Straumann (2024), https://www.straumann.com/group/en/home/investors/corporate-governance/group-structure.html.
[36] *Align Technology, Inc. v. ClearCorrect, Inc. et. al.*, No. 11-cv-00695, Dkt. 213 at 3 (S.D. Tex. Oct. 31, 2017); *see also Align Technology, Inc. v. ClearCorrect, Inc. et. al.*, No. 11-cv-00695, Dkt. 213-1 at Appx. 004 (¶ 7), Appx. 008 (¶ 5) (S.D. Tex. Oct. 31, 2017) (Straumann USA, LLC VP and Regional General Counsel and ClearCorrect CEO affirming same).
[37] *See Search our Jobs*, Straumann (2021), https://careers.straumann.com/global/en/search-results.
[38] *See* clearcorrect.com; https://www.straumann.com/clearcorrect/en/doctors.html.
[39] *See* https://dr.clearcorrect.com/authentication.

advertises ClearCorrect's infringing aligners to doctors and consumers,[40] provides consumers with a portal to locate prescribing doctors,[41] helps consumers confirm their eligibility for treatment,[42] redirects doctors to ClearCorrect's portal through which they can order the infringing aligners (dr.clearcorrect.com),[43] and provides doctors with access to ClearCorrect's ClearPilot software through Straumann's eShop website.[44] On information and belief, Straumann's promotion of ClearCorrect's aligners causes doctors and consumers to buy them and, thus, ClearCorrect to manufacture, sell, and offer for sale aligners. For example, Creekwood Dental Arts, located in Waco, Texas, advertises ClearCorrect aligners for sale to their patients.[45] So does Contemporary Cosmetic Dentistry, located in Austin, Texas.[46]

75. Both ClearCorrect and Straumann have known of the '613 patent, their infringement of the same, and of doctors and consumers' infringement of the same since at least service of this Complaint.

76. On information and belief, ClearCorrect knew of the '613 patent, its infringement of the same, and doctors and consumers' infringement of the same since before service of this Complaint. For example, a former ClearCorrect executive conceded its awareness of Align's "extensive patent portfolio."[47] On information and belief, ClearCorrect also was familiar with

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[40] *ClearCorrect®: Unlock the potential of your smile*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients.html; *ClearCorrect: your partner in ortho*, Straumann (2024), https://www.straumann.com/content/clearcorrect/us/en/website/doctors.html.
[41] *Find a Doctor*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients/find-a-doctor.html.
[42] *Is ClearCorrect right for you?*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/am-i-a-candidate.html.
[43] *ClearCorrect: your partner in ortho*, Straumann (2024), https://www.straumann.com/clearcorrect/en/doctors.html ("Doctor Portal" at bottom of page redirecting to dr.clearcorrect.com).
[44] ClearPilot™ 7.0 - Use of ClearPilot and 3D Controls, ClearCorrect (2024), https://support.clearcorrect.com/hc/en-us/articles/4617115008279-ClearPilot-7-0-Use-of-ClearPilot-and-3D-Controls.
[45] *The Virtually Invisible Orthodontic Solution*, Creekwood Dental Arts, https://www.creekwooddentalarts.com/clear-correct/.
[46] *ClearCorrect*, Contemporary Cosmetic Dentistry (2024), https://www.cosmeticdentistryaustin.com/clearcorrect.
[47] *Bay Materials LLC v. 3M Company*, No. 21-cv-01610-RGA-JLH, Dkt. 18, ¶¶ 2, 13 (D. Del. Nov. 22, 2021).

Align's patent portfolio because the ClearCorrect and Align have a long history of litigating patent infringement. Align and ClearCorrect have litigated twice in the Southern District of Texas[48] and Align has filed two ITC actions against ClearCorrect.[49] ClearCorrect, meanwhile, has filed two petitions for *inter partes* review against Align's patents,[50] including against Align's '444 patent, which Align never asserted against ClearCorrect before this Complaint. In recent years, Straumann entities also have hired numerous Align employees as officers to manage those companies' orthodontics business—including ClearCorrect's orthodontics business. On information and belief, some or all of those former Align employees know of Align's extensive patent portfolio, including the existence of patents covering its proprietary materials, treatment planning software, and scanner technologies. These facts give rise to a reasonable inference that ClearCorrect monitors Align's patent portfolio and evaluates whether its products and services practice Align's patents, including the '613 patent.

77. On information and belief, Straumann also knew of the '613 patent, that ClearCorrect was directly infringing that patent, and that doctors and consumers were directly infringing that patent since before service of this Complaint. For example, the ClearCorrect executive who in 2021 conceded its awareness of Align's "extensive patent portfolio" self-identifies as having been a Straumann Group employee through July 2023.[51] An employee for a Straumann-controlled company also cited and discussed a family member of Align's asserted '613, '384, '090, and '091 patents in a sworn declaration.[52] That same company also had a

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[48] *ClearCorrect, Inc. v. Align Technology, Inc.*, No. 09-cv-00470-GHM (S.D. Tex.); *Align Technology, Inc. v. ClearCorrect, Inc. et al.*, No. 11-cv-00695-VDG (S.D. Tex.).
[49] *In the Matter of Certain Incremental Dental Position Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Terminated); *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-833 (Terminated).
[50] *ClearCorrect Operating, LLC et al. v. Align Technology, Inc.*, IPR2016-00270 (P.T.A.B.); *ClearCorrect Operating, LLC et al. v. Align Technology, Inc.*, IPR2017-01829 (P.T.A.B.).
[51] *Bay Materials LLC v. 3M Company*, No. 21-cv-01610-RGA-JLH, Dkt. 18, ¶ 2, 13 (D. Del. Nov. 22, 2021); *see also LinkedIn Profile for Christophe Carsault*, LinkedIn, https://www.linkedin.com/in/christophe-carsault-72ba7b2a/ (holding self out as Straumann Group employee between January 2010 and July 2023).
[52] *Bay Materials LLC v. 3M Company*, No. 21-cv-01610-RGA-JLH, Dkt. 19, ¶ 15 (D. Del. Nov. 22, 2021).

member of ’613, ’384,’090, and ’091 patents cited as prior art against it in *inter partes* review proceedings.[53] Further, in 2019, Straumann negotiated the settlement of patent litigation with Align on ClearCorrect’s behalf. By doing so, Straumann learned of Align’s patent portfolio and, on information and belief, any adverse determinations of infringement by ClearCorrect at that time.[54] In recent years, Straumann entities also have hired numerous Align employees as officers to manage those companies’ orthodontics business—including ClearCorrect’s orthodontics business. On information and belief, some or all of those former Align employees know of Align’s extensive patent portfolio, including the existence of patents covering its proprietary materials, treatment planning software, and scanner technologies. These facts give rise to a reasonable inference that Straumann monitors Align’s patent portfolio and evaluates whether ClearCorrect’s products and services practice Align’s patents, including the ’613 patent.

78. On information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’613 patent and their infringement of the same, and of doctors and consumers’ infringement of the ’613 patent. In view of the facts set forth in paragraphs 76-77 of this Complaint, ClearCorrect and Straumann was aware of the high probability that their products and services infringed Align’s patents. Under these circumstances, if they did not assess that infringement risk, that reflects a deliberate decision to avoid learning of and confirming their infringement.

79. Thus, on information and belief, ClearCorrect and Straumann knowingly induced infringement of at least claim 1 of the ’613 patent and had specific intent to cause such direct infringement.

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[53] *3M Co. v. Bay Materials LLC*, Case No. IPR2023-00243, Paper 3 at 23 (P.T.A.B. Dec. 5, 2022) (citing U.S. Patent No. 9,655,691).

[54] *Align Technology, Inc. v. ClearCorrect, Inc. et. al.*, No. 11-cv-00695, Dkt. 213 at 3 (S.D. Tex. Oct. 31, 2017) (ClearCorrect: “The parties [ClearCorrect and Straumann Holding] obviously had to discuss the Align litigation during the acquisition process . . . [o]n the issue of defending Align’s patent claims, ClearCorrect and Straumann’s interests were identical”); *see also Align Technology, Inc. v. ClearCorrect, Inc. et. al.*, No. 11-cv-00695, Dkt. 213-1 at Appx. 004 (¶ 11), Appx. 008 (¶ 7) (S.D. Tex. Oct. 31, 2017) (similar).

80. ClearCorrect and Straumann's infringement of the '613 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys' fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

81. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann's infringement of the '613 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align's innovative technologies, and loss of Align's exclusive right to license its invention.

82. Align has sustained and will continue to sustain damages as a result of ClearCorrect and Straumann's infringement of the '613 patent, and Align is entitled to recover damages sustained as a result of that infringement in an amount to be proven at trial.

83. ClearCorrect's method of manufacturing its ClearQuartz aligners practices at least claim 1 of the '613 patent as set forth below.

Direct Infringement of Claim 1 of the '613 Patent

84. Claim 1 of the '613 patent recites a method of making a dental appliance for positioning a patient's teeth, the method comprising:

- providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:
    - a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and
    - a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;
- providing a positive model of the patient's teeth in a target position; and
- fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

85. On information and belief, and if the preamble is found to be limiting, ClearCorrect manufactures its aligners, which are dental appliances for positioning patients' teeth.[55]

86. On information and belief, ClearCorrect makes its aligners from three-layer polymer sheets. The following graphic from Straumann's website states that ClearCorrect's aligners are made from a "tri-layer material":[56]

87. On information and belief, ClearCorrect's aligners include a hard polymer layer made from either Tritan MX-710 or MX-711, both of which are co-polyesters. On information and belief, Tritan MX-710 and MX-711 both have a flexural modulus of about 225,000 psi.[57]

88. On information and belief, ClearCorrect's aligners include a soft polymer layer made from Tecothane TPU-Clear TT 1065-D, which is a thermoplastic polyurethane elastomer. On information and belief, Tecothane TPU-Clear TT 1065-D has an elongation at break of 300% and a hardness of 64D.[58]

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[55] *See, e.g.*, *ClearCorrect Announces Faster Manufacturing Turnaround Time for Clear Aligners*, Business Wire (June 1, 2021), https://www.businesswire.com/news/home/20210601005088/en/ClearCorrect-Announces-Faster-Manufacturing-Turnaround-Time-for-Clear-Aligners ("For patients in the U.S. and Canada, aligners have always been manufactured solely in Texas").

[56] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html; *see also ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

[57] *See Technical Data Sheet: Eastman Tritan Copolyester MX0710*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070148&pn=Tritan+Copolyester+MX710; *Technical Data Sheet: Eastman Tritan Copolyester MX0711*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070154&pn=Tritan+Copolyester+MX711.

[58] *See Tecothane TPU – Clear Datasheet*, Lubrizol LifeSciences (July 8, 2019), https://www.lubrizol.com/-/media/Lubrizol/Health/TDS/Tecothane-TPU-Clear.pdf.

89. On information and belief, ClearCorrect's aligner manufacturing process includes providing a positive mold of a patient's teeth in a target position, *i.e.*, the configuration to which the treatment plan indicates a patient's teeth should move at a particular stage.[59] For example, on August 19, 2020, ClearCorrect announced that it was expanding its use of Stratasys 3D printers, which it uses to "create accurate 3D printed models in Stratasys' VeroDent material, which are then thermoformed with a specially formulated plastic to create custom, clear aligners."[60] An image of the 3D-printed mold and thermoformed aligner from that announcement is shown below: [61]

90. On information and belief, ClearCorrect's aligner manufacturing process includes thermoforming a sheet of ClearQuartz plastic over the positive mold of the patient's teeth in the target position, thereby creating a negative of the positive mold.[62]

COUNT 5

INFRINGEMENT OF U.S. PATENT NO. 11,154,384

91. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

92. On information and belief, ClearCorrect has been and is now directly infringing the '384 patent in this district and elsewhere, in violation of 35 U.S.C. §§ 271(a) and 271(g) at least by making, selling, and/or offering for sale aligners from ClearQuartz plastic. For example,

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[59] *See Clearcorrect expands production capacity for orthodontic aligners by 30 percent*, stratsys (Aug. 19, 2020), https://www.stratasys.com/en/resources/blog/clearcorrect-3d-printing/.
[60] *Id.*
[61] *Id.*
[62] *See id.*; *see also* Ex. 11, ¶ 8.

on information and belief, ClearCorrect's manufacture, offering for sale, and sale of ClearQuartz aligners infringes at least claim 1 of the '384 patent.

93. On information and belief, ClearCorrect and Straumann have been and are now indirectly infringing the '384 patent in violation of 35 U.S.C. § 271(b), at least by inducing doctors and consumers to use, sell, and offer for sale ClearCorrect's ClearQuartz aligners. For example, on information and belief, ClearCorrect and Straumann induce doctors to sell ClearCorrect's ClearQuartz aligners to their patients by advertising those aligners to doctors.[63] And, on information and belief, ClearCorrect and Straumann also induce those doctors' patients to use ClearCorrect's ClearQuartz aligners via direct advertising to consumers of dental services.[64]

94. On information and belief, Straumann also has been and is now indirectly infringing the '384 patent in violation of 35 U.S.C. § 271(b) by inducing ClearCorrect to make, sell, and offer for sale aligners that practice one or more claims of the '384 patent. On information and belief, Straumann induces ClearCorrect's infringement of the '384 patent as set forth in paragraphs 72-74 of this Complaint.

95. Both ClearCorrect and Straumann have known of the '384 patent, their infringement of the same, and of doctors and consumers' infringement of the same since at least service of this Complaint.

96. On information and belief, ClearCorrect knew of the '384 patent, its infringement of the same, and doctors and consumers' infringement of the same since before service of this Complaint. On information and belief, ClearCorrect was familiar with Align's patent portfolio

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[63] *See, e.g.*, *How to register as a ClearCorrect provider*, ClearCorrect (May 4, 2023), https://support.clearcorrect.com/hc/en-us/articles/115006554767-How-to-register-as-a-ClearCorrect-provider; *ClearCorrect: your partner in ortho*, Straumann (2024), https://www.straumann.com/content/clearcorrect/us/en/website/doctors.html.

[64] *See, e.g.*, *Education and Resources for Patients*, ClearCorrect (Feb. 2, 2022), https://support.clearcorrect.com/hc/en-us/articles/115007996827-Education-and-Resources-for-Patients; *ClearCorrect®: Unlock the potential of your smile*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients.html.

and knew it infringed the ’384 patent for the same reasons as set forth in paragraph 76 of this Complaint.

97. On information and belief, Straumann also knew of the ’384 patent, that ClearCorrect was directly infringing that patent, and that doctors and consumers were directly infringing that patent since before service of this Complaint. On information and belief, Straumann knew of Align’s patents and ClearCorrect’s infringement for the same reasons as set forth in paragraph 77 of this Complaint.

98. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’384 patent and their infringement of the ’384 patent for the same reasons as set forth in paragraph 78 of this Complaint.

99. Thus, on information and belief, Straumann and ClearCorrect knowingly induced infringement of at least claim 1 of the ’384 patent and had specific intent to cause such direct infringement.

100. ClearCorrect and Straumann’s infringement of the ’384 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys’ fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

101. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann’s infringement of the ’384 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align’s innovative technologies, and loss of Align’s exclusive right to license its invention.

102. Align has sustained and will continue to sustain damages as a result of ClearCorrect and Straumann’s infringement of the ’384 patent, and Align is entitled to recover damages sustained as a result of that infringement in an amount to be proven at trial.

103. ClearCorrect’s ClearQuartz aligners practice at least claim 1 of the ’384 patent as set forth below.

Direct Infringement of Claim 1 of the ’384 Patent

104. Claim 1 of the ’384 patent recites a dental appliance for positioning a patient’s teeth from a first arrangement toward a second arrangement, the dental appliance comprising:

- a plurality of tooth-receiving cavities shaped to receive and resiliently reposition the patient’s teeth from the first arrangement toward the second arrangement;
- three or more polymer layers, the three or more polymer layers comprising:
    - a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and
    - a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D.

105. On information and belief, and if the preamble is found to be limiting, ClearCorrect’s aligners are dental appliances for positioning patients’ teeth from a first arrangement toward a second arrangement.[65]

106. On information and belief, ClearCorrect’s aligners include a plurality of tooth-receiving cavities to receive a patient’s teeth and are intended to resiliently reposition the patient’s teeth from a first arrangement toward a second arrangement.[66]

107. On information and belief, ClearCorrect’s aligners are made from ClearQuartz plastic, which is a three-layer polymer. The following graphic from Straumann’s website states that ClearCorrect’s aligners are made from a “tri-layer material”:[67]

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[65] *See, e.g.*, Ex. 11, ¶ 8; *Patients*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients.html; *ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

[66] *See id.*

[67] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html; *see also ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

108. On information and belief, ClearCorrect's aligners include a hard polymer layer made from either Tritan MX-710 or MX-711, both of which are co-polyesters. On information and belief, Tritan MX-710 and MX-711 both have a flexural modulus of about 225,000 psi.[68]

109. On information and belief, ClearCorrect's aligners include a soft polymer layer made from Tecothane TPU-Clear TT 1065-D, which is a thermoplastic polyurethane elastomer. On information and belief, Tecothane TPU-Clear TT 1065-D has an elongation at break of 300% and a hardness of 64D.[69]

COUNT 6

INFRINGEMENT OF U.S. PATENT NO. 11,648,090

110. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

111. On information and belief, ClearCorrect has been and is now directly infringing the '090 patent in this district and elsewhere, in violation of 35 U.S.C. §§ 271(a) and 271(g) at least by making, selling, and/or offering for sale aligners from ClearQuartz plastic. For example, on information and belief, ClearCorrect's manufacture, offering for sale, and sale of ClearQuartz aligners infringes at least claim 1 of the '090 patent.

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[68] *See Technical Data Sheet: Eastman Tritan Copolyester MX0710*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070148&pn=Tritan+Copolyester+MX710; *Technical Data Sheet: Eastman Tritan Copolyester MX0711*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070154&pn=Tritan+Copolyester+MX711.

[69] *See Tecothane TPU – Clear Datasheet*, Lubrizol LifeSciences (July 8, 2019), https://www.lubrizol.com/-/media/Lubrizol/Health/TDS/Tecothane-TPU-Clear.pdf.

112. On information and belief, ClearCorrect and Straumann have been and are now indirectly infringing the ’090 patent in violation of 35 U.S.C. § 271(b), at least by inducing doctors and consumers to use, sell, and offer for sale ClearCorrect’s ClearQuartz aligners. For example, on information and belief, ClearCorrect and Straumann induce doctors to sell ClearCorrect’s ClearQuartz aligners to their patients by advertising those aligners to doctors.[70] And, on information and belief, ClearCorrect and Straumann also induce those doctors’ patients to use ClearCorrect’s ClearQuartz aligners via direct advertising to consumers of dental services.[71]

113. On information and belief, Straumann has been and is now indirectly infringing the ’090 patent in violation of 35 U.S.C. § 271(b) by inducing ClearCorrect to make, sell, and offer for sale aligners that practice one or more claims of the ’090 patent. On information and belief, Straumann induces ClearCorrect’s infringement of the ’090 patent as set forth in paragraphs 72-74 of this Complaint.

114. Both ClearCorrect and Straumann have known of the ’090 patent, their infringement of the same, and of doctors and consumers’ infringement of the same since at least service of this Complaint.

115. On information and belief, ClearCorrect knew of the ’090 patent, its infringement of the same, and doctors and consumers’ infringement of the same since before service of this Complaint. On information and belief, ClearCorrect was familiar with Align’s patent portfolio and knew it infringed the ’090 patent for the same reasons as set forth in paragraphs 76 of this Complaint.

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[70] *See, e.g.*, *How to register as a ClearCorrect provider*, ClearCorrect (May 4, 2023), https://support.clearcorrect.com/hc/en-us/articles/115006554767-How-to-register-as-a-ClearCorrect-provider; *ClearCorrect: your partner in ortho*, Straumann (2024), https://www.straumann.com/content/clearcorrect/us/en/website/doctors.html.

[71] *See, e.g.*, *Education and Resources for Patients*, ClearCorrect (Feb. 2, 2022), https://support.clearcorrect.com/hc/en-us/articles/115007996827-Education-and-Resources-for-Patients; *ClearCorrect®: Unlock the potential of your smile*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients.html.

116. On information and belief, Straumann also knew of the ’090 patent, that ClearCorrect was directly infringing that patent, and that doctors and consumers were directly infringing that patent since before service of this Complaint. On information and belief, Straumann knew of Align’s patents and ClearCorrect’s infringement for the same reasons as set forth in paragraphs 77 of this Complaint.

117. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’090 patent and their infringement of the ’090 patent for the same reasons as set forth in paragraph 78 of this Complaint.

118. Thus, on information and belief, Straumann and ClearCorrect knowingly induced infringement of at least claim 1 of the ’090 patent and had specific intent to cause such direct infringement.

119. ClearCorrect and Straumann’s infringement of the ’090 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys’ fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

120. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann’s infringement of the ’090 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align’s innovative technologies, and loss of Align’s exclusive right to license its invention.

121. Align has sustained and will continue to sustain damages as a result of ClearCorrect and Straumann’s infringement of the ’090 patent, and Align is entitled to recover damages sustained as a result of that infringement in an amount to be proven at trial.

122. ClearCorrect’s method of manufacturing its ClearQuartz aligners practices at least claim 1 of the ’090 patent as set forth below.

Direct Infringement of Claim 1 of the ’090 Patent

123. Claim 1 of the ’090 patent recites a method of making a multilayer dental aligner for repositioning a patient’s teeth from a first arrangement toward a second arrangement, the method comprising:

- providing a multilayer sheet comprising three polymer layers, the three polymer layers comprising:
    - a first layer consisting of a co-polyester, the co-polyester having a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and
    - a second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and
    - a third layer;
    - wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer;
- providing a mold;
- thermoforming the multilayer sheet over the mold to form a plurality of tooth-receiving cavities configured to receive and reposition the patient’s teeth from the first arrangement toward the second arrangement; and
- trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner.

124. On information and belief, and if the preamble is found to be limiting, ClearCorrect's manufactures its aligners, which have multiple layers and are for repositioning a patient's teeth from a first arrangement toward a second arrangement.[72]

125. On information and belief, ClearCorrect makes its aligners from three-layer polymer sheets. The following graphic from Straumann's website states that ClearCorrect's aligners are made from a "tri-layer material":[73]

126. On information and belief, ClearCorrect's aligners include a first, hard polymer layer made from either Tritan MX-710 or MX-711, both of which are co-polyesters. On information and belief, Tritan MX-710 and MX-711 both have a flexural modulus of about 225,000 psi, an elongation at yield of 6%, a tensile modulus of 225,000 psi, a tensile strength at yield of 6,236 psi, and an elongation at break of 210%.[74]

127. On information and belief, ClearCorrect's aligners include a second, soft polymer layer made from Tecothane TPU-Clear TT-1065D, which is a thermoplastic polyurethane

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[72] *See, e.g.*, Ex. 11, ¶ 8; *About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html; *see also ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

[73] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html; *see also ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

[74] *See Technical Data Sheet: Eastman Tritan Copolyester MX0710*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070148&pn=Tritan+Copolyester+MX710; *Technical Data Sheet: Eastman Tritan Copolyester MX0711*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070154&pn=Tritan+Copolyester+MX711.

elastomer. On information and belief, Tecothane TPU-Clear TT-1065D has an ultimate tensile strength of 10,000 psi, an elongation at break of 300%, and a hardness of 64D.[75]

128. On information and belief, ClearCorrect's aligners include a third layer.[76]

129. On information and belief, Tritan MX-710 or MX-711 both have an elastic modulus greater than Tecothane TPU-Clear TT-1065D. On information and belief, Tritan MX-710 and -711 both have a tensile modulus, *i.e.*, an elastic modulus, of 225,000 psi.[77] On information and belief, Tecothane TPU-Clear TT-1065D has a tensile modulus, *i.e.*, an elastic modulus, of 2,800 psi at 100% elongation and 7,800 psi at break.[78]

130. On information and belief, ClearCorrect's aligner manufacturing process includes providing a 3D-printed mold of a patient's teeth.[79]

131. On information and belief, and as explained in paragraph 89 of this Complaint, ClearCorrect's aligner manufacturing process includes thermoforming a sheet of ClearQuartz plastic over the 3D-printed of the patient's teeth and thereby forming a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from a first arrangement toward a second arrangement.[80]

132. On information and belief, ClearCorrect's aligner manufacturing process includes trimming excess material from the ClearQuartz plastic blank to form the aligner's trimline.[81]

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[75] *See Tecothane TPU – Clear Datasheet*, Lubrizol LifeSciences (July 8, 2019), https://www.lubrizol.com/-/media/Lubrizol/Health/TDS/Tecothane-TPU-Clear.pdf.
[76] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html.
[77] *See Technical Data Sheet: Eastman Tritan Copolyester MX0710*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070148&pn=Tritan+Copolyester+MX710; *Technical Data Sheet: Eastman Tritan Copolyester MX0711*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070154&pn=Tritan+Copolyester+MX711.
[78] *See Tecothane TPU – Clear Datasheet*, Lubrizol LifeSciences (July 8, 2019), https://www.lubrizol.com/-/media/Lubrizol/Health/TDS/Tecothane-TPU-Clear.pdf.
[79] *See A Clear Orthodontic Advantage*, Stratasys (Aug. 19, 2020), https://www.stratasys.com/en/resources/blog/clearcorrect-3d-printing/.
[80] *See id.*; *see also* Ex. 11, ¶ 8.
[81] *See ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

COUNT 7

INFRINGEMENT OF U.S. PATENT NO. 11,648,091

133. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

134. On information and belief, ClearCorrect has been and is now directly infringing the ’091 patent in this district and elsewhere, in violation of 35 U.S.C. §§ 271(a) and 271(g) at least by making, selling, and/or offering for sale aligners from ClearQuartz plastic. For example, on information and belief, ClearCorrect’s manufacture, offering for sale, and sale of ClearQuartz aligners infringes at least claim 1 of the ’091 patent.

135. On information and belief, ClearCorrect and Straumann have been and are now indirectly infringing the ’091 patent in violation of 35 U.S.C. § 271(b), at least by inducing doctors and consumers to use, sell, and offer for sale ClearCorrect’s ClearQuartz aligners. For example, on information and belief, ClearCorrect and Straumann induce doctors to sell ClearCorrect’s ClearQuartz aligners to their patients by advertising those aligners to doctors.[82] And, on information and belief, ClearCorrect and Straumann also induce those doctors’ patients to use ClearCorrect’s ClearQuartz aligners via direct advertising to consumers of dental services.[83]

136. On information and belief, Straumann has been and is now indirectly infringing the ’091 patent in violation of 35 U.S.C. § 271(b) by inducing ClearCorrect to make, sell, and offer for sale aligners that practice one or more claims of the ’091 patent. On information and belief, Straumann induces ClearCorrect’s infringement of the ’091 patent as set forth in paragraphs 72-74 of this Complaint.

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[82] *See, e.g.*, *How to register as a ClearCorrect provider*, ClearCorrect (May 4, 2023), https://support.clearcorrect.com/hc/en-us/articles/115006554767-How-to-register-as-a-ClearCorrect-provider; *ClearCorrect: your partner in ortho*, Straumann (2024), https://www.straumann.com/content/clearcorrect/us/en/website/doctors.html.

[83] *See, e.g.*, *Education and Resources for Patients*, ClearCorrect (Feb. 2, 2022), https://support.clearcorrect.com/hc/en-us/articles/115007996827-Education-and-Resources-for-Patients; *ClearCorrect®: Unlock the potential of your smile*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/patients.html.

137. Both ClearCorrect and Straumann have known of the ’091 patent, their infringement of the same, and of doctors and consumers’ infringement of the same since at least service of this Complaint.

138. On information and belief, ClearCorrect knew of the ’091 patent, its infringement of the same, and doctors and consumers’ infringement of the same since before service of this Complaint. On information and belief, ClearCorrect was familiar with Align’s patent portfolio and knew it infringed the ’091 patent for the same reasons as set forth in paragraph 76 of this Complaint.

139. On information and belief, Straumann also knew of the ’091 patent, that ClearCorrect was directly infringing that patent, and that doctors and consumers were directly infringing that patent since before service of this Complaint. On information and belief, Straumann knew of Align’s patents and any determination by ClearCorrect of infringement for the same reasons as set forth in paragraph 77 of this Complaint.

140. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’091 patent and their infringement of the ’091 patent for the same reasons as set forth in paragraph 78 of this Complaint.

141. Thus, on information and belief, Straumann and ClearCorrect knowingly induced infringement of at least claim 1 of the ’091 patent and had specific intent to cause such direct infringement.

142. ClearCorrect and Straumann’s infringement of the ’091 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys’ fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

143. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann’s infringement of the ’091 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of

market share, lost business opportunities and sales, loss of goodwill associated with Align's innovative technologies, and loss of Align's exclusive right to license its invention.

144. Align has sustained and will continue to sustain damages as a result of ClearCorrect and Straumann's infringement of the '091 patent, and Align is entitled to recover damages sustained as a result of that infringement in an amount to be proven at trial.

145. ClearCorrect's method of manufacturing its ClearQuartz aligners practices at least claim 1 of the '091 patent as set forth below.

Direct Infringement of Claim 1 of the '091 Patent

146. Claim 1 of the '091 patent recites a multilayer sheet comprising:

- a first layer containing a single polymer, wherein the single polymer of the first layer is a co-polyester, and wherein the first layer has a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and
- a second layer containing a single polymer, wherein the single polymer of the second layer is a thermoplastic polyurethane elastomer, and wherein the second layer has an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and
- a third layer;
- wherein the first layer has an elastic modulus greater than the second layer; and
- wherein the multilayer sheet is incorporated into an orthodontic appliance.

147. On information and belief, and if the preamble is found to be limiting, ClearCorrect makes its aligners from three-layer polymer sheets. The following graphic from Straumann's website states that ClearCorrect's aligners are made from a "tri-layer material":[84]

[84] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html; *see also ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

148. On information and belief, the sheets from which ClearCorrect forms its aligners include a first, hard polymer layer made from either Tritan MX-710 or MX-711, both of which are co-polyesters. On information and belief, Tritan MX-710 and MX-711 both have a flexural modulus of about 225,000 psi, an elongation at yield of 6%, a tensile modulus of 225,000 psi, a tensile strength at yield of 6,236 psi, and an elongation at break of 210%.[85]

149. On information and belief, the sheets from which ClearCorrect forms its aligners include a second, soft polymer layer made from Tecothane TPU-Clear TT-1065D, which is a thermoplastic polyurethane elastomer. On information and belief, Tecothane TPU-Clear TT-1065D has an ultimate tensile strength of 10,000 psi, an elongation at break of 300%, and a hardness of 64D.[86]

150. On information and belief, the sheets from which ClearCorrect forms its aligners include a third layer.[87]

151. On information and belief, Tritan MX-710 or MX-711 both have an elastic modulus greater than Tecothane TPU-Clear TT-1065D. On information and belief, Tritan MX-

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[85] *See Technical Data Sheet: Eastman Tritan Copolyester MX0710*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070148&pn=Tritan+Copolyester+MX710; *Technical Data Sheet: Eastman Tritan Copolyester MX0711*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070154&pn=Tritan+Copolyester+MX711.

[86] *See Tecothane TPU – Clear Datasheet*, Lubrizol LifeSciences (July 8, 2019), https://www.lubrizol.com/-/media/Lubrizol/Health/TDS/Tecothane-TPU-Clear.pdf.

[87] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html.

710 and -711 both have a tensile modulus, *i.e.*, an elastic modulus, of 225,000 psi.[88] On information and belief, Tecothane TPU-Clear TT-1065D has a tensile modulus, *i.e.*, an elastic modulus, of 2,800 psi at 100% elongation and 7,800 psi at break.[89]

152. On information and belief, ClearCorrect incorporates the ClearQuartz three-layer polymer sheets into its aligners.[90]

COUNT 8

INFRINGEMENT OF U.S. PATENT NO. 8,038,444

153. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

154. On information and belief, ClearCorrect has been and is now directly infringing the ’444 patent in this district and elsewhere in violation of 35 U.S.C. § 271(a) at least by making and using software that practices one or more claims of the ’444 patent. For example, on information and belief, ClearCorrect’s use of its treatment planning software to perform treatment planning infringes at least claim 1 of the ’444 patent.

155. On information and belief, ClearCorrect has been and is now directly infringing the ’444 patent in this district and elsewhere in violation of 35 U.S.C. § 271(g) at least by importing into the United States or offering to sell, selling, and using, to manufacture aligners, treatment plans made according to the methods claimed in the ’444 patent.

156. On information and belief, Straumann has been and is now indirectly infringing the ’444 patent in violation of 35 U.S.C. § 271(b), at least by inducing ClearCorrect to make and

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[88] *See Technical Data Sheet: Eastman Tritan Copolyester MX0710*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070148&pn=Tritan+Copolyester+MX710; *Technical Data Sheet: Eastman Tritan Copolyester MX0711*, Eastman (Sept. 12, 2019), https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71070154&pn=Tritan+Copolyester+MX711.

[89] *See Tecothane TPU – Clear Datasheet*, Lubrizol LifeSciences (July 8, 2019), https://www.lubrizol.com/-/media/Lubrizol/Health/TDS/Tecothane-TPU-Clear.pdf.

[90] *See About the Aligners*, Straumann (2024), https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html; *see also ClearCorrect Aligners*, ClearCorrect (Mar. 12, 2024), https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners.

use software that practices one or more claims of the ’444 patent and/or by inducing ClearCorrect to use and/or import in the United States treatment plans made according to the methods claimed in one or more claims of the ’444 patent. On information and belief, Straumann induces ClearCorrect to manufacture, offer for sale, and sell aligners as set forth in paragraphs 72-74 of this Complaint. On information and belief, because manufacturing aligners requires treatment planning and/or using treatment plans, those same acts by Straumann also induce ClearCorrect to perform infringing treatment planning methods and to use infringing treatment plans, all at its Texas headquarters. For instance, ClearCorrect’s website states that its “[t]reatment simulation[s,] [the] 3D sequential animation of tooth movement through aligner treatment” are “[c]reated by ClearCorrect technicians.”[91] And websites like indeed.com and LinkedIn show that ClearCorrect or Straumann employs “Manufacturing Technician[s]” in Texas, confirming that the technicians making and using the treatment plans are based in Texas.[92] Also, on information and belief, Straumann advertises ClearCorrect’s infringing treatment planning services on its website, straumann.com,[93] and provides access to ClearCorrect’s ClearPilot software through Straumann’s eShop website,[94] both of which drive doctors to ClearCorrect seeking those services and thereby increase the volume of ClearCorrect’s infringement.

157. Both ClearCorrect and Straumann have known of the ’444 patent and their infringement of the same since at least service of this Complaint.

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[91] *ClearPilot 7.0 - Use of ClearPilot and 3D Controls*, ClearCorrect (2024), https://support.clearcorrect.com/hc/en-us/articles/4617115008279-ClearPilot-7-0-Use-of-ClearPilot-and-3D-Controls.

[92] *ClearCorrect Employee Reviews for Manufacturing Technician*, indeed (Apr. 2, 2020), https://www.indeed.com/cmp/Clearcorrect/reviews?fjobtitle=Manufacturing+Technician; *LinkedIn Profile for Gregory Amor*, LinkedIn, https://www.linkedin.com/in/gregory-amor-08ab27185/.

[93] *See, e.g.*, *ClearPilot*, Straumann (2024), https://www.straumann.com/clearcorrect/us/en/doctors/clearpilot.html.

[94] *ClearPilot™ 7.0 - Use of ClearPilot and 3D Controls*, ClearCorrect (2024), https://support.clearcorrect.com/hc/en-us/articles/4617115008279-ClearPilot-7-0-Use-of-ClearPilot-and-3D-Controls.

158. ClearCorrect also knew of the ’444 patent by at least July 20, 2017, when it petitioned for *inter partes* review of the ’444 patent in IPR Proceeding No. 2017-01829. It knew that the ’444 patent is valid: in addition to the statutory presumption of validity, the Patent Trial and Appeal Board denied ClearCorrect’s petition and declined to institute *inter partes* review.[95] And, on information and belief, ClearCorrect also knew that its treatment planning services infringed the ’444 patent as of at least July 20, 2017. Before this Complaint, Align never asserted the ’444 patent against ClearCorrect and, thus, the most likely explanation why ClearCorrect tried to cancel the ’444 patent is that it knew that it was infringing that patent. Additionally, on information and belief, ClearCorrect was familiar with Align’s patent portfolio and knew it infringed the ’444 patent for the same reasons as set forth in paragraph 76 of this Complaint.

159. On information and belief, Straumann knew of the ’444 patent and ClearCorrect’s infringement of the same when it acquired ClearCorrect in August 2017 because ClearCorrect would have disclosed its petition seeking cancellation of Align’s ’444 patent and its knowledge that it was infringing Align’s ’444 patent to Straumann during acquisition discussions. On information and belief, Straumann also knew of the ’444 patent and ClearCorrect’s direct infringement of the same by at least 2019, when it settled litigation between Align and ClearCorrect on ClearCorrect’s behalf. That litigation was pending at the same time as ClearCorrect’s petition to cancel Align’s ’444 patent and, on information and belief, Straumann would have known of both actions and of ClearCorrect’s likely rationale for seeking cancellation of the ’444 patent—that ClearCorrect’s treatment planning services infringed the ’444 patent. Additionally, on information and belief, Straumann knew of Align’s patents and ClearCorrect’s infringement for the same reasons as set forth in paragraph 77 of this Complaint.

160. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’444 patent and their infringement of the ’444 patent. As

[95] *See, e.g.*, *ClearCorrect Operating, LLC et al v. Align Technology, Inc.*, IPR2017-01829, Paper 10 at 2 (P.T.A.B. Feb. 5, 2018).

explained in paragraphs 158-159 of this Complaint, ClearCorrect tried to cancel the ’444 patent, and Straumann knew of that effort. ClearCorrect and Straumann were aware of the high probability that ClearCorrect’s products and services infringed the ’444 patent. Under these circumstances, if they decided not to assess that infringement risk, that reflects a deliberate decision to avoid learning of and confirming infringement.

161. Thus, on information and belief, Straumann knowingly induced ClearCorrect to directly infringe at least claim 1 of the ’444 patent, and Straumann possessed specific intent to cause such direct infringement.

162. ClearCorrect and Straumann’s infringement of the ’444 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys’ fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

163. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann’s infringement of the ’444 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align’s innovative technologies, and loss of Align’s exclusive right to license its invention.

164. Align has sustained and will continue to sustain damages as a result of Defendants’ infringement of the ’444 patent, and Align is entitled to recover damages sustained as a result of Defendants’ infringement in an amount to be proven at trial.

165. ClearCorrect method of computing treatment plans practices at least claim 1 of the ’444 patent, as set forth below.

Direct Infringement of Claim 1 of the ’444 Patent

166. Claim 1 of the ’444 patent recites a computer-implemented method for staging the movement of a plurality of dental objects, the method comprising:

- receiving, at a host computer, an electronic representation of each dental object of the plurality of dental objects in relation to one another;

- receiving, by the host computer, an electronic representation of a desired final position for each respective dental object; and
- determining, by the host computer, an order of movement for each respective dental object such that the dental objects avoid colliding with or obstructing each other on their respective routes from said initial position to said desired final position through at least one of staggering and round-tripping of at least one dental object.

167. On information and belief, and if the preamble is found to be limiting, ClearCorrect's treatment planning software provides a computer implemented method for staging the movement of a plurality of dental objects. In an October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software uses initial and final positions of patients' teeth to "interpret[] a series of intermediate states that adhere to [a] defined maximum tooth motions and clinician instructions."[96] On information and belief, the phrase "interpret[] a series of intermediate states"[97] refers to staging the movement of a patient's teeth for each phase of treatment with aligners.

168. On information and belief, a computer running ClearCorrect's treatment planning software receives an electronic representation of a patient's teeth. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated, "ClearCorrect technicians using the ClearCorrect Cut and Stage software use a scan of a PVS impression or the output of an intra-oral scanner of the patient's untreated oral anatomy . . . ."[98] For the technicians to use such a scan, the computer must have received it. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which computes treatment plans based on an electronic representation of a patient's teeth received at the computer running Align's treatment planning software.[99]

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[96] Ex. 12 at 8.
[97] *Id.*
[98] *Id.*
[99] *Id.*

169. On information and belief, a computer running ClearCorrect's treatment planning software receives an electronic representation of a desired final state of a patient's teeth. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its technicians "using the ClearCorrect Cut and Stage software" and "the prescription details" will "derive the desired final patient tooth positions[,]" and that the software then uses "this desired state" to calculate a treatment plan.[100] To use the desired final state of a patient's teeth to calculate a treatment plan, the computer must have received it. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which computes treatment plans based on an electronic representation of a desired final position of each of a patient's teeth received by the computer running that software.

170. Alternatively, ClearCorrect's treatment planning software receives an electronic representation of a desired final state of a patient's teeth after a doctor digitally edits the desired final positions via ClearCorrect's ClearPilot software. A doctor can access the ClearPilot software via both ClearCorrect's dr.clearcorrect.com portal and via Straumann's eShop website.[101] According to ClearCorrect's website, "[a]fter the clinician submits the desired final position and the instructions related to these changes, the technician will adjust the setup according to the edits made by the clinician."[102] On information and belief, the technician's computer running ClearCorrect's treatment planning software receives an electronic representation of the updated Treatment Setup with desired final positions of teeth.

171. On information and belief, a computer running ClearCorrect's treatment planning software determines an order of movement for each tooth during treatment planning. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software "interprets a series of intermediate states that adhere to defined maximum tooth motions and

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[100] *Id.*
[101] *ClearPilot™ 7.0 - Use of ClearPilot and 3D Controls,* ClearCorrect (2024), https://support.clearcorrect.com/hc/en-us/articles/4617115008279-ClearPilot-7-0-Use-of-ClearPilot-and-3D-Controls.
[102] *Id.*

clinician instructions."[103] Then, only "as necessary," a "technician further refines these intermediate states."[104] On information and belief, the phrase "interpret[] a series of intermediate states" refers to staging the movement of a patient's teeth for each phase of treatment with aligners, which would include determining the order in which the teeth moved. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which determines an order of movement for each tooth during treatment planning.

172. On information and belief, ClearCorrect's treatment planning software determines an order of movement for each of a patient's teeth that avoids collisions between teeth or one tooth obstructing another en route to each tooth's final position through at least one of staggering and round-tripping. ClearCorrect advertises that its technicians will, by default, treatment plan for "Moderate-Severe Crowding (Class II)" using "anterior round tripping as needed."[105] And, as explained in paragraph 23 of this Complaint, ClearCorrect published a YouTube video showing its ClearPilot software animating a treatment plan with staggering.[106] ClearCorrect also stated, in its October 2022, 510(k) submission to the FDA, that its "internal" software is "functionally equivalent to" Align's software, which uses round-tripping and staggering, where necessary, to avoid collisions between teeth and teeth obstructing other teeth en route to their final positions.[107]

COUNT 9

INFRINGEMENT OF U.S. PATENT NO. 10,456,217

173. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

174. On information and belief, ClearCorrect has been and is now directly infringing the '217 patent in this district and elsewhere, in violation of 35 U.S.C. § 271(a) at least by

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[103] Ex. 12 at 8
[104] *Id.*
[105] *Treatment Preferences*, ClearCorrect (Oct. 20, 2023), https://support.clearcorrect.com/hc/en-us/articles/4416586057495-Treatment-Preferences.
[106] *ClearPilot features: The Control is in Your Hands*, ClearCorrect (Jan. 25, 2021), https://www.youtube.com/watch?v=DYVS21zqH0c.
[107] Ex. 12 at 8.

making and using software that practices one or more claims of the ’217 patent. For example, on information and belief, ClearCorrect’s use of its treatment planning software to perform treatment planning infringes at least claim 1 of the ’217 patent.

175. On information and belief, ClearCorrect has been and is now directly infringing the ’217 patent in this district and elsewhere in violation of 35 U.S.C. § 271(g) at least by importing into the United States or offering to sell, selling, and using, to manufacture aligners, treatment plans made according to the methods claimed in the ’217 patent.

176. On information and belief, Straumann has been and is now indirectly infringing the ’217 patent in violation of 35 U.S.C. § 271(b), at least by inducing ClearCorrect to make and use software that practices one or more claims of the ’217 patent and/or by inducing ClearCorrect to use and/or import in the United States treatment plans made according to the methods claimed in one or more claims of the ’217 patent. On information and belief, Straumann induces ClearCorrect to perform treatment planning and use treatment plans as explained in paragraph 156 of this Complaint.

177. Both ClearCorrect and Straumann have known of the ’217 patent and their infringement of the same since at least service of this Complaint.

178. On information and belief, ClearCorrect and Straumann knew of the ’217 patent and their infringement of the same since before service of this Complaint. As explained in paragraphs 158-159 of this Complaint, and on information and belief, ClearCorrect and Straumann knew that ClearCorrect was infringing Align’s ’444 patent—a patent related to the ’217 patent—since at least 2017. These facts, as well as the facts set forth in paragraph 76-77 of this Complaint, give rise to a reasonable inference that ClearCorrect and Straumann monitor the ’444 patent family, have assessed the related ’217 patent, and have determined that ClearCorrect’s also is infringing that patent.

179. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’217 patent and their infringement of the ’217 patent for the

reasons set forth in paragraph 78 of this Complaint, and because their subjective belief in infringement of the ’444 patent led them to form the same belief as to the related ’217 patent.

180. Thus, on information and belief, Straumann knowingly induced ClearCorrect to infringe at least claim 1 of the ’217 patent directly, and Straumann possessed specific intent to cause such direct infringement.

181. ClearCorrect and Straumann’s infringement of the ’217 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys’ fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

182. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann’s infringement of the ’217 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align’s innovative technologies, and loss of Align’s exclusive right to license its invention.

183. Align has sustained and will continue to sustain damages as a result of Defendants’ infringement of the ’217 patent, and Align is entitled to recover damages sustained as a result of Defendants’ infringement in an amount to be proven at trial.

184. ClearCorrect’s method of computing treatment plans practices at least claim 1 of the ’217 patent, as set forth below.

Direct Infringement of Claim 1 of the ’217 Patent

185. Claim 1 of the ’217 patent recites a method comprising:

- selecting a movement pattern from a plurality of movement patterns for moving dental objects from an initial arrangement toward a final arrangement, the dental objects being based on output of a scanning device, the movement pattern defining a schedule of movement of the dental objects during treatment stages as each of the dental objects moves from a respective initial position toward a respective final position;

- calculating, by a computer processor, a respective treatment path for each of the dental objects between its respective initial and final positions;
- identifying, by a computer processor, a collision between a first of the dental objects and a second of the dental objects based at least on one of the respective treatment paths; and
- performing, by a computer processor, a first modification of the schedule of movement in response to the identifying, the first modification comprising:
    - round-tripping the first dental object.

186. On information and belief, and if the preamble is found to be limiting, ClearCorrect performs a method as discussed in the following paragraphs 187-191 of this Complaint.

187. On information and belief, during treatment planning, a computer running ClearCorrect's treatment planning software or a human technician selects a movement pattern from a plurality of movement patterns for moving a patient's teeth, *i.e.*, dental objects, from their initial positions to their final positions. For example, ClearCorrect advertises that, by "[d]efault[,]" ClearCorrect will treatment plan for "Class II Corrections" using "[u]pper molar distalization with ***sequential*** movement[,]" *i.e.*, scheduling some teeth to move before others.[108] It also offers, alternatively, "[n]o class II correction (no molar changes)."[109]

Class II Corrections

Preference Name	Default Preference	Preference Option 2
Class II Corrections	Upper molar distalization with sequential movement	No class II correction (no molar changes).

Additionally, in its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its "internal" software is "functionally equivalent to" Align's software, which preselects a

[108] *Treatment Preferences*, Straumann (Oct. 20, 2023), https://support.clearcorrect.com/hc/en-us/articles/4416586057495-Treatment-Preferences (emphasis added).
[109] *Id.*

movement pattern for moving a patient's teeth and which also allows a technician to override that preselection and select a different movement pattern.[110]

188. On information and belief, ClearCorrect's treatment planning software calculates treatment plans for patients' teeth using electronic representations of patients' teeth based on the output of an intraoral scanner. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated, "ClearCorrect technicians using the ClearCorrect Cut and Stage software use a scan of a PVS impression or the output of an intra-oral scanner of the patient's untreated oral anatomy . . . ."[111] It also stated that its "internal" software is "functionally equivalent to" Align's software, which computes treatment plans based on an electronic representation of a patient's teeth received from, in many cases, an intraoral scanner.[112]

189. On information and belief, a computer running ClearCorrect's treatment planning software calculates a treatment path for each tooth during treatment planning. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software "interprets a series of intermediate states that adhere to defined maximum tooth motions and clinician instructions."[113] Then, only "as necessary," a "technician further refines these intermediate states."[114] On information and belief, the phrase "interpret[] a series of intermediate states" refers to staging the movement of a patient's teeth for each phase of treatment with aligners, which would include calculating a treatment path for each tooth. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which calculates a treatment path for each tooth during treatment planning, including each intermediate state for each tooth between each tooth's respective initial and final positions.[115]

190. On information and belief, a computer running ClearCorrect's treatment planning software detects collisions between teeth that would occur according to some treatment paths.

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[110] Ex. 12 at 8.
[111] *Id.*
[112] *Id.*
[113] *Id.*
[114] *Id.*
[115] *Id.*

For example, ClearCorrect advertises that its ClearPilot software can perform "collision management."[116] ClearCorrect's treatment planning software also must detect collisions between teeth because, otherwise, it could not plot a treatment plan that avoided collisions and thereby allowed a patient's teeth to reach their final positions. Finally, in its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its "internal" software is "functionally equivalent to" Align's software, which detects collisions.[117]

191. On information and belief, a computer running ClearCorrect's treatment planning software will modify a treatment plan via round-tripping, where necessary, to avoid a collision between teeth. ClearCorrect advertises that its technicians will, by default, treatment plan for "Moderate-Severe Crowding (Class II)" using "anterior round tripping as needed[,]" *i.e.*, to avoid a collision.[118] ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which iteratively modifies its treatment plans to avoid collisions, including via round-tripping.[119]

COUNT 10

INFRINGEMENT OF U.S. PATENT NO. 10,524,879

192. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

193. On information and belief, ClearCorrect has been and is now directly infringing the '879 patent in this district and elsewhere, in violation of 35 U.S.C. § 271(a) at least by making and using software that practices one or more claims of the '879 patent. For example, on information and belief, ClearCorrect's use of its treatment planning software to perform treatment planning infringes at least claim 1 of the '879 patent.

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[116] *See, e.g.*,*ClearPilot™ 7.0 - Use of ClearPilot and 3D Controls*, ClearCorrect (2024), https://support.clearcorrect.com/hc/en-us/articles/4617115008279-ClearPilot-7-0-Use-of-ClearPilot-and-3D-Controls.
[117] Ex. 12 at 8.
[118] *Treatment Preferences*, ClearCorrect (Oct. 20, 2023), https://support.clearcorrect.com/hc/en-us/articles/4416586057495-Treatment-Preferences.
[119] Ex. 12 at 8.

194. On information and belief, ClearCorrect has been and is now directly infringing the ’879 patent in this district and elsewhere in violation of 35 U.S.C. § 271(g) at least by importing into the United States or offering to sell, selling, and using, to manufacture aligners, treatment plans made according to the methods claimed in the ’879 patent.

195. On information and belief, Straumann has been and is now indirectly infringing the ’879 patent in violation of 35 U.S.C. § 271(b), at least by inducing ClearCorrect to make and use software that practices one or more claims of the ’879 patent and/or by inducing ClearCorrect to use and/or import in the United States treatment plans made according to the methods claimed in one or more claims of the ’879 patent. On information and belief, Straumann induces ClearCorrect to perform treatment planning and use treatment plans as explained in paragraph 156 of this Complaint.

196. Both ClearCorrect and Straumann have known of the ’879 patent and their infringement of the same since at least service of this Complaint.

197. On information and belief, ClearCorrect and Straumann knew of the ’879 patent and their infringement of the same since before service of this Complaint. As explained in paragraphs 158-159 of this Complaint, and on information and belief, ClearCorrect and Straumann knew that ClearCorrect was infringing Align’s ’444 patent—a patent related to the ’879 patent—since at least 2017. These facts, as well as the facts set forth in paragraphs 76-77 of this Complaint, give rise to a reasonable inference that ClearCorrect and Straumann monitor the ’444 patent family, have assessed the related ’879 patent, and have determined that ClearCorrect also is infringing that patent.

198. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the ’879 patent and their infringement of the ’879 patent for the reasons set forth in paragraph 78 of this Complaint, and because their subjective belief in infringement of the ’444 patent led them to form the same belief as to the related ’879 patent.

199. Thus, on information and belief, Straumann knowingly induced ClearCorrect to directly infringe at least claim 1 of the ’879 patent, and Straumann possessed specific intent to cause such direct infringement.

200. ClearCorrect and Straumann’s infringement of the ’879 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys’ fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

201. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann’s infringement of the ’879 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align’s innovative technologies, and loss of Align’s exclusive right to license its invention.

202. Align has sustained and will continue to sustain damages as a result of Defendants’ infringement of the ’879 patent, and Align is entitled to recover damages sustained as a result of Defendants’ infringement in an amount to be proven at trial.

203. ClearCorrect’s method of computing treatment plans practices at least claim 1 of the ’879 patent, as set forth below.

Direct Infringement of Claim 1 of the ’879 Patent

204. Claim 1 of the ’879 patent recites a computer-implemented method comprising:

- determining, by one or more computer processors, a schedule of movement for dental objects during treatment stages, the dental objects being based on output of a scanning device, wherein the schedule of movement indicates whether each of the dental objects moves during each of the treatment stages;
- calculating, by one or more computer processors, a respective route from an initial position toward a final position for each of the dental objects during the treatment stages; and

- modifying, by one or more computer processors, the schedule of movement to avoid a collision or obstruction between two of the dental objects on their respective routes, the modifying comprising:
    - delaying initial movement of one of the dental objects; and
    - round-tripping one of the dental objects.

205. On information and belief, and if the preamble is found to be limiting, a computer running ClearCorrect's and Stage software performs a computer implemented method as discussed the following paragraphs 206-209 of this Complaint.

206. On information and belief, a computer running ClearCorrect's treatment planning software determines a schedule of movement for each tooth during treatment planning. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software "interprets a series of intermediate states that adhere to defined maximum tooth motions and clinician instructions."[120] Then, only "as necessary," a "technician further refines these intermediate states."[121] On information and belief, the phrase "interpret[] a series of intermediate states" refers to staging the movement of a patient's teeth for each phase of treatment with aligners, which would include determining a schedule of movement indicating whether each tooth moves during each phase. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which determines a schedule of movement for each tooth during treatment planning, including whether each tooth moves during each treatment stage.[122]

207. On information and belief, ClearCorrect's treatment planning software calculates treatment plans for patients' teeth using electronic representations of patients' teeth based on the output of an intraoral scanner. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated, "ClearCorrect technicians using the ClearCorrect Cut and Stage software use a scan of a PVS impression or the output of an intra-oral scanner of the patient's untreated oral anatomy . . .

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[120] Ex. 12 at 8.
[121] *Id.*
[122] *Id.*

."[123] It also stated that its "internal" software is "functionally equivalent to" Align's software, which computes treatment plans based on an electronic representation of a patient's teeth received from, in many cases, an intraoral scanner.[124]

208. On information and belief, a computer running ClearCorrect's treatment planning software calculates a route for each tooth during treatment planning. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software "interprets a series of intermediate states that adhere to defined maximum tooth motions and clinician instructions."[125] Then, only "as necessary," a "technician further refines these intermediate states."[126] On information and belief, the phrase "interpret[] a series of intermediate states" refers to staging the movement of a patient's teeth for each phase of treatment with aligners, which would include calculating the route for each tooth. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which calculates a route for each tooth during treatment planning from each tooth's respective initial position to its final position.[127]

209. On information and belief, a computer running ClearCorrect's treatment planning software will modify a treatment plan via delaying an initial movement of one or more teeth (*i.e.*, staggering) and via round-tripping, where necessary, to avoid collisions between teeth. ClearCorrect advertises that its technicians will, by default, treatment plan for "Moderate-Severe Crowding (Class II)" using "anterior round tripping as needed."[128] And, as explained in paragraph 23 of this Complaint, ClearCorrect published YouTube video showing its ClearPilot software animating a treatment plan with staggering.[129] Finally, ClearCorrect also stated that its

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[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] *Id.*
[128] *Treatment Preferences*, ClearCorrect (Oct. 20, 2023), https://support.clearcorrect.com/hc/en-us/articles/4416586057495-Treatment-Preferences.
[129] *ClearPilot features: The Control is in Your Hands*, ClearCorrect (Jan. 25, 2021), https://www.youtube.com/watch?v=DYVS21zqH0c.

"internal" software is "functionally equivalent to" Align's software, which iteratively modifies its treatment plans to avoid collisions, including via staggering and round-tripping.[130]

COUNT 11

INFRINGEMENT OF U.S. PATENT NO. 11,369,456

210. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

211. On information and belief, ClearCorrect has been and is now directly infringing the '456 patent in this district and elsewhere, in violation of 35 U.S.C. § 271(a) at least by making and using software that practices one or more claims of the '456 patent. For example, on information and belief, ClearCorrect's use of its treatment planning software to perform treatment planning infringes at least claim 1 of the '456 patent.

212. On information and belief, ClearCorrect has been and is now directly infringing the '456 patent in this district and elsewhere in violation of 35 U.S.C. § 271(g) at least by importing into the United States or offering to sell, selling, and using, to manufacture aligners, treatment plans made according to the methods claimed in the '456 patent.

213. On information and belief, Straumann has been and is now indirectly infringing the '456 patent in violation of 35 U.S.C. § 271(b), at least by inducing ClearCorrect to make and use software that practices one or more claims of the '456 patent and/or by inducing ClearCorrect to use and/or import in the United States treatment plans made according to the methods claimed in one or more claims of the '456 patent. On information and belief, Straumann induces ClearCorrect to perform treatment planning and use treatment plans as explained in paragraph 156 of this Complaint.

214. Both ClearCorrect and Straumann have known of the '456 patent and their infringement of the same since at least service of this Complaint.

215. On information and belief, ClearCorrect and Straumann knew of the '456 patent and their infringement of the same since before service of this Complaint. As explained in

[130] Ex. 12 at 8.

paragraphs 158-159 of this Complaint, and on information and belief, ClearCorrect and Straumann knew that ClearCorrect was infringing Align's '444 patent—a patent related to the '456 patent—since at least 2017. These facts, as well as the facts set forth in paragraphs 76-77 of this Complaint, give rise to a reasonable inference that ClearCorrect and Straumann monitor the '444 patent family, have assessed the related '456 patent, and have determined that ClearCorrect also is infringing that patent.

216. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the '456 patent and their infringement of the '456 patent for the reasons set forth in paragraph 78 of this Complaint, and because their subjective belief in infringement of the '444 patent led them to form the same belief as to the related '456 patent.

217. Thus, on information and belief, Straumann knowingly induced ClearCorrect to directly infringe at least claim 1 of the '456 patent, and Straumann possessed specific intent to cause such direct infringement.

218. ClearCorrect and Straumann's infringement of the '456 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys' fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

219. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann's infringement of the '456 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align's innovative technologies, and loss of Align's exclusive right to license its invention.

220. Align has sustained and will continue to sustain damages as a result of Defendants' infringement of the '456 patent, and Align is entitled to recover damages sustained as a result of Defendants' infringement in an amount to be proven at trial.

221. ClearCorrect method of computing treatment plans practices at least claim 1 of the '456 patent, as set forth below.

Direct Infringement of Claim 1 of the ’456 Patent

222. Claim 1 of the ’456 patent recites a computer implemented method comprising:

- determining a schedule of movement for dental objects during treatment stages of an orthodontic treatment, wherein the schedule of movement indicates whether or not each of the dental objects moves during each of the treatment stages;
- calculating a respective treatment path for each of the dental objects between their respective initial position and respective final position;
- identifying a collision between a first of the dental objects and a second of the dental objects based at least on the schedule of movement of the dental objects and the respective treatment paths;
- performing a first modification of the schedule of movement in response to the identifying, the first modification of the schedule of movement modifying whether or not at least one of the dental objects move during at least one of the treatment stages;
- determining that the first modification does not avoid a collision between the first of the dental objects and the second of the dental objects; and
- performing a second modification of the schedule of movement after the determining that the first modification does not avoid a collision, the second modification of the schedule of movement modifying whether or not at least one of the dental objects move during at least one of the treatment stages.

223. On information and belief, and if the preamble is found to be limiting, a computer running ClearCorrect’s treatment planning software performs a computer implemented method as discussed the following paragraphs 224-230 of this Complaint.

224. On information and belief, a computer running ClearCorrect’s treatment planning software determines a schedule of movement for each tooth during treatment planning. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software “interprets a series of intermediate states that adhere to defined maximum tooth motions and

clinician instructions."[131] Then, only "as necessary," a "technician further refines these intermediate states."[132] On information and belief, the phrase "interpret[] a series of intermediate states" refers to staging the movement of a patient's teeth for each phase of treatment with aligners, including determining whether each tooth moves during each stage of treatment. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which determines a schedule of movement for each tooth during treatment planning, including whether each tooth moves during each treatment stage.[133]

225. On information and belief, a computer running ClearCorrect's treatment planning software calculates a treatment path for each tooth during treatment planning. In its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its Cut and Stage software "interprets a series of intermediate states that adhere to defined maximum tooth motions and clinician instructions."[134] Then, only "as necessary," a "technician further refines these intermediate states."[135] On information and belief, the phrase "interpret[] a series of intermediate states" refers to staging the movement of a patient's teeth for each phase of treatment with aligners, which includes determining the path that each tooth takes during treatment between its initial and final positions. ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which calculates a treatment path for each tooth during treatment planning, including each intermediate state for each tooth between each tooth's respective initial and final positions.[136]

226. On information and belief, a computer running ClearCorrect's treatment planning software identifies collisions between teeth that would occur based on a treatment plan, which includes the schedule of movement and the treatment paths of each tooth. For example,

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[131] Ex. 12 at 8.
[132] *Id.*
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] *Id.*

ClearCorrect advertises that its ClearPilot software can perform "collision management."[137] ClearCorrect's treatment planning software also must identify collisions between teeth because, otherwise, it could not plot a treatment plan that avoided collisions and thereby allowed a patient's teeth to reach their final positions. Finally, in its October 2022, 510(k) submission to the FDA, ClearCorrect stated that its "internal" software is "functionally equivalent to" Align's software, which identifies collisions.[138]

227. On information and belief, a computer running ClearCorrect's treatment planning software will modify a treatment plan by modifying whether at least one tooth moves during treatment in response to identifying a collision. For example, as explained in paragraph 23 of this Complaint, ClearCorrect published a YouTube video showing its ClearPilot software animating a treatment plan including staggering a tooth to avoid a collision.[139] ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which iteratively modifies its treatment plans—including by staggering—to avoid collisions.[140]

228. On information and belief, a computer running ClearCorrect's treatment planning software sometimes will determine that the first modification does not avoid a collision between two dental objects. On information and belief, this is so because treatment planning involves iteratively calculating possible treatment plans and rejecting treatment plans that result in collisions. Indeed, ClearCorrect stated that its "internal" software is "functionally equivalent to" Align's software, which iteratively calculates its treatment plans to avoid collisions.[141]

229. On information and belief, a computer running ClearCorrect's treatment planning software will perform a second modification of a treatment plan by modifying whether at least one tooth moves during treatment in response to the failure of the first modification to avoid a

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[137] *See, e.g.*,*ClearPilot™ 7.0 - Use of ClearPilot and 3D Controls*, ClearCorrect (2024), https://support.clearcorrect.com/hc/en-us/articles/4617115008279-ClearPilot-7-0-Use-of-ClearPilot-and-3D-Controls.
[138] Ex. 12 at 8.
[139] *ClearPilot features: The Control is in Your Hands*, ClearCorrect (Jan. 25, 2021), https://www.youtube.com/watch?v=DYVS21zqH0c.
[140] Ex. 12 at 8.
[141] *Id.*

collision. As explained in paragraph 23 of this Complaint, ClearCorrect published a YouTube video showing its ClearPilot software animating a treatment plan including staggering a tooth to avoid a collision.[142] ClearCorrect also stated that its "internal" software is "functionally equivalent to" Align's software, which iteratively modifies its treatment plans—including by staggering—to avoid collisions.[143]

230. The following stills from a ClearCorrect YouTube video of its ClearPilot software animating a treatment plan further confirm that a computer running ClearCorrect's treatment planning software iteratively modifies whether teeth move to avoid collisions as claimed.[144] As shown in the below stills, a tooth circled in green moves first, followed by a tooth circled in blue and then a tooth circled in red. On information and belief, creating the treatment plan reflected in these stills involved a computer iteratively checking whether the tooth circled in red could move to its final position without colliding with the tooth circled in blue and iteratively delaying movement until after both the blue- and green-circled teeth had moved out of the way.

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[142] *ClearPilot features: The Control is in Your Hands*, ClearCorrect (Jan. 25, 2021), https://www.youtube.com/watch?v=DYVS21zqH0c.
[143] Ex. 12 at 8.
[144] *ClearPilot features: The Control is in Your Hands*, ClearCorrect (Jan. 25, 2021), https://www.youtube.com/watch?v=DYVS21zqH0c.

COUNT 12

INFRINGEMENT OF U.S. PATENT NO. 10,791,936

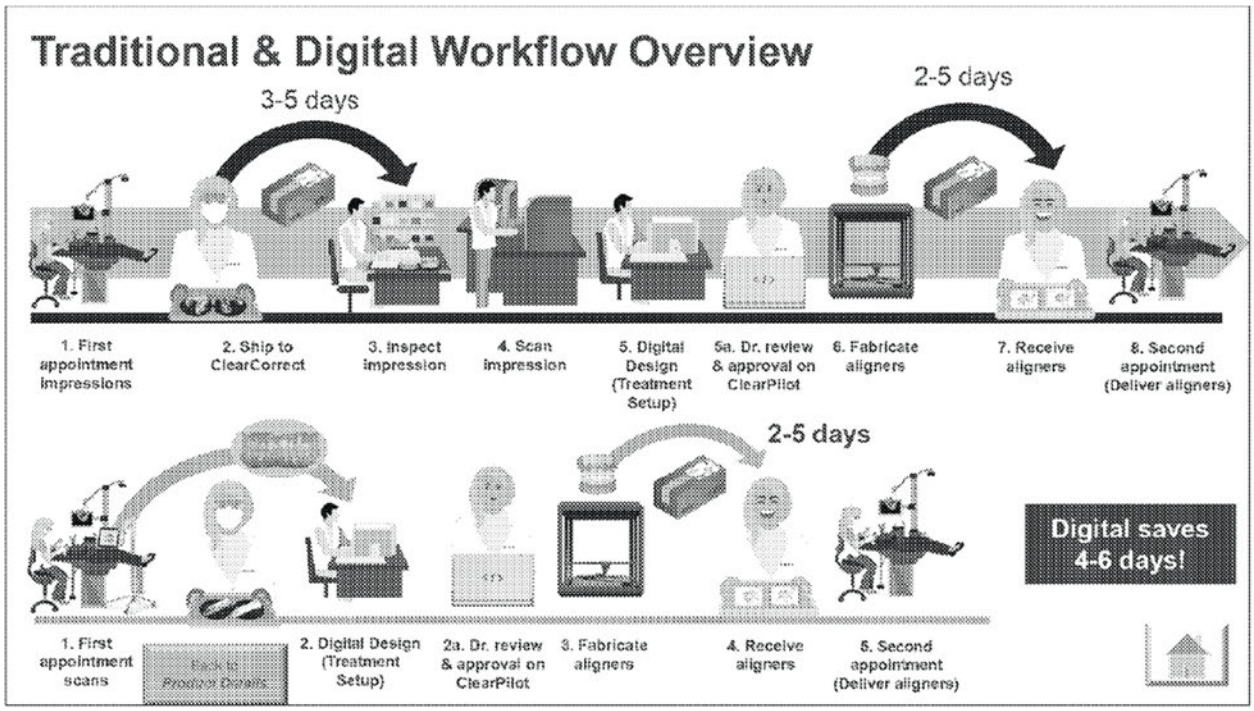
231. Align realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

232. On information and belief, Straumann and ClearCorrect have been and are now indirectly infringing the '936 patent in violation of 35 U.S.C. § 271(b) by inducing doctors to use intraoral scanner systems that practice one or more claims of the '936 patent. On information and belief, ClearCorrect directs doctors to scan their patients' teeth using Straumann's Virtuo Vivo intraoral scanner system in connection with ClearCorrect's aligner business.[145] Similarly, on information and belief, Straumann advertises the Virtuo Vivo intraoral scanner on its website and publishes content that instructs doctors how to use that system.[146] Underscoring that

[145] *See How to Submit a Case with a Virtuo Vivo Scanner Tutorial*, ClearCorrect (June 19, 2023), https://support.clearcorrect.com/hc/en-us/articles/4415474813463-How-to-Submit-a-Case-with-a-Virtuo-Vivo-Scanner-Tutorial.

[146] *See Virtuo Vivo™ Intraoral Scanner*, Straumann (2024), https://www.straumann.com/en/dental-professionals/products-and-solutions/cares-digital-

ClearCorrect's aligner sales motivate doctors to scan their patients' teeth using intraoral scanners, a ClearCorrect slide deck admits that "ClearAligners are driving digital deployment in the clinic[.]"[147] That slide deck specifically encourages doctors to use intraoral scanners rather than conventional impression kits, as illustrated below:[148]



233. Both ClearCorrect and Straumann have known of the '936 patent and their infringement of the same since at least service of this Complaint.

234. On information and belief, ClearCorrect knew of the '936 patent and its infringement of the same since before service of this Complaint. On information and belief, ClearCorrect was familiar with Align's patent portfolio because the ClearCorrect and Align have a long history of litigating patent infringement. Align and ClearCorrect have litigated twice in

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solutions/equipment/io-scanners/virtuo-vivo.html; *Digital Academy*, Straumann (2024), https://www.straumann.com/en/dental-professionals/products-and-solutions/cares-digital-solutions/digital-academy.html.

[147] *Bay Materials LLC v. 3M Company*, No. 21-cv-01610-RGA-JLH, Dkt. No. 92-3 at 21 (D. Del. March 3, 2022).

[148] *Id.* at 78.

the Southern District of Texas[149] and Align has filed two ITC actions against ClearCorrect.[150] ClearCorrect, meanwhile, has filed two petitions for *inter partes* review against Align's patents,[151] including against Align's '444 patent, which Align never asserted against ClearCorrect before this Complaint. These facts, as well as the facts set forth in paragraph 76 of this Complaint, give rise to a reasonable inference that ClearCorrect monitors Align's patent portfolio and evaluates whether its actions infringe Align's patents, including the '936 patent.

235. On information and belief, Straumann also knew of the '936 patent and that it was infringing that patent since before service of this Complaint. On information and belief, Straumann was familiar with Align's patent portfolio at least because, in 2019, Straumann negotiated ClearCorrect's settlement of patent litigation with Align. These facts, as well as the facts set forth in paragraph 77 of this Complaint, give rise to a reasonable inference that Straumann monitors Align's patent portfolio and evaluates whether its actions infringe Align's patents, including the '936 patent.

236. Furthermore, on information and belief, ClearCorrect and Straumann were at least willfully blind to the existence of the '936 patent and their infringement of that patent for the reasons set forth in paragraph 78 of this Complaint.

237. Thus, on information and belief, Straumann and ClearCorrect knowingly induced infringement of at least claim 1 of the '936 patent and had specific intent to cause such direct infringement.

238. ClearCorrect and Straumann's infringement of the '936 patent also was and continues to be deliberate and willful, and this is therefore an exceptional case warranting an award of enhanced damages and attorneys' fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

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[149] *ClearCorrect, Inc. v. Align Technology, Inc.*, No. 09-cv-00470-GHM (S.D. Tex.); *Align Technology, Inc. v. ClearCorrect, Inc. et al*, No. 11-cv-00695-VDG (S.D. Tex.).
[150] *In the Matter of Certain Incremental Dental Position Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Terminated); *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-833 (Terminated).
[151] *ClearCorrect Operating, LLC et al v. Align Technology, Inc.*, IPR2016-00270 (P.T.A.B.); *ClearCorrect Operating, LLC et al v. Align Technology, Inc.*, IPR2017-01829 (P.T.A.B.).

239. Unless ClearCorrect and Straumann are enjoined, Align will continue to suffer irreparable harm for which there is no adequate remedy at law. On information and belief, ClearCorrect and Straumann's infringement of the '936 patent has caused and continues to cause irreparable harm to Align, including in this district, in the form of, among other things, loss of market share, lost business opportunities and sales, loss of goodwill associated with Align's innovative technologies, and loss of Align's exclusive right to license its invention.

240. Align has sustained and will continue to sustain damages as a result of ClearCorrect and Straumann's infringement of the '936 patent, and Align is entitled to recover damages sustained as a result of that infringement in an amount to be proven at trial.

241. The Virtuo Vivo intraoral scanner system practices at least claim 1 of the '936 patent as set forth below.

Direct Infringement of Claim 1 of the '936 Patent

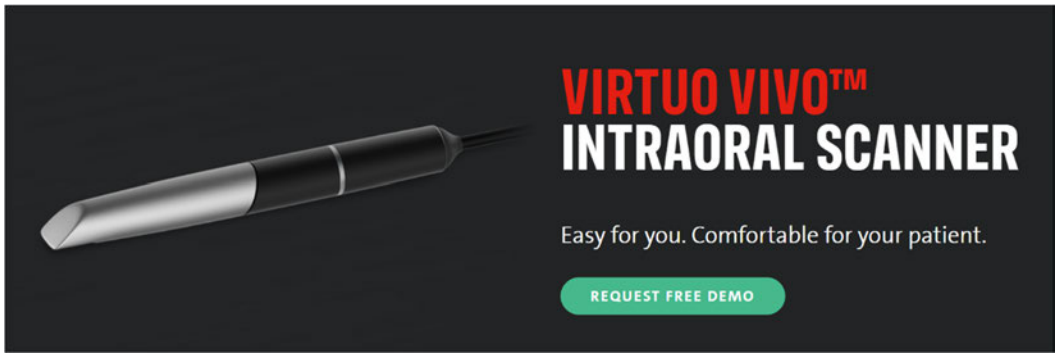
242. Claim 1 of the '936 patent recites a system for scanning a patient's teeth for a dental procedure. The system of the claimed method comprises:

- A hand-held intraoral scanner; and
- A computer readable medium including instructions that, when executed by a computer system, cause the computer system to:
    - Receive first scan data of the patient's teeth from the hand-held intraoral scanner;
    - 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;
    - Receive user input defining a portion of the model to be removed;
    - Remove, from the displayed model, a removed surface portion of the model to be removed according to the user input;
    - Receive second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a physically changed portion of the patient's intraoral cavity; and

- Replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity; and
- Output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data.

243. On information and belief, and if the preamble is found to be limiting, the Virtuo Vivo intraoral scanner wand and accompanying computer, display, and software is a system for scanning a patient's teeth for a dental procedure.

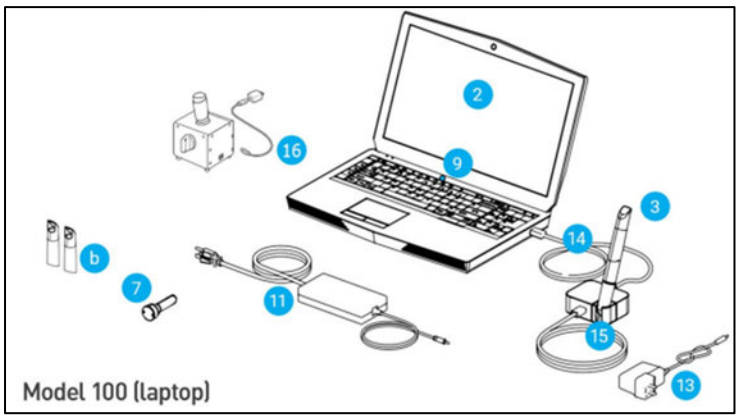
244. On information and belief, the Virtuo Vivo intraoral scanner wand is a hand-held scanner.[152] An image of the scanner wand from Straumann's website is shown below:



245. On information and belief, the Virtuo Vivo intraoral scanner system includes a computer.[153] An image of the system, including a laptop computer, is shown below:

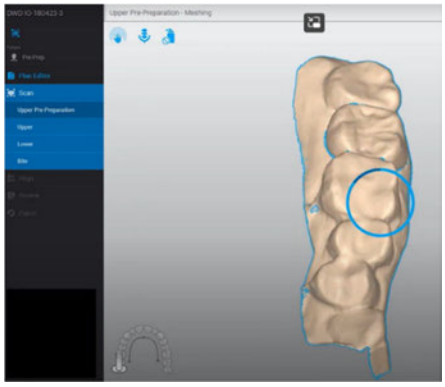
[152] *See Virtuo Vivo Intraoral Scanner*, Straumann (2024), https://www.straumann.com/en/dental-professionals/products-and-solutions/cares-digital-solutions/equipment/io-scanners/virtuo-vivo.html.
[153] *See Intraoral Scanner: Instructions for Use* at 17, Dental Wings https://ifu.dentalwings.com/ifu/vivo/archive/hp3/Intraoral%20Scanner%20Instructions%20for%20Use_EN_v.4.1.0.pdf.

246. On information and belief, the Virtuo Vivo computer is configured to receive scan data of the patient's teeth from the intraoral scanner. For instance, the following image from the Virtuo Vivo intraoral scanner system's manual shows a USB cable 14 connecting the scanner wand to the computer:[154]

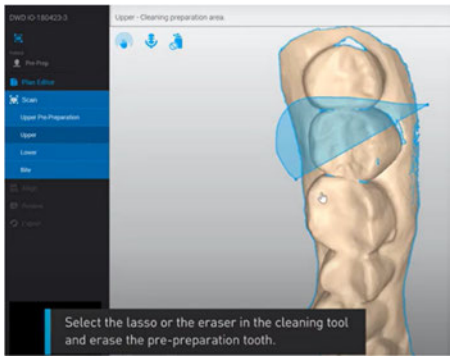


[154] *Id.* at 17, 48.

247. On information and belief, the Virtuo Vivo intraoral scanner system's display is configured to show a model of the patient's teeth, where the model of the patient's teeth is based on the received first scan data of the patient's teeth. On information and belief, the system is configured to render the virtual model based on the received first scan data of the patient's teeth both during acquisition and upon completion of the first scan. For example, below is a still from a YouTube video that, on information and belief, shows the system rendering an initial scan of a patient's teeth:[155]

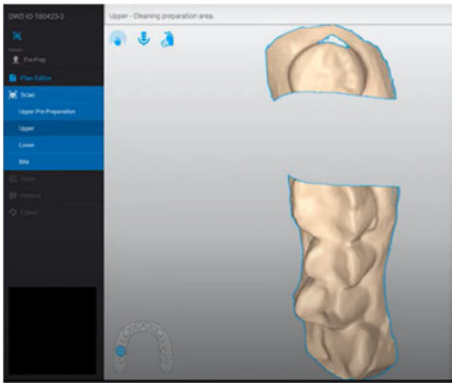


248. On information and belief, the system is configured to receive a user input defining a portion of the model to be removed. For example, below is still from a YouTube video that, on information and belief, shows the system receiving such input:[156]

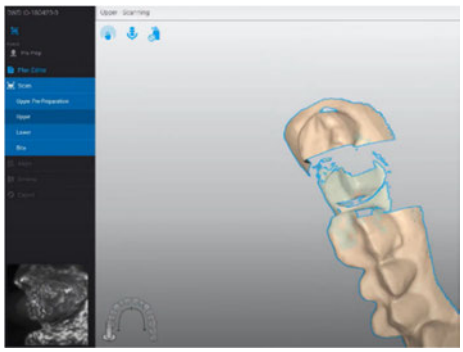


[155] *See Pre Preparation Workflow* Video at 1:23, Dental Wings (Apr. 5, 2019) https://www.youtube.com/watch?v=TsOMsxjWTUk.
[156] *Id.* at 1:41.

249. On information and belief, the system is configured to remove, from the displayed model, a portion of the model according to user input. For example, below is a still from a YouTube video that shows the system removing the defined region:[157]

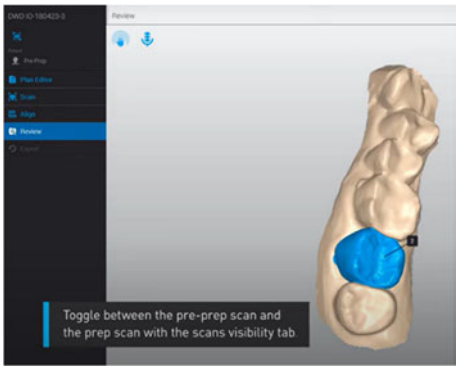


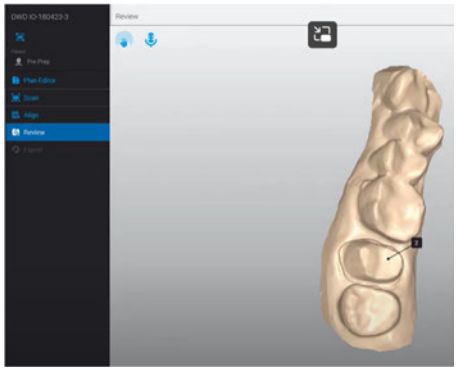
250. On information and belief, the system is configured to receive additional scan data of the patient's teeth from the scanner wand, where the scan data includes surface data of a physically changed portion of the patient's intraoral cavity. For example, below is a still from a YouTube video that shows the system receiving scan data of a physically changed tooth:[158]



251. On information and belief, the system is configured to output, to the display, a revised 3D model of the patient's teeth incorporating the additional scan data. For example, below are two stills from a YouTube video that show the system replacing a (blue) removed portion of the 3D model with a beige scan of the physically changed tooth:[159]

[157] *Id.* at 1:47.
[158] *Id.* at 1:54-1:59.
[159] *Id.* at 4:12 (left, old data) and 4:21 (right, new data).


Review
Toggle between the pre-prep scan and
the prep scan with the scans visibility tab.


Review

PRAYER FOR RELIEF

WHEREFORE, Align prays for the following relief:

a) A judgment in favor of Align that ClearCorrect and Straumann have engaged in false advertising under 15 U.S.C. § 1125(a), unfair competition, and a civil conspiracy;

b) A judgment in favor of Align requiring ClearCorrect and Straumann to pay Align damages adequate to compensate it for their false advertising, unfair competition, and civil conspiracy in an amount reflecting Align's lost profits, costs of corrective advertising, and damage to its goodwill and the disgorgement of ClearCorrect and Straumann's profits, with an accounting, as needed, and pre-judgment and post-judgment interest, fees, and costs;

c) A judgment in favor of Align that damages and profits be trebled and awarded to Align under 15 U.S.C. § 1117, as a result of ClearCorrect and Straumann's willful violation of the Lanham Act;

d) An order requiring ClearCorrect and Straumann, their officers, agents, servants, employees, attorneys, and all others in active concert or participation to remedy their false advertising, including by:

   (1) Placing corrective advertising on their websites informing consumers of their earlier misrepresentations; and

   (2) Contacting providers to whom they distributed false advertising to correct the misrepresentations made;

e) A permanent injunction enjoining ClearCorrect, Straumann, and their respective officers, agents, servants, employees, and attorneys and those persons in active concert or participation with them from:

   (1) Making false or misleading statements comparing ClearCorrect's aligners to Align's aligners;

   (2) Making false or misleading statements regarding the superiority of ClearCorrect's aligners; and

(3) Committing any other unlawful business practices directed toward obtaining the business and customers of Align;

f) A judgment in favor of Align that ClearCorrect and Straumann have directly and/or indirectly infringed on or more claims of the Asserted Patents under 35 U.S.C. § 271;

g) A judgment in favor of Align requiring ClearCorrect and Straumann to pay Align damages adequate to compensate it for their infringement of the Asserted Patents, in an amount reflecting its lost profits and not less than a reasonable royalty, and including supplemental damages for any continuing post-verdict infringement up until the entry of judgment, with an accounting, as needed, pre-judgment and post-judgment interest, and costs pursuant to 35 U.S.C. § 284;

h) A judgment in favor of Align that ClearCorrect and Straumann's infringement of the Asserted Patents was willful, and awarding Align enhanced damages under 35 U.S.C. § 284;

i) A judgment in favor of Align that this case is exceptional under 35 U.S.C. § 285 and awarding Align its attorney's fees;

j) A permanent injunction enjoining ClearCorrect, Straumann, and their respective officers, agents, servants, employees, and attorneys and those persons in active concert or participation with them, from directly or indirectly infringing the Asserted Patents in violation of 35 U.S.C. § 271; and

k) Further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Align demands trial by jury on all issues raised by the Complaint.

Dated: April 11, 2024

Respectfully submitted,

/s/ Brian C. Nash

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