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IN THE 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.	Civil Action No. 6:24-cv-00187-ADA-DTG **JURY TRIAL DEMANDED** **PATENT CASE** [redacted] **PUBLIC VERSION**
CLEARCORRECT OPERATING, LLC, CLEARCORRECT, HOLDINGS, INC., & STRAUMANN USA, LLC, Counterclaim-Plaintiffs, v. **ALIGN TECHNOLOGY, INC.,** Counterclaim-Defendant.	

DEFENDANTS CLEARCORRECT OPERATING, LLC AND CLEARCORRECT HOLDINGS, INC.'S ANSWER AND AFFIRMATIVE DEFENSES AND COUNTERCLAIM-PLAINTIFFS' COUNTERCLAIMS TO ALIGN TECHNOLOGY, INC.'S COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

Plaintiff Align Technology, Inc.'s ("Align" or "Plaintiff") Complaint declares that "ClearCorrect and Straumann are welcome to compete for sales of orthodontic treatments," Dkt. 1 at ¶ 7, but Align's own monopolistic conduct forecloses the free and fair competition to which ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. (collectively, for purposes of the Answer and Affirmative Defenses, "ClearCorrect") are entitled. Align's Complaint maintains

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that it has achieved marketplace success through continued research and development (purportedly resulting in the patents it asserts in this case), *id*. at ¶¶ 1, 14, but in fact its dominant positions with respect to clear aligners and intraoral scanners are the result of unlawful coercion of dental practitioners—leveraging its Invisalign® monopoly to build what it refers to as a "competitive moat" that unlawfully forces doctors to buy its iTero® scanner and locks them into Invisalign® exclusively or nearly exclusively. Align's Complaint alleges that ClearCorrect has engaged in false advertising (although Align tellingly stops short of saying ClearCorrect's advertising claims are untrue in any way), *id*. at ¶¶ 33-37, but it is Align that is perpetually misleading the market about Invisalign® and unfairly degrading competitors through its own ongoing campaign of false advertising. Finally, Align's Complaint baselessly accuses ClearCorrect and Institut Straumann AG of infringing various Align patents, *id*. at ¶¶ 68-251, but neither ClearCorrect nor Institut Straumann AG infringe any valid Align patent, and the Complaint itself is just the latest attempt by Align to continue to suppress fair competition in the market for clear aligners.

ClearCorrect has developed its own innovative technology for clear aligner products and treatments, and ClearCorrect is attempting to compete against Align on its own technological and economic merits—by offering a better product at a lower price. Align's baseless infringement allegations seek to intimidate ClearCorrect and to impair ClearCorrect's ability to compete. Moreover, these infringement allegations are made against the backdrop of a comprehensive exclusionary scheme and false advertising campaign by Align to unlawfully foreclose competition and tilt that marketplace in Align's favor—preventing fair competition on a level playing field. Thus, the purported damages and "lost profits" Align seeks in this case do not in any way reflect any gains ClearCorrect obtained unfairly from Align; rather they reflect the

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minimal inroads ClearCorrect has been able to make despite the unlawful barriers to fair competition Align has erected against all potentially viable competitors.

ClearCorrect denies the infringement and false advertising allegations (as set out herein) and brings counterclaims to hold Align accountable for its unlawful exclusionary conduct. ClearCorrect seeks to end Align's predatory campaign to suppress competition in the doctor-directed clear aligner market—and ClearCorrect thereby seeks the freedom to compete on the merits, to the benefit of consumers and patients.

ANSWER TO COMPLAINT

Defendants ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. (collectively, for purposes of the Answer and Affirmative Defenses, "ClearCorrect") hereby submit their Answer and Affirmative Defenses,[1] and Counterclaim-Plaintiffs ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc., and Straumann USA, LLC (collectively, for purposes of the Counterclaims, "ClearCorrect" or the "Counterclaim-Plaintiffs") hereby submit their Counterclaims to the Complaint for Damages and Injunctive Relief ("Complaint") filed by Align Technology, Inc. on April 11, 2024 (Dkt. 1). ClearCorrect denies all allegations and characterizations in the Complaint unless expressly admitted below.

[1] On June 20, 2024, ClearCorrect filed a motion to dismiss Plaintiff's complaint for failure to state of claim under Fed. R. Civ. P. 12(b)(6). Institut Straumann AG also filed a motion to dismiss Plaintiff's complaint for lack of personal jurisdiction under Fed. R. Civ. P. 12(b)(2), and it conditionally joined ClearCorrect's 12(b)(6) motion. In view of the motion to dismiss for lack of personal jurisdiction, Institut Straumann does not join ClearCorrect in this Answer. By submitting this Answer, ClearCorrect does not waive any arguments presented in its motion to dismiss for failure to state a claim. *See, e.g.*, *Brunig v. Clark*, 560 F.3d 292, 294 (5th Cir. 2009) ("In accordance with [Fed. R. Civ. P. 12(b)], Appellees filed their motion to dismiss before their answer and they were not obligated to wait to answer until the court had ruled on the motion."). Align makes allegations regarding Institut Straumann AG; ClearCorrect has answered these allegations based on its own information and belief, which is not the same as Institut Straumann AG's information and belief. As described in Institut Straumann AG's motion to dismiss, Institut Straumann AG and ClearCorrect are distinct, separate companies. *See* Institut Straumann AG's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(2), filed June 20, 2024 (Dkt. 30).

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NATURE OF THE ACTION[2]

1. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 1 and therefore denies those allegations.

2. The allegations in Paragraph 2 of the Complaint constitute legal conclusions and Align's characterizations of prior litigation, to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect was founded in 2006 and sells customized medical devices that are intended to treat orthodontic conditions to fill a doctor's prescription. ClearCorrect, however, denies that its medical devices were not independently developed—to the contrary, ClearCorrect's aligner solutions are the direct result of years of research by ClearCorrect and its sister companies. ClearCorrect admits that ClearCorrect and Align were engaged in prior litigation. ClearCorrect admits the parties agreed to settle their claims and that the settlement agreement speaks for itself as to form and content. ClearCorrect admits that Straumann Holding AG is the ultimate parent company to ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc., Institut Straumann AG, DrSmile BeNeLux B.V., DrSmile Iberia S.L., DrSmile Polska sp. z o.o., DrSmile Sverige AB, DrSmile France SAS, and DrSmile Italia srl. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 2.

3. The allegations in Paragraph 3 of the Complaint constitute legal conclusions and Align's characterizations of ClearCorrect's business to which no response is required. To the extent a response is required, ClearCorrect denies that its aligners are "copycat aligners." ClearCorrect denies creating and distributing advertising that misleads consumers. ClearCorrect admits that its website includes an image showing the results of stain-resistance testing in which

[2] For ease of reference, ClearCorrect's Answer utilizes the headings used in Align's Complaint, with bracketed text added by ClearCorrect. In so doing, ClearCorrect does not admit any of the allegations contained in those headings. In addition, ClearCorrect's responses to Align's allegations correspond to the numbered paragraphs in Align's Complaint.

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ClearCorrect aligners and aligners from a "Leading Competitor" were immersed in various substances, including mustard, for 24 hours at 37°C, and that the ClearCorrect aligner soaked in mustard does not appear stained, while the competitor aligner soaked in mustard appears yellow. ClearCorrect admits that on straumann.com there is an image showing the results of stain-resistance testing in which ClearCorrect aligners and "[o]ther aligners" were immersed in various substances, including mustard, for 24 hours at 37°C, and that the ClearCorrect aligner soaked in mustard does not appear stained, while the other aligner soaked in mustard appears yellow. ClearCorrect denies that either its website or straumann.com states or implies that patients typically soak their aligners in mustard for 24 hours or that patients eat mustard for 24 hours straight. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 3. To the extent Align's allegations in Paragraph 3 are directed toward Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that they are false for at least the reasons set forth above.

4. The allegations in Paragraph 4 of the Complaint constitute legal conclusions and Align's characterization of ClearCorrect's business, to which no response is required. To the extent a response is required, ClearCorrect denies that Straumann Holding AG acquired Bay Materials LLC. ClearCorrect admits that, in 2019, Straumann Manufacturing, Inc., acquired Bay Materials LLC. ClearCorrect admits that, in or about 2018, Bay Materials released a tri-layer plastic called Zendura FLX. ClearCorrect admits that Bay Materials was a former Align supplier. [redacted] ClearCorrect, however, denies that its ClearQuartz aligners infringe any Align patents and, except as expressly admitted, ClearCorrect denies the remaining allegations of Paragraph 4.

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5. The allegations in Paragraph 5 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that it launched the "ClearPilot" treatment planning software in or about 2020. ClearCorrect admits that it also offers software called "Cut and Stage." ClearCorrect generally lacks sufficient knowledge or information to form a belief regarding the truth of whether "a Straumann entity hired a former Align senior software engineer"—indeed, Align's complaint fails to identify any such hire—and, on that basis, ClearCorrect denies the allegation. ClearCorrect denies that its software has infringed or continues to infringe any claim of Align's patents. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 5.

6. ClearCorrect denies that it promotes or advertises an intraoral scanner system. ClearCorrect denies that this system is "like Align's," and it denies that the system infringes any Align patent. To the extent Align's allegations in Paragraph 6 are directed toward Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that they are false for at least the same reasons set for the herein with respect to ClearCorrect. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 6.

7. The allegations in Paragraph 7 of the Complaint constitute legal conclusions and Align's characterization of ClearCorrect's business and the parties' prior litigation, to which no response is required. ClearCorrect admits that it is entitled to compete with Align. Except as expressly admitted, ClearCorrect denies the remaining allegations of Paragraph 7.

BACKGROUND

Align's Invisalign® System

8. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 8 and therefore denies those allegations.

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9. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 9 and therefore denies those allegations.

10. ClearCorrect denies the characterization of Align's technology as "proprietary" and "state-of-the-art." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 10 and therefore denies those allegations.

11. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 11 and therefore denies those allegations.

12. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 12 and therefore denies those allegations.

13. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 13 and therefore denies those allegations.

Align's [Purported] Proprietary Invisalign® Technologies

14. ClearCorrect denies the characterization of Align's technology as "acclaimed." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 14 and therefore denies those allegations.

15. ClearCorrect denies the characterization of Align's technology as "proprietary." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 15 and therefore denies those allegations.

SmartTrack®: Align's Three-Layer Plastic Aligners

16. ClearCorrect admits that treatment with clear aligner therapy requires the use of a material that is capable of applying force to move the teeth, durable enough for the patient's use, and substantially clear. ClearCorrect denies the characterization of Align's technology as

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"proprietary." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 16 and therefore denies those allegations.

17. The allegations in Paragraph 17 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, ClearCorrect denies that it was copying or that it copied Align's clear aligner product or development of that product. ClearCorrect admits that ClearCorrect, Inc. submitted a 510(k) to the FDA in 2008, which speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect admits that footnotes 3, 4, and the first link in footnote 5 of Paragraph 17 is a link to a webpage titled, "Premarket Notification 510(k)," which speaks for itself as to form and content. ClearCorrect, however, denies that it describes or depicts any infringing conduct. ClearCorrect admits that the second link in footnote 5 of Paragraph 17 is a link to a webpage titled, "Premarket Approval (PMA)," which speaks for itself as to form and content. ClearCorrect, however, denies that it describes or depicts any infringing conduct. The remaining allegations in Paragraph 17 consist of conclusions of law to which no response is required. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 17.

18. ClearCorrect denies that its three-layer aligners and their manufacture practice or have ever practiced Align's U.S. Patent Nos. 10,973,613, 11,154,384, 11,648,090, and 11,648,091. To the contrary, the technology incorporated into ClearCorrect's aligners, including its proprietary tri-layer material, was independently developed and the direct result of years of research by ClearCorrect and related company Bay Materials. ClearCorrect admits that it manufactures aligners with ClearQuartz material in the United States. ClearCorrect admits that it

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obtains the plastic for its aligners from Bay Materials, LLC, a member of the Straumann Group. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect admits that footnote 7 of Paragraph 18 is a link to a webpage for DrSmile titled, "The best technologies for your confident smile" that speaks for itself as to form and content, but ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect admits that footnote 8 of Paragraph 18 is a link to a webpage titled "Aligner Materials – FAQs" that speaks for itself as to form and content but ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect admits it performs customary and lawful market analyses including regarding Align's anticompetitive and exclusionary sales practices but denies any implication that ClearCorrect has gained improper access to nonpublic information about Align's business operations or has copied any Align technology. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 18.

SmartStage®: Align's [Purportedly] Innovative Treatment Planning Software

19. Upon information and belief, ClearCorrect admits that Align was founded in 1997. ClearCorrect admits that devising a treatment may depend on a variety of factors, including those identified in Paragraph 19. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 19 and therefore denies those allegations.

20. ClearCorrect denies the characterization of Align's treatment planning technology as "critical advancements." On information and belief, ClearCorrect admits that Align is the assignee of U.S. Patent Nos. 8,038,444, 10,456,217, 10524,879, and 11,369,456. ClearCorrect

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lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 20 and therefore denies those allegations.

21. ClearCorrect denies that it "imitate[s]" or has ever "imitated" Align. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of whether OrthoClear was founded by the former chairman and CEO of Align and whether Align entered into an agreement with OrthoClear in 2006, including the contents of that agreement. Therefore, ClearCorrect denies the allegations. ClearCorrect also lacks sufficient knowledge or information to form a belief regarding the truth of whether "former Align employees" "work[ed] for … ClearCorrect Pakistan" supplying "treatment plans to ClearCorrect in the United States." Indeed, Align's complaint fails to identify any such employee and, therefore, ClearCorrect denies the allegation. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 21.

22. ClearCorrect admits that Align previously sued ClearCorrect for patent infringement and that the case settled. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 22.

23. ClearCorrect denies that its treatment planning software has "similar features" to Align's treatment planning software. ClearCorrect's software was independently developed through the hard work of its engineers, practitioners, and developers. ClearCorrect admits that the link in footnote 15 of Paragraph 23 is a link to a webpage titled, "Treatment Preferences" and that the page speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect admits that the link in footnote 16 of Paragraph 23 is a link to a YouTube video titled, "ClearPilot features: The Control is in Your Hands" and that the video speaks for itself as to form and content; ClearCorrect denies that it describes or depicts

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any infringing conduct. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 23.

24. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA and that the submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. The 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 24.

Align's Intraoral Scanner Technology

25. ClearCorrect admits that intraoral scanning may have certain benefits over previous casting methods for patient's teeth. ClearCorrect denies Align's characterizations of its technology as "pioneering" and "advanced." ClearCorrect admits that Align asserts U.S. Patent No. 10,791,936 in this case and that it purports to cover certain scanning techniques. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 25 and therefore denies those allegations.

26. ClearCorrect denies that the Virtuo Vivo intraoral scanner infringes or that it promotes an "infringing alternative" to the "Invisalign® system." On information and belief, ClearCorrect also denies that Institut Straumann AG promotes an "infringing alternative" to the "Invisalign® system." ClearCorrect admits that the link in footnote 18 of Paragraph 26 is a link to a webpage titled, "How to Submit a Case with a Virtuo Vivo Scanner Tutorial," which speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect admits that the link in footnote 19 of Paragraph 26 is a link to a webpage titled, "Virtuo Vivo™ Intraoral Scanner," which speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect admits that

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the link in footnote 19 of Paragraph 26 is a link to a webpage titled, "Virtuo Vivo™ Intraoral Scanner," which speaks for itself as to form and content and denies that it describes or depicts any infringing conduct. ClearCorrect admits that the Virtuo Vivo system is capable of scanning. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 26.

Align's [Purportedly] Complementary Technologies

27. ClearCorrect admits that effective aligner treatments generally involve accurate and precise plans for tooth movement and high-quality materials. ClearCorrect denies Align's characterization of its technology as "more than the sum of [its] parts." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 27 and therefore denies those allegations.

28. ClearCorrect admits that intraoral scanner technology, when available, generally may represent an improvement over conventional, putty-based methods of taking physical molds of patients' teeth. ClearCorrect denies Align's characterization of its scanner technology as "innovative." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 28 and therefore denies those allegations.

29. ClearCorrect admits a digital impression can be an input used to create a treatment plan and that the treatment plan may depend on variables including those in Paragraph 29. ClearCorrect denies Align's characterization of its technology as "high-quality." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 29 and therefore denies those allegations.

30. ClearCorrect admits that a high-quality treatment plan may not guarantee success. ClearCorrect admits that the mechanical properties of the aligner material can affect the success of a treatment plan. ClearCorrect lacks sufficient knowledge or information to form a belief

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regarding the truth of the allegations regarding SmartTrack and the remaining allegations in Paragraph 30 and therefore denies those allegations.

31. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 31 and therefore denies those allegations.

32. ClearCorrect denies that it promotes and sells competing technologies "in an effort to reap the same benefits provided by Align's technologies." On information and belief, ClearCorrect also denies that Institut Straumann AG promotes and sells competing technologies "in an effort to reap the same benefits provided by Align's technologies." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations in Paragraph 32 and therefore denies those allegations.

Straumann and ClearCorrect's [Alleged] False Advertising

33. The allegations in Paragraph 33 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 33—ClearCorrect's advertising accurately summarizes and depicts the results of valid testing.

34. ClearCorrect admits that the link in footnotes 20 and 21 of Paragraph 34 is a link to a straumann.com webpage titled, "Premier Aligner" which speaks for itself as to form and content; ClearCorrect denies that it shows any false or misleading advertising. ClearCorrect admits that Exhibit 13 purports to be a trademark registration for U.S. Trademark No. 5,290,579 to Align. ClearCorrect admits that Exhibit 14 purports to be a trademark registration for U.S. Trademark No. 3,911,988 to Align. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the last sentence of paragraph 34, and therefore denies them. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 34.

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35. ClearCorrect admits that the link in footnote 24 of Paragraph 35 is a link to a ClearCorrect webpage titled, "ClearCorrect Aligners," which speaks for itself as to form and content; ClearCorrect denies that it shows any false or misleading advertising. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 35.

36. The allegations in Paragraph 36 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Clear Correct admits that the link in footnote 27 of Paragraph 36 is a link to a document entitled, "Use and Care Instructions for your Invisalign Aligners," which speaks for itself as to form and content; ClearCorrect denies that it shows any false or misleading advertising. ClearCorrect admits that the link in footnote 28 of Paragraph 36 is a link to a ClearCorrect webpage titled, "Wear & Care," which speaks for itself as to form and content; ClearCorrect denies that it shows any false or misleading advertising. ClearCorrect denies that its website states or implies that a "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)." Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 36. To the extent Align's allegations in Paragraph 36 are directed toward Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that they are false for at least the same reasons set for the herein with respect to ClearCorrect.

37. The allegations in Paragraph 37 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 37.

THE PARTIES

38. Upon information and belief, admitted.

39. Admitted.

[redacted]

40. Admitted.

41. Admitted.

THE ASSERTED PATENTS

42. ClearCorrect admits that Align has brought an action purporting to assert infringement of 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") (collectively, the "Asserted Patents"). ClearCorrect denies that it has infringed (directly or indirectly) any claims of the Asserted Patents.

43. ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the allegations in Paragraph 43 and therefore denies those allegations.

The Material Patents

44. ClearCorrect admits that the '613 patent is titled, "Multilayer Dental Appliances and Related Methods and Systems," issued on April 13, 2021 and purports to have issued 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. ClearCorrect admits that Exhibit 1 to Align's complaint purports to be the '613 patent. ClearCorrect denies that the '613 patent was "duly and legally issued." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 44 and therefore denies those allegations.

45. ClearCorrect admits that the '384 patent is titled, "Multilayer Dental Appliances and Related Methods and Systems," issued on October 26, 2021 and purports to have issued from U.S. Application No. 17/214,487 and names Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. ClearCorrect admits that Exhibit 2 to

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Align's complaint purports to be the '384 patent. ClearCorrect denies that the '384 patent was "duly and legally issued." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 45 and therefore denies those allegations.

46. ClearCorrect admits that the '090 patent is titled, "Multilayer Polymer Sheets," issued on May 16, 2023 and purports to have issued from U.S. Application No. 17/858,825 and names Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. ClearCorrect admits that Exhibit 3 to Align's complaint purports to be the '090 patent. ClearCorrect denies that the '090 patent was "duly and legally issued." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 46 and therefore denies those allegations.

47. ClearCorrect admits that the '091 patent is titled, "Multilayer Polymer Sheets," issued on May 16, 2023 and purports to have issued from U.S. Application No. 17/902,445 and names Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert as inventors. ClearCorrect admits that Exhibit 4 to Align's complaint purports to be the '091 patent. ClearCorrect denies that the '091 patent was "duly and legally issued." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 47 and therefore denies those allegations.

The Treatment Planning Patents

48. ClearCorrect admits that the '444 patent is titled, "Automated Treatment Staging for Teeth," issued on October 18, 2011 and purports to have issued from U.S. Application No. 11/848,172 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. ClearCorrect admits that Exhibit 5 to Align's complaint purports to be the '444 patent. ClearCorrect denies that the '444 patent was "duly and legally issued." ClearCorrect lacks

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sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 48 and therefore denies those allegations.

49. ClearCorrect admits that the ’217 patent is titled, “Automated Treatment Staging for Teeth,” issued on October 29, 2019 and purports to have issued from U.S. Application No. 15/834,608 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. ClearCorrect admits that Exhibit 6 to Align’s complaint purports to be the ’217 patent. ClearCorrect denies that the ’217 patent was “duly and legally issued.” ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 49 and therefore denies those allegations.

50. ClearCorrect admits that the ’879 patent is titled, “Automated Treatment Staging for Teeth,” issued on January 7, 2020 and purports to have issued from U.S. Application No. 15/834,649 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. ClearCorrect admits that Exhibit 7 to Align’s complaint purports to be the ’879 patent. ClearCorrect denies that the ’879 patent was “duly and legally issued.” ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 50 and therefore denies those allegations.

51. ClearCorrect admits that the ’456 patent is titled, “Automated Treatment Staging for Teeth,” issued on June 28, 2022 and purports to have issued from U.S. Application No. 16/723,706 and names Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as inventors. ClearCorrect admits that Exhibit 8 to Align’s complaint purports to be the ’456 patent. ClearCorrect denies that the ’456 patent was “duly and legally issued.” ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 51 and therefore denies those allegations.

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The Scanner Patent

52. ClearCorrect admits that the '936 patent is titled, "Methods and Systems for Creating and Interacting with Three Dimensional Virtual Models," issued on October 6, 2020 and purports to have issued from U.S. Application No. 16/586,528 and names Avi Kopelman as the inventor. ClearCorrect admits that Exhibit 9 to Align's complaint purports to be the '936 patent. ClearCorrect denies that the '936 patent was "duly and legally issued." ClearCorrect lacks sufficient knowledge or information to form a belief regarding the truth of the remaining allegations of Paragraph 52 and therefore denies those allegations.

JURISDICTION AND VENUE

53. ClearCorrect admits that Align purports to bring an 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. Paragraph 54 states conclusions of law for which no response is required. To the extent a response is required, ClearCorrect admits that the court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a)-(b). To the extent Align's allegations in Paragraph 54 are directed toward Institut Straumann AG, and upon information and belief, ClearCorrect denies that the Court has jurisdiction over Institut Straumann AG for the reasons explained in its motion to dismiss under Fed. R. Civ. P. 12(b)(2).

55. The allegations in Paragraph 55 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the court has jurisdiction over claims arising under the laws of the State of Texas pursuant to 28 U.S.C. § 1367. To the extent Align's allegations in Paragraph 54 are directed toward Institut Straumann AG, and upon information and belief, ClearCorrect denies that the Court has jurisdiction over Institut Straumann AG for the reasons explained in its motion to dismiss under Fed. R. Civ. P. 12(b)(2).

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56. The allegations in Paragraph 56 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect Operating, LLC is incorporated in Texas and that ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. have a principal place of business in Texas. ClearCorrect Operating, LLC admits that it conducts business in the State of Texas and in the Western District of Texas and that this Court has personal jurisdiction over ClearCorrect in connection with this action. ClearCorrect otherwise denies the allegations in Paragraph 56.

57. The allegations of Paragraph 57 are directed to Institut Straumann AG. Upon information and belief, ClearCorrect denies that the Court has jurisdiction over Institut Straumann AG for the reasons explained in Institut Straumann AG's motion to dismiss under Fed. R. Civ. P. 12(b)(2).

58. The allegations in Paragraph 58 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that this Court has personal jurisdiction over ClearCorrect in connection with this action. The remaining allegations of Paragraph 58 are directed to Institut Straumann AG. Upon information and belief, ClearCorrect denies that the Court has jurisdiction over Institut Straumann AG for the reasons explained in Institut Straumann AG's motion to dismiss under Fed. R. Civ. P. 12(b)(2).

59. The allegations in Paragraph 59 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect Operating, LLC resides in this District and that ClearCorrect Operating, LLC and ClearCorrect Holdings, Inc. have a regularly established place of business in this District. ClearCorrect denies that it has committed acts of infringement in this District. ClearCorrect admits that Institut Straumann AG is a foreign corporation. The remaining allegations of Paragraph 59 are directed to Institut

[redacted]

Straumann AG. Upon information and belief, ClearCorrect denies that venue is proper in this District with respect to Institut Straumann AG for the reasons explained in Institut Straumann AG's motion to dismiss under Fed. R. Civ. P. 12(b)(2). Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 59.[3]

Count 1: [Align's] False Advertising [Claim] Under the Lanham Act

60. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 59 above, as if set forth fully herein.

61. The allegations in Paragraph 61 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 61.

62. ClearCorrect admits that ClearCorrect aligners are manufactured in Round Rock, Texas and sold nationwide. The remaining allegations in Paragraph 62 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 62.

63. ClearCorrect admits that, in the experiment depicted on its website, the aligners were submerged in various other substances, including mustard, for 24 hours at 37°C. ClearCorrect reasonably believes that, in the experiment depicted on straumann.com, the aligners were submerged in various other substances, including mustard, for 24 hours at 37°C. ClearCorrect denies that either its website or straumann.com states or implies that patients

[redacted] For the avoidance of doubt, ClearCorrect preserves and does not waive any and all objections to venue including under 28 U.S.C § 1404, the doctrine of forum non conveniens, [redacted] The Court's schedule under its Standing Order Governing Proceedings contemplates that motions to transfer shall be filed within three weeks of the Case Management Conference or within eight weeks of receiving or waiving service of the complaint, whichever is later.

typically soak aligners in mustard for 24 hours or that patients eat mustard for 24 hours straight. The remaining allegations in Paragraph 63 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 63.

Count 2: [Align's] Unfair Competition [Claim]

64. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 63 above, as if set forth fully herein.

65. The allegations in Paragraph 65 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 65.

Count 3: [Align's] Civil Conspiracy [Claim]

66. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 65 above, as if set forth fully herein.

67. The allegations in Paragraph 67 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 67.

Count 4: [Alleged] Infringement of U.S. Patent No. 10,973,613

68. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 67 above, as if set forth fully herein.

69. The allegations in Paragraph 69 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 69.

70. The allegations in Paragraph 70 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the first link in footnote

[redacted]

29 of Paragraph 70 is a link to a webpage titled, "How to register as a ClearCorrect provider" and that the second link is to a webpage titled, "ClearCorrect: your partner in ortho." These webpages speak for themselves as to form and content; ClearCorrect denies that they describe or depict any inducement or infringing conduct. ClearCorrect admits that the first link in footnote 30 of Paragraph 70 is a link to a webpage titled, "Education and Resources for Patients" and that the second link is to a webpage titled, "Unlock the potential of your smile." These webpages speak for themselves as to form and content, but ClearCorrect denies that they describe or depict any infringing conduct. Except as expressly admitted, ClearCorrect denies each and every allegation in Paragraph 70.

71. The allegations in Paragraph 71 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 71.

72. The allegations in Paragraph 72 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe the '613 patent either directly or indirectly. ClearCorrect further denies that Institut Straumann AG induces ClearCorrect to commit infringing acts—Institut Straumann AG and ClearCorrect are separate corporate entities with wholly separate offices and operations.[4] The sources cited in paragraph 72 speak for themselves as to form and content; ClearCorrect denies that they depict any infringing conduct, including inducement to infringe. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 72.

73. The allegations in Paragraph 73 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe the '613 patent

[4] *See* Institut Straumann AG's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(2), filed June 20, 2024 (Dkt. 30).

either directly or indirectly. ClearCorrect further denies that Institut Straumann AG has "control over ClearCorrect" and that any such "control" causes ClearCorrect to commit infringing acts—Institut Straumann AG and ClearCorrect are separate corporate entities with wholly separate offices and operations.[5] The sources cited in paragraph 73 speak for themselves as to form and content; ClearCorrect denies that they depict any infringing conduct, including inducement to infringe. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 73.

74. The allegations in Paragraph 74 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe the '613 patent either directly or indirectly. ClearCorrect denies that Institut Straumann AG induced or induces ClearCorrect to commit direct infringement—Institut Straumann AG and ClearCorrect are separate corporate entities with wholly separate offices and operations.[6] ClearCorrect admits that the webpage cited in footnote 45 of paragraph 74 is titled, "The Virtually Invisible Orthodontic Solution," which speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct, including inducement to infringe. ClearCorrect admits that the webpage cited in footnote 46 of paragraph 74 is titled, "ClearCorrect," which speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct, including inducement to infringe. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 74.

75. The allegations in Paragraph 75 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that it currently has knowledge of the '613 patent but denies that it infringes any claim of the '613 patent. To the extent Align's allegations in Paragraph 75 are directed to Institut Straumann AG, on information

[5] *See* Institut Straumann AG's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(2), filed June 20, 2024 (Dkt. 30).
[6] *Id.*

and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the '613 patent, but denies that it infringes any claim of the '613 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 75.

76. The allegations in Paragraph 76 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect's investigation and diligence with respect to Align's allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect expressly denies knowledge of infringement of the '613 patent before service of this Complaint. ClearCorrect admits that ClearCorrect and Align have previously litigated patent disputes but denies that those disputes involved the '613 patent. ClearCorrect admits that Align has filed ITC actions against ClearCorrect but denies that those actions involved the '613 patent. ClearCorrect admits that ClearCorrect Operating, LLC petitioned for *inter partes* review of U.S. Patent 6,699,037 on December 1, 2015 and the '444 patent on July 20, 2017. ClearCorrect admits that it has hired former Align employees. ClearCorrect denies the characterization of Align's technology as "proprietary." ClearCorrect generally lacks sufficient knowledge or information to form a belief regarding the truth of whether "Straumann entities also have hired numerous Align employees as officers to manage those companies' orthodontics business"—indeed, Align's complaint does not identify any such hire—and, therefore, ClearCorrect denies the allegation. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 76.

77. The allegations in Paragraph 77 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes the '613 patent or did infringe the '613 patent before service of Align's Complaint. To the extent Align's

[redacted]

allegations in Paragraph 77 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG did not have knowledge of the '613 patent before service of this Complaint, and ClearCorrect further believes that no reasonable inference can be drawn that Institut Straumann AG knew about the '613 patent before service of this Complaint. ClearCorrect admits that it entered an agreement with Align to settle prior patent litigation. ClearCorrect admits that Institut Straumann AG is aware of the 2019 settlement agreement with Align, but ClearCorrect denies any inferences that Align purports to draw from that agreement, including any knowledge of the '613 patent. The sources cited in paragraph 77 speak for themselves as to form and content; they do not reveal any infringing conduct or knowledge of the '613 patent. ClearCorrect denies the characterization of Align's technology as "proprietary." ClearCorrect generally lacks sufficient knowledge or information to form a belief regarding the truth of whether "Straumann entities also have hired numerous Align employees as officers to manage those companies' orthodontics business"—indeed, Align's complaint does not identify any such hire—and, therefore, ClearCorrect denies the allegation.

78. The allegations in Paragraph 78 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates the responses to Paragraphs 76 and 77 and denies each and every allegation in Paragraph 78.

79. The allegations in Paragraph 79 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 79.

80. The allegations in Paragraph 80 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 80. The material used in ClearCorrect aligners was independently developed after extensive

[redacted]

research by related company, Bay Materials. Align's allegations of willful infringement are therefore baseless and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims for willful infringement.

81. The allegations of Paragraph 81 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 81.

82. The allegations of Paragraph 82 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 82.

83. The allegations of Paragraph 83 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '613 patent and denies the allegations in Paragraph 83.

[Alleged] Direct Infringement of Claim 1 of the '613 Patent

84. Admitted, but ClearCorrect denies that claim 1 of the '613 patent is valid, enforceable, or infringed by ClearCorrect.

85. Paragraph 85 parrots language directly from the claims of the '613 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '613 patent and the allegations in this paragraph.

86. Paragraph 86 parrots language directly from the claims of the '613 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect admits that the excerpt in Paragraph 86 is an excerpt from

[redacted]

https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html that speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '613 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 86.

87. Paragraph 87 parrots language directly from the claims of the '613 patent and does not accurately address the actual composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '613 patent. ClearCorrect denies that it uses Tritan MX-710 or MX-711 in its aligners. ClearCorrect admits that the webpages cited in footnote 57 recite certain properties purportedly associated with Tritan MX-710 and MX-711. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 87, and therefore denies them.

88. Paragraph 88 parrots language directly from the claims of the '613 patent and does not accurately address the actual composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '613 patent. ClearCorrect admits that the webpage cited in footnote 58 recites certain properties purportedly associated with TPU-Clear TT-1065D. ClearCorrect denies that it uses Tecothane TPU-Clear TT-1065D in its aligners. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 88, and therefore denies them.

89. Paragraph 89 parrots language directly from the claims of the '613 patent and does not accurately address ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it

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infringes any claim of the '613 patent. ClearCorrect admits that the excerpt in Paragraph 89 is an excerpt from https://www.stratasys.com/en/resources/blog/clearcorrect-3d-printing/ that speaks for itself as to form and content; ClearCorrect denies that it describes or depicts any infringing conduct. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 89.

90. Paragraph 90 parrots language directly from the claims of the '613 patent and does not accurately address ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '613 patent and the allegations in Paragraph 90.

Count 5: [Alleged] Infringement of U.S. Patent No. 11,154,384

91. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 90 above, as if set forth fully herein.

92. The allegations in Paragraph 92 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 92.

93. The allegations in Paragraph 93 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the first link in footnote 63 of Paragraph 93 is a link to a webpage titled, "How to register as a ClearCorrect provider" and that the second link is to a webpage titled, "ClearCorrect: your partner in ortho." These webpages speak for themselves as to form and content; ClearCorrect denies that they describe or depict any inducement or infringing conduct. ClearCorrect admits that the first link in footnote 64 of Paragraph 93 is a link to a webpage titled, "Education and Resources for Patients" and that the second link is to a webpage titled, "Unlock the potential of your smile." These webpages speak for themselves as to form and content; ClearCorrect denies that they describe or depict any

[redacted]

infringing conduct. Except as expressly admitted, ClearCorrect denies each and every allegation in Paragraph 93.

94. The allegations in Paragraph 94 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraphs 72-74 and denies each and every allegation in Paragraph 94.

95. ClearCorrect admits that it currently has knowledge of the ’384 patent, but denies that it infringes any claim of the ’384 patent. To the extent Align’s allegations in Paragraph 75 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the ’384 patent, but denies that it infringes any claim of the ’384 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 95.

96. The allegations in Paragraph 96 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect’s investigation and diligence with respect to Align’s allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect expressly denies knowledge of infringement of the ’384 patent before service of this Complaint. ClearCorrect incorporates its response to Paragraph 76. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 96.

97. The allegations in Paragraph 97 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes any claim of the ’384 patent or did infringe the ’384 patent before service of Align’s Complaint. ClearCorrect incorporates its response to Paragraph 77. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 97.

[redacted]

98. The allegations in Paragraph 98 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 78 and denies each and every allegation in Paragraph 98.

99. The allegations in Paragraph 99 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 99.

100. The allegations in Paragraph 100 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 100. The material used in the ClearCorrect aligners was independently developed after extensive research by related company Bay Materials. Align's allegations of willful infringement are therefore baseless and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims for willful infringement.

101. The allegations of Paragraph 101 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 101.

102. The allegations of Paragraph 102 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 102.

103. The allegations of Paragraph 103 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '384 patent and denies the allegations in Paragraph 103.

[Alleged] Direct Infringement of Claim 1 of the '384 Patent

104. Admitted, but ClearCorrect denies that claim 1 of the '384 patent is valid, enforceable, or infringed by ClearCorrect.

[redacted]

105. Paragraph 105 parrots language directly from the claims of the '384 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '384 patent and the allegations in this paragraph.

106. Paragraph 106 parrots language directly from the claims of the '384 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, the sources cited in Paragraph 106 speak for themselves as to form and content but ClearCorrect denies that they describe or depict any infringing conduct. ClearCorrect denies that it infringes any claim of the '384 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 106.

107. Paragraph 107 parrots language directly from the claims of the '384 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect admits that the excerpt in Paragraph 107 is an excerpt from https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html that speaks for itself as to form and content but ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '384 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 107.

108. Paragraph 108 parrots language directly from the claims of the '384 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required,

[redacted]

ClearCorrect denies that it infringes any claim of the '384 patent. ClearCorrect admits that the webpages cited in footnote 68 recite certain properties purportedly associated with Tritan MX-710 and MX-711. ClearCorrect denies that it uses Tritan MX-710 or MX-711 in its aligners. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 108, and therefore denies them.

109. Paragraph 109 parrots language directly from the claims of the '384 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '384 patent. ClearCorrect admits that the webpage cited in footnote 69 recites certain properties purportedly associated with TPU-Clear TT-1065D. ClearCorrect denies that it uses Tecothane TPU-Clear TT-1065D in its aligners. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 109, and therefore denies them.

Count 6: [Alleged] Infringement of U.S. Patent No. 11,648,090

110. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 109 above, as if set forth fully herein.

111. The allegations in Paragraph 111 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 111.

112. The allegations in Paragraph 112 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the first link in footnote 70 of Paragraph 112 is a link to a webpage titled, "How to register as a ClearCorrect provider" and the second link is to a webpage titled "ClearCorrect: your partner in ortho." These webpages speak for themselves as to form and content, but ClearCorrect denies that they describe or depict

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any inducement or infringing conduct. ClearCorrect admits that the first link in footnote 71 of Paragraph 112 is a link to a webpage titled, "Education and Resources for Patients" and that the second link is to a webpage titled, "Unlock the potential of your smile." These webpages speak for themselves as to form and content but ClearCorrect denies that they describe or depict any infringing conduct. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 112.

113. The allegations in Paragraph 113 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraphs 72-74 and denies each and every the allegations in Paragraph 113.

114. ClearCorrect admits that it currently has knowledge of the '090 patent, but denies that it infringes any claim of the '090 patent. To the extent Align's allegations in Paragraph 75 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the '090 patent, but denies that it infringes any claim of the '090 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 114.

115. The allegations in Paragraph 115 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect's investigation and diligence with respect to Align's allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect expressly denies knowledge of infringement of the '090 patent before service of this Complaint. ClearCorrect incorporates its response to Paragraph 76. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 115.

[redacted]

116. The allegations in Paragraph 116 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes the '090 patent or did infringe the '090 patent before service of Align's Complaint. ClearCorrect incorporates its response to Paragraph 77. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 116.

117. The allegations in Paragraph 117 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 78 and denies each and every allegation in Paragraph 78.

118. The allegations in Paragraph 118 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 118.

119. The allegations in Paragraph 119 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 119. The material used in ClearCorrect aligners was independently developed after extensive research by a related company, Bay Materials. Align's allegations of willful infringement are therefore baseless and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims for willful infringement.

120. The allegations of Paragraph 120 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 120.

121. The allegations of Paragraph 121 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 121.

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122. The allegations of Paragraph 122 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '090 patent and denies the allegations in Paragraph 122.

[Alleged] Direct Infringement of Claim 1 of the '090 Patent

123. Admitted, but ClearCorrect denies that claim 1 of the '090 patent is valid, enforceable, or infringed by ClearCorrect.

124. Paragraph 124 parrots language directly from the claims of the '090 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent and the allegations in this paragraph.

125. Paragraph 125 parrots language directly from the claims of the '090 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect admits that the excerpt in Paragraph 125 is an excerpt from https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html that speaks for itself as to form and content, but ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '090 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 125.

126. Paragraph 126 parrots language directly from the claims of the '090 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent. ClearCorrect admits that the webpages cited in footnote 74 recite certain properties purportedly associated with Tritan MX-

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710 and MX-711. ClearCorrect denies that it uses Tritan MX-710 or MX-711 in its aligners. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 126, and therefore denies them.

127. Paragraph 127 parrots language directly from the claims of the '090 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent. ClearCorrect admits that the webpage cited in footnote 75 recites certain properties purportedly associated with TPU-Clear TT-1065D. ClearCorrect denies that it uses Tecothane TPU-Clear TT-1065D in its aligners. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 127, and therefore denies them.

128. Paragraph 128 parrots language directly from the claims of the '090 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent.

129. Paragraph 129 parrots language directly from the claims of the '090 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent. ClearCorrect admits that the webpages cited in footnote 77 recite certain properties purportedly associated with Tritan MX-710 and MX-711. ClearCorrect admits that the webpages cited in footnote 78 recite certain properties purportedly associated with Tecothane TPU-Clear TT-1065D. ClearCorrect lacks

[redacted]

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 129, and therefore denies them.

130. Paragraph 130 parrots language directly from the claims of the '090 patent and does not accurately address ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent and the allegations in Paragraph 130.

131. Paragraph 131 parrots language directly from the claims of the '090 patent and does not accurately address ClearCorrect's products; it further states legal conclusions to which no response is required. ClearCorrect incorporates its response to Paragraph 89. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent and the allegations in Paragraph 131.

132. Paragraph 132 parrots language directly from the claims of the '090 patent and does not accurately address ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '090 patent and the allegations in Paragraph 132.

Count 7: [Alleged] Infringement of U.S. Patent No. 11,648,091

133. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 132 above, as if set forth fully herein.

134. The allegations in Paragraph 134 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation of Paragraph 134.

135. The allegations in Paragraph 135 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the first link in footnote 82 of Paragraph 135 is a link to a webpage titled, "How to register as a ClearCorrect provider"

[redacted]

and that the second link is to a webpage titled, "ClearCorrect: your partner in ortho." The webpages speak for themselves as to form and content, but ClearCorrect denies that they describe or depict any inducement or infringing conduct. ClearCorrect admits that the first link in footnote 83 of Paragraph 135 is a link to a webpage titled, "Education and Resources for Patients" and that the second link is to a webpage titled, "Unlock the potential of your smile." The webpages speak for themselves as to form and content, but ClearCorrect denies that they describe or depict any infringing conduct. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 135.

136. The allegations in Paragraph 136 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraphs 72-74 and denies each and every allegation in Paragraph 136.

137. ClearCorrect admits that it currently has knowledge of the '091 patent, but denies that it infringes any claim of the '091 patent. To the extent Align's allegations in Paragraph 75 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the '091 patent, but denies that it infringes any claim of the '091 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 137.

138. The allegations in Paragraph 138 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect's investigation and diligence with respect to Align's allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect expressly denies knowledge of infringement of the '091 patent before service of

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this Complaint. ClearCorrect incorporates its response to Paragraph 76. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 138.

139. The allegations in Paragraph 139 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes the '091 patent or did infringe the '091 patent before service of Align's Complaint. ClearCorrect incorporates its response to Paragraph 77. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 139.

140. The allegations in Paragraph 140 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 78 and denies each and every allegation in Paragraph 140.

141. The allegations in Paragraph 141 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 141.

142. The allegations in Paragraph 142 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 142. The material used in ClearCorrect aligners was independently developed after extensive research by a related company, Bay Materials. Align's allegations of willful infringement are therefore baseless and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims for willful infringement.

143. The allegations of Paragraph 143 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 143.

[redacted]

144. The allegations of Paragraph 144 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 144.

145. The allegations of Paragraph 145 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '091 patent and denies the allegations in Paragraph 145.

[Alleged] Direct Infringement of Claim 1 of the '091 Patent

146. Admitted, but ClearCorrect denies that claim 1 of the '091 patent is valid, enforceable, or infringed by ClearCorrect.

147. Paragraph 147 parrots language directly from the claims of the '091 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect admits that the excerpt in Paragraph 147 is an excerpt from https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html that speaks for itself as to form and content, but ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '091 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 147.

148. Paragraph 148 parrots language directly from the claims of the '091 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '091 patent. ClearCorrect admits that the webpages cited in footnote 85 recite certain properties purportedly associated with Tritan MX-710 and MX-711. ClearCorrect denies that it uses Tritan MX-710 or MX-711 in its aligners.

[redacted]

ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 148, and therefore denies them.

149. Paragraph 149 parrots language directly from the claims of the '091 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '091 patent. ClearCorrect admits that the webpage cited in footnote 86 recites certain properties purportedly associated with TPU-Clear TT-1065D. ClearCorrect denies that it uses Tecothane TPU-Clear TT-1065D in its aligners. ClearCorrect lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 149, and therefore denies them.

150. Paragraph 150 parrots language directly from the claims of the '091 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '091 patent and denies the allegations in Paragraph 150.

151. Paragraph 151 parrots language directly from the claims of the '091 patent and does not accurately address the composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect denies that it infringes any claim of the '091 patent. ClearCorrect admits that the webpages cited in footnote 88 recite certain properties purportedly associated with Tritan MX-710 and MX-711. ClearCorrect admits that the webpages cited in footnote 89 recite certain properties purportedly associated with Tecothane TPU-Clear TT-1065D. ClearCorrect lacks

[redacted]

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 151, and therefore denies them.

152. Paragraph 152 parrots language directly from the claims of the '091 patent and does not accurately address the actual composition of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect admits that its aligners incorporate ClearQuartz. ClearCorrect admits that the first link in footnote 90 of paragraph 152 is a page titled, "About the aligners" and that the second link is to a page titled, "ClearCorrect® Aligners." These webpages speak for themselves as to form and content, but ClearCorrect denies that it describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '091 patent and denies the allegations in Paragraph 152.

Count 8: [Alleged] Infringement of U.S. Patent No. 8,038,444

153. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 152 above, as if set forth fully herein.

154. The allegations in Paragraph 154 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 154.

155. The allegations in Paragraph 155 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 155.

156. The allegations in Paragraph 156 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe the '444 patent either directly or indirectly. ClearCorrect further denies that Institut Straumann AG induces ClearCorrect to commit infringing acts—Institut Straumann AG and ClearCorrect are separate

[redacted]

corporate entities with wholly separate offices and operations.[7] ClearCorrect further incorporates its response in Paragraphs 72-74 of the Complaint. ClearCorrect admits that the link in footnotes 91 and 94 of Paragraph 156 is a link which redirects to a webpage titled, "ClearPilot™ 8.0 - Introduction and Use of ClearPilot" but ClearCorrect denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that the first link in footnote 92 of Paragraph 156 is a link to a webpage titled, "ClearCorrect Employee Reviews for Manufacturing Technician" but ClearCorrect denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that the second link in footnote 92 of Paragraph 156 appears to be a link to a LinkedIn profile for an individual named "Gregory Amor" but ClearCorrect denies that the profile describes or depicts any infringing conduct. ClearCorrect admits that the link in footnote 93 of Paragraph 156 is a link to a webpage titled, "clearpilot™" but ClearCorrect denies that the webpage describes or depicts any infringing conduct. Except as expressly admitted, ClearCorrect denies the allegations of Paragraph 156.

157. The allegations in Paragraph 157 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that it currently has knowledge of the '444 patent, but ClearCorrect denies that it infringes any claim of the '444 patent. To the extent Align's allegations in Paragraph 157 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the '444 patent, but denies that it infringes any claim of the '444 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 157.

158. The allegations in Paragraph 158 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect Operating,

[7] *See* Institut Straumann AG's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(2), filed June 20, 2024 (Dkt. 30).

[redacted]

LLC petitioned for *inter partes* review of the '444 patent on July 20, 2017 and knew of the '444 patent as of that date. The '444 patent is not valid or infringed by ClearCorrect, and ClearCorrect denies the allegation that ClearCorrect somehow believed it was valid or infringed by any ClearCorrect product. Align's allegations as to ClearCorrect's intent in petitioning for *inter partes* review of the '444 patent are baseless. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 158.

159. The allegations in Paragraph 159 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes or has infringed Align's '444 patent and that it made any such disclosure to Institut Straumann AG during acquisition discussions. ClearCorrect admits that ClearCorrect Operating, LLC petitioned for *inter partes* review of the '444 patent. The '444 patent is not valid or infringed by ClearCorrect. ClearCorrect denies the allegation that ClearCorrect somehow believed it was valid or infringed by any ClearCorrect product—Align's allegations as to ClearCorrect's intent in petitioning for *inter partes* review of the '444 patent are baseless. ClearCorrect admits that it entered an agreement with Align to settle prior patent litigation. ClearCorrect admits that Institut Straumann AG is aware of the 2019 settlement agreement with Align, but ClearCorrect denies any inferences that Align purports to draw from that agreement, including any knowledge by Institut Straumann AG of the '444 patent. ClearCorrect incorporates its response to Paragraph 77. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 159.

160. The allegations in Paragraph 160 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates the responses to Paragraphs 158-59 of this Complaint. ClearCorrect further denies that it infringes or has infringed Align's '444 patent. ClearCorrect admits that ClearCorrect Operating, LLC petitioned

[redacted]

for *inter partes* review of the '444 patent on July 20, 2017, but denies any inferences that Align purports to draw regarding Institut Straumann AG's knowledge of the '444 patent from that petition. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 160.

161. The allegations in Paragraph 161 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 161.

162. The allegations in Paragraph 162 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 162. ClearCorrect's products are the result of years of independent development. Align's allegations of willful infringement are therefore baseless and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims of willful infringement.

163. The allegations of Paragraph 163 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 163.

164. The allegations of Paragraph 164 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 164.

165. The allegations of Paragraph 165 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '444 patent and denies the allegations in Paragraph 165.

[Alleged] Direct Infringement of Claim 1 of the '444 Patent

[redacted]

166. Admitted, but ClearCorrect denies that claim 1 of the ’444 patent is valid, enforceable, or infringed by ClearCorrect.

167. Paragraph 167 parrots language directly from the claims of the ’444 patent and does not accurately address the operation of ClearCorrect’s products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, Inc. submitted a 510(k) to the FDA in 2008, which speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the ’444 patent and denies the allegations in Paragraph 167.

168. Paragraph 168 parrots language directly from the claims of the ’444 patent and does not accurately address the operation of ClearCorrect’s products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, Inc. submitted a 510(k) to the FDA in 2008, which speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the ’444 patent and denies the allegations in Paragraph 168.

169. Paragraph 169 parrots language directly from the claims of the ’444 patent and does not accurately address the operation of ClearCorrect’s products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect

admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '444 patent and denies the allegations in Paragraph 169.

170. Paragraph 170 parrots language directly from the claims of the '444 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnotes 101 and 102 of Paragraph 170 is a link to a webpage titled, "ClearPilot™ 8.0 – Introduction and Use of ClearPilot" but ClearCorrect denies that the webpage describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '444 patent and denies the allegations of Paragraph 170.

171. Paragraph 171 parrots language directly from the claims of the '444 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '444 patent and denies the allegations of Paragraph 171.

[redacted]

172. Paragraph 172 parrots language directly from the claims of the '444 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 105 of Paragraph 172 is a link to a webpage titled, "Treatment Preferences" but ClearCorrect denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that the link in footnote 106 of Paragraph 172 is a link to a YouTube video titled, "ClearPilot features: The Control is in Your Hands" but it denies that the video depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '444 patent and denies the allegations in Paragraph 172.

Count 9: [Alleged] Infringement of U.S. Patent No. 10,456,217

173. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 172 above, as if set forth fully herein.

174. The allegations in Paragraph 174 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 174.

175. The allegations in Paragraph 175 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 175.

[redacted]

176. The allegations in Paragraph 176 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 156 of this Complaint. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 176.

177. The allegations in Paragraph 177 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that it currently has knowledge of the ’217 patent but denies that it infringes any claim of the ’217 patent. To the extent Align’s allegations in Paragraph 177 are directed toward Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the ’217 patent, but denies that it infringes any claim of the ’217 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 177.

178. The allegations in Paragraph 178 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect’s investigation and diligence with respect to Align’s allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect denies that it infringes the ’217 patent or did infringe the ’217 patent before service of Align’s Complaint. ClearCorrect expressly denies knowledge of infringement of the ’217 patent before service of this Complaint. ClearCorrect admits that ClearCorrect Operating, LLC petitioned for *inter partes* review of the ’444 patent on July 20, 2017 and knew of the ’444 patent as of that date but ClearCorrect denies that any reasonable inference can be drawn that ClearCorrect knew about the ’217 patent based on its petition on the ’444 patent. ClearCorrect incorporates its response to Paragraphs 76-77 and 158-59 of this Complaint. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 158.

[redacted]

179. The allegations in Paragraph 179 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates the response to Paragraph 78 and denies each and every allegation in Paragraph 179.

180. The allegations in Paragraph 180 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 180.

181. The allegations in Paragraph 181 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 181. ClearCorrect's products are the result of years of independent development. Align's allegations of willful infringement are therefore baseless, and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims of willful infringement.

182. The allegations in Paragraph 182 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 182.

183. The allegations in Paragraph 183 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 183.

184. The allegations in paragraph 184 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '217 patent and denies the allegations in Paragraph 184.

[Alleged] Direct Infringement of Claim 1 of the '217 Patent

185. Admitted, but ClearCorrect denies that claim 1 of the '217 patent is valid, enforceable, or infringed by ClearCorrect.

[redacted]

186. Paragraph 186 states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect incorporates its responses to Paragraphs 187 through 191. ClearCorrect denies that it infringes any claim of the '217 patent and the allegations in Paragraph 186.

187. Paragraph 187 parrots language directly from the claims of the '217 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 108 of Paragraph 187 is a link to a webpage titled, "Treatment Preferences" but denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '217 patent and denies the allegations in Paragraph 187.

188. Paragraph 188 parrots language directly from the claims of the '217 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific

[redacted]

patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '217 patent and denies the allegations in Paragraph 188.

189. Paragraph 189 parrots language directly from the claims of the '217 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '217 patent and denies the allegations in Paragraph 189.

190. Paragraph 190 parrots language directly from the claims of the '217 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 116 of Paragraph 190 is a link to a webpage titled, "ClearPilot™ 8.0 - Use of ClearPilot and 3D Controls" but denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '217 patent and denies the allegations in Paragraph 190.

[redacted]

191. Paragraph 191 parrots language directly from the claims of the '217 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 118 of Paragraph 191 is a link to a webpage titled, "Treatment Preferences" but denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies that it infringes any claim of the '217 patent and denies the allegations in Paragraph 191.

Count 10: [Alleged] Infringement of U.S. Patent No. 10,524,879

192. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 191 above, as if set forth fully herein.

193. The allegations in Paragraph 193 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 193.

194. The allegations in Paragraph 194 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 194.

195. The allegations in Paragraph 195 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 156 and denies each and every allegation in Paragraph 195.

[redacted]

196. The allegations in Paragraph 196 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that it currently has knowledge of the '879 patent but denies that it infringes any claim of the '879 patent. To the extent Align's allegations in Paragraph 196 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the '879 patent, but denies that it infringes any claim of the '879 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 196.

197. The allegations in Paragraph 197 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect's investigation and diligence with respect to Align's allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect denies that it infringes the '879 patent or did infringe the '879 patent before service of Align's Complaint. ClearCorrect expressly denies knowledge of infringement of the '879 patent before service of this Complaint. ClearCorrect admits that ClearCorrect Operating, LLC petitioned for *inter partes* review of the '444 patent on July 20, 2017 and knew of the '444 patent as of that date but ClearCorrect denies that any reasonable inference can be drawn that ClearCorrect knew about the '879 patent based on its petition on the '444 patent. ClearCorrect incorporates its response to Paragraphs 158-59 of this Complaint. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 197.

198. The allegations in Paragraph 198 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 78 and denies each and every allegation in Paragraph 198.

[redacted]

199. The allegations in Paragraph 199 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 199.

200. The allegations in Paragraph 200 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 200. ClearCorrect's products are the result of years of independent development. Align's allegations of willful infringement are therefore baseless, and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims of willful infringement.

201. The allegations in Paragraph 201 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 201.

202. The allegations in Paragraph 202 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 202.

203. The allegations in Paragraph 203 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '879 patent and denies the allegations in Paragraph 203.

[Alleged] Direct Infringement of Claim 1 of the '879 Patent

204. Admitted, but ClearCorrect denies that claim 1 of the '879 patent is valid, enforceable, or infringed by ClearCorrect.

205. Paragraph 205 parrots language directly from the claims of the '879 patent and does not accurately address the operation of ClearCorrect's products; it further states legal

[redacted]

conclusions to which no response is required. To the extent a response is required, ClearCorrect incorporates its responses to Paragraphs 206 through 209. ClearCorrect denies the allegations in Paragraph 205 and denies that it infringes any claim of the '879 patent.

206. Paragraph 206 parrots language directly from the claims of the '879 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 206 and denies that it infringes any claim of the '879 patent.

207. Paragraph 207 parrots language directly from the claims of the '879 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 207 and denies that it infringes any claim of the '879 patent.

208. Paragraph 208 parrots language directly from the claims of the '879 patent and does not accurately address the operation of ClearCorrect's products; it further states legal

[redacted]

conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 208 and denies that it infringes any claim of the '879 patent.

209. Paragraph 209 parrots language directly from the claims of the '879 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 128 of Paragraph 209 is a link to a webpage titled, "Treatment Preferences" but denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that the link in footnote 129 of Paragraph 209 is a link to a YouTube video titled, "ClearPilot features: The Control is in Your Hands" but denies that the video depicts any infringing conduct. ClearCorrect further admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 209 and denies that it infringes any claim of the '879 patent.

Count 11: [Alleged] Infringement of U.S. Patent No. 11,369,456

210. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 209 above, as if set forth fully herein.

[redacted]

211. The allegations in Paragraph 211 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 211.

212. The allegations in Paragraph 212 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 212.

213. The allegations in Paragraph 213 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 156 and denies each and every allegation in Paragraph 213.

214. The allegations in Paragraph 214 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that it currently has knowledge of the '456 patent but denies that it infringes any claim of the '456 patent. To the extent Align's allegations in Paragraph 214 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the '456 patent, but denies that it infringes any claim of the '456 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 214.

215. The allegations in Paragraph 215 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect's investigation and diligence with respect to Align's allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect denies that it infringes the '456 patent or did infringe the '456 patent before service of Align's Complaint. ClearCorrect expressly denies knowledge of infringement of the '456 patent before service of this Complaint. ClearCorrect admits that it had knowledge of the '444

[redacted]

patent before service of the Complaint but ClearCorrect denies that any reasonable inference can be drawn that ClearCorrect knew about the '456 patent based on its knowledge of the '444 patent. ClearCorrect incorporates its response to Paragraphs 76-77 and 158-59 of this Complaint. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 158.

216. The allegations in Paragraph 216 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates its response to Paragraph 78 and denies each and every allegation in Paragraph 216.

217. The allegations in Paragraph 217 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 217.

218. The allegations in Paragraph 218 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 218. ClearCorrect's products are the result of years of independent development. Align's allegations of willful infringement are therefore baseless, and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims of willful infringement.

219. The allegations in Paragraph 219 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 219.

220. The allegations in Paragraph 220 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 220.

[redacted]

221. The allegations in Paragraph 221 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '456 patent and denies the allegations in Paragraph 221.

[Alleged] Direct Infringement of Claim 1 of the '456 Patent

222. Admitted, but ClearCorrect denies that claim 1 of the '456 patent is valid, enforceable, or infringed by ClearCorrect.

223. Paragraph 223 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect incorporates its responses to Paragraphs 224 through 230. ClearCorrect denies the allegations in Paragraph 223 and denies that it infringes any claim of the '456 patent.

224. Paragraph 224 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 224 and denies that it infringes any claim of the '456 patent.

225. Paragraph 225 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect

admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 225 and denies that it infringes any claim of the '456 patent.

226. Paragraph 226 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 137 of Paragraph 226 is a link to a webpage titled, "ClearPilot™ 8.0 - Use of ClearPilot and 3D Controls" but ClearCorrect denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 226 and denies that it infringes any claim of the '456 patent.

227. Paragraph 227 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 139 of Paragraph 227 is a link to a YouTube video titled, "ClearPilot features: The Control is in Your Hands" but ClearCorrect denies that the video

[redacted]

depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 227 and denies that it infringes any claim of the '456 patent.

228. Paragraph 228 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content. ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 228 and denies that it infringes any claim of the '456 patent.

229. Paragraph 229 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 142 of Paragraph 229 is a link to a YouTube video titled, "ClearPilot features: The Control is in Your Hands" but denies that the video depicts any infringing conduct. ClearCorrect admits that ClearCorrect, LLC submitted 510(k) No. K220140 to the FDA in October 2022 and that submission speaks for itself as to form and content.

[redacted]

ClearCorrect denies that the 510(k) submission describes or depicts any infringing conduct. In this case, the 510(k) submission and the substantial equivalent standard have no bearing on copying, infringement, the specific patents, or the specific claims in the instant action. ClearCorrect denies the allegations in Paragraph 229 and denies that it infringes any claim of the '456 patent.

230. Paragraph 230 parrots language directly from the claims of the '456 patent and does not accurately address the operation of ClearCorrect's products; it further states conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the images in Paragraph 230 are stills from a YouTube video titled, "ClearPilot features: The Control is in Your Hands" but ClearCorrect denies that the images describe or depict any infringing conduct. ClearCorrect denies the allegations in Paragraph 230 and denies that it infringes any claim of the '456 patent.

Count 12: [Alleged] Infringement of U.S. Patent No. 10,791,936

231. ClearCorrect repeats and realleges all of the responses in paragraphs 1 through 230 above, as if set forth fully herein.

232. The allegations in paragraph 232 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 145 of Paragraph 232 is a link to a webpage titled, "How to Submit a Case with a Virtuo Vivo Scanner Tutorial," which speaks for itself as to form and content, but ClearCorrect denies that the webpage describes or depicts any infringing conduct. ClearCorrect admits that the first link in footnote 146 of Paragraph 232 is a link to a webpage titled, "Virtuo Vivo," which speaks for itself as to form and content, but ClearCorrect denies that the web page describes or depicts any infringing conduct. ClearCorrect admits that the second link in footnote 146 of Paragraph 232 is a link to a webpage titled, "Digital Academy," which speaks for itself as to form and content, but

[redacted]

ClearCorrect denies that the web page describes or depicts any infringing conduct. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 232.

233. The allegations in Paragraph 233 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect admits that it currently has knowledge of the ’936 patent but denies that it infringes any claim of the ’936 patent. To the extent Align’s allegations in Paragraph 233 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG currently has knowledge of the ‘936 patent, but denies that it infringes any claim of the ’936 patent. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 233.

234. The allegations in Paragraph 234 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect’s investigation and diligence with respect to Align’s allegations regarding its knowledge of the patent are ongoing and, thus, at the present time, ClearCorrect lacks information sufficient to admit or deny those aspects. ClearCorrect denies that it infringes the ’936 patent or did infringe the ’936 patent before service of Align’s Complaint. ClearCorrect expressly denies knowledge of infringement of the ’936 patent before service of this Complaint. ClearCorrect admits that it had knowledge of the ’444 patent before service of the Complaint and that the parties were involved in prior patent litigation in district court and the ITC but ClearCorrect denies that any reasonable inference can be drawn that ClearCorrect knew about the ’936 patent based on those facts. ClearCorrect incorporates its response to Paragraphs 76 of this Complaint. Except as expressly admitted, ClearCorrect denies the allegations in Paragraph 234.

235. The allegations in Paragraph 235 are conclusions of law to which no response is required. To the extent a response is required, Clear Correct denies that it infringes the ’936

[redacted]

patent or did infringe the '936 patent before service of Align's Complaint. To the extent Align's allegations in Paragraph 235 are directed to Institut Straumann AG, on information and belief, ClearCorrect reasonably believes that Institut Straumann AG did not have knowledge of the '936 patent before service of this Complaint, and ClearCorrect further believes that no reasonable inference can be drawn that Institut Straumann AG knew about the '936 patent before service of this Complaint. ClearCorrect admits that it entered an agreement with Align to settle prior patent litigation. ClearCorrect admits that Institut Straumann AG is aware of the 2019 settlement agreement with Align, but ClearCorrect denies any inferences that Align purports to draw from that agreement, including any knowledge of the '936 patent. ClearCorrect incorporates its response to Paragraph 77. ClearCorrect denies the remaining allegations in Paragraph 235.

236. The allegations of Paragraph 236 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect incorporates the response to Paragraphs 78 of the Complaint and denies each and every allegation in Paragraph 236.

237. The allegations in Paragraph 237 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies each and every allegation in Paragraph 237.

238. The allegations in Paragraph 238 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 238. ClearCorrect's products are the result of years of independent development. Align's allegations of willful infringement are therefore baseless and ClearCorrect reserves all rights, including the right to seek attorneys' fees and sanctions, should Align pursue claims of willful infringement.

[redacted]

239. The allegations of Paragraph 239 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 239.

240. The allegations of Paragraph 240 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect denies the allegations in Paragraph 240.

241. The allegations of Paragraph 241 are conclusions of law to which no response is required. To the extent a response is required, ClearCorrect does not infringe any claim of the '936 patent and denies the allegations in Paragraph 241.

[Alleged] Direct Infringement of Claim 1 of the '936 Patent

242. Admitted, but ClearCorrect denies that claim 1 of the '936 patent is valid, enforceable, or infringed by the Virtuo Vivo intraoral scanner or use thereof.

243. Paragraph 243 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes any claim of the '936 patent and denies the allegations of Paragraph 243.

244. Paragraph 244 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent that a response is required, ClearCorrect admits that the excerpt in Paragraph 244 is an excerpt from https://www.straumann.com/en/dental-professionals/products-and-solutions/cares-digital-solutions/equipment/io-scanners/virtuo-vivo.html but denies that the excerpt describes or depicts

[redacted]

any infringing conduct. ClearCorrect denies that it infringes any claim of the '936 patent and denies the allegations in Paragraph 244.

245. Paragraph 245 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes any claim of the '936 patent and the allegations in Paragraph 245.

246. Paragraph 246 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect denies that it infringes any claim of the '936 patent and the remaining allegations in Paragraph 246.

247. Paragraph 247 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the link in footnote 155 of Paragraph 247 is a link to a YouTube video titled, "Pre Preparation Workflow" and that the image in Paragraph 247 is a still image from the video, but ClearCorrect denies that the video or the image describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '936 patent and the allegations in Paragraph 247.

248. Paragraph 248 parrots language directly from the claims of the '936 patent and does not accurately address the actual operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the image in Paragraph 248 is a still image from the YouTube video linked in

[redacted]

footnote 155 of Paragraph 247, but ClearCorrect denies that the image describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '936 patent and the remaining allegations in Paragraph 248.

249. Paragraph 249 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the image in Paragraph 249 is a still image from the YouTube video linked in footnote 155 of Paragraph 247, but ClearCorrect denies that the image describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '936 patent and the remaining allegations in Paragraph 249.

250. Paragraph 250 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the image in Paragraph 250 is a still image from the YouTube video linked in footnote 155 of Paragraph 247, but ClearCorrect denies that the image describes or depicts any infringing conduct. ClearCorrect denies that it infringes any claim of the '936 patent and the remaining allegations in Paragraph 250.

251. Paragraph 251 parrots language directly from the claims of the '936 patent and does not accurately address the operation of ClearCorrect's products; it further states legal conclusions to which no response is required. To the extent a response is required, ClearCorrect admits that the images in Paragraph 251 are still images from the YouTube video linked in footnote 155 of Paragraph 247, but ClearCorrect denies that the images describe or depict any

[redacted]

infringing conduct. ClearCorrect denies that it infringes any claim of the '936 patent and the remaining allegations in Paragraph 251.

PRAYER FOR RELIEF

ClearCorrect denies that it has infringed any asserted patent, directly or indirectly. ClearCorrect denies that the statements Align identified in its Complaint constitute false advertising. ClearCorrect denies that Align is entitled to any of the grounds for relief enumerated in the Complaint or any other relief, and respectfully requests that the Court enter judgment against Align on each of Align's claims. To the extent the Prayer for Relief includes any factual allegations, ClearCorrect denies those allegations.

JURY DEMANDED

ClearCorrect demands a trial by jury on all issues so triable.

GENERAL DENIAL

ClearCorrect denies all allegations, prayers, requests (including requests for relief), statements, or assertions of Align's Complaint not expressly admitted.

[redacted]

AFFIRMATIVE AND OTHER DEFENSES

Subject to the responses above, ClearCorrect alleges and asserts the defenses set forth below, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. ClearCorrect reserves the right to modify, amend, and/or expand upon these defenses as discovery proceeds, and to allege additional defenses that become known through the course of discovery.

First Affirmative Defense

Failure to State a Claim

1. The Complaint, and each purported claim for relief asserted therein, fails to state a claim upon which relief can be granted.

Second Affirmative Defense

Non-Infringement

2. ClearCorrect does not make, use, sell, offer for sale, or import into the United States, and has not made, used, sold, offered for sale or imported into the United States, any products or methods that infringe any valid and enforceable claim of the patents asserted in the Complaint, either directly, indirectly, contributorily, literally or through the doctrine of equivalents, or otherwise, and has not induced others to infringe, or otherwise indirectly infringed, any valid and enforceable claim of the patents asserted in the Complaint.

Third Affirmative Defense

Invalidity/Patent Ineligibility/Unenforceability

3. One or more claims of the patents asserted in the Complaint are invalid and/or unenforceable for failure to meet the conditions of patentability and/or otherwise comply with one or more provisions of 35 U.S.C. §§ 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

Fourth Affirmative Defense

Limitation on Damages / Failure to Mark / Failure to Mitigate

4. Align's claims for monetary damages are limited by the statute of limitations and/or limited to acts of infringement occurring within six years of the date of initiating this suit under 35 U.S.C. § 286. The relief sought by Align based on ClearCorrect's alleged infringement of the Asserted Patents is further limited by 35 U.S.C. § 287 to the extent the owner(s) of the Asserted Patents, and/or their licensees, failed to mark allegedly practicing products. Align also has failed to mitigate the harm it claims to have sustained, if any.

Fifth Affirmative Defense

No False Advertising

5. ClearCorrect's webpage describing and depicting the results of stain-resistance testing of its aligners and those of a "leading aligner brand" does not constitute false advertising in violation of the federal Lanham Act (15 U.S.C. § 1125(a)) or the Texas common law of unfair competition.

Sixth Affirmative Defense

Waiver, Estoppel, Prosecution Laches, Acquiescence, and Unclean Hands

6. On information and belief, Align's claims for relief are barred in whole or in part by waiver, prosecution laches, equitable estoppel (including, without limitation, judicial estoppel and administrative estoppel), acquiescence, unclean hands, and/or other equitable doctrines.

Seventh Affirmative Defense

Prosecution History Estoppel and Disclaimer

7. Align has disclaimed and/or is estopped, based on statements, representations, and admissions made during prosecution of the patent applications that led to the Asserted Patents, from asserting that the claims of the Asserted Patents are infringed by ClearCorrect or

[redacted]

ClearCorrect's products or services, either directly, indirectly, contributorily, through the doctrine of equivalents, or otherwise.

Eighth Affirmative Defense

No Equitable Entitlement to Injunctive Relief

8. On information and belief, Align is not entitled to equitable relief with respect to the Asserted Patents under any theory because Align has not and will not suffer irreparable harm, Align has not established that it practices the Asserted Patents, Align is not without adequate remedy at law, the balance of the hardships do not favor entry of an injunction, and/or public policy concerns weigh against any equitable relief.

Ninth Affirmative Defense

No Costs

9. On information and belief, Align is barred from recovering costs associated with this action with respect to the Asserted Patents under 35 U.S.C. § 288.

Tenth Affirmative Defense

Ensnarement

10. To the extent that Align claims infringement under the doctrine of equivalents, Align's claims are barred under the ensnarement doctrine, which prohibits Align from asserting an infringement theory under the doctrine of equivalents that encompasses, or "ensnares," the prior art.

Eleventh Affirmative Defense

Lack of Standing

11. To the extent any third party has or should have ownership rights in the Asserted Patents, Align lacks standing in this action.

[redacted]

Twelfth Affirmative Defense

License/Patent Exhaustion

12. One or more of Align's claims are barred, in whole or in part, to the extent that rights to the Asserted Patents have been exhausted and/or are licensed to ClearCorrect.

Thirteenth Affirmative Defense

No Willfulness / No Enhanced Damages / No Exceptional Case

13. Align has failed to state facts and/or a legal basis sufficient to support willfulness and/or willful infringement. Align has failed to state facts and/or a legal basis sufficient to permit recovery of enhanced damages or an exceptional case finding, including under 35 U.S.C. § 285 or 15 U.S.C. § 1117.

Fourteenth Affirmative Defense

Lack of Causation

14. Align has failed to state facts and/or a legal basis sufficient to establish that any purported false advertising by ClearCorrect has resulted in harm to Align.

Fifteenth Affirmative Defense

[redacted]

Sixteenth Affirmative Defense

No Civil Conspiracy

[redacted]

16. Align has failed to state facts and/or a legal basis sufficient to establish any underlying tort or requisite elements of civil conspiracy.

Reservation of Defenses

17. ClearCorrect reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, the Lanham Act, and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation.

[redacted]

COUNTERCLAIMS

For its counterclaims against Align, Counterclaim-Plaintiffs ClearCorrect Operating LLC, ClearCorrect Holdings, Inc., and Straumann USA, LLC (collectively, for purposes of the Counterclaims, "ClearCorrect" or the "Counterclaim-Plaintiffs") allege as follows:

INTRODUCTION

1. Align is the maker of Invisalign® and has long been the dominant supplier of clear aligners in the United States. For years, Align preserved that dominance by broadly construing and aggressively enforcing a set of what it considered "key patents" covering Invisalign® treatments. But, as early as 2013, Align anticipated the expiration of those patents—publicly acknowledging to its investors that its core patents on Invisalign® would expire in 2017 and predicting that enhanced competition would follow.[8] That competition promised more choice, better products, and lower prices. Yet while new and innovative competitive offerings came, including from some of the leading suppliers in the dental industry, free and fair competition did not; nor did the consumer benefits that would have flowed from that competition. Instead, would-be competitors found themselves unable to secure a meaningful foothold in the market because Align is a pernicious, bold monopolist, engaged in an interconnected, synergistic anticompetitive scheme to entrench and maintain its monopoly position at the expense of competitors, dental practitioners, and ultimately patients.

2. Indeed, in 2021, years after those purportedly "key patents" associated with Invisalign® expired, Align CEO Joe Hogan still boasted that Align has ***"never reacted one time to a competitive aligner price ….***"[9] Nearly every year since 2017, including this year, Align has

[8] Align Technology Inc., Annual Rep. (Form 10-K), at 18 (Mar. 1, 2013) ("The expiration of key certain patents commencing in 2017 owned by us may result in additional competition.").
[9] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2021 Investor Day Transcript (Oct. 29, 2021).

[redacted]

raised the price of Invisalign® treatment to doctors. Invisalign® remains insulated from price competition because no competing aligner product has been able to secure a meaningful foothold in the market.

3. Through a series of reinforcing exclusionary acts, Align maintains the ability to charge exorbitant, supracompetitive prices and earn excessive profits for Invisalign® and to increase those prices year after year without fear of meaningful competition from alternative clear aligner suppliers.

4. ClearCorrect®—an aligner product offered by one of the leading innovators in the dental industry, the Straumann Group—is a higher quality aligner than Invisalign®. It is made with a material that is more durable, applies more consistent, gentler forces on teeth which enhance patient comfort and the effectiveness of treatment, and is more resistant to stains. ClearCorrect® is also offered to dentists and orthodontists (collectively, "doctors") at a significantly lower price than Invisalign®. Yet, despite the price and performance benefits of ClearCorrect®, Align's conduct—as described throughout these Counterclaims—has impaired ClearCorrect's (and others') ability to compete, has therefore foreclosed meaningful competition among clear aligner products in the United States, and has deprived ClearCorrect access to the level competitive playing field the antitrust laws demand. By foreclosing competition, Align's conduct thus has increased prices, decreased output, and reduced quality.

5. Align extended and maintained its Invisalign® monopoly by digging what it called a "competitive moat" around its clear aligner business through a multi-pronged strategy.

[redacted]

This "moat" involved coercing doctors into what is effectively a closed system that locks them into purchasing clear aligners nearly exclusively from Align.[10]

6. Align's monopoly maintenance scheme first wields its established Invisalign® monopoly power to coerce doctors into using a clear aligner order workflow built around Align's intraoral scanner, the iTero®, which serves as an insurmountable entry barrier for Align's clear aligner competitors. These coerced scanner purchases are then leveraged by Align to further tighten its chokehold on the doctor-directed clear aligner market.

7. An intraoral scanner creates a digital file with an impression (or a digital image) of a patient's gumline, teeth, and bite alignment. This digital impression is then used by clear aligner manufacturers to create a treatment plan for the patient that will incrementally adjust the patient's teeth as the patient wears a sequence of clear aligners. Intraoral scanners are a critical element of the manufacture and sale of clear aligners. As Align recognizes, scanners have become the "gate" through which a doctor must pass to purchase aligners through a "digital workflow."[11]

8. Prior to the expiry of its "key patents," Align accepted scans from doctors who used leading third-party scanners and earned significant profit on those sales. But faced with the prospect of enhanced clear aligner competition following the expiration of those allegedly "core" patents, Align reversed course, and adopted a policy of effectively refusing to accept scans for clear aligners from customers in the United States unless the scan was sent from an iTero® scanner. To cement this policy, Align turned down clear aligner business from doctors who

[10] *E.g.*, Raj Pudipeddi, Chief Marketing Officer, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023) ("I wanted to think about the scale and the breadth of the Align Digital platform. And what does it do from a competitive moat standpoint, right? … A platform is a platform only if it delivers a seamless end-to-end solution. A platform makes sense when it delivers a competitive moat for the company…. We've got all of those.").
[11] Yuval Shaked, Senior Vice President of iTero Scanner and Services Business, Align Technology Inc., 2018 Investor Day Transcript (May 23, 2018).

[redacted]

submitted scans from other intraoral scanners, sacrificing the short-term profits it would have earned on those Invisalign® sales. Align did so with no justification other than to coerce doctors into purchasing Align's iTero®.

9. There is no technological reason or procompetitive business justification for Align's refusal to accept scans from doctors using third-party scanners. The scans produced by many other scanners are of equal, and in many cases better, quality than those produced by Align's iTero®. In fact, outside the United States, including in Canada and throughout Europe, Align does not restrict access to Invisalign® in this way. Align's ongoing refusal to accept non-iTero® scans from its own customers is solely for the purpose of maintaining its lucrative Invisalign® monopoly in the United States. In practical effect, Align's policy requires any doctor in the United States who wishes to offer Invisalign® to first purchase an iTero® intraoral scanner. This tying scheme has succeeded, resulting in the "largest installed base" of intraoral scanners in the United States.[12] On information and belief, the iTero® scanner is now responsible for over 75% of clear aligner orders from doctors in the United States. Align has confirmed that maintaining the dominance of the iTero® is "critical for [Align] going forward."[13]

10. This vast installed base of iTero® scanners serves as a "competitive moat" because Align wraps the iTero® scanner with various technological impediments, financial penalties, and contractual commitments that are intended to, and do, coerce doctors to purchase Invisalign® exclusively or nearly exclusively. Through these mutually reinforcing restraints, the iTero® locks doctors into the Invisalign® system. Align thus creates an exclusionary market dynamic wherein the only practical way to access Invisalign®—i.e., the iTero®—becomes a

[12] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q1 2023 Earnings Call (April 26, 2023).
[13] *Id.*

[redacted]

barrier to purchasing any other clear aligner, effectively preventing most doctors from purchasing any meaningful volume of lower-priced, competing clear aligners that are of better quality. This perpetuates Align's monopoly position.

11. To purchase an iTero®, Align requires many doctors to sign various contracts of adhesion that dictate the doctor must not send scans from the iTero® to competitors, must not promote competing aligners to patients, and must grant Align title to and exclusive use of the scan produced by the scanner. These contracts, by their terms, cast a cloud over competing options—being "disloyal" to Invisalign® invites risk of a breach of contract or other claims from Align, a notoriously litigious company that has an established track record of suing orthodontists and dentists that have switched to competing suppliers. This risk alone chills doctor's willingness to work with competing providers of clear aligners.

12. To further cement Align's control over doctors, the design of the iTero® frustrates doctors' attempts to use an iTero® scan to order clear aligners from any of Align's competitors. Although an iTero® scan can be sent near instantaneously to Align to place an order for Invisalign®, the iTero® throws multiple technical impediments in doctors' paths if they attempt to purchase from a competing aligner company, none of which are technologically justified. Once a doctor scans a patient with an iTero®, a scan file is automatically uploaded to Align's cloud storage system, and the doctor then can only access the scan file by logging into Align's cloud storage portal. To access that portal for the purpose of downloading the scan file, a doctor must engage in an onerous, multistep process that can take upwards of 48 hours to complete, wasting valuable doctor time and needlessly raising doctors' costs to deal with Align's competitors. These impediments create significant artificial barriers for competing aligner companies attempting to sell to doctors who were forced to purchase the iTero®. Repeated

[redacted]

complaints from doctors have fallen on deaf ears at Align because those technical impediments are a feature, not a bug, of the iTero®.

13. Align further raises the cost of "disloyalty" by charging doctors a fee to download scans. To export the scan files, a doctor must either pay a subscription fee—on information and belief approximately $360 per month for one scanner and approximately $180 per month for each additional scanner—or pay a significant fee per download. By contrast, a doctor does not need to pay any subscription fee to order Invisalign®. These fees act effectively as a penalty or tax on doctors' purchases of competing aligners. Align has thus used the installed iTero® base to artificially inflate a doctor's cost of using any competing aligner option, including ClearCorrect®.

14. Even if a doctor were to jump through these unnecessary technical hoops, and pay the tax Align imposes on competing aligners, the iTero® regularly generates corrupt scan files when downloaded from Align's cloud storage system, requiring yet more cumbersome troubleshooting. Often, the scan files downloaded from Align's cloud storage system—although they would have been effective for ordering Invisalign®—are completely corrupted, rendering them unusable by competing aligner companies. At other times, the downloads are only partial, leaving out critical scan information, including for example information on a patient's bite alignment, undermining the ability to craft effective treatment plans for patients. Foreseeably, the iTero®'s notorious degradation of downloaded scans has interfered with doctors' decisions to order aligners from competitors and chilled others from even trying.

15. As part of its overall scheme, Align also weaponizes the pricing of the iTero® scanner to harm clear aligner competition. Align lists the iTero® at an enormously supracompetitive price (on information and belief approximately twice as much or more than

[redacted]

other leading scanners of equal or better quality), but then offers so-called "discounts" on the iTero® if a doctor commits to purchasing a significant volume of Invisalign® from Align. These exclusionary deals—including most famously the "Fusion" program—tie the price of the iTero® to purchase commitments for Invisalign®. On information and belief, the Fusion program and other similar arrangements, including many *ad hoc* agreements with specific doctors, (collectively, the "iTero® commitments") offer an upfront reduction in the iTero® price but require doctors to pay back the "discount" as penalties if they do not hit their Invisalign® "commitments." These "discounts" are no discount at all. Instead, the iTero® commitments operate to penalize doctors who purchase the iTero® and then attempt to use the iTero® to purchase from competing aligner companies. If the doctor does not send "enough" scans to Invisalign®, they are required to pay stiff financial penalties. While Align conceals the details, publicly available information reveals penalties of at least $12,999, or a purported discount of $4,333 per year for three years. For many doctors, these iTero® commitments compel them to purchase Invisalign® exclusively or nearly exclusively because they conclude they must satisfy their "commitments" to Align to afford their iTero®.

16. Moreover, these iTero® commitments feed directly into and bolster Align's general pricing strategy for Invisalign® itself, including its so-called "Advantage" program. As with the iTero®, Align charges an exorbitant list price for Invisalign® and agrees to ease this price (albeit to a still supracompetitive level) only if the doctor hits excessive volume targets set by Align. As a result, a rational doctor who desires to offer ***some*** Invisalign® (as most doctors do given Align's entrenched monopoly position) is financially compelled to sell almost exclusively Invisalign® to avoid exorbitant, penalty prices. Align makes clear to its investors

[redacted]

that this penalty pricing scheme is intended to develop "customer stickiness" and to ensure that doctors "rely almost exclusively on [Align's] product lines."[14]

17. Finally, Align resorts to targeted and ongoing harassment of doctors who dare to support or promote competing aligner products, making most Invisalign® doctors fearful of supporting other brands in any way. Align has threatened doctors who have publicly expressed preference for competing aligner products or promoted the superiority of those other products (including ClearCorrect®), promising to boycott those doctors and even serving baseless cease and desist letters upon then. And Align can closely monitor "disloyalty." Because the iTero® automatically and immediately transmits patient scans to Align's cloud storage, whether or not the case is ultimately sent to Invisalign®, Align is able to detect any business diverted to competitors. On information and belief, Align then uses aggressive sales tactics to attempt to coerce the diverting doctor to remain "loyal" to Invisalign. The threat of Align's aggressive sales tactics raises yet another cost of doing business with Align's competitors.

18. Each part of Align's multifaceted, reinforcing exclusionary scheme is designed to drive what Align has deemed the "right behavior"—i.e., doctors purchasing exclusively Invisalign® and foreclosing competitors' access to the market—which is "key to [Align's] strategy" to ensure that it remains the "market leader."[15]

19. Align's suffocating conduct does not allow any equally efficient competitor to effectively challenge Align's market dominance. To get past the iTero® "moat," a competitor would need to overcome the technical impediments to using the iTero® with the competitor's

[14] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q3 2018 Earnings Call Transcript (Oct. 24, 2018); Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q2 2019 Earnings Call Transcript (July 24, 2019).

[15] *E.g.*, John Morici, Chief Financial Officer, Align Technology Inc., Bank of America Merrill Lynch Health Care Conference Transcript (May 10, 2019).

[redacted]

aligner, the risk of corrupted scans, the added fees imposed on the doctor, and penalties associated with Align's pricing programs, not to mention the effect of Align's many anti-steering and other restrictive contractual provisions. Nor can a competing aligner company realistically break the doctor free of the iTero® handcuff itself, because to the doctor, switching away from the iTero® involves sunk costs and additional penalties for missed "commitments," disruption in the doctor's ability to continue to provide Invisalign® to customers who are in the middle of treatment, and the complete inability to provide the product with an entrenched dominant market position among consumers. Align knows that, because of its entrenched monopoly position, most doctors feel compelled to offer at least some Invisalign® (indeed, because of Align's monopoly, many customers believe "Invisalign®" refers to clear aligners generally). Align weaponizes that monopoly power, however, to strong-arm doctors and prevent them from being able to offer choice to consumers. It is no wonder why so many doctors tell ClearCorrect® that they would love to be free to offer their patients other products in addition to Invisalign®, but believe they are stuck with offering Invisalign® alone.

20. Through this conduct, viewed both individually and collectively, Align has foreclosed a significant percentage (on information and belief, well in excess of 60%) of the market for doctor-directed clear aligners in the United States (i.e., clear aligners sold to and by doctors), and for an indefinite period. Because of Align's conduct, ClearCorrect®—the leading alternative clear aligner option on the market—has been unable to take anything beyond a minimal share from Align in the United States, despite offering a higher quality product at a lower price. As result, Align's monopoly remains immune from fair competition, and doctors and patients have to continue to pay inflated prices for Invisalign®.

[redacted]

21. Align's unfair competition, however, extends even beyond coercively locking-in doctors. Align systematically deceives consumers through a campaign of false advertising that falsely overstates Invisalign®'s capabilities and falsely denigrates its competition, including ClearCorrect®. Its advertisements mislead consumers into believing that only Invisalign® offers customized, doctor-directed treatment plans, that only Invisalign® offers key product features like bite-ramps, and that Invisalign® can treat everyone. None of this is true. This misinformation, however, reinforces its monopolistic scheme described above, and injures rivals like ClearCorrect.

22. Finally, Align continues to use the courts, and baseless claims of patent infringement, as an anticompetitive weapon. Like it has with so many targets before, Align brings meritless patent claims against ClearCorrect to raise its rival's costs, to cast a cloud over ClearCorrect's product in the marketplace, and to coerce ClearCorrect out of the market. [redacted]

23. This conduct, described in detail herein, violates federal and state antitrust law as well as federal and state false advertising and unfair competition law. [redacted] And the patents Align asserted should be declared invalid and not infringed.

PARTIES

24. Align is a Delaware corporation with its principal place of business at 410 North Scottsdale Road, Suite 1300, Tempe, Arizona. Align sells Invisalign® and the iTero® and monopolizes the markets in which both products compete in the United States.

[redacted]

25. ClearCorrect Operating LLC is a Texas LLC with its principal place of business at 21 Cypress Blvd., Suite 1180, Round Rock, Texas. ClearCorrect Operating LLC manufacturers and distributes ClearCorrect® aligners throughout the United States.

26. ClearCorrect Holdings, Inc. is a Delaware corporation with its principal place of business at 21 Cypress Blvd., Suite 1180, Round Rock, Texas. ClearCorrect Operating, LLC is a wholly owned subsidiary of ClearCorrect Holdings, Inc.

27. Straumann USA, LLC is a Delaware LLC with its principal place of business at 60 Minuteman Road, Andover, Massachusetts. Straumann USA, LLC markets and sells ClearCorrect® aligners to doctors throughout the United States.

28. For purposes of these Counterclaims, Counterclaim-Plaintiffs ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc., and Straumann USA, LLC will together be referred to as "ClearCorrect."

JURISDICTION AND VENUE

29. Counts 1 and 2 of these counterclaims are brought under Sections 4 and 16 of the Clayton Act (15 U.S.C. §§ 15, 26) to recover treble damages, costs of suit, and attorneys' fees for, and to obtain equitable relief from, Align's ongoing violation of Section 2 of the Sherman Act (15 U.S.C. § 2). The Court has original federal question jurisdiction over these Sherman Act counterclaims pursuant to 28 U.S.C. §§ 1331, 1137.

30. This Court has at least supplemental jurisdiction under 28 U.S.C. § 1367 over ClearCorrect's Texas antitrust law claims (Counts 3-4) because those claims form part of the same case or controversy as the federal antitrust law claims.

31. This Court has subject matter jurisdiction over ClearCorrect's false advertising claim under the Lanham Act claim (Count 5) under 28 U.S.C. § 1331 and subject matter jurisdiction over ClearCorrect's unfair competition claim under Texas common law (Count 6)

[redacted]

pursuant to 28 U.S.C. § 1367 because of its similarity to ClearCorrect's Lanham Act claim. The Court has personal jurisdiction over Align for its false advertising and unfair competition claims because Align availed itself of the jurisdiction of this Court by initiating this action. Venue is appropriate in this Court because Align chose to bring this action in this forum.

32. This Court has subject matter jurisdiction over ClearCorrect's declaratory judgment counterclaim of no false advertising under the Lanham Act (Count 10) under 28 U.S.C. § 1331, and subject matter jurisdiction over ClearCorrect's declaratory judgment counterclaims of no unfair competition and no civil conspiracy (Counts 11-12) under 28 U.S.C. § 1367 as the state law claims form part of the same case or controversy as the federal claim.

33. This Court has subject matter jurisdiction over ClearCorrect's declaratory judgment counterclaims of non-infringement and invalidity (Counts 13-30) arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Thus, this Court has subject-matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in combination with 28 U.S.C. §§ 2201-2202. An actual controversy exists under the Declaratory Judgment Act because Align has asserted and is asserting infringement of the '613 patent, '384 patent, '090 patent, '091 patent, '444 patent, '217 patent, '879 patent, '456 patent, and '936 patent (collectively, the "Asserted Patents") by ClearCorrect, and ClearCorrect denies those assertions.

34. [redacted]

[redacted]

35. This Court has personal jurisdiction over Align because Align availed itself of the jurisdiction of this Court by initiating this action. In the alternative, personal jurisdiction is appropriate over Align under 15 U.S.C. § 22(a), because Align transacts business in this judicial district, including by selling iTero® and Invisalign® products to dentists and orthodontists in this district. Align further transacts a substantial amount of business in Texas and ClearCorrect's counterclaims arise out of Align's conduct that occurs in Texas.

36. Venue is appropriate in this Court because Align chose to bring this action in this forum. In the alternative, venue is appropriate under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b), (c), and (d) because Align transacts business within this district, and the interstate trade and commerce described in this complaint was carried out in substantial part in this district. [redacted]

37. As noted above and for the avoidance of doubt, ClearCorrect preserves and does not waive any and all objections to venue including under 28 U.S.C § 1404, the doctrine of forum non conveniens, [redacted] The Court's schedule under

[redacted]

its Standing Order Governing Proceedings contemplates that motions to transfer shall be filed within three weeks of the Case Management Conference or within eight weeks of receiving or waiving service of the complaint, whichever is later.

ALIGN'S MONOPOLIZATION

A. Clear Aligner Market Dynamics

38. The structure and dynamics of the market for doctor-directed clear aligners are necessary to understand the foreclosure caused by Align's multi-faceted exclusionary scheme.

39. Clear aligners are FDA-regulated orthodontic devices that are designed to reorient or move a patient's teeth for both cosmetic and medical reasons. Clear aligners are thin, transparent plastic shells that fit over existing teeth and move the teeth in small increments when worn consistently.

40. As Align has recognized, the use of aligners to move teeth is not a new concept, with its roots in research conducted by doctors in the 1940s.[16] Today, clear aligners are custom-manufactured products based on a treatment plan that most often starts from a digital impression of a patient's teeth and mouth. Over time, a treatment plan is designed to move a patient through a series of aligners or "trays" designed to adjust teeth with minimal pain to create a straighter smile. Because they are made of near transparent plastic, clear aligners are markedly less noticeable when worn than traditional metal braces.

41. The average length of clear aligner treatment is 10 to 24 months depending on the significance of adjustment required, but treatment can last up to 5 years. Throughout treatment, the patient will receive new trays every few weeks. Patients are generally advised to wear the trays for 22 hours per day.

[16] U.S. Patent No. 6,217,325 (Apr. 17, 2001).

[redacted]

42. Align has offered its Invisalign® product in the United States since 1999. Other clear aligner brands include ClearCorrect's ClearCorrect®, Ormco's Spark®, and Dentsply's SureSmile®. Invisalign® and ClearCorrect® regularly treat gapped, cramped, crooked or crowded teeth, as well as overbite, underbite, open bite, and cross bite.

43. Prior to the introduction of clear aligners, the primary method for moving a patient's teeth was the installation of wires and brackets in the form of braces. Clear aligners provide obvious advantages over braces, particularly for adult patients. Braces require more visits to doctors (including, for example, emergency visits due to brackets or wires breaking); can negatively, and permanently, impact the appearance and health of a patient's teeth; limit a user's ability to maintain proper dental hygiene; eliminate certain categories of food that a patient can eat during treatment; can cause pain and discomfort; come with social stigma that clear aligners avoid; and can take up to five months longer to properly orient a patient's teeth.

44. Throughout the relevant period (and at least since 2017), the price to doctors for metal brackets and wires has remained approximately the same, while at the same time, the price for Invisalign® to doctors has increased year after year. Despite the relative price increasing for Invisalign® consistently over time, purchasers have not shifted away from clear aligners to braces. To the contrary, sales of Invisalign® have increased. Doctors price Invisalign® treatment significantly higher than the price for braces, often by thousands of dollars. Align does not set its prices to compete with the price charged by suppliers of wires and brackets.

45. Invisalign® is the most expensive clear aligner product available on the market, and its price far exceeds the price for ClearCorrect®. On information and belief, Align's pricing structure, even inclusive of so-called "discounts," far exceeds (by approximately 30% or more according to some estimates) ClearCorrect®'s pricing on comparable product offerings even

[redacted]

though ClearCorrect®'s offering includes more aligners and greater flexibility. Indeed, on further information and belief, ClearCorrect®'s less expensive offerings include more "revisions" or "refinements" (i.e., a correction to the treatment plan if the patient's teeth are not moving as intended), free retainers, and cheaper pricing if a doctor needs to order additional single aligners.

46. Clear aligners are manufactured from virtual models of teeth. The vast majority of clear aligner treatments begin with a doctor conducting an initial digital scan of a patient's mouth using an intraoral scanner. Intraoral scanners are handheld devices used to directly create digital impressions of a patient's mouth. Intraoral scanners can be used to capture information on the shape and size of dental arches, reproduce three-dimensional models of teeth and soft tissues of the mouth, and provide information on a patient's bite pattern and alignment. The data produced by an intraoral scanner can also be sent to a dental lab to create restorations and implants.

47. For aligner treatment, an intraoral scan can be used to map the position of teeth and a patient's bite pattern and alignment, to model potential movement and improvement of teeth and bite alignment, and to create digital files that may be used to manufacture aligners for treatment. Intraoral scanners capture these images in an industry-standard format called a stereolithographic or "STL" file. The STL is the standard file type that is used for producing clear aligners and, on information and belief, has been and is used by every major aligner and dental laboratory to create aligners and other dental devices. STL files are thus beneficial for doctors because they may use the file for multiple purposes and can place orders with multiple suppliers using a single file type.

[redacted]

48. As described below, Align manufactures and sells its own intraoral scanner, the iTero®. There are several generations of iTero® scanner on the market, which on information and belief can reach over $65,000 per scanner. Other intraoral scanners that capture images and can be used to create clear aligners include 3Shape's TRIOS series, Dentsply Sirona's Primescan, and Medit's scanners. On information and belief, most of these other intraoral scanners are sold at half the list price of iTero®, or less.

49. The only alternative method of capturing the position of teeth and patient's bite pattern and alignment is by using a polyvinyl siloxane impression (PVS). PVS involves placing putty into a mold, pressing it into a patient's mouth for minutes until it dries, and then mailing the physical mold to the manufacturer, which then must create a model from the mold, scan the model, export an STL file from that scan to begin treatment planning, and then create the aligner. PVS impressions are uncomfortable for patients (often gagging a patient), are less efficient and precise than a digital scanner, require extra labor by a doctor and their staff, often require a patient to revisit a dental office in the (relatively common) event that a PVS impression is rejected, have extended wait times before the aligners are received (including the time to mail the impression and have the impression processed at the manufacturer), and in Align's case, come with additional processing charges. PVS is thus a substantially inferior means of placing orders for clear aligners and is an inadequate method for doctors to order clear aligners, at least for those who treat any more than a *de minimis* number of clear aligner patients.

50. Clear aligners are prescribed by orthodontists and general practitioner dentists. This "doctor-directed" care occurs almost exclusively in dental and orthodontic offices. Orthodontists are tooth movement specialists—tooth alignment is the primary service they offer.

[redacted]

General dentistry, by contrast, can include tooth alignment, but also includes routine health checkups, examinations, cleanings, and restorations (e.g., implants, crowns and bridges).

51. While both general dentists and orthodontists prescribe clear aligners, Align's own estimates show that the average orthodontist places nearly seven times more orders for clear aligners than the average general dentist.[17] Accordingly, most clear aligners are provided to patients through orthodontists.

52. Direct-to-consumer companies such as SmileDirectClub have offered patients access to clear aligners for simple cases without a dental or orthodontic practice involved in the treatment. The direct-to-consumer channel, however, is limited in scope. These direct-to-consumer options send a prospective patient a mouth mold and PVS putty, so that a consumer can take a mold of their teeth at home. The patient must then mail the physical impression to the manufacturer to make the clear aligners, which often takes four to six weeks to produce. It is difficult even for a doctor to take an accurate model of a patient's teeth with a PVS impression, let alone a consumer in their own home, and the process of taking a PVS impression is inherently unpleasant. Moreover, to receive treatment for overbite, underbite, open bite, cross bite, or complex misalignment, a patient must seek an aligner through a doctor.

53. SmileDirectClub was the most successful entrant in the direct-to-consumer market, and, to a large extent, its initial success demonstrated consumer demand for a lower cost alternative to Invisalign®. Launched in 2014, SmileDirectClub offered clear aligners to patients following virtual consultations. Patients completed at-home PVS impressions which were then sent to SmileDirectClub and reviewed by doctors who then oversaw the remote treatment

[17] Align Tech. Inc., Annual Rep. (Form 10-K), at 41 (Feb. 28, 2024) ("The utilization rate among our North American orthodontist customers was 94.5 cases per doctor in 2023 … and the utilization rate among our North American GP customers was 14.0 cases per doctor in 2023.").

process. Because of the lack of direct involvement between a doctor and the patient, direct-to-consumer aligners were relatively simple in nature and treated only mild alignment issues.

54. In 2015, however, Align sued SmileDirectClub for alleged patent infringement and false advertising. To settle that litigation, Align and SmileDirectClub entered into a series of agreements. Key terms of the settlement agreement and supply agreement between the two parties prohibited SmileDirectClub from offering a doctor-directed clear aligner product but allowed SmileDirectClub to continue to sell its direct-to-consumer products. Further, SmileDirectClub agreed to refer all patients who were not candidates for its direct-to-consumer product (approximately 30% of consumers who contacted it) to an Invisalign® doctor.[18] Align additionally purchased a 17% share of SmileDirectClub and obtained a seat on SmileDirectClub's board.

55. These agreements demonstrate that Align's true fear of SmileDirectClub was not that its direct-to-consumer offerings would compete with and undermine Align's profits on Invisalign®, but instead that SmileDirectClub would enter the doctor-directed clear aligner market and compete head-to-head with Align. The market allocation provisions thus neutralized a nascent threat to Align's doctor-directed clear aligner monopoly. The settlement peace resulting from this unlawful market allocation was short lived, however. Consistent with its long history of using the courts to crush rivals, Align aggressively pursued SmileDirectClub through further litigation, leading SmileDirectClub to file for bankruptcy in September 2023, and ultimately to shut down operations in December 2023.

56. Today, the direct-to-consumer market has essentially disappeared in the United States, and the few remaining companies, Byte and AlignerCo, offer direct-to-consumer options

[18] Align Technology, Inc., Q2 2016 Financial Results Presentation, at 14. (July 28, 2016).

[redacted]

at significantly lower volumes than SmileDirectClub had achieved. The American Dental Association and the American Association of Orthodontists oppose direct-to-consumer dentistry including direct-to-consumer clear aligners, arguing that those products have the potential to cause "irreversible harm to individuals." Both organizations have lobbied aggressively to prohibit their sale, with much success. Today, several states have laws that require dentists or orthodontists to perform scans for any orthodontic appliance orders (including clear aligners). Other states have passed laws that require x-ray scans to be submitted with an order for clear aligners, effectively requiring that a consumer seek doctor-directed care. Thus, a direct-to-consumer model—to the extent that it ever was a competitive constraint on Align—is not a viable means of competing against Invisalign® in the United States. In fact, Align has assured its investors that the direct-to-consumer channel is insignificant and imposes no threat to its dominant position.[19]

57. Align's Invisalign® has experienced minimal erosion of share since 2017. On information and belief, Invisalign®'s market share remains above 80% in the market for doctor-directed clear aligners in the United States. Align also enjoys an approximately 70% market share for its iTero® scanner in the market for intraoral scanners for use with clear aligners in the United States.

B. Align's Monopolization Scheme

58. Align's strategy for protecting its monopoly position begins by weaponizing its original monopoly in clear aligners to imbed the iTero® scanner in doctor offices as a barrier to competition from other clear aligner providers. Align maintains its monopoly through two types

[19] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q2 2016 Earnings Call Transcript (July 28, 2016) (explaining direct-to-consumer options have "less than 2%" market overlap with Invisalign®); Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q1 2020 Earnings Call Transcript (Apr. 29, 2020) (stating that direct-to-consumer is "not a model that competes with us").

[redacted]

of inextricably intertwined conduct: (1) coercing doctors to purchase one or more iTero® scanners and (2) coercing doctors that have purchased an iTero® to purchase clear aligners exclusively, or nearly exclusively, from Align. This coercion occurs through technological tying, contractual restraints, financial penalties, and outright threats of boycott. Through its exclusionary conduct, Align has created a self-reinforcing cycle that ensures it has durable monopoly power in the United States market for clear aligners.

i. Align Feared The Competition That Would Follow Expiration Of Its "Key Patents" On Invisalign®

59. For almost twenty years, Align enjoyed total dominance of the clear aligner market by broadly construing and aggressively deploying its patent portfolio against potential competitors. Align controlled well over 80% of the market, charged supracompetitive prices for clear aligners, and enjoyed excessive, durable profit margins.

60. In 2017, Align's so-called "key patents" relating to the treatment methods of Invisalign®, which it had long used to restrain competitors, expired. Align had been preparing for this patent expiration for some time. Shortly before patent expiration, Align told investors that "[w]hen patents expire, we lose the protection and competitive advantages they provided to us, which could negatively impact our operating results."[20] As early as 2013, Align began disclosing the impending patent expiration in its filings with the Securities and Exchange Commission ("SEC"), stating that "expiration of key certain patents commencing in 2017 owned by us may result in additional competition."[21]

61. Following patent expiration, experienced companies in the dental supply space began either offering or expanding their offering for clear aligners, including ClearCorrect,

[20] Align Technology Inc., Annual Rep. (Form 10-K), at 10 (Feb. 28, 2017).
[21] Align Technology Inc., Annual Rep. (Form 10-K), at 18 (Mar. 1, 2013).

[redacted]

Ormco, and Dentsply. To be clear, ClearCorrect® did not grow because ClearCorrect® had previously been utilizing Align technology—rather, Align had broadly and aggressively construed its patents, and patent expiration removed the threat of a potential patent lawsuit from Align, and the attendant costs and burdens of defending against those allegations. The incipient competition from ClearCorrect® and other brands promised increased choice and output, reduced prices, and improved quality.

62. Align determined, however, that it would not subject itself to free and fair competition, and instead decided to use its entrenched monopoly power over the doctor-directed clear aligner market to prevent it. Align engaged in a series of exclusionary acts in the markets for handheld intraoral scanners and in the doctor-directed clear aligner market including technological tying, anti-steering provisions, coercive penalties and fees for sending scans to competitive aligner companies, harassment, and other exclusionary conduct. These exclusionary strategies provided Align with what it calls its "competitive moat" around Invisalign®.

ii. Align Leverages Its Clear Aligner Monopoly To Acquire The Largest Installed Base In Intraoral Scanners

63. The first prong of Align's anticompetitive scheme was to tie sales of its market-dominant Invisalign® clear aligners to Align's own intraoral scanner.

64. Align purchased digital scanner technology, the iTero® scanner, from Cadent Holdings, Inc. in 2011. This technology became the lynchpin to Align's exclusionary strategy.

65. Initially, Align's approach was *not* to tie sales of Invisalign® to the iTero®. In fact, Align promised the opposite. In 2015, when Align began selling the iTero Element®—Align's so-called "next generation" iteration of the iTero scanner[22]—Align's former CEO Tom

[22] Press Release, Align Technology Inc., *Align Technology Announces Next Generation iTero® Element™ Intraoral Scanner* (Mar. 9, 2015), *accessible at* https://investor.aligntech.com/news-releases/news-release-details/align-technology-announces-next-generation-iteror-elementtm (last visited: July 9, 2024).

[redacted]

Prescott assured the market that Align "believe[d] very much in open systems," and stated that Align would "rather be competing for that scanner slot on our own merits." Prescott explained that Align *would not* take the position that the iTero® was the "only way" that a doctor could send Align a scan to purchase Invisalign®. He said that giving purchasers choice in scanner technology was the "right thing for our customers."[23] In a press release in 2016, Align again assured the market that it believed in "an open systems approach to digital impressions."[24]

66. There are at least two ways a clear aligner company can "accept" an intraoral scan from a doctor. The company can have an interoperability agreement with the intraoral scanner company, which facilitates a technical connection between the systems—usually resulting in a simplified "click to send" option for the scan once it is complete. But an interoperability agreement is not required for a doctor to send a scan to a clear aligner company. Because the scans are recorded in an industry-standard STL format, a doctor could simply download or save the scan and submit it to the manufacturer themselves.

67. Consistent with its pre-2017 "open policy," Align not only accepted STL scans from other intraoral scanners, but it entered into interoperability agreements with several scanner companies to simplify the process for doctors. Align entered into specific interoperability agreements with several intraoral scanners, including 3M's True Definition (2014 agreement), Dentsply's CEREC Omnicam (2015 agreement), and beginning in 2016, the market-leading TRIOS 3® scanner from 3Shape. These interoperability agreements facilitated "click of a

[23] Tom Prescott, Former Chief Executive Officer, Align Technology Inc., ROTH Conference Transcript (Mar. 10, 2015).
[24] Press Release, Align Technology Inc., *Align Technology And 3Shape Announce New Workflow Integration Including TRIOS Scanner Interoperability with the Invisalign Case Submission Process* (Apr. 28, 2016), *accessible at* https://investor.aligntech.com/news-releases/news-release-details/align-technology-and-3shape-announce-new-workflow-integration (last visited: July 9, 2024)

button" type workflow integration but were not technically required for Align to accept scans from those intraoral scanners, which create scans in STL format.

68. Thus, prior to the expiration of Align's purportedly "key patents" doctors were not required to purchase and use an iTero® to place orders for Invisalign®. Instead, a doctor could choose the best aligner for their practice based on their own assessment of price, product specifications, product specifications, support services, and whatever other factors those doctors deemed relevant, without being handcuffed to the brand of scanner they carried in their office.

69. The tides began to shift the year before Align's "key patents" expired. In 2016, Align's new CEO, Joe Hogan, told investors that the reason Align was "in the scanner business" was because it believed "scanners will help [Align] sell more Invisalign®. ***It's the only reason we invest in it, the only reason we have that business***."[25] In an earnings call for the second quarter of 2017, Hogan again told investors that Align was "in the clear aligner business," and that Align would do anything that would "help[] [it] sell more clear aligners."[26] This, according to Hogan, was "why [Align] ha[s] the scanner business;" the iTero® was not being sold from a "diversification standpoint" but was instead sold to doctors "because it allows [Align] to sell more clear aligners."[27]

70. Hogan's statements on Align's iTero® strategy became even more clear on December 20, 2017, when Align announced that in the United States that not only was it terminating its interoperability agreement with the 3Shape TRIOS 3®, but it would no longer accept scans for Invisalign® from doctors that had generated the STL file by using a 3Shape

[25] Joseph Hogan, Chief Executive Officer, Align Technology Inc., ROTH Conference Transcript (Mar. 14, 2016).
[26] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2017 Q2 Earning Call Transcript (July 27, 2017).
[27] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2017 Q2 Earning Call Transcript (July 27, 2017).

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TRIOS 3® regardless of how the scan was submitted.[28] This was an important step to Align's scheme—rather than simply removing the interoperability that made sending scans between TRIOS 3® and Invisalign® *seamless*, Align enacted a new policy where it would *refuse* a doctor's order if the scan accompanying that order was performed on a TRIOS 3®.[29]

71. While Align needed to terminate its agreement with 3Shape's TRIOS 3® in the United States to effectuate its monopolistic scheme, it was not necessary to terminate its other interoperability agreements because by 2017, when Align rescinded its policy of accepting scans from competing aligners, the True Definition and Omnicam scanners were not fit for purpose for scans for ordering clear aligners. While neither had ever been suited to full-mouth scans (the True Definition required the use of powder to take a scan, which no modern scanner requires, and only created black-and-white images, while the Omnicam does not have a built-in heater or fan and fogs up when performing full mouth scans and has not been updated since 2012), scanner technology had evolved by 2017 such that many advanced options, including the TRIOS 3®, existed that could perform accurate, high-quality scans perfect for ordering clear aligners.

[28] *See* Press Release, Align Technology Inc., *Align Technology to Discontinue Acceptance of Digital Scan Submissions from 3Shape Trios Scanners in the United States, accessible at* https://investor.aligntech.com/news-releases/news-release-details/align-technology-discontinue-acceptance-digital-scan-submissions (last visited: July 9, 2024) ("[Align] terminate[s] its Invisalign interoperability contract with 3Shape and will no longer be able to accept digital scans for new Invisalign treatment and/or retention cases from TRIOS scanners in the United States, effective January 31*, 2018.").

[29] Align has historically conflated its description of which scanners it will accept scans from with which scanner companies it has interoperability agreements with. For example, in its document "Invisalign Aligner Case Submission Third-Party Intraoral Scanner Interoperability," Align lists scanners with "Intraoral Scanner Interoperability" for "Invisalign Aligner Case Submission" (the Omnicam and True Definition, and the TRIOS 3® *outside* the United States, Japan, and China) but also describes those scanners as producing "scans that can be used for Invisalign aligner case submission." As Align's press release terminating its interoperability agreement with TRIOS 3® *and* discontinuing accepting digital scans for clear aligner treatment from TRIOS 3® shows, the two paths are distinct and not dependent on one another.

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True Definition and Omnicam were essentially obsolete.[30] Indeed, Align's employees have testified that these scanners "are outdated."

72. Therefore, since Align announced that it would no longer accept scans from the TRIOS 3®, and continuing to this day, doctors in the United States with any modern scanner beside the iTero®, regardless of the quality of the scan, cannot place orders for Invisalign® using a digital scan.

73. Align's refusal to accept scans from a scanner other than the iTero® is not based on technical or procedural reasons. In fact, on information and belief, Align terminated the interoperability agreement with 3Shape only after 3Shape refused to enter into an exclusivity agreement with Align. Had 3Shape agreed to impose anticompetitive barriers on competing aligners (and tie itself to Invisalign®), Align would have continued to accept STL scans from 3Shape scanners. Further, outside the United States, throughout much of the rest of the world and even in Canada, Align still accepts STL scans directly from the TRIOS 3® for Invisalign®. There is nothing distinct about the technology, file type, or other interoperability elements or concerns between a scan taken on a TRIOS 3® in Detroit, Michigan, and one taken on the same device across the river in Windsor, Ontario, yet one can be used to order Invisalign®, and one cannot.

74. Nor can Align's policy be justified by perceived superiority of the iTero®. In fact, the TRIOS® series of scanners is more accurate and produces higher quality scans than the iTero®. Compared to the TRIOS®, the iTero® is slower, more difficult to use, is large and

[30] 3M no longer sells the True Definition scanner, and Midmark, the company that purchased the True Definition technology, no longer advertises it for sale. On information and belief, the orders of Invisalign® placed through those scanners were, and remain, de minimis. Moreover, while Align has historically referenced interoperability with these scanners in its annual 10-K filing with the SEC, Align removed any reference to those scanners as of its 10-K for 2019. Indeed, consistent with its shift in policy, Align more broadly has removed all language related to its commitment to a so-called "open system" for scanners.

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unwieldy, and is (now) a closed system, which is inherently unattractive to doctors. Align's Chief Marketing Officer, Raphael Pascaud, has testified that the TRIOS® scanners are "great" and are well regarded because of their scanning accuracy and precision. In 2017, when Align reneged on its prior policy of accepting scans from TRIOS 3®, TRIOS 3® had been named the best intraoral scanner by one industry organization five years in a row, and the most accurate in an independent American Dental Association study.

75. As discussed above, even without any "interoperability" agreement, Align could accept third-party scans submitted by doctors. In fact, after Align terminated its "interoperability" agreement with 3Shape, some doctors who used 3Shape's TRIOS 3® scanner and other scanners sent STL scans to Align by email to purchase Invisalign® for their patients. Align initially fulfilled those orders, demonstrating again that there is no technical or legitimate business impediment to doing so. But Align shut down even that option, leaving doctors with no choice but to replace their existing scanners with an iTero® if they wished to be able to offer Invisalign® aligners to their patients.

76. The predatory intent of Align's insistence that doctors use iTero® only is further demonstrated by Align's continued willingness to accept orders based on PVS impressions. At a minimum, competing scanners produce models of a patient's teeth that are multifold more precise and accurate than the results from PVS impressions. That Align will accept an archaic, analog, method of creating an impression, but not high-quality scans, demonstrates that there is no technological justification for its policy. The policy is intended to force doctors who use intraoral scanners for their clear aligner practice (the vast majority of doctors) to purchase an iTero®. Because Align refuses to accept (in the United States) STL scans generated by a third-party scanner, whether transmitted directly from the scanner or separately from doctors as a

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downloaded file, doctors who desire to offer *any* Invisalign® to their patients need to buy an iTero®. Otherwise, the doctor would need to use the non-digital PVS impressions, which is not a viable alternative to digital scanning.

77. At first glance, of course, Align's policy could result in *reduced* sales of Invisalign®, because a doctor in the United States who has a perfectly good scan of a patient's mouth from a different scanner, and who is willing to pay retail price for Invisalign®, cannot purchase Invisalign® from Align. But Align has been clear as to *why* it was willing to accept this short term profit sacrifice: Align's CEO has repeated its general aim is to have "more iTeros in [doctors'] offices, so we can sell more Invisalign," which was the reason Align "bought iTero in the first place."[31] Align could accept the short term loss in sales of Invisalign® from doctors without an iTero® because the reality was that doctors needed to be able to buy *some* Invisalign® in order to attract certain patients. Align enjoyed an entrenched and dominant market position, leading most doctors to believe that they needed to be able to offer Invisalign® because many customers may seek out that brand specifically. Thus, given its dominant position in the marketplace, the vast majority of doctors seeking to sell clear aligners feel compelled to offer at least some Invisalign® to their patients. Align's strategy thus forces a doctor that may want to offer Invisalign® as an option to purchase an iTero®. Therefore, any loss in Invisalign® sales by refusing scans from third-party scanners was going to be temporary. Those doctors would conclude that they needed to buy an iTero®.

78. And they did. Align's policy of requiring the purchase of an iTero® to purchase Invisalign® resulted in a significant increase in sales of the iTero. Align's revenue from the iTero® increased from $121.5 million in 2016 to $275.0 million in 2018.[32] For 2018, Align

[31] Joseph Hogan, Chief Executive Officer, Align Technology Inc., M&A Call Transcript (Mar. 4, 2020).
[32] Align Technology Inc., Annual Rep. (Form 10-K), at 38 (Feb. 28, 2019).

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reported a 77.2% increase in volume of iTero® sold compared to 2017.[33] Align acknowledged in April 2023, that it has the "largest installed base" in the "scanner marketplace."[34]

79. Align was not satisfied with coercing individual doctors to purchase iTero® scanners. In addition to contract terms with specific doctors, Align has entered into agreements with Dental Service Organizations ("DSOs") and Orthodontic Service Organizations ("OSOs") to install iTero® scanners in as many dental and orthodontic offices as possible, and to therefore expand the reach and impact of their anticompetitive scheme.

80. DSOs and OSOs are similar to group purchasing organizations that purchase in bulk to secure volume discounts for members. DSOs and OSOs have varying levels of involvement in the day-to-day operations of the member doctors but have the ability to bind member doctors to contractual commitments made to suppliers.

81. On July 25, 2018, Align announced a multi-year deal with Heartland Dental, the largest DSO in North America, "to extend iTero Element intraoral scanners to [Heartland's] supported dentists and teams nationwide." This agreement resulted in "the industry's single-largest scanner deployment and investment," with over 900 scanners sold.[35] In 2023, Align and Heartland renewed and extended this agreement to upgrade Heartland Dental's iTero® scanners to the iTero Element 5D Plus®.[36]

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[33] Q4 2018 Financial Results Presentation, at 17 (Jan. 29, 2019).
[34] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q1 2023 Earnings Call Transcript (Apr. 26, 2023); John Morici, Chief Financial Officer, Align Technology Inc., Jefferies Healthcare Conference Transcript (June 4, 2024).
[35] Press Release, Heartland Dental, LLC, *Heartland Dental Fortifies Its Footprint with iTero Element Intraoral Scanners* (July 25, 2018), *accessible at* https://www.globenewswire.com/news-release/2018/07/25/1542293/0/en/Heartland-Dental-Fortifies-Its-Footprint-with-iTero-Element-Intraoral-Scanners.html (last visited: July 9, 2024)
[36] *E.g.*, Press Release, Heartland Dental, LLC, *Heartland Dental today supports more than 2,800 doctors in more than 1,700 offices across 38 states and the District of Columbia* (Jan. 31, 2024), *accessible at* https://blog.heartland.com/heartland-dental-celebrates-record-new-construction-affiliation-growth-and-technology-enhancements-in-2023 (last visited: July 9, 2024).

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82. Align has described its agreements with DSOs and OSOs as acting as a "force multiplier" allowing the placement of numerous iTero® scanners in a single agreement.[37] These agreements often contain exclusivity and other anti-steering provisions described below that further compound Align's anticompetitive strategy.

83. Align has not been shy about its iTero® strategy. With a significant installed base of iTero® scanners with doctors, Align developed a "foundation" to "drive more Invisalign" sales.[38] Align's Chief Marketing Officer has explained that the iTero® and its digital platform "deliver[] a competitive moat for the company," and the purpose of the iTero® is to "drive[] the core"—that is, clear aligner sales.[39] Align's CEO has further explained that Align has used the iTero® to cultivate a "doctor advantage," which among other things, is a "mote[] [sic] around [Align's] business from a competitive standpoint."[40]

iii. Align Designs the iTero to Lock Doctors Practically And Financially Into Invisalign®

84. As Align's executives have made clear, the ultimate motive of forcing the iTero® on doctors was to lock up the clear aligner market. It achieves that result because Align designs the iTero® to raise the costs to a doctor who attempts to send scans to competing aligner companies, and thereby effectively raise Align's rivals' costs. These functional limitations alone impair competing clear aligner suppliers' ability to obtain any substantial business from a doctor who uses an iTero.

85. The iTero® can send a scan to Align with the literal click of a button. In fact, *every* scan completed on an iTero® is sent automatically and instantaneously to Align, regardless

[37] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q3 2019 Earnings Call Transcript (Oct. 23, 2019).
[38] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q4 2021 Earnings Call Transcript (Feb. 2, 2022).
[39] Raj Pudipeddi, Chief Marketing Officer, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023).
[40] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2018 Investor Day Transcript (May 23, 2018).

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of whether the doctor or patient seeks to use Invisalign®. If a doctor wishes to purchase Invisalign® using a scan from an iTero®, it takes less than a matter of moments to do so.

86. But Align went further than just making it convenient to purchase Invisalign® from the iTero®, the design of the iTero® makes it unreasonably inconvenient and costly to purchase any competing aligner product. The design of the iTero® system knowingly frustrates, delays, impedes, and otherwise increases costs to a doctor attempting to send a scan taken on an iTero to a competing aligner company. And there are no technological justifications for those design choices. On information and belief, those choices are motivated purely by predatory intent.

87. As an initial matter, Align charges doctors a fee to access and download a scan taken on an iTero®, which is a necessary prerequisite to sending a scan to a competing aligner company. This "iRecord" fee is *not* imposed if the scan is sent to Align for an Invisalign® order. In the alternative, a doctor can purchase a subscription package that provides access to iRecord and costs, on information and belief, approximately $360 per month for the first scanner and approximately $180 per month for each additional scanner.

88. In addition to paying the extra fee, if a doctor using an iTero® wishes to purchase aligners from an Invisalign® competitor, the doctor must go through a complex, time-consuming multi-step process to export an STL file. On information and belief, Align intentionally designed the multistep process to deter doctors from sending iTero® scans to competing clear aligner suppliers, like ClearCorrect®. Doctors have testified that Align's process for exporting STLs to a clear aligner competitor of Align is so cumbersome, and confusing, that it is impractical and deters doctors from using competing aligners, including ClearCorrect®.[41]

[41] *Snow v. Align Tech., Inc.*, Case No. 3:21-cv-03269-VC, Dkt. 506-8; Dkt. 506-9; Dkt. 506-10.

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89. As an example, a doctor wishing to send a scan from an iTero® to ClearCorrect® must navigate a series of complicated steps, some of which can take up to 48 hours to complete. To start, the doctor must set the scanner on an "iRecord" setting that is misleadingly described in Align's manuals as a "simple scan" used for "studying purposes." Failure to use the iRecord setting renders the scan unavailable for anything but Invisalign®, and it cannot be downloaded. Assuming the doctor correctly set the scanner, the scan will eventually become available for download (either through myaligntech.com or myitero.com) but only after an extended wait—ranging from 15 minutes to 48 hours. Even 15 minutes is unacceptable given the realities of doctor workflow requirements, but the labor and opportunity costs becoming increasingly prohibitive the longer it takes to access the scan. Even then, though, the scans are not readily accessible—the search is complicated and onerous, requiring doctors to navigate through drop-down menus and search bars. Once located (if located), the doctor must correctly export the files, choosing from a series of non-intuitive options like "Open Shells" and "Two files (arches oriented in occlusion)," rename and save the folders, potentially export files from a zip, and choose the correct files from a number of files to upload, with any error along the way resulting in unusable files that will need to be downloaded again.

90. Of course, none of these are intuitive steps, and none of these steps are required by the other major scanners. Competing aligner companies need to try to teach doctors how to navigate through Align's needless technical hoops to order a competing aligner. Even the need to educate doctors represents an additional barrier and cost to those competitors like ClearCorrect®.

91. Nor is this complex process technologically necessary in any respect. By contrast, a doctor sending a scan from 3Shape's TRIOS® series or any other competing scanner

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company to ClearCorrect® may either use the integrated feature to send directly to ClearCorrect®, where there is an interoperability agreement in place, or simply click "export scan" after completing the scan to save the file on the user's desktop. The export features on these devices are analogous to saving a Word file, and unlike Align's iTero®, do not require an upload and download process to access the STL in the first instance. 3Shape's TRIOS® even includes the option to automatically export files to a predetermined folder upon completing each scan. Once a scan is exported, the scan is then available to upload to any clear aligner company or dental laboratory, including ClearCorrect®.

92. This extended delay in sending a scan from an iTero® to a competing clear aligner company is significant to doctors. Doctors operate busy practices and prioritize "workflow"—the process of getting a patient into the chair and through treatment. Workflow is essential to successful dental and orthodontic practice, and doctors seek to maximize the number of patients they see in a given day. Moreover, in many instances, additional follow-up scans are needed for a patient during the ordinary course of treatment. The same cumbersome process must be repeated for each scan throughout a treatment course.

93. Align has received requests from doctors to simplify the process for sending iTero® scans to competing aligner companies. On information and belief, Align has declined to simplify the process for competing aligner companies to maintain barriers to doctors ordering from competing aligner companies.

94. Further, on information and belief, over significant periods of time and even to this day, scans sent from iTero® scanners to competing aligner companies have been frequently corrupted or rendered incomplete such that they cannot be used for ordering clear aligners.

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These scans appear normal when conducted, but after export from the iTero® and upload to the competing aligner company, the scans arrive corrupted and unsuitable for use.

95. Once a scan file is corrupted or rendered incomplete, a doctor must spend extensive time with technological support with both Align and the competing supplier. If the corrupted scan cannot be resolved, the doctor may need to recall and rescan the patient, days after the original scan. This significantly increases costs to the doctor and, importantly, chills doctor and patient interest in trying out new and competing alternatives to Invisalign®.

96. Align's design of the iTero® thus raises a number of artificial costs for doctors to purchase from a competitor, including costs associated with training staff on how to use an iTero® to send scans to a competing aligner company, the labor costs associated with following the steps to order from a competing aligner company, the labor costs associated with trouble shooting issues with the scan file, the opportunity costs associated with having an employee engage in this type of work when they could be doing patient-facing work that generates profit for the business, and the fee that Align charges doctors to order from a competitor.

97. While the frequent occurrence of corrupted files when sent to third-party clear aligner suppliers would (and has) damaged the reputation of iTero®, doctors still need to purchase the iTero® because it is essential to being able to supply Invisalign®. The net effect of the technical complications is, instead, to deter use of competing aligners.

98. Thus, to be able to compete with Align to supply competing clear aligners (like ClearCorrect®) to a doctor using an iTero®, a competing aligner company must not merely match or beat Align's price and/or product quality; it must overcome all the artificial costs and inefficiencies that Align intentionally stacks in its favor through the iTero "moat."

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99. Nor is it a solution, at least for most doctors, to purchase and use two scanners—i.e., an iTero® for Invisalign® and another scanner for non-Invisalign® business. The purchase of intraoral scanners is a significant investment (of up to $65,000 or more in the case of the iTero®). iTero® scanners are the most expensive intraoral scanners on the market. Because of its high cost, each chair in a doctor's office is unlikely to have more than one scanner. Further, because each scanner requires unique training and expertise, doctors are unlikely to own more than one type of scanner in their offices.

100. Thus, Align's preexisting monopoly power with respect to Invisalign® enabled Align to impose an iTero® on most doctors selling clear aligners, which in turn created artificial hurdles for those doctors to use any (or at least a meaningful number of) competing clear aligners. The additional costs Align imposes on doctors to send iTero® scans to competing clear aligner companies also provide Align a buffer from meaningful price competition and ensure that an equally (and even a more) efficient competitor cannot effectively challenge Align's dominant position. Because of Align's conduct, Align has been able to raise its clear aligner prices to a monopolistic level to the detriment of doctors and downstream consumers.

iv. Align Coerces Doctors Through Financial Penalties To Purchase Invisalign®

101. Align imposes further economic barriers to coerce doctors to order only Invisalign® such that even were a doctor willing to go through the cumbersome technical process to place an order with a competing aligner company, the cost to do so is prohibitive.

102. Intraoral scanners are expensive pieces of equipment. Align's iTero® has a list price set at an artificially high level, placing it as the most expensive intraoral scanner available on the market by a significant amount. Align, however, rarely sells the iTero® at that artificially high list price. Instead, Align regularly induces doctors to commit to high volumes of

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Invisalign® sales in exchange for needed relief from the iTero® list price. For example, on information and belief, Align has pushed a "Fusion" program that provides $12,999 in iTero® pricing relief (or $4,333 per year spread over the three years of the program). But to obtain the iTero® through the Fusion program, the doctor must commit to sending a specified, and significant, minimum number of orders for Invisalign® (which Align refers to as "cases") per year. The Fusion program, however, is just one example. Align enters into other agreements, including ad hoc agreements, with many doctors coercing them into making expansive purchase commitments for Invisalign® in exchange for price relief for the iTero®.

103. If the doctor does not hit the case minimum threshold set by Align for its bundling programs, they are financially penalized for a "Missed Case Commitment." For the Fusion program, for example, a doctor is penalized in the amount of at least $4,333 (plus taxes) per year per scanner for each year they do not meet the commitment. Align sends invoices to reflect these "Missed Case Commitments" to doctors, requiring additional penalty payment. To further coerce doctors to meet these "commitments," Align regularly sues doctors who do not pay this penalty.

104. On information and belief, the Fusion program requires a doctor to send *at minimum* between 15 and 20 patient cases to Invisalign® per year. Further, the Fusion program increases the case commitment each year. But, on further information and belief, the number of cases a doctors must commit to send to Invisalign® per year varies based on the existing volume of business a doctor sends to Invisalign®, and therefore can extend far beyond the minimum 15 to 20 cases per year. Thus, larger practices must commit to a far higher "Minimum Case Commitment" to obtain the Fusion price for the iTero®. And, beyond the Fusion program, a series of ad hoc commitments are designed to force doctors to offer Invisalign® exclusively, or

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nearly exclusively, to obtain pricing relief on the iTero® Align forced them to buy in order to have access to Invisalign® at all.

105. In this way, Align locks up both general practitioners and orthodontists. For many general practitioners, whose businesses do not focus on straightening teeth, the 15 to 20 cases per year commitment represents all or most of that doctor's total annual caseload. Therefore, there is no room for many general practitioners to send *any* orders to a competing aligner company without risking a "Missed Case Commitment" penalty. For orthodontists, where the case commitment increases based on existing volumes, Align can tailor the commitment to lock-up an orthodontist's expected entire clear aligner volume, or at least most of it.

106. This "Missed Case Commitment" penalty operates to coerce doctors to send cases to Invisalign®. If a doctor is considering, for example, the better prices offered by a competing clear aligner company, they cannot simply compare, on a patient-by-patient basis, the price of Invisalign® aligners to the price of the competing clear aligners. Instead, the doctor must also account for the financial penalties Align will impose if they do not send the case to Invisalign® and do not meet their case commitments. Accordingly, it may be, for example, that ClearCorrect® is cheaper for a patient's specific treatment, but if giving ClearCorrect that patient's business threatens missing the doctor's overall case commitment, there is no way ClearCorrect (or any other supplier) could offer a discount significant enough to offset the eventual penalty fees from Align.

107. Thus, while Align styles the Fusion program and its other agreements with doctors for the iTero® as "discounts" from the price of the iTero®, as described above, the programs operate instead to impose the threat of costly penalties and thereby drive and coerce

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doctor behavior. It acts as a barrier to competition because it provides strong disincentives for doctors even to trial a small number of competing aligners.

108. Furthermore, the Fusion program and other price relief programs operate on a repeating cycle. By contract, Align provides that it will provide support for any purchased iTero® for only a five-year period of time. On information and belief, at the end of the five-year support period for Align's intraoral scanners, Align remotely disables the doctor's iTero®. By designing obsolescence into the iTero®, Align ensures that doctors continue purchasing new iterations of the iTero®—restarting the case commitment requirements for pricing relief, and locking in doctors once again.

109. The case commitments within these various iTero pricing programs, and associated penalties, operate in conjunction with Align's "Advantage" program, another program that is similarly styled as a "discount" program, but likewise operates as a penalty on doctors who do not send all or substantially all their cases to Invisalign®.

110. Align's "Advantage" program provides for what Align calls pricing "tiers" based on the volume of Invisalign® cases sent to Align within a six-month period. On information and belief, the Advantage tiers include Bronze, Silver, Gold I, Gold II, Platinum I, Platinum II, Platinum elite I, Platinum elite II, Diamond I and Diamond II. Each tier is associated with a number of points. Points are obtained primarily through treatments. An Invisalign® express treatment is worth 30 points. An Invisalign® Comprehensive Treatment is worth 100 points. Points can also be obtained through attending online or in person education. The total number of points that can be obtained from education is 200 points.

111. On information and belief, Bronze is the base level which requires between 0-999 points and brings a 0% discount. Silver tier, which requires 1000-2000 points receive a 10%

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"discount." The "discount" increases through each tier until Diamond II, where the required points are 20,830 for a 46% "discount." These tiers are also reflected externally to prospective patients in Align's "Find a Doctor" or "Doctor Locator" feature that allows patients to find Invisalign® providers in their area. The doctor's discount rank (e.g., "Diamond II") is, on information and belief, also used to order the search results within Align's doctor-locator feature.

112. The "discount" scheme runs from July 1 to June 30 annually, but on information and belief operates on a six-month cadence—that is, the number of cases a provider submits to Invisalign® in a six-month period will determine the price tier they are subject to for the following six-month period, and the number of cases during that second six-month period will determine the tier for the third, and so on. This operates to constrain doctors' ability to consider competing aligner companies, as doctors are consistently chasing case volume with Invisalign® to avoid higher pricing for the next six months. Doctors are thus *constantly* trying to send sufficient cases to Invisalign® to attain or maintain the necessary pricing level.

113. These tiers operate as penalties for not ordering sufficient Invisalign® cases. Like the iTero®, the list price for Invisalign® is significantly more expensive than competing aligner companies. To avoid exorbitant list prices for Invisalign®, a doctor must send significant volumes of cases to Align to achieve Align's tiers and avoid paying artificially inflated higher prices, including potentially the list price.

114. The cadence of clear aligner treatment is central to the operation of this Advantage program and how it coerces doctor behavior. Doctors enter into contracts with patients at the start of treatment that generally includes a single set price for treatment. This means that increasing the price in the middle of treatment is impractical. Yet, as explained above, clear aligner treatment can last up to five years, and on average last from 10 to 24 months.

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Align offers packages that include different amounts of aligners. Those packages include an upfront cost and then additional costs if more aligners or refinements (changes to the treatment plan) are required. Patients transition through new trays every few weeks, with a median number of 20 trays per course of treatment. If a doctor offers a patient Invisalign® during a period where they are a Platinum I provider, and therefore paying 30% less than the artificially inflated list price for each Invisalign® tray, the doctor *must maintain that tier throughout the treatment* to obtain that 30% price on the additional trays/aligners or refinements that they provide to the patient. Because the patient generally agrees to the price up-front for their Invisalign® course, the doctor bears the financial risk if any pricing tier is lost because of insufficient volumes sent to Invisalign®.

115. This dynamic imposes intense pressure on the doctor with ongoing Invisalign® treatments to continue to meet the same or higher tier, forcing them—every six months—to continue to meet the requisite volumes. This economic coercion is intended to and does handcuff the doctors to Invisalign®.

116. Thus, the Advantage program does not involve "discounts" at all, in any ordinary sense of the word. Align's CEO has explained that this scheme is intended to ensure "customer stickiness," and Align's CFO has stated that it is intended to "drive the right behavior" and is "key" to Align's marketplace strategy.[42] The result of this pricing structure is that, according to Align's CEO, most doctors "rely almost exclusively on [Align's] product lines."[43]

[42] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q3 2018 Earnings Call Transcript (Oct. 24, 2018); John Morici, Chief Financial Officer, Align Technology Inc., Bank of America Merrill Lynch Health Care Conference Transcript (May 10, 2019).
[43] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q2 2019 Earnings Call Transcript (July 24, 2019).

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117. Although each is independently anticompetitive, the iTero® volume commitments (including the Fusion program) as well as the Advantage programs, work hand-in-hand and reinforce one another. Put together, a purchaser of an iTero® must send a minimum number of aligner cases to Align to avoid a financial penalty on the iTero®, and then the doctor must send even more cases to Align to avoid financial penalties on the aligner cases that they were required to place to avoid the iTero® penalty. It is a never-ending cycle of minimum order requirements that prevents doctors from offering customers any choices beside Invisalign®, even if those other options (including ClearCorrect®) would be cheaper and better for the patient.

118. These programs—which effectively penalize "disloyalty"—act in conjunction with the additional costs the iTero® imposes on competing aligners. Independently and collectively these factors significantly raise doctors' costs of purchasing competing aligners, creating an artificial barrier to competition that insulates Invisalign® from free and fair competition, and allows Align to maintain its monopoly by means other than competition on the merits. The contractual restrictions, technical impediments, and penalties all act to reduce doctor choice and dampen competition.

v. Align Imposes Contractual Terms That Lock Doctors Into Invisalign®

119. In addition to the technical impediments it imposes on competition and the coercive penalties for "disloyalty," Align coerces doctors into sending scans almost exclusively to Align for Invisalign® through explicit anti-steering and similar exclusivity provisions. Align requires purchasers of the iTero® to agree to a series of contracts of adhesion that contain terms that effectively, or literally, prohibit a doctor from placing an order for clear aligners with a competing aligner supplier.

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120. At its most egregious, Align includes within the extended payment terms for the overpriced iTero® an explicit anti-steering provision. To obtain the extended payment terms for iTero® (which is an agreement to defray the significant upfront cost of the iTero® across twelve monthly payments), doctors must commit to maintain "Good Standing" with Align. To maintain "Good Standing," ***the doctor must agree not to "divert patients who are prospective patients for Invisalign to other non-Invisalign treatments."*** "Prospective patients for Invisalign" would essentially all be prospective ClearCorrect patients, and many prospective patients for Invisalign® would be prospective patients for other clear aligner treatments. This unlawful provision therefore *explicitly bars* doctors from sending cases to ClearCorrect and other clear aligner providers. Align has admitted in public documents that it has entered contracts with doctors that require the doctors to "promote only Invisalign."

121. Align's exclusionary provisions do not end there. Even if a doctor is not participating in Align's extended payment plan, other iTero® agreements include sweeping and vague language seemingly barring doctors from using iTero® scans for competing aligners. For example, a version of the iTero Product Agreement includes a provision that states: "***Customer hereby agrees that Invisalign scans will only be used exclusively for Invisalign treatments.***" The agreement nowhere defines the phrase "Invisalign scans." This provision thereby likely deters at least some doctors from using scans generated by an iTero® to place orders with competing aligner companies. Other iTero Product Agreement provisions state that a doctor must "assign[] to Align to the fullest extent permitted by law the entire right, title and interest in and to the copyright to all scans created using the iTero Scanners," and those provisions further state that a doctor may only use the iTero® scans for maintaining "patient records." Doctors are also separately required to accept terms and conditions that, among other things, require the

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doctor to agree that they are using Align's software and website only "for the purpose of a good faith relationship with Align" and for "ordering Products or Services offered by Align." These provisions thus require doctors to repeatedly affirm their loyalty to Align.

122. Similarly, after artificially creating this intense economic pressure on doctors to continue to sell high volumes of Invisalign®, Align further tightens the lock-in effect through another anti-steering provision. Align offers to list Invisalign® prescribers on its website in the "Find A Doctor" search function, but only if the doctors remains in "Good Standing," which requires that the doctor never divert any prospective patients for Invisalign® to a competing product. Doctors are coerced into accepting this because of the pressure placed on them, depriving them of the ability to offer their patients choice (even patients who never visited the Invisalign® website). In fact, many doctors complain that Align has turned them into Invisalign® sales representatives, but they feel they have to comply because they are locked-in.

123. Align is a notoriously litigious company, and it has intentionally developed that reputation. Not only does Align baselessly sue its competitors and potential competitors (as it has done in this case against ClearCorrect), but it regularly sues doctors who are disloyal to Invisalign®. These suits are intended to, and do, send a clear message to other doctors.[44] Thus, at a minimum, the risk of enforcement of these unlawful, anticompetitive provisions chills doctor willingness to purchase competing aligner treatments.

124. In addition to restrictive terms with individual doctors, Align has entered into contracts with DSOs and OSOs to further its monopoly position in doctor-directed clear aligners.

[44] On May 7, Align sued Bill Dischinger, DMD of Lake Oswego, Oregon, accusing Dr. Dischinger of false advertising and misuse of trademarks for allegedly advertising Invisalign® on the practice's website while not offering Invisalign treatment. In 2022, Align sued Smiles of Virgina Family Dental Center accusing Dr. Niels Oestervemb of false advertising and misuse of trademarks on similar grounds.

[redacted]

These agreements act to further restrict the choice of the organizations' member doctors and lock them into ordering Invisalign® for their patients.

125. Align has identified DSOs and OSOs as the next vehicle for growth for Invisalign®. Align has stated that DSOs and OSOs are the "fastest-growing segment in the dental industry," and its agreements with DSOs and OSOs are a "strategic part of [Align's] overall strategy."[45] In 2022, the proportion of dentist offices affiliated with a DSO was estimated at approximately 23%. In 2022, that share was forecast to grow to around 39% by 2026.

126. Align has entered into agreements with Heartland, one of the largest DSOs in the United States. On information and belief, these agreements require Heartland to exclusively promote Invisalign®.[46] Align has also entered into at least eight additional agreements with DSOs and OSOs that require the exclusive promotion of Invisalign® and condition certain pricing terms on that exclusivity. These include agreements with: (1) Smile Doctors Orthodontists, an OSO covering over 400 offices and touting "the largest network for Diamond Plus Invisalign® providers"; (2) MB2, a DSO with nearly 1,500 dentist members, (3) myOrthos, an OSO with over 50 member practices, (4) 42 North Dental, a DSO with over 300 dentist members, (5) Apex Dental, a DSO with over 250 dental members, (6) Jefferson Dental, a DSO with over 70 dental offices, (7) Mid-Atlantic Dental Partners, a DSO with over 200 member

[45] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q4 2016 Earnings Call Transcript (Jan. 31, 2017); Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q1 2018 Earnings Call Transcript (Apr. 25, 2018).

[46] In addition to these long-standing contractual restraints, within the last two years, Align has purchased $150 million in equity in Heartland Dental, giving it even more leverage over Heartland Dental's purchasing decisions going forward.

[redacted]

offices, and (8) Orthodontic Management Company LLC (on information and belief, this OSO does business as Diamond Braces), an OSO with over 25 member offices.[47]

127. On information and belief, all of Align's contracts with DSOs and OSOs have provisions that require the DSO and OSO, and their members, to exclusively promote Invisalign® to their patients. These anti-steering provisions mean that a doctor cannot recommend that patients use a competing aligner option, effectively foreclosing competition for that doctor's business. Align's contracts with DSOs and OSOs further condition certain pricing terms on Invisalign® on the DSO or OSO exclusively selling Invisalign®. Thus, even if a patient were to enter the office and independently request ClearCorrect®, Align's contracts coerce the doctor into persuading the patient to purchase Invisalign®. On information and belief, some of Align's contracts with DSOs and OSOs even include express provisions that outright prohibit working with Align's competitors. The practical effect of these agreements is to drive members of DSOs and OSOs to the exclusive use of Invisalign®. By preventing DSOs and OSOs from promoting competing aligners, Align practically locks those doctors into selling Invisalign®.

128. As a result of these agreements, Align's sales to its DSO and OSO partners now represent over 25% of Align's revenues. The share of Align's sales to DSOs and OSOs is projected to increase over the long term, to comprise up to 50% of Align's revenue.

129. Align's agreements with DSOs and OSOs effectively foreclose sales of competing clear aligners to the largest volume purchasers in the United States. On information and belief, at a minimum, these DSO and OSO agreements alone forecloses competitor access to at least 20% of the relevant market. In aggregate, however, the contractual provisions and other

[47] Mid-Atlantic Dental was acquired by Western Dental in May 2022. The combined firm has over 500 dental offices.

[redacted]

exclusionary conduct described throughout these Counterclaims apply to the substantial majority of Align's business, which itself represents the dominant share of the market.

vi. Align Coerces Doctors Through Threats To Terminate Access To Invisalign®

130. When all else fails, Align also engages in harassment and intimidation to discipline and control doctor behavior.

131. Every intraoral scan generated by an iTero scanner is automatically uploaded to Align's internal cloud storage system. Doctors have no method for preventing this upload or otherwise limiting Align's ability to access the iTero® scans on patients. For example, there is no way to download an iTero® scan except by downloading the scan through Align's cloud-based platform (through the onerous and time-consuming process described above). On information and belief, Align monitors doctors' use of those scans to ensure that doctors primarily or exclusively order Invisalign®.

132. In the event that a doctor does attempt to download and use a scan to purchase aligners from a competitor, on information and belief, Align has a practice of contacting the doctor to pressure the doctor into returning its orders to Align through aggressive sales tactics, including through threats to doctor pricing (e.g., by suggesting a doctor will not meet their minimum case requirement). Align engages in this conduct through in-person visits and phone calls from Align's sales force to pressure doctors.

133. Align also harasses doctors to attempt to restrict the free flow of information necessary for competing aligners to effectively enter and expand in the market. For example, Align has threatened to withhold Invisalign® or otherwise financially penalize doctors who seek to publish scientific studies that include favorable results for competing aligners, or who publicly support a competing aligner company. Align has further terminated relationships with doctors

[redacted]

that have publicly voiced criticism of Align or Invisalign®. This coercive behavior has the effect of chilling doctors' willingness to entertain offers from competing aligner companies.

C. ClearCorrect® Is Well Positioned To Be An Effective Competitor In A Properly Functioning Market

134. Align's monopolistic practices described herein have resulted in substantial foreclosure of market access to rivals, including ClearCorrect.

135. ClearCorrect was founded in November 2006 in Houston, Texas, by Dr. Willis Pumphrey. At the time of founding, Dr. Pumphrey and his team made all of the ClearCorrect aligners by hand in the back room of Dr. Pumphrey's office.

136. In 2007, ClearCorrect expanded to its own offices and began using computer numerical control ("CNC") machines to mill physical aligner models from digital models. As its customer base grew, ClearCorrect moved to more sophisticated CNC machines.

137. In 2009, Align imposed a policy of requiring doctors to sell minimum volumes of Invisalign® (10 cases per year) and to participate in Invisalign® educational courses. ClearCorrect emerged as a compelling alternative to doctors who were frustrated or angered by this policy. As a result, Align quickly recognized that ClearCorrect was an emerging competitive threat that needed to be restrained. That same year at a dental conference in San Antonio, Align falsely claimed that ClearCorrect was a successor company to OrthoClear (a former competitor to Align that Align had driven out of business through litigation). Align stated that it would "go after them again" (referring to ClearCorrect).

138. Despite placing this cloud over ClearCorrect in the marketplace, ClearCorrect continued to build a positive reputation. In 2011, *Inc.* magazine named ClearCorrect the fastest growing health company in the United States with a three-year growth rate of 8,625%. But Align then brought expansive patent litigation against ClearCorrect that would last the next eight

[redacted]

years. The cost of that litigation hampered ClearCorrect's growth. The parties finally resolved that litigation by settlement in 2019 (the "2019 Settlement") with no admission of liability.

139. On August 18, 2017, the Straumann Group announced its acquisition of ClearCorrect. The Straumann Group has operated in the dental industry for over seventy years and is a global leader in tooth replacement and orthodontic solutions. The Straumann Group's investment in ClearCorrect brought experience, capital, and existing contacts within the dental industry.

140. ClearCorrect also became armed with the latest in aligner materials, FLX, which would allow it to enhance its product offering. Bay Materials LLC developed a material that was more durable, more tear-resistant, more comfortable for patients, more stain resistant, and more effective at treating patients than prior aligner materials, including the material used by Align. This next generation material was commercially released in November 2018.

141. Compared to other aligner materials—including the material used to produce Align's Invisalign®—FLX puts less initial force on teeth but sustains that lower force throughout treatment to achieve better movement. Because there is less initial force, FLX reduces the pain and discomfort for patients. The Straumann Group acquired Bay Materials in October 2019.

142. Free from the burdens of Align's oppressive litigation, and with the benefit of the Straumann Group's investment and expertise, and the innovative FLX materials, ClearCorrect was, and is, well positioned to compete against Invisalign® in the clear aligner market, and to end Align's market dominance. That competition would bring (or would have brought) better choices at lower prices. But due to Align's persistent monopolistic conduct described herein, ClearCorrect has been unable to take any significant share from Align.

[redacted]

143. ClearCorrect cannot get past Align's "competitive moat" simply by offering its own scanner-aligner bundle or product discounts. Align, in fact, has recognized that even though ClearCorrect has a "price-favorable line," Align has not changed its pricing strategy in response to ClearCorrect.[48] Although ClearCorrect offers a better product at a lower price, most doctors express that they are unable even to trial ClearCorrect® on a few patients. They express concern about the financial penalties associated with disloyalty to Invisalign®, as well as the time, burden, and uncertainty of trying to order ClearCorrect® aligners from an iTero® scanner. Most orthodontist practices, and many general dentistry practices with significant clear aligner business, are completely locked-into Invisalign®. This marketplace reality is the natural, foreseeable, intended result of Align's coercive practices described above.

144. The combination of technical impediments, added costs and penalties, and contractual restrictions work synergistically to prevent ClearCorrect from achieving the marketplace growth that its product and pricing would achieve in a free and fair market. Doctors face significant financial and time penalties for any case they send to a competing clear aligner company, including ClearCorrect®. As a result, it is too costly, burdensome, and risky for most doctors to send any significant amount of business to a competing clear aligner company. While the few doctors who are able to run the gamut of Align's other restrictions may be able to convert some cases to alternative clear aligners at the margins—for example, the 21st case after they have hit their 20-case minimum case commitment to avoid the iTero® penalty—they cannot send any more than marginal cases. No discount or product promotion by ClearCorrect, or any other equally efficient aligner supplier, can overcome this marketplace disadvantage.

[48] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q1 2019 Earnings Call Transcript (Apr. 24, 2019).

[redacted]

145. Therefore, the only theoretical way to peel off sufficient business from Align to scale and grow beyond the margins (and to achieve market share above the single-digits where competitors have been trapped for many years), would be to displace the Invisalign® business entirely and convince the doctor to switch scanner systems (incurring the necessary Align penalties), such that a doctor could escape the coercive power of the locked-in Align system. But that is not feasible because of Align's entrenched monopoly position. Given Align's entrenched dominance, few doctors are prepared to forego the ability to offer any Invisalign® (which would happen if they moved away from the iTero®).

146. Most doctors conclude that, given Align's current, dominant "brand advantage," they need to be able to provide that brand to remain a viable provider in the marketplace.[49] Doctors conclude that, because many consumers will search for "Invisalign" (mistaking the brand name for the generic name of the product itself) and others may demand the leading brand name (as a material portion of the population typically does in most markets), they need to be able to offer Invisalign®. Align, however, has created a dynamic where it is not economically feasible for doctors to offer significant volumes of alternatives to Invisalign®, while still being able to keep Invisalign® as an option for the subset of patients who demand it. And that, in turn, prevents competitors from growing significantly enough to challenge Invisalign® for that leading spot and to dilute Invisalign®'s brand advantage.

147. As detailed below, Align's campaign of false advertising contributes to this distorted market dynamic, thereby fortifying Invisalign®'s entrenched brand advantage. Align misleads consumers by falsely promoting Invisalign® as the only brand that provides

[49] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2018 Investor Day Transcript (May 23, 2018).

[redacted]

customized, doctor-directed clear aligner treatment, and further falsely denigrates the capabilities of competitors in the market, including ClearCorrect.

148. Even if doctors otherwise were willing to switch their practices entirely from Invisalign® to ClearCorrect® (or to any other aligner product), to convince a doctor to switch substantial volumes of their business away from Invisalign® would require an overhaul that would be disruptive to existing Invisalign® cases (which require ongoing scanning with the iTero®, and may last several years) and would result in ongoing financial penalties for those existing cases.

149. But for Align's suffocating monopolistic practices, doctors would be significantly more likely to try competitors to Align—particularly where a doctor is able to explain the quality and price benefits of a competitor product in comparison to Invisalign®. Indeed, most doctors would prefer to offer their patients a choice of multiple aligner options. That option is key to effective competition. It enables new and innovative products, like ClearCorrect®, to develop a growing reputation among doctors, who will then recommend the product to consumers. That competition in turn places competitive pressures on the dominant player (here Align) to discount in response to those competitive threats—something Align boasts it has never had to do. The beneficiaries of that competition are doctors and consumers.

150. As a result of these marketplace dynamics caused by Align's monopolistic scheme, ClearCorrect has suffered, and will continue to suffer, lost sales and lost profits. Furthermore, because of that restrained growth, ClearCorrect has invested less in continued product development and improvement than it would have, and achieved fewer cost efficiencies of scale than it would have. But for Align's monopolistic scheme described herein, ClearCorrect would enjoy a stronger market position and would have weakened, or ended, Align's long-

[redacted]

standing monopoly. Align has maintained its monopoly position with respect to Invisalign® only because it has used its monopoly power to prevent competition on the merits. This has led to higher prices, less output, less choice, and less innovation.

RELEVANT ANTITRUST MARKET AND MONOPOLY POWER

A. Align Has Monopoly Power In A Relevant Market For Doctor-Directed Clear Aligners

151. Align possesses monopoly power with respect to Invisalign®, which has been and remains the dominant doctor-directed clear aligner product on the market today. The doctor-directed clear aligner product market is an intermediary market in which companies compete to sell their aligners to doctors, who in turn sell those aligners, and their services, to a patient. Align's monopoly power in this market enables it to continue to charge supracompetitive prices for Invisalign®, and to continue to wield its dominant position to exclude competition.

152. Align publicly acknowledges that it faces no meaningful price-retraining competition with respect to Invisalign®. As recently as May 30, 2024, Align's CEO stated that Align has "pricing power" with respect to Invisalign® and that although doctors "don't like" the regular Invisalign® price increases, those doctors "accept" those price increases from Align.[50]

153. Align's CEO has further stated that competition "isn't really affecting [Align] from a price standpoint."[51] He has explained that Align has not suffered "systemic loss to our traditional competitors in any way" despite Align's higher price points, and that Align has not "reacted one time to a competitive aligner price."[52]

[50] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Jaws & Paws Conference Transcript (May 30, 2024).
[51] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q4 2021 Earnings Call Transcript (Feb. 2, 2022).
[52] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q2 2019 Earnings Call Transcript (July 24, 2019); Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2021 Investor Day Transcript (Oct. 29, 2021).

[redacted]

154. Align's CFO has stated that "[w]e haven't had to do anything from a pricing standpoint, from a competition standpoint. Our ASPs [average selling prices] have been – actually have increased over the last several quarters. So we haven't priced to compete in that way."[53]

155. To the extent it is necessary to define a relevant antitrust product market, the relevant product market for purposes of assessing the conduct in this case is the market for doctor-directed clear aligners—that is, clear aligners sold to doctors and prescribed by and purchased through dental practitioners and exclusive of clear aligners sold direct-to-consumer.

156. The only other product used to treat some of the same dental conditions as clear aligners do are traditional metal braces, but braces are not a reasonable substitute for clear aligners. Clear aligners have several significant functional and aesthetic advantages over braces such that braces do not act as a competitive constraint to clear aligner pricing.

157. On a functional level, clear aligners prevent damage to a patient's teeth that would normally come from the physical application of wires and brackets and eliminate the discomfort associated with metal brackets. Braces result in 70% of patients experiencing white spot lesions on their teeth or suffering permanent dental damage.[54] Indeed, Align's Chief Marketing Officer at an Investor Day in 2023 likened braces to "medieval torture instruments."[55] Clear aligners are

[53] John Morici, Chief Financial Officer, Align Technology Inc., Jaws & Paws Conference Transcript (June 1, 2022).
[54] *E.g.*, Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2018 Investor Day Transcript (May 23, 2018) ("I just hope that someday, we're thinking about patients first and what would a patient rather have? If you rather have wires and brackets in your mouth and 70% white spot lesions and permanent detention damage that happens in 70% of cases, not eat food you want to eat[.]").
[55] *E.g.*, Raj Pudipeddi, Chief Marketing Officer, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023).

[redacted]

better suited to address certain dental conditions, including closing "open bites."[56] Clear aligners can also treat a patient up to five months faster than braces.[57] Because clear aligners can be removed, clear aligners also allow patients to maintain better dental hygiene during the course of treatment (e.g., easier brushing and flossing). Braces further are generally not recommended for patients who are involved in certain physical activities, such as contact sports.

158. On an aesthetic level, clear aligners are less noticeable than metal brackets and wires and eliminate the social stigma and appearance concerns that hold many patients back from seeking treatment for their teeth. For many patients, the social stigma attached to wearing wires and brackets is so severe that they will not consider using braces at any price.

159. For doctors, an aligner treatment system also comes with the promise of economic and practical benefits. Clear aligners require up to 30% fewer visits to doctors because a doctor does not need to physically adjust wires and brackets and does not need to respond to emergency calls (for example, where a wire might break out of a bracket).[58]

160. These significant functional and aesthetic differences between clear aligners and braces mean that braces do not constrain clear aligner pricing. Indeed, Align's CEO has stated

[56] *E.g.*, Zelko Relic, Chief Technical Officer and Senior Vice President of Global Research & Development, Align Technology Inc., 2018 Investor Day Transcript (May 23, 2018) ("Many doctors actually don't want to do some treatments with braces…. Let me give you an example, open bites. This is the – you have a gap upfront. Many of our doctors are choosing Invisalign to treat open bites. I can give you many, many quotes from many, many doctors. And the reason is very simple: because we have the ability for a vertical control better. We can do this anterior extrusion and posterior intrusion and close that bite…. And the problem with arched wires is that, actually, you can get [unwounded] which only makes your open bite even worse. This is just an example. I can give you many more.").

[57] *E.g.*, Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q4 2022 Earnings Call Transcript (Feb. 1, 2023) ("So versus wires and bracket, … [o]n an average, we do patient cases 5 months fast[er] and 35% fewer visits to a doctor."); Mitra Derkhshan, Senior Vice President Global Clinical, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023) ("We know what's important to moms, less pain, better oral health and faster treatment times … than braces…. [W]e learned over time by the evidence of not only efficacy, but the efficiency and efficiencies that we've seen, 30% fewer visits, 5 months faster treatment times than braces, better throughput for our customers.").

[58] Mitra Derkhshan, Senior Vice President Global Clinical, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023) ("So the idea of adopting digital practice is now being seen in very obvious things like less emergencies or fewer visits, but more meaningful evidence for doctors, such as 30% fewer visits or faster treatment times to braces. And this is becoming quite meaningful for doctors as they adopt.").

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that the price of Invisalign® to doctors is "4x" the price of wires and brackets.[59] This price difference is unsurprising, considering that unlike the highly concentrated market for clear aligners, which is dominated by a single supplier (Align), the market to supply wires and brackets to doctors for metal braces is characterized by several suppliers—including 3M, Ormco, DynaFlex, RMO, and others—that compete on price with one another. This price differential is alone strong evidence that clear aligners prices are not meaningfully constrained by the price of wires and brackets for braces, and that the market for doctor-directed clear aligners is a properly defined relevant market.

161. Moreover, clear aligners are widely recognized by the industry and the public as operating in a distinct market. Prominent industry reports are published on the clear aligner market segment and track market shares in that market, exclusive of traditional metal braces. Clear aligners have peculiar characteristics and uses (including, for example, that the aligners are clear and can treat certain conditions that braces cannot). Clear aligners require unique production facilities to produce, including specialized manufacturing capabilities related to preparing and manufacturing clear aligners, software and technology capabilities, and achieve significant benefit from economies of scale. By contrast, wires and brackets are simply applied by doctors in their offices. Clear aligners also have distinct prices—as noted above, the price of Invisalign® to doctors is four times the price for wires and brackets—and as explained above, increases in price of Invisalign® have not caused Align to lose sales to wires and brackets.

162. There is also a submarket for clear aligners for adults. Although Align charges supracompetitive prices to both teenage and adult patients, Align has price discriminated

[59] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q4 2018 Earnings Call Transcript (Jan. 29, 2019) ("[W]hen you go with a clear aligner product versus wires and brackets, [doctors'] cost overall are about 4x from a variable cost standpoint of which you'd have with wires and brackets.").

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between adult and teen patients, through among other things offering discounts for cases for teenagers, and therefore has targeted adult cases for even higher prices. Because aligners are products that are customized to a particular patient's mouth, there is no potential for arbitrage—i.e., that a purchaser could purchase at the non-discriminatory price and then resell to those purchasers subject to the higher, discriminatory price. Adults have a uniquely inelastic demand for clear aligners because of the social stigma attached to wires and braces. Align's CEO has recognized that most adults "wouldn't take wires and brackets," and Align's CFO recently explained that "adults get to a point … and say, look, I'm not going to get braces."[60]

163. What remains of the direct-to-consumer companies do not constrain Align's pricing of its aligners to doctors. The price for direct-to-consumer aligners is thousands of dollars lower than the price charged by doctors for Invisalign®. The remaining direct-to-consumer companies, consistent with their business model, do not sell to doctors and therefore doctors cannot or will not substitute to direct-to-consumer aligners in the event of a price increase. Moreover, direct-to-consumer aligner products are not reasonably interchangeable with aligners received by prescription through a doctors from the perspective of patients and do not constrain upstream pricing of aligners to doctors. Direct-to-consumer products are simple products that typically only resolve issues with the so-called "Social 6," which are the top six most visibly apparent teeth in a person's mouth. These products are not designed to resolve moderate to severe dental conditions and are limited in their application to straightforward cases. These products are also not capable of significant tooth movement, which requires the presence of a doctor to oversee (and potentially take x-rays and other scans to assess the roots of a patient's teeth to ensure proper tooth movement). The presence of a doctor is further necessary

[60] Joseph Hogan, Chief Executive Officer, Align Technology Inc., ROTH Conference Transcript (Mar. 14, 2016); John Morici, Chief Financial Officer, Align Technology Inc., William Blair Conference Transcript (May 23, 2023).

[redacted]

to resolve potential issues related to root absorption or potential risks of tooth loss during treatment.[61] Moreover, direct-to-consumer aligners take longer to receive and require a purchaser to undergo an uncomfortable at-home process to create their own PVS impressions (impressions that even doctors struggle to effectively create). Align's CEO has further stated expressly that direct-to-consumer is "not a model that competes with us."[62]

164. The factors described above indicate that there is a low cross-price elasticity of demand between doctor-directed clear aligner products and other products for aligning teeth. Cross-price elasticity of demand measures the increase in the demand of one product (braces or direct-to-consumer products) in response to an increase in the price of another product (doctor-directed clear aligners). Where there is a high cross-price elasticity of demand, the products are considered reasonable substitutes for one another, and thus properly within the same antitrust market. This premise is the basis for a key tool used to determine a proper antitrust product market known as the "hypothetical monopolist test."

165. As explained in the Merger Guidelines published by the Federal Trade Commission and Department of Justice,[63] the hypothetical monopolist test imagines a hypothetical monopolist that controls all production of a good within a proposed relevant product market and asks whether that monopolist could profitably increase the price of the product(s) above the competitive level, typically by 5% (also referred to as a small but significant nontransitory increase in price or SSNIP) or otherwise worsening the terms of dealing for a

[61] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2021 Investor Day (Oct. 29, 2021) ("If your question is, are we going direct to consumer, we're not going to do that. It's just – to us, doesn't make any sense. You want a doctor in the middle of this thing. It's fairly serious when you're moving teeth through bone. You want to make sure that they actually see a doctor upfront, understand the detention that they have, make nay corrections needed so you don't lose teeth during treatment. Follow those things, make sure there's no root absorption.").
[62] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q1 2020 Earnings Call Transcript (Apr. 29, 2020).
[63] U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines, at § 4.3.A (2023).

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period of one year.[64] The test posits that if such an increase would *not* be profitable for the hypothetical monopolist (that is, the price increase would result in volume losses that offset any gains from higher price), there must be additional substitutes to the products in the proposed relevant market available to consumers and therefore, the proposed market is overly narrow.

166. In the present context, Align's pricing practices show that there is a low cross-price elasticity of demand between doctor-directed clear aligners and other products. Align has increased its price year after year without losing significant sales to braces or direct-to-consumer aligners, while increasing its profits. Indeed, Align has reported that its revenue has increased by more than 20% year-over-year even as it has increased prices.[65] This pattern of consistent and sustained price increases in turn indicates that a hypothetical monopolist of doctor-directed clear aligners would be able to profitably implement a SSNIP. Thus, doctor-directed clear aligners represent a proper relevant product market, and the inclusion of metal braces and/or direct-to-consumer aligners would result in a relevant market that is overly broad.

B. The Relevant Geographic Market Is The United States

167. To the extent ClearCorrect's claims require the definition of a relevant geographic market for aligners, the relevant geographic market is the United States. The Food and Drug Administration approves medical devices, including aligners and intraoral scanners sold to doctors. Doctors in the United States cannot practically seek alternative aligners from other countries that have not been approved for sale and use in the United States. Further, in the face of a SSNIP on clear aligners supplied to practitioners in the United States, few, if any, doctors

[64] Where, as here, one market participant already has a dominant position in the proposed relevant market, the appropriate starting point for performing the SSNIP test is the price "that likely would prevail in a more competitive market." *Id.* This is because where monopoly power has already been exercised the SSNIP test "using prevailing prices can lead to defining markets too broadly." *Id.* n.83.
[65] Align Technology Inc., Q1 2024 Financial Results Presentation, at 8 (Apr. 24, 2024).

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would move their practices outside of the United States. Therefore, aligners that are available for sale outside of the United States but are not approved for distribution and use in the United States, do not constrain the pricing of clear aligners sold in the United States.

C. Align Has A Dominant Market Share In The United States Market For Doctor-Directed Clear Aligners

168. On information and belief Align has continued to enjoy a market share of over 80% of the doctor-directed clear aligner market in the United States. Other products in the relevant market include ClearCorrect's aligners, Ormco's Spark® aligners, and Dentsply's SureSmile® clear aligners. Those products, however, combine for only a small share of the relevant market.

169. There are significant barriers to entry into the doctor-directed clear aligner market that are sufficient to protect Align's monopoly position.

170. Align's ongoing monopolistic scheme, as described in these Counterclaims, acts as significant barriers to entry and expansion for all existing and potential competitors in the market for clear aligners, including ClearCorrect.

171. There are numerous additional barriers to entry, including start-up costs, research and development costs, intellectual property costs, costs associated with marketing, scale, and building reputation, among others barriers to entry. Indeed, Align's CEO assured investors prior to patent expiration in 2017 that competition would be delayed in entering the market, explaining that there are "big barriers to entry" to the clear aligner space, including the necessity of developing skills related to "biomechanicals," "material science," "software," and "manufacturing."[66] Furthermore, to effectively compete, a business must have sufficient sales to achieve economies of scale. As Align's CEO has explained, a clear aligner business is one that

[66] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2016 Investor Day Transcript (June 2, 2016).

[redacted]

"truly relies on scale, whether it's software or hardware or manufacturing."[67] Further, clear aligners must be cleared by the Food and Drug Administration, which poses yet another hurdle to entering the market as such approval is costly, time consuming, and uncertain.[68]

172. Even if the Court were to define a broader product market for clear aligners generally, inclusive of those sold direct-to-consumer (despite the foregoing reasons why direct-to-consumer products are not within the same antitrust market), Align would still holds monopoly power (with a share in excess of 75%), and the conduct alleged herein would still result in substantial foreclosure. Direct-to-consumers sales are subject to structural and legal limitations such that no competitor could displace Align's monopoly through a direct-to-consumer model, a fact acknowledged by Align. After announcing a partnership with SmileDirectClub—a former direct to consumer business—Align told its investors that there is less than a 2% overlap between downstream patients who desire a doctor-directed clear aligner treatment and those willing to accept a direct-to-consumer aligner. Align assured its investors that there would be only a "minimum amount of cannibalization" between SmileDirectClub's business and Invisalign®.[69] Indeed, Align's CEO recently told a conference that the market has seen the "demise of the direct-to-consumer companies in clear aligners."[70]

D. There Is A Relevant Market For Hand-Held Digital Intraoral Scanners[71]

[67] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023).
[68] *E.g.*, *id.* ("Regulatory clearance and guidance, … for us, it's critical because this is getting, we're a Class II medical device when you look at aligners. And it's getting more and more difficult all over the world with different regulations. So we have to make sure we stay on top of this.").
[69] Joseph Hogan, Chief Executive Officer, Align Technology Inc., Q2 2016 Earnings Call Transcript (July 28, 2016).
[70] Joseph Hogan, Chief Executive Officer, Align Technology, Inc., Stifel Jaws & Paws Conference Transcript (June 1, 2022).
[71] Counterclaim-Plaintiffs' antitrust claim arises from the antitrust injury to ClearCorrect in the market for clear aligners. Counterclaim-Plaintiffs do not assert distinct claims for monopolization of the separate market for hand-held intraoral scanners. That said, the conduct alleged herein constitutes monopolization of that market and the monopolization of that scanner market has allowed Align to unlawfully maintain its monopoly in the clear aligner market.

[redacted]

173. Align also has monopoly power in a distinct market for intraoral digital scanners designed for ordering aligners. That monopoly developed from artificially tying the iTero® to Invisalign® and refusing to accept from doctors any scan produced by a competing scanner. As a result of that monopolization, Align has maintained the price of iTero® scanners at supracompetitive levels profitably without losing substantial sales to other products.

174. The only other means to map a patient's teeth for purposes of creating clear aligners for that patient is through the use of PVS impressions, but PVS impressions are not a reasonable substitute for digital scans generated by intraoral scanners. In other litigation, Align has alleged that PVS impressions have a high rate of "restoration 'remakes,'" come with "mess [and] discomfort" and are "subjective."[72] Align has separately recognized that the rejection rate for PVS is more than ten times higher than the rejection rate for an iTero digital scan.[73] Moreover, the availability of PVS has not disciplined the price of scanners, which are priced at tens of thousands of dollars. Align has reported that 95% of case orders placed by doctors in North America were through digital files sent by scanners, only 5% were submitted through PVS.[74] Although Align does not report data for the United States alone, these numbers are likely higher in the United States given the quick adoption of intraoral scanners in United States offices.

[72] Complaint ¶ 17, *Align Technology, Inc. v. Strauss Diamond Inst., Inc.*, Case No. 3:18-cv-06663 (N.D. Cal. Nov. 1, 2018) ("By enabling the dental practitioner to create a 3D image of the patient's teeth (digital scan) using a handheld intraoral scanner inside the mouth, digital scanning is more efficient and precise and more comfortable for patients, compared to the mess, discomfort and subjective nature of taking physical impressions); *id.* ¶ 18 ("The digitally scanned model is also more accurate than a physical impression and substantially reduces the rate of restoration 'remakes' so that patients are recalled less often and the appointment time for the restoration is shorter because of fewer adjustments which results in greater overall patient satisfaction.").

[73] Align Technology, Inc., *The Invisalign Difference*, https://www.invisalign.ca/the-invisalign-difference/parent (last visited: July 9, 2024) ("10x fewer rejections when compared to PVS impressions.").

[74] Align Tech. Inc., Annual Rep. (Form 10-K), at 41 (Feb. 28, 2024).

[redacted]

175. On information and belief, Align has maintained a 70% share in the market for intraoral scanners used for producing clear aligners in the United States. Align's iTero® scanner is responsible for more than 75% of clear aligner orders in the United States.

176. Align's dominant monopoly position is supported by substantial barriers to entry for potential competitors in the scanner market. Align's anticompetitive conduct, described throughout these counterclaims, acts as barriers to entry and expansion. The production of competitive scanners requires significant investment in capital, research and development, and manufacturing facilities. To be used in a doctor's office, these scanners must also be FDA cleared.

EFFECT ON COMPETITION

177. Align's exclusionary conduct has allowed it to maintain a monopoly in the market for doctor-directed clear aligners in the United States. As described herein, Align engaged in a pattern of coercive conduct that is intended to and does lock doctors into supplying Invisalign® exclusively or nearly exclusively. Align did so with the specific intent, and stated purpose, of maintaining its monopoly in the market for doctor-directed clear aligners in the United States.

178. Align's exclusionary conduct has inflicted and continues to inflict harm to its competitors in the market for doctor-directed clear aligners in the form of lost business, lost goodwill, lost investment opportunities, and increased costs. Align's conduct has and threatens to further chill and foreclose competition in the market for doctor-directed clear aligners. Align's conduct has resulted in significant foreclosure, of at least 60% or more, of the market for doctor-directed clear aligners in the United States to competing suppliers like ClearCorrect.

179. By impairing its competitors' ability to compete, and by depriving those competitors of a level playing field, Align has prevented equally (if not more) efficient competitors from being able to compete effectively in a way that would have displaced Align's

[redacted]

monopoly position. In doing so, Align's conduct has hurt both doctors and end consumers in the market for doctor-directed clear aligners in the United States by denying them access to competitive products and services at competitive prices. Align's conduct has resulted in increased prices, decreased customer choice, decreased output, reduced innovation, and lower quality products in the market for doctor-directed clear aligners in the United States.

ANTITRUST INJURY TO CLEARCORRECT

180. Align's monopolistic conduct and attempted monopolistic conduct has resulted in significant and ongoing antitrust injury to ClearCorrect.

181. Align's exclusionary sales practices have harmed ClearCorrect through lost business opportunities, lost sales, and lost profits. Align coerces doctors to purchase the iTero® by making it functionally impossible to place orders of Invisalign® without first purchasing an iTero®, and Align coerces doctors with an iTero® to send consistent and increasing volumes of cases to Invisalign®, thereby substantially foreclosing the market for clear aligners and substantially foreclosing ClearCorrect's growth. Indeed, doctors have told ClearCorrect that but-for Align's conduct, they would purchase the competing products from ClearCorrect. ClearCorrect would have achieved significantly higher sales, and therefore greater profits, but-for Align's exclusionary conduct.

182. Furthermore, ClearCorrect would have been able to scale its clear aligner business to better support customers, improve product quality, invest in further innovation, reduce price, grow its sales force, and otherwise compete more aggressively and successfully against Align. Scale is crucial to effectively compete in the market for clear aligners. Align's CEO, for example, has recognized that "this is a business that truly relies on scale, whether it's software or

[redacted]

hardware or manufacturing."[75] By foreclosing a substantial portion of the efficient means of distribution in the relevant market (i.e., sales to doctors), Align has deprived ClearCorrect® of the necessary scale to effectively compete.

EFFECT ON INTERSTATE COMMERCE

183. At all material times, Align and ClearCorrect have sold clear aligners for the treatment of malocclusion and related products and services across state lines and sold to customers located outside the states in which Align and ClearCorrect are incorporated. Each business sells their aligners in multiple states within the United States.

184. During the relevant period, in connection with the sale of clear aligners, money as well as contracts, bills, invoices, and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines.

ALIGN'S FALSE ADVERTISING

185. Besides Align's anticompetitive practices detailed above, Align also unfairly competes with ClearCorrect through a calculated disinformation campaign that relies on false and/or misleading advertisements to promote Align's products. To maintain its dominant market position, Align has made, and continues to make, false and misleading statements comparing Invisalign® aligners and the Invisalign® system to competitors' clear aligners, including ClearCorrect aligners, as well as unsupported claims about the capabilities of Invisalign® aligners. These statements appear across the spectrum of Align's advertising, including its website and social media platforms. Align's repeated false, misleading, and unsupported statements harm competitors, including ClearCorrect, and violate federal and state laws regulating false advertising and unfair and deceptive practices.

[75] Joseph Hogan, Chief Executive Officer, Align Technology Inc., 2023 Investor Day Transcript (Sept. 6, 2023).

[redacted]

186. Align's disinformation campaign relies on false assertions that Invisalign® aligners are the only clear aligners that offer certain features.

187. For example, as seen in a post from Align's Instagram page, Align promotes its aligners to consumers on the basis that they offer a "[c]ustomized treatment plan from your doctor & in-person consultations throughout the treatment," while "[o]ther clear aligners" do not.[76]

[76] Invisalign March 6, 2024 Instagram Post *accessible at* https://www.instagram.com/p/C4L7DWkMDeu/ (last visited July 9, 2024); Invisalign March 6, 2024 Facebook Post *accessible at* https://www.facebook.com/invisalign/posts/pfbid02gR81KyDNoF7VBQL7EmbmLpPwqqmEifNoyTx67Zqj1gvJkfL3c8ZXuqHPc9MnMxj2l (last visited July 9, 2024).

[redacted]

188. This statement is untrue because other clear aligners, including those offered by ClearCorrect, offer customized treatment plans from a patient's doctor as well as in-person consultations throughout the treatment.

189. For example, as ClearCorrect informs patients, it will "work with your doctor to develop your digital treatment plan."[77]

190. Indeed, ClearCorrect's treatment setup platform allows a doctor to prepare a customized treatment plan, including allowing the doctor to define treatment preferences.[78]

191. Further, once a patient's aligners are ready, his or her doctor will meet with them in-person to ensure that the aligners fit and instruct them on how to use the aligners based on their unique treatment plan.[79]

192. ClearCorrect also sends doctors "daily summary emails" informing them when a patient's next set of aligners has shipped so that they know when to schedule the patient for their next treatment appointment, and it provides doctors detailed guidelines about steps to take during each of the appointments.[80]

193. Accordingly, Align's claim that Invisalign® aligners offer a "[c]ustomized treatment plan from your doctor & in-person consultations throughout the treatment," while "[o]ther clear aligners" do not, is demonstrably false.

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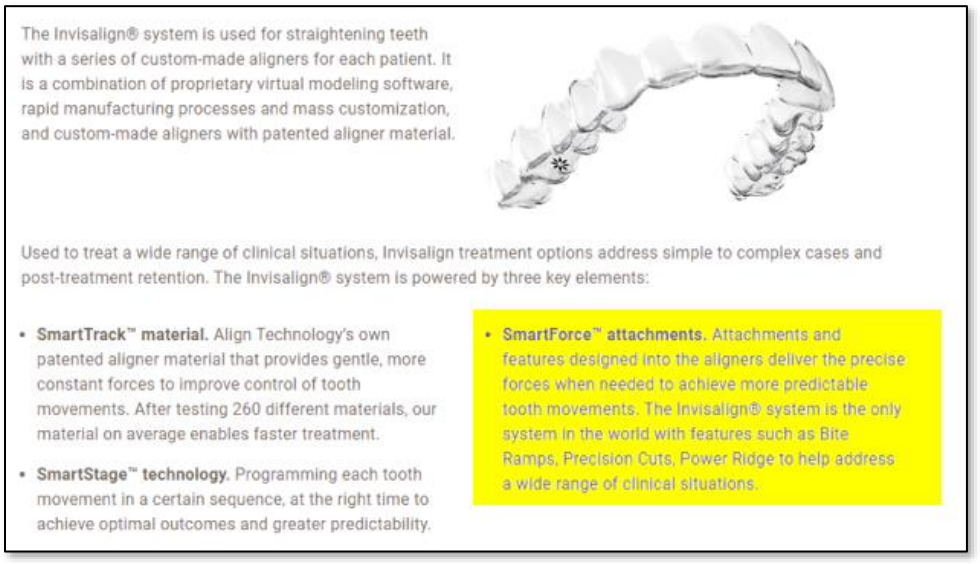
[77] *See, e.g.*, Hassle Free Treatment, ClearCorrect® aligners, ClearCorrect *accessible at* https://www.straumann.com/clearcorrect/us/en/patients/easy-to-wear-easy-to-get.html (last visited July 9, 2024).
[78] *See, e.g.*, ClearPilot, Straumann *accessible at* https://www.straumann.com/clearcorrect/us/en/doctors/clearpilot.html (including embedded video) (last visited July 9, 2024); *see also* Treatment Preferences, ClearCorrect *accessible at* https://support.clearcorrect.com/hc/en-us/articles/4416586057495-Treatment-Preferences#1 (last visited July 9, 2024).
[79] *See, e.g.*, Hassle Free Treatment, ClearCorrect® aligners, ClearCorrect *accessible at* https://www.straumann.com/clearcorrect/us/en/patients/easy-to-wear-easy-to-get.html (last visited July 9, 2024).
[80] *See, e.g.*, Checkup Appointments, ClearCorrect *accessible at* https://support.clearcorrect.com/hc/en-us/articles/204516057-Checkup-Appointments (including embedded video) (last visited July 9, 2024); *see also* Checklist for Clear Aligner Success, ClearCorrect *accessible at* https://support.clearcorrect.com/hc/en-us/articles/115013627447-Checklist-for-clear-aligner-success (last visited July 9, 2024).

[redacted]

194. As another example, Align advertises on its website that the "Invisalign® system is the only system in the world" with a feature known as "Bite Ramps."[81]



195. A bite ramp is an attachment that prevents a patient from biting down completely and helps to correct certain malocclusions like overbites.

196. Contrary to Align's advertising, Invisalign® is not the only system in the world with bite ramps. ClearCorrect also offers bite ramps[82] and on information and belief, so do other aligner companies. As such, Align's statement is clearly false.

197. In addition to the false and/or misleading statements Align uses to suggest superiority of its products over competitor products, Align also overpromises on the efficacy of its products.

[81] The Invisalign® System, Aligntech *accessible at* https://www.aligntech.com/solutions (highlighting added) (last visited July 9, 2024).
[82] Bite Ramps, ClearCorrect, *accessible at* https://support.clearcorrect.com/hc/en-us/articles/5725163712663-Bite-Ramps (last visited July 9, 2024).

[redacted]

198. For example, Align promotes that its "Invisalign aligners can treat all kinds of smiles,"[83] suggesting that Align's Invisalign® aligners can effectively treat all malocclusions, regardless of the type or severity.

199. Invisalign® aligners, however, cannot be used to treat all types of smiles—there are some types of malocclusions that Invisalign® aligners cannot treat. For example, tucked away on Align's website, in the expanded view of the frequently asked questions section for "Treatment," Align acknowledges that "Invisalign clear aligners can treat ***nearly*** all common teeth-straightening issues" [84]—not all smiles. Notwithstanding that Align promotes Invisalign® aligners as being able to treat all kinds of smiles, Invisalign treatment is not for everyone, including those who have neuromuscular issues that result in severe bite alignment issues, as well those who have severely misshapen, crooked, or rotated teeth, or who have either severe overcrowding or large gaps between teeth.[85]

[83] *See, e.g.*, Invisalign® Aligners for Adults, Invisalign, *accessible at* https://www.invisalign.com/why-invisalign/adults (last visited July 9, 2024); *see also* Invisalign® Aligners vs. Other Clear Aligners *accessible at* https://www.invisalign.com/why-invisalign/invisalign-vs-aligners (last visited July 9, 2024).
[84] *See, e.g.*, Frequently Asked Questions, Invisalign, *accessible at* https://www.invisalign.com/frequently-asked-questions (last visited July 9, 2024) (emphasis added).
[85] *See, e.g.*, Who Can Wear Invisalign, Parris Orthodontics, *accessible at* https://www.parrisorthodontics.com/blog/posts/will-invisalign-work-for-me (last visited July 9, 2024); Who Shouldn't Get Invisalign: Understanding the Restrictions, Comfort Care Dental, *accessible at* https://comfortcaredental.com.au/who-shouldnt-get-invisalign-understanding-the-restrictions/#:~:text=Invisalign%20has%20limitations%20and%20may,wearing%20the%20aligners%20as%20prescribed. (last visited July 9, 2024).

[redacted]

200. On information and belief, Align's advertising misleads customers to believe that Align's aligners and aligner systems are superior to competitors', such as by offering more features or being able to treat a wider range of malocclusions than competitors. On information and belief, these false statements drive customers to select Align's aligners over ClearCorrect's aligners, thus resulting in harm to ClearCorrect.

[redacted]

201. [redacted]

202. [redacted]

[redacted]

203. [redacted]

204. [redacted]

205. [redacted]

206. [redacted]

[redacted]

[redacted]

[redacted]

207. [redacted]

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208. [redacted]

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[redacted]

209. [redacted]

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[redacted]

[redacted]

[redacted]

210. [redacted]

[redacted]

[redacted]

PATENT ASSERTIONS

211. In its Complaint, Align alleges that it is the owner of 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") (collectively, the "Asserted Patents").

212. In its Complaint, Align alleges that ClearCorrect's method of manufacturing its ClearQuartz aligners and/or ClearCorrect's ClearQuartz aligner products infringe the '613, '384, '090, and '091 patents.

213. In its Complaint, Align alleges that ClearCorrect's method of treatment planning infringes the '444, '217, '879, and '456 patents.

214. In its Complaint, Align alleges that the Virtuo Vivo intraoral scanner system infringes the '936 patent.

215. ClearCorrect denies each and every such infringement allegation.

216. As a result of Align's actions and statements, including the filing of the Complaint, an actual and justiciable controversy exists between Align and ClearCorrect with respect to the validity and infringement of the Asserted Patents.

217. A judicial determination is necessary and appropriate at this time given Align's allegations against ClearCorrect and in order for ClearCorrect to ascertain its rights and duties with respect to the Asserted Patents.

[redacted]

CLAIMS FOR RELIEF

Count 1: Violation of Section 2 of the Sherman Act (15 U.S.C. § 2) for Monopolization

218. The allegations contained in the preceding paragraphs are incorporated by reference herein.

219. There exists a well-defined antitrust market for doctor-directed clear aligners in the United States.

220. Align is engaged in an overall exclusionary scheme to maintain its monopoly in the market for doctor-directed clear aligners.

221. Align has unlawfully monopolized the doctor-directed clear aligner market through a course of exclusionary conduct described herein. While each of Align's actions increased, maintained, or protected its clear aligner monopoly power in the market for doctor-directed clear aligners and adjacent markets, the following exclusionary conduct—taken together—played a particularly important role in unlawfully establishing and maintaining the doctor-directed clear aligner monopoly:

a. Align's leveraging of its existing monopoly in clear aligners to coerce doctors to purchase an iTero intraoral scanner by technologically tying the iTero® to Invisalign®.

b. Align's intentional creation of technological, contractual, and financial barriers to doctors sending cases to competing clear aligners, including ClearCorrect®, including by:

   i. Intentionally making it difficult for a doctor to send a scan from an iTero® to competing clear aligner companies including ClearCorrect,

[redacted]

including by erecting unnecessary technological barriers and even corrupting the scan;

ii. Forcing doctors to sign contracts of adhesion that include explicit anti-steering provisions barring doctors from sending cases to competing clear aligner companies including ClearCorrect;

iii. Imposing financial penalties on iTero® and Invisalign® purchases on doctors who send cases to competing clear aligner companies including ClearCorrect;

iv. Intimidating and harassing doctors who take scans on iTero® but send those cases to competing clear aligner companies including ClearCorrect®.

222. Each of these acts is independently exclusionary, but the acts also act synergistically and cumulatively to harm competition, the competitive process, and ClearCorrect®.

223. Through its scheme, Align has leveraged its existing monopoly position in the market for doctor-directed clear aligners, to create, extend and maintain a monopoly in the related market for intraoral scanners, which it then uses to secure, extend, and preserve its monopoly in the market for clear aligners. This scheme operates to foreclose the channels of distribution for doctor-directed clear aligners—dentists and orthodontists—by imposing on them significant and coercive costs should they endeavor to sell another company's competing clear aligner product.

224. Align's anticompetitive conduct lacks a procompetitive justification that offsets the anticompetitive harm caused. The sole purpose for each component of the exclusionary

[redacted]

scheme described herein was to impair the ability of rivals to compete in the market for doctor-directed clear aligners, and to foreclose those rivals', including ClearCorrect's, ability to challenge Align's monopoly position.

225. Align's anticompetitive scheme has allowed it to enjoy a market share above 80% and to charge supracompetitive prices on Invisalign® entirely unperturbed by competitive entry.

226. Align's anticompetitive scheme has foreclosed a substantial share in excess of 60% of the market for doctor-directed clear aligners in the United States.

227. Align's anticompetitive scheme has caused economic injury to ClearCorrect, in the form of lost sales and lost profits.

228. Align's monopolistic conduct is ongoing and, unless enjoined, will continue to exclude competition and cause antitrust injury to ClearCorrect.

Count 2: Violation of Section 2 of the Sherman Act (15 U.S.C. § 2) for Attempted Monopolization

229. The allegations contained in the preceding paragraphs are incorporated by reference herein.

230. There exists a well-defined antitrust market for doctor-directed clear aligners in the United States.

231. Align is engaged in an overall exclusionary scheme to maintain its monopoly in the market for doctor-directed clear aligners.

232. Align has unlawfully monopolized the doctor-directed clear aligner market through a course of exclusionary conduct described herein. While each of Align's actions increased, maintained, or protected its clear aligner monopoly in the market for doctor-directed clear aligners and adjacent markets, the following exclusionary conduct—taken together—

[redacted]

played a particularly important role in unlawfully establishing and maintaining the doctor-directed clear aligner monopoly:

a. Align's leveraging of its existing monopoly in clear aligners to coerce doctors to purchase an iTero® intraoral scanner by technologically tying the iTero® to Invisalign®.

b. Align's intentional creation of technological, contractual, and financial barriers to doctors sending cases to competing clear aligner companies, including ClearCorrect, including by:

i. Intentionally making it difficult for a doctor to send a scan from an iTero to a competing clear aligner companies including ClearCorrect, including by erecting unnecessary technological barriers and even corrupting the scan;

ii. Forcing doctors to sign contracts of adhesion that include explicit anti-steering provisions barring doctors from sending cases to competing clear aligner companies including ClearCorrect®;

iii. Imposing financial penalties on iTero® and Invisalign® purchases on doctors who send cases to competing clear aligner companies including ClearCorrect®;

iv. Intimidating and harassing doctors who take scans on iTero® but send those cases to competing clear aligner companies including ClearCorrect.

233. Each of these acts is independently exclusionary, but the acts also act synergistically and cumulatively to harm competition, the competitive process, and ClearCorrect.

[redacted]

234. Through its scheme, Align has leveraged its existing monopoly position in the market for doctor-directed clear aligners, to create, extend and maintain a monopoly in the related market for intraoral scanners, which it then uses to secure, extend, and preserve its monopoly in the market for clear aligners. This scheme operates to foreclose the channels of distribution for doctor-directed clear aligners—dentists and orthodontists—by imposing on them significant and coercive costs should they endeavor to sell another company's competing clear aligner product.

235. Align's anticompetitive conduct lacks a procompetitive justification that offsets the anticompetitive harm caused. The sole purpose for each component of the exclusionary scheme described herein was to impair the ability of rivals to compete in the market for doctor-directed clear aligners, and to foreclose those rivals', including ClearCorrect's, ability to challenge Align's monopoly position.

236. Align has acted with a specific intent to monopolize, and to destroy competition in, the doctor-directed clear aligner market.

237. Align's anticompetitive scheme has allowed it to enjoy a market share above 80% and to charge supracompetitive prices on Invisalign® entirely unperturbed by competitive entry.

238. Align's anticompetitive scheme has foreclosed a substantial share in excess of 60% of the market for doctor-directed clear aligners in the United States.

239. Align's anticompetitive scheme has caused economic injury to ClearCorrect, in the form of lost sales and lost profits.

240. Align's monopolistic conduct is ongoing and creates a dangerous probability of Align gaining market power in the market for doctor-directed clear aligners.

Count 3: Violation of Tex. Bus. & Com. Code § 15.05(b) for Monopolization

241. The allegations in the preceding paragraphs are incorporated by reference.

[redacted]

242. Align has willfully maintained and abused its monopoly power in the doctor-directed clear aligner market through anticompetitive and exclusionary conduct that has locked up critical channels of distribution for ClearCorrect's clear aligners in and outside of Texas.

243. Align's exclusionary conduct has foreclosed a substantial share at least in excess of 60% of the doctor-directed clear aligner market.

244. Align's anticompetitive conduct has had harmful effects on competition and consumers of clear aligners in and outside of Texas.

245. The anticompetitive effects of Align's anticompetitive conduct outweigh any procompetitive benefits, or those procompetitive benefits can be achieved through less restrictive means. The sole purpose for each component of the exclusionary scheme described herein was to impair the ability of rivals to compete in the market for doctor-directed clear aligners, and to foreclose those rivals', including ClearCorrect's, ability to challenge Align's monopoly position.

246. Align's anticompetitive and exclusionary practices thus violate Texas Business & Commercial Code § 15.05(b), which provides that it is "unlawful for any person to monopolize … any part of trade or commerce."

247. Align sells a substantial volume of its clear aligners and scanners in the State of Texas. Align has targeted a substantial number of doctors in Texas with its scheme, and customers in Texas bear the supracompetitive prices Align has been able to charge as a result.

248. As a direct and proximate result of Align's anticompetitive conduct, ClearCorrect has been injured in its business and property.

Count 4: Violation of Tex. Bus. & Com. Code § 15.05(b) for Attempted Monopolization

249. The allegations in the preceding paragraphs are incorporated by reference.

[redacted]

250. Align has monopoly power, or at minimum, a dangerous probability of acquiring monopoly power. Align has willfully, knowingly, and with specific intent to do so, attempted to monopolize the doctor-directed clear aligner market.

251. To the extent Align does not already have monopoly power, in the alternative, Align is at least attempting to achieve monopoly power through anticompetitive means. There is at least a dangerous probability that, unless restrained, Align will obtain monopoly power.

252. Align's exclusionary conduct has foreclosed a substantial share of the doctor-directed clear aligner market.

253. Align's anticompetitive conduct has had harmful effects on competition and consumers of clear aligners.

254. The anticompetitive effects of Align's anticompetitive conduct outweigh any procompetitive benefits, or those procompetitive benefits can be achieved through less restrictive means. The sole purpose for each component of the exclusionary scheme described herein was to impair the ability of rivals to compete in the market for doctor-directed clear aligners, and to foreclose those rivals', including ClearCorrect's, ability to challenge Align's monopoly position.

255. Align's anticompetitive and exclusionary practices thus violate Texas Business & Commercial Code § 15.05(b), which provides that it is "unlawful for any person to … attempt to monopolize … any part of trade or commerce."

256. Align sells a substantial volume of its clear aligners and scanners in the State of Texas. Align has targeted a substantial number of doctors in Texas with its scheme, and customers in Texas bear the supracompetitive prices Align has been able to charge as a result.

257. As a direct and proximate result of Align's anticompetitive conduct, ClearCorrect has been injured in its business and property.

[redacted]

Count 5: False Advertising Under the Lanham Act

258. ClearCorrect hereby alleges and incorporates by reference the foregoing allegations in ¶¶ 1-257 as if fully set forth herein.

259. Align's promotional materials, including its website and social media platforms, contain numerous false and/or misleading statements comparing Invisalign® aligners to other clear aligners, including ClearCorrect aligners.

260. As set forth in ¶¶ 187-193 above, Align advertises that Invisalign® aligners offer a "[c]ustomized treatment plan from your doctor & in-person consultations throughout the treatment," while "[o]ther clear aligners" do not. This statement is false because other clear aligners, including in particular ClearCorrect's aligners, also offer a "[c]ustomized treatment plan" from a patient's doctor" and "in-person consultations throughout the treatment."

261. Similarly, as set forth in ¶¶ 194-196 above, Align advertises that the "Invisalign® system is the only system in the world" with a feature known as a "Bite Ramp." This statement is false because other clear aligner systems, including in particular the ClearCorrect system, also offers bite ramps.

262. In addition, as set forth in ¶¶ 197-199 above, Align claims that "Invisalign aligners can treat all kinds of similes."[86] In suggesting to consumers that Invisalign® aligners can effectively treat all malocclusions, regardless of the type or severity, the statement is false and/or misleading because there are certain types of cases that Invisalign aligners cannot treat, or cannot treat without additional steps (such as surgery) or equipment.

[86] *See, e.g.*, Invisalign® Aligners for Adults, Invisalign, *accessible at* https://www.invisalign.com/why-invisalign/adults (last visited July 9, 2024); *see also* Invisalign® Aligners vs. Other Clear Aligners *accessible at* https://www.invisalign.com/why-invisalign/invisalign-vs-aligners (last visited July 9, 2024).

[redacted]

263. Align's false and/or misleading statements were made in connection with the commercial advertising or promotion of Align's Invisalign® aligners and aligner systems and misrepresent the characteristics of ClearCorrect's aligners and aligner systems.

264. Both parties' products travel in interstate commerce.

265. Align's statements discussed in ¶¶ 185-200 are false and thus presumed both material and deceptive.

266. Further, Align's statements discussed in ¶¶ 185-200 were (and are) material in that they were designed to, and are likely to, influence purchasing decisions by customers. For example, Align's false and/or misleading statements regarding what it purports to be unique features of Align's Invisalign® aligners or the Invisalign® system, on information and belief, would lead doctors and patients into believing that ClearCorrect does not offer these features, such as customized treatment plans, in-person consultations, or features to address overbites (i.e., bite ramps). Similarly, Align advertising that Invisalign® aligners can treat all kinds of smiles, on information and belief, would lead doctors and patients to select Invisalign® over ClearCorrect aligners because they erroneously believe that Invisalign® aligners are effective in treating any type of smile, no matter the type or severity of the malocclusion, while ClearCorrect aligners are not capable of treating such a broad array of malocclusions.

267. Align's false and/or misleading statements either have deceived or have the capacity to deceive a substantial number of customers or potential customers of clear aligners.

268. On information and belief, Align engaged in such deceptive conduct willfully, knowing that its statements were false and misleading. For example, it is apparent through Align's Complaint in this case that it has reviewed and analyzed ClearCorrect's aligners and systems. For example, in Paragraphs 68-152 of Align's Complaint, Align discusses

[redacted]

ClearCorrect's aligners and in Paragraphs 153-230 of Align's Complaint, Align discusses ClearCorrect's treatment planning software. In addition, on information and belief, Align knows that, contrary to its claims, its Invisalign® aligners cannot treat all smiles. For example, Align on its website acknowledges: "Invisalign clear aligners can treat ***nearly*** all common teeth-straightening issues"—not all smiles.[87]

269. Align's deceptive advertising has caused, and will continue to cause, ongoing and irreparable injury and damages to ClearCorrect, in the form of lost customers, lost sales, loss of market share, and loss of customer goodwill. On information and belief, ClearCorrect will continue to suffer such injury and damages as a result of Align's false advertisements unless and until this Court grants equitable relief.

Count 6: Unfair Competition Under Texas Common Law

270. ClearCorrect hereby alleges and incorporate by reference the foregoing allegations in ¶¶ 185-200 and ¶¶ 258-269 as if fully set forth herein.

271. Align's false advertising is contrary to honest business practice in industrial and commercial matters.

272. Align's false advertising has interfered and continues to interfere with ClearCorrect's ability to conduct business because, on information and belief, it unfairly leads customers to select Align's aligners over ClearCorrect's aligners.

273. Align's false advertising in violation of the Lanham Act constitutes unfair competition under Texas common law.

[87] *See, e.g.*, Frequently Asked Questions, Invisalign, *accessible at* https://www.invisalign.com/frequently-asked-questions (last visited July 9, 2024) (emphasis added).

[redacted]

Count 7: [redacted]

274. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 273 of this Counterclaim, above, as if set forth fully herein.

275. [redacted]

276. [redacted]

277. [redacted]

278. [redacted]

279. [redacted]

Count 8: [redacted]

280. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 279 of this Counterclaim, above, as if set forth fully herein.

281. [redacted]

282. [redacted]

283. [redacted]

[redacted]

284. [redacted]

285. [redacted]

286. [redacted]

Count 9: [redacted]

287. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 286 of this Counterclaim, above, as if set forth fully herein.

288. [redacted]

289. [redacted]

290. [redacted]

291. [redacted]

292. [redacted]

293. [redacted]

Count 10: Declaratory Judgment of No False Advertising Under the Lanham Act

294. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 293of this Counterclaim, above, as if set forth fully herein.

[redacted]

295. Align's Complaint alleges that "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)." Complaint ¶ 61.

296. Align is incorrect. The statements that Align points to are neither false nor misleading. Instead, the statements accurately reflect the results of valid stain-resistant testing in which the respective "Aligners [are] immersed in the respective substances for 24 hours at 37°C."[88]

297. The statements at issue have not deceived, and do not have the capacity to deceive, consumers. For example, the webpages clearly disclose how the test results are obtained: "Aligners [are] immersed in the respective substances for 24 hours at 37°C."[89] There is nothing deceiving about the statements at issue.

298. Similarly, Align cannot prove that consumers would have found the statements to be material.

299. Align has not been injured, and it not likely to be injured, as a result of the statements at issue.

300. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties. Therefore, ClearCorrect counterclaims against Align pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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[88] *See, e.g.*, Complaint ¶¶ 34 (citing ClearCorrect® Aligners, ClearCorrect, *accessible at* https://support.clearcorrect.com/hc/en-us/articles/4410091639063-ClearCorrect-Aligners (last visited July 9, 2024); Premier Aligner. Proven Results, Straumann, *accessible at* https://www.straumann.com/clearcorrect/en/doctors/clearcorrect-aligners.html (last visited July 9, 2024)).
[89] *See* n.88.

[redacted]

301. ClearCorrect is entitled to a declaratory judgment that it has not engaged in false advertising under the Lanham Act.

Count 11: Declaratory Judgment of No Unfair Competition

302. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 301 of this Counterclaim, above, as if set forth fully herein.

303. Align's Complaint alleges that "Straumann and ClearCorrect's violation of the Lanham Act also constitutes unfair competition under Texas common law." Complaint ¶ 65.

304. Align does not allege a separate basis for its false advertising claims under the Lanham Act and its unfair competition claims under.

305. As discussed in paragraphs 294-301, the statements Align has identified in its Complaint do not constitute false advertising. Therefore, false advertising cannot constitute the basis for an unfair competition claim, and thus ClearCorrect has not engaged in unfair competition under Texas common law.

306. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties. Therefore, ClearCorrect counterclaims against Align pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

307. ClearCorrect is entitled to a declaratory judgment that it has not engaged in unfair competition under Texas common law.

Count 12: Declaratory Judgment of No Civil Conspiracy

308. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 307 of this Counterclaim, above, as if set forth fully herein.

[redacted]

309. Align alleges that "[Institut] Straumann and ClearCorrect are members of a civil conspiracy against Align" and that their "object was and is to drive consumers from Align to ClearCorrect via the false and misleading comparative advertisements," that they "had a meeting of the minds on this object," that "[Institut] Straumann and ClearCorrect posted substantially the same false and misleading advertisements on their websites," that "[Institut] Straumann exercises control over ClearCorrect," that "[Institut] Straumann and ClearCorrect also had the specific intent to and committed unlawful, overt acts of false advertising to further their object," and that "[Institut] Straumann and ClearCorrect's false advertising injured Align." Complaint ¶ 67.

310. ClearCorrect has not engaged in civil conspiracy. For example, ClearCorrect has not engaged in an underlying tort nor has ClearCorrect engaged in unlawful conduct. As discussed in paragraphs 294-307, ClearCorrect has not engaged in false advertising. Thus, Align's civil conspiracy claim fails.

311. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties. Therefore, ClearCorrect counterclaims against Align pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

312. ClearCorrect is entitled to a declaratory judgment that it has not engaged in a civil conspiracy.

Count 13 Declaratory Judgment of Non-Infringement of the '613 Patent

313. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 312 of this Counterclaim, above, as if set forth fully herein.

[redacted]

314. Align claims that it is the owner of all rights, title, and interest in and to the '613 patent. Align has expressly charged ClearCorrect with infringement of the '613 patent by filing a Complaint against ClearCorrect.

315. Align's Complaint, for example, alleges that "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" and that "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." Complaint ¶¶ 69-70. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

316. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '613 patent.

317. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '613 patent. For example, the products do not meet at least the following elements of claim 1:

> "providing a sheet comprising 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 break of greater than about 200%, and a hardness from about 60 A to about 85 D."

318. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

[redacted]

319. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

320. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '613 patent.

Count 14: Declaratory Judgment of Invalidity of the '613 Patent

321. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 320 of this Counterclaim, above, as if set forth fully herein.

322. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '613 patent.

323. Align's Complaint alleges that the '613 patent is valid and enforceable, stating that the '613 patent is "duly and legally issued." Complaint ¶ 44.

324. ClearCorrect contests the validity and enforceability of the '613 patent, and ClearCorrect does not infringe the '613 patent at least because the claims of the '613 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

325. Indeed, the claims of the '613 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 4,253,828

[redacted]

- U.S. Patent No. 4,346,195
- U.S. Patent No. 4,410,595
- U.S. Patent No. 4,739,012
- U.S. Patent No. 4,755,139
- U.S. Patent No. 4,791,156
- U.S. Patent No. 4,824,723
- U.S. Patent No. 4,843,124
- U.S. Patent No. 5,024,790
- U.S. Patent No. 5,335,675
- U.S. Patent No. 5,975,893
- U.S. Patent No. 6,077,075
- U.S. Patent No. 6,183,248
- U.S. Patent No. 6,454,565
- U.S. Patent No. 6,524,101
- U.S. Patent No. 6,746,757
- U.S. Patent No. 7,201,575
- U.S. Patent No. 7,641,828
- U.S. Patent No. 8,235,713
- U.S. Patent No. 8,496,473
- U.S. Patent Pub. No. 2001/0041320
- U.S. Patent Pub. No. 2002/0146549
- U.S. Patent Pub. No. 2004/0146670
- U.S. Patent Pub. No. 2005/0082703

[redacted]

- U.S. Patent Pub. No. 2005/0100853
- U.S. Patent Pub. No. 2006/0078688
- U.S. Patent Pub. No. 2006/0078841
- U.S. Patent Pub. No. 2007/0148608
- U.S. Patent Pub. No. 2007 /0087300
- U.S. Patent Pub. No. 2008/0044786
- U.S. Patent Pub. No. 2008/0248438
- U.S. Patent Pub. No. 2008/0299507
- U.S. Patent Pub. No. 2009/0061380
- U.S. Patent Pub. No. 2009/0087808
- U.S. Patent Pub. No. 2009/0239188
- U.S. Patent Pub. No. 2009/0246724
- U.S. Patent Pub. No. 2009/0298006
- U.S. Patent Pub. No. 2009/0306327
- U.S. Patent Pub No. 2010/0055639
- U.S. Patent Pub No. 2011/0020761
- U.S. Patent Pub No. 2011/0039223
- U.S. Patent Pub. No. 2011/0062609
- U.S. Patent Pub. No. 2011/0069134
- U.S. Patent Pub. No. 2012/0101417
- U.S. Patent Pub. No. 2012/0315484
- U.S. Patent Pub. No. 2015/0140300
- U.S. Patent Pub. No. 2015/0374464

[redacted]

- U.S. Patent Pub. No. 2017/0202641
- U.S. Patent Pub. No. 2019/0286291
- DE 20-2013-001392 U
- DE 102010036107
- JP 06-256630
- JP 2004-099656
- CN 103374211
- CN 108394152
- WO 2006/096558
- WO 2010/043419
- WO 2010/074789

326. ClearCorrect will provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

327. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

328. ClearCorrect is entitled to a declaratory judgment that the claims of the '613 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

Count 15: Declaratory Judgment of Non-Infringement of the '384 Patent

329. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 328 of this Counterclaim, above, as if set forth fully herein.

330. Align claims that it is the owner of all rights, title, and interest in and to the '384 patent. Align has expressly charged ClearCorrect with infringement of the '384 patent by filing a Complaint against ClearCorrect.

331. Align's Complaint, for example, alleges that "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" and that "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." Complaint ¶¶ 92-93. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

332. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '384 patent.

333. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '384 patent. For example, the products do not meet at least the following elements of claim 1:

> "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 polyurethan elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D."

[redacted]

334. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

335. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

336. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

337. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '384 patent.

Count 16: Declaratory Judgment of Invalidity of the '384 Patent

338. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 337 of this Counterclaim, above, as if set forth fully herein.

339. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '384 patent.

340. Align's Complaint alleges that the '384 patent is valid and enforceable, stating that the '384 patent is "duly and legally issued." Complaint ¶ 45.

341. ClearCorrect contests the validity and enforceability of the '384 patent, and ClearCorrect does not infringe the '384 patent at least because the claims of the '384 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

342. Indeed, the claims of the ’384 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 4,253,828
- U.S. Patent No. 4,346,195
- U.S. Patent No. 4,410,595
- U.S. Patent No. 4,739,012
- U.S. Patent No. 4,755,139
- U.S. Patent No. 4,791,156
- U.S. Patent No. 4,824,723
- U.S. Patent No. 4,843,124
- U.S. Patent No. 5,024,790
- U.S. Patent No. 5,335,675
- U.S. Patent No. 5,975,893
- U.S. Patent No. 6,077,075
- U.S. Patent No. 6,183,248
- U.S. Patent No. 6,454,565
- U.S. Patent No. 6,524,101
- U.S. Patent No. 6,746,757
- U.S. Patent No. 7,201,575
- U.S. Patent No. 7,641,828
- U.S. Patent No. 8,235,713
- U.S. Patent No. 8,496,473

[redacted]

- U.S. Patent Pub. No. 2001/0041320
- U.S. Patent Pub. No. 2002/0146549
- U.S. Patent Pub. No. 2004/0146670
- U.S. Patent Pub. No. 2005/0082703
- U.S. Patent Pub. No. 2005/0100853
- U.S. Patent Pub. No. 2006/0078688
- U.S. Patent Pub. No. 2006/0078841
- U.S. Patent Pub. No. 2007/0148608
- U.S. Patent Pub. No. 2007 /0087300
- U.S. Patent Pub. No. 2008/0044786
- U.S. Patent Pub. No. 2008/0248438
- U.S. Patent Pub. No. 2008/0299507
- U.S. Patent Pub. No. 2009/0061380
- U.S. Patent Pub. No. 2009/0087808
- U.S. Patent Pub. No. 2009/0239188
- U.S. Patent Pub. No. 2009/0246724
- U.S. Patent Pub. No. 2009/0298006
- U.S. Patent Pub. No. 2009/0306327
- U.S. Patent Pub No. 2010/0055639
- U.S. Patent Pub No. 2011/0020761
- U.S. Patent Pub No. 2011/0039223
- U.S. Patent Pub. No. 2011/0062609
- U.S. Patent Pub. No. 2011/0069134

[redacted]

- U.S. Patent Pub. No. 2012/0101417
- U.S. Patent Pub. No. 2012/0315484
- U.S. Patent Pub. No. 2015/0140300
- U.S. Patent Pub. No. 2015/0374464
- U.S. Patent Pub. No. 2017/0202641
- U.S. Patent Pub. No. 2019/0286291
- DE 20-2013-001392 U
- DE 102010036107
- JP 06-256630
- JP 2004-099656
- CN 103374211
- CN 108394152
- WO 2006/096558
- WO 2010/043419
- WO 2010/074789

343. ClearCorrect will provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

344. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

[redacted]

345. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

346. ClearCorrect is entitled to a declaratory judgment that the claims of the '384 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

Count 17: Declaratory Judgment of Non-Infringement of the '090 Patent

347. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 346 of this Counterclaim, above, as if set forth fully herein.

348. Align claims that it is the owner of all rights, title, and interest in and to the '090 patent. Align has expressly charged ClearCorrect with infringement of the '090 patent by filing a Complaint against ClearCorrect.

349. Align's Complaint, for example, alleges that "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" and that "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." Complaint ¶¶ 111-112. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

350. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '090 patent.

[redacted]

351. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '090 patent. For example, the products do not meet at least the following limitations of claim 1:

> "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 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."

352. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

353. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

354. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

355. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '090 patent.

[redacted]

Count 18: Declaratory Judgment of Invalidity of the '090 Patent

356. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 355 of this Counterclaim, above, as if set forth fully herein.

357. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '090 patent.

358. Align's Complaint alleges that the '090 patent is valid and enforceable, stating that the '090 patent is "duly and legally issued." Complaint ¶ 46.

359. ClearCorrect contests the validity and enforceability of the '090 patent, and ClearCorrect does not infringe the '090 patent at least because the claims of the '090 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

360. Indeed, the claims of the '090 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 4,253,828
- U.S. Patent No. 4,346,195
- U.S. Patent No. 4,410,595
- U.S. Patent No. 4,739,012
- U.S. Patent No. 4,755,139
- U.S. Patent No. 4,791,156
- U.S. Patent No. 4,824,723
- U.S. Patent No. 4,843,124
- U.S. Patent No. 5,024,790

[redacted]

- U.S. Patent No. 5,335,675
- U.S. Patent No. 5,975,893
- U.S. Patent No. 6,077,075
- U.S. Patent No. 6,183,248
- U.S. Patent No. 6,454,565
- U.S. Patent No. 6,524,101
- U.S. Patent No. 6,746,757
- U.S. Patent No. 7,201,575
- U.S. Patent No. 7,641,828
- U.S. Patent No. 8,235,713
- U.S. Patent No. 8,496,473
- U.S. Patent Pub. No. 2001/0041320
- U.S. Patent Pub. No. 2002/0146549
- U.S. Patent Pub. No. 2004/0146670
- U.S. Patent Pub. No. 2005/0082703
- U.S. Patent Pub. No. 2005/0100853
- U.S. Patent Pub. No. 2006/0078688
- U.S. Patent Pub. No. 2006/0078841
- U.S. Patent Pub. No. 2007/0148608
- U.S. Patent Pub. No. 2007 /0087300
- U.S. Patent Pub. No. 2008/0044786
- U.S. Patent Pub. No. 2008/0248438
- U.S. Patent Pub. No. 2008/0299507

[redacted]

- U.S. Patent Pub. No. 2009/0061380
- U.S. Patent Pub. No. 2009/0087808
- U.S. Patent Pub. No. 2009/0239188
- U.S. Patent Pub. No. 2009/0246724
- U.S. Patent Pub. No. 2009/0298006
- U.S. Patent Pub. No. 2009/0306327
- U.S. Patent Pub No. 2010/0055639
- U.S. Patent Pub No. 2011/0020761
- U.S. Patent Pub No. 2011/0039223
- U.S. Patent Pub. No. 2011/0062609
- U.S. Patent Pub. No. 2011/0069134
- U.S. Patent Pub. No. 2012/0101417
- U.S. Patent Pub. No. 2012/0315484
- U.S. Patent Pub. No. 2015/0140300
- U.S. Patent Pub. No. 2015/0374464
- U.S. Patent Pub. No. 2017/0202641
- U.S. Patent Pub. No. 2019/0286291
- DE 20-2013-001392 U
- DE 102010036107
- JP 06-256630
- JP 2004-099656
- CN 103374211
- CN 108394152

[redacted]

- WO 2006/096558
- WO 2010/043419
- WO 2010/074789

361. ClearCorrect will provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

362. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

363. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

364. ClearCorrect is entitled to a declaratory judgment that the claims of the '090 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

Count 19: Declaratory Judgment of Non-Infringement of the '091 Patent

365. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 364 of this Counterclaim, above, as if set forth fully herein.

366. Align claims that it is the owner of all rights, title, and interest in and to the '091 patent. Align has expressly charged ClearCorrect with infringement of the '091 patent by filing a Complaint against ClearCorrect.

367. Align's Complaint, for example, alleges that "ClearCorrect has been and is now directly infringing the '091 patent in this district and elsewhere, in violation of 35 U.S.C. §§

[redacted]

271(a) and 271(g) at least by making, selling, and/or offering for sale aligners from ClearQuartz plastic" and that "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." Complaint ¶¶ 134-135. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

368. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '091 patent.

369. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '091 patent. For example, the products do not meet at least the following elements of claim 1:

> "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 15 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 20 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."

370. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

[redacted]

371. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

372. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

373. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '091 patent.

Count 20: Declaratory Judgment of Invalidity of the '091 Patent

374. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 373 of this Counterclaim, above, as if set forth fully herein.

375. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '091 patent.

376. Align's Complaint alleges that the '091 patent is valid and enforceable, stating that the '091 patent is "duly and legally issued." Complaint ¶ 47.

377. ClearCorrect contests the validity and enforceability of the '091 patent, and ClearCorrect does not infringe the '091 patent at least because the claims of the '091 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

378. Indeed, the claims of the '091 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 4,253,828

[redacted]

- U.S. Patent No. 4,346,195
- U.S. Patent No. 4,410,595
- U.S. Patent No. 4,739,012
- U.S. Patent No. 4,755,139
- U.S. Patent No. 4,791,156
- U.S. Patent No. 4,824,723
- U.S. Patent No. 4,843,124
- U.S. Patent No. 5,024,790
- U.S. Patent No. 5,335,675
- U.S. Patent No. 5,975,893
- U.S. Patent No. 6,077,075
- U.S. Patent No. 6,183,248
- U.S. Patent No. 6,454,565
- U.S. Patent No. 6,524,101
- U.S. Patent No. 6,746,757
- U.S. Patent No. 7,201,575
- U.S. Patent No. 7,641,828
- U.S. Patent No. 8,235,713
- U.S. Patent No. 8,496,473
- U.S. Patent Pub. No. 2001/0041320
- U.S. Patent Pub. No. 2002/0146549
- U.S. Patent Pub. No. 2004/0146670
- U.S. Patent Pub. No. 2005/0082703

[redacted]

- U.S. Patent Pub. No. 2005/0100853
- U.S. Patent Pub. No. 2006/0078688
- U.S. Patent Pub. No. 2006/0078841
- U.S. Patent Pub. No. 2007/0148608
- U.S. Patent Pub. No. 2007 /0087300
- U.S. Patent Pub. No. 2008/0044786
- U.S. Patent Pub. No. 2008/0248438
- U.S. Patent Pub. No. 2008/0299507
- U.S. Patent Pub. No. 2009/0061380
- U.S. Patent Pub. No. 2009/0087808
- U.S. Patent Pub. No. 2009/0239188
- U.S. Patent Pub. No. 2009/0246724
- U.S. Patent Pub. No. 2009/0298006
- U.S. Patent Pub. No. 2009/0306327
- U.S. Patent Pub No. 2010/0055639
- U.S. Patent Pub No. 2011/0020761
- U.S. Patent Pub No. 2011/0039223
- U.S. Patent Pub. No. 2011/0062609
- U.S. Patent Pub. No. 2011/0069134
- U.S. Patent Pub. No. 2012/0101417
- U.S. Patent Pub. No. 2012/0315484
- U.S. Patent Pub. No. 2015/0140300
- U.S. Patent Pub. No. 2015/0374464

[redacted]

- U.S. Patent Pub. No. 2017/0202641
- U.S. Patent Pub. No. 2019/0286291
- DE 20-2013-001392 U
- DE 102010036107
- JP 06-256630
- JP 2004-099656
- CN 103374211
- CN 108394152
- WO 2006/096558
- WO 2010/043419
- WO 2010/074789

379. ClearCorrect will provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

380. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

381. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

382. ClearCorrect is entitled to a declaratory judgment that the claims of the '091 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

Count 21: Declaratory Judgment of Non-Infringement of the '444 Patent

383. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 382 of this Counterclaim, above, as if set forth fully herein.

384. Align claims that it is the owner of all rights, title, and interest in and to the '444 patent. Align has expressly charged ClearCorrect with infringement of the '444 patent by filing a Complaint against ClearCorrect.

385. Align's Complaint, for example, alleges that "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" and that "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." Complaint ¶¶ 154-155. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

386. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '444 patent.

387. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '444 patent. For example, the products do not meet at least the following elements of claim 1:

> "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."

[redacted]

388. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

389. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

390. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

391. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '444 patent.

Count 22: Declaratory Judgment of Invalidity of the '444 Patent

392. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 391 of this Counterclaim, above, as if set forth fully herein.

393. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '444 patent.

394. Align's Complaint alleges that the '444 patent is valid and enforceable, stating that the '444 patent is "duly and legally issued." Complaint ¶ 48.

395. ClearCorrect contests the validity and enforceability of the '444 patent, and ClearCorrect does not infringe the '444 patent at least because the claims of the '444 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

396. Indeed, the claims of the ’444 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 6,217,325
- U.S. Patent No. 6,309,215
- U.S. Patent No. 6,350,120
- U.S. Patent No. 6,471,511
- U.S. Patent No. 6,682,346
- U.S. Patent No. 6,729,876
- U.S. Patent No. 7.331,783
- U.S. Patent No. 7,377,778
- U.S. Patent No. 7,435,083
- U.S. Patent No. 7,578,674
- U.S. Patent No. 7,637,740
- U.S. Patent No. 7,658,610
- U.S. Patent No. 7,819,659
- U.S. Patent No. 7,844,356
- U.S. Patent No. 7,844.429
- U.S. Patent No. 7,904,307
- U.S. Patent Pub. No. 2002/0064746
- U.S. Patent Pub. No. 2002/0072027
- U.S. Patent Pub. No. 2004/0137400
- U.S. Patent Pub. No. 2006/0275736

[redacted]

397. The ’444 patent is invalid at least for the reasons described in ClearCorrect’s motion to dismiss pursuant to 12(b)(6) with regard to § 101. Dkt. 30 at 14-17. ClearCorrect will also provide invalidity contentions, which are incorporated by reference herein, consistent with the schedule ordered by the Court and following Align’s infringement contentions.

398. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

399. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

400. ClearCorrect is entitled to a declaratory judgment that the claims of the ’444 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

Count 23: Declaratory Judgment of Non-Infringement of the ’217 Patent

401. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 400 of this Counterclaim, above, as if set forth fully herein.

402. Align claims that it is the owner of all rights, title, and interest in and to the ’217 patent. Align has expressly charged ClearCorrect with infringement of the ’217 patent by filing a Complaint against ClearCorrect.

403. Align’s Complaint, for example, alleges that “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 making and using software that practices one or more claims of the ’217 patent” and that “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

[redacted]

offering to sell, selling, and using, to manufacture aligners, treatment plans made according to the methods claimed in the '217 patent." Complaint ¶¶ 174-175. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

404. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '217 patent.

405. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '217 patent. For example, the products do not meet at least the following elements of claim 1:

> "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."

406. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

407. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

408. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

409. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '217 patent.

[redacted]

Count 24: Declaratory Judgment of Invalidity of the ’217 Patent

410. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 409 of this Counterclaim, above, as if set forth fully herein.

411. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the ’217 patent.

412. Align’s Complaint alleges that the ’217 patent is valid and enforceable, stating that the ’217 patent is “duly and legally issued.” Complaint ¶ 49.

413. ClearCorrect contests the validity and enforceability of the ’217 patent, and ClearCorrect does not infringe the ’217 patent at least because the claims of the ’217 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

414. Indeed, the claims of the ’217 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 6,217,325
- U.S. Patent No. 6,309,215
- U.S. Patent No. 6,350,120
- U.S. Patent No. 6,471,511
- U.S. Patent No. 6,682,346
- U.S. Patent No. 6,729,876
- U.S. Patent No. 7.331,783
- U.S. Patent No. 7,377,778
- U.S. Patent No. 7,435,083

[redacted]

- U.S. Patent No. 7,578,674
- U.S. Patent No. 7,637,740
- U.S. Patent No. 7,658,610
- U.S. Patent No. 7,819,659
- U.S. Patent No. 7,844,356
- U.S. Patent No. 7,844.429
- U.S. Patent No. 7,904,307
- U.S. Patent Pub. No. 2002/0064746
- U.S. Patent Pub. No. 2002/0072027
- U.S. Patent Pub. No. 2004/0137400
- U.S. Patent Pub. No. 2006/0275736

415. The ’217 patent is invalid at least for the reasons described in ClearCorrect’s motion to dismiss pursuant to 12(b)(6) with regard to § 101. Dkt. 31 at 14-17. ClearCorrect will provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align’s infringement contentions.

416. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

417. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[redacted]

418. ClearCorrect is entitled to a declaratory judgment that the claims of the '217 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

Count 25: Declaratory Judgment of Non-Infringement of the '879 Patent

419. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 418 of this Counterclaim, above, as if set forth fully herein.

420. Align claims that it is the owner of all rights, title, and interest in and to the '879 patent. Align has expressly charged ClearCorrect with infringement of the '879 patent by filing a Complaint against ClearCorrect.

421. Align's Complaint, for example, alleges that "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" and that "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." Complaint ¶¶ 193-194. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

422. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '879 patent.

423. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '879 patent. For example, the products do not meet at least the following elements of claim 1:

> "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 rotes, the modifying comprising:

[redacted]

delaying initial movement of one of the dental objects; and

round-tripping one of the dental objects."

424. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

425. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

426. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

427. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '879 patent.

Count 26: Declaratory Judgment of Invalidity of the '879 Patent

428. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 427 of this Counterclaim, above, as if set forth fully herein.

429. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '879 patent.

430. Align's Complaint alleges that the '879 patent is valid and enforceable, stating that the '879 patent is "duly and legally issued." Complaint ¶ 50.

431. ClearCorrect contests the validity and enforceability of the '879 patent, and ClearCorrect does not infringe the '879 patent at least because the claims of the '879 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

432. Indeed, the claims of the ’879 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 6,217,325
- U.S. Patent No. 6,309,215
- U.S. Patent No. 6,350,120
- U.S. Patent No. 6,471,511
- U.S. Patent No. 6,682,346
- U.S. Patent No. 6,729,876
- U.S. Patent No. 7.331,783
- U.S. Patent No. 7,377,778
- U.S. Patent No. 7,435,083
- U.S. Patent No. 7,578,674
- U.S. Patent No. 7,637,740
- U.S. Patent No. 7,658,610
- U.S. Patent No. 7,819,659
- U.S. Patent No. 7,844,356
- U.S. Patent No. 7,844.429
- U.S. Patent No. 7,904,307
- U.S. Patent Pub. No. 2002/0064746
- U.S. Patent Pub. No. 2002/0072027
- U.S. Patent Pub. No. 2004/0137400

433. U.S. Patent Pub. No. 2006/0275736

[redacted]

434. The ’879 patent is invalid at least for the reasons described in ClearCorrect’s motion to dismiss pursuant to 12(b)(6) with regard to § 101. Dkt. 31 at 14-17. ClearCorrect will also provide invalidity contentions, which are incorporated by reference herein, consistent with the schedule ordered by the Court and following Align’s infringement contentions.

435. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

436. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

437. ClearCorrect is entitled to a declaratory judgment that the claims of the ’879 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

Count 27: Declaratory Judgment of Non-Infringement of the ’456 Patent

438. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 436 of this Counterclaim, above, as if set forth fully herein.

439. Align claims that it is the owner of all rights, title, and interest in and to the ’456 patent. Align has expressly charged ClearCorrect with infringement of the ’456 patent by filing a Complaint against ClearCorrect.

440. Align’s Complaint, for example, alleges that “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” and that “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

[redacted]

States or offering to sell, selling, and using, to manufacture aligners, treatment plans made according to the methods claimed in the '456 patent." Complaint ¶¶ 211-212. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

441. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '456 patent.

442. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '456 patent. For example, the products do not meet at least the following elements of claim 1:

> "computer implemented method comprising: . . .
>
> 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."

443. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

444. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

445. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[redacted]

446. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the ’456 patent.

Count 28: Declaratory Judgment of Invalidity of the ’456 Patent

447. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 445 of this Counterclaim, above, as if set forth fully herein.

448. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the ’456 patent.

449. Align’s Complaint alleges that the ’456 patent is valid and enforceable, stating that the ’456 patent is “duly and legally issued.” Complaint ¶ 51.

450. ClearCorrect contests the validity and enforceability of the ’456 patent, and ClearCorrect does not infringe the ’456 patent at least because the claims of the ’456 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

451. Indeed, the claims of the ’456 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 6,217,325
- U.S. Patent No. 6,309,215
- U.S. Patent No. 6,350,120
- U.S. Patent No. 6,471,511
- U.S. Patent No. 6,682,346
- U.S. Patent No. 6,729,876
- U.S. Patent No. 7.331,783

[redacted]

- U.S. Patent No. 7,377,778
- U.S. Patent No. 7,435,083
- U.S. Patent No. 7,578,674
- U.S. Patent No. 7,637,740
- U.S. Patent No. 7,658,610
- U.S. Patent No. 7,819,659
- U.S. Patent No. 7,844,356
- U.S. Patent No. 7,844.429
- U.S. Patent No. 7,904,307
- U.S. Patent Pub. No. 2002/0064746
- U.S. Patent Pub. No. 2002/0072027
- U.S. Patent Pub. No. 2004/0137400

452. U.S. Patent Pub. No. 2006/0275736

453. The ’456 patent is invalid at least for the reasons described in ClearCorrect’s motion to dismiss pursuant to 12(b)(6) with regard to § 101. Dkt. 31 at 14-17. ClearCorrect will also provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align’s infringement contentions.

454. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

455. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[redacted]

456. ClearCorrect is entitled to a declaratory judgment that the claims of the '456 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

Count 29: Declaratory Judgment of Non-Infringement of the '936 Patent

457. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 454 of this Counterclaim, above, as if set forth fully herein.

458. Align claims that it is the owner of all rights, title, and interest in and to the '936 patent. Align has expressly charged ClearCorrect with infringement of the '936 patent by filing a Complaint against ClearCorrect.

459. Align's Complaint, for example, alleges that "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." Complaint ¶¶ 232. Accordingly, a valid and justiciable controversy has arisen and exists between Align and ClearCorrect.

460. ClearCorrect has not infringed and does not infringe, directly or indirectly, any valid or enforceable claim of the '936 patent.

461. Indeed, the products Align accuses of infringement do not meet all of the elements of any of the claims of the '936 patent. For example, the products do not meet at least the following elements of claim 1:

> "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."

[redacted]

462. ClearCorrect will provide its non-infringement positions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align's infringement contentions.

463. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

464. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

465. ClearCorrect is entitled to a declaratory judgment that it has not infringed, and does not infringe, any valid, patent-eligible, and enforceable claim of the '936 patent.

Count 30: Declaratory Judgment of Invalidity of the '936 Patent

466. ClearCorrect repeats and realleges the allegations set forth in paragraphs 1 through 463 of this Counterclaim, above, as if set forth fully herein.

467. In its Complaint, Align alleges that ClearCorrect is directly and indirectly infringing the '936 patent.

468. Align's Complaint alleges that the '936 patent is valid and enforceable, stating that the '936 patent is "duly and legally issued." Complaint ¶ 52.

469. ClearCorrect contests the validity and enforceability of the '936 patent, and ClearCorrect does not infringe the '936 patent at least because the claims of the '936 patent are invalid for failure to comply with the conditions for patentability, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

[redacted]

470. Indeed, the claims of the ’936 patent are invalid at least because they are obvious in view of single reference obviousness or combinations of at least one or more of the following prior art:

- U.S. Patent No. 7,347,686
- U.S. Patent No. 7,476,100
- U.S. Patent Pub. No. 2002/0006217
- U.S. Patent Pub. No. 2004/0155975
- U.S. Patent Pub. No. 2005/0283065
- U.S. Patent Pub. No. 2007/0172112
- U.S. Patent Pub. No. 2007/0236494
- WO 2007084647

471. The ’936 patent is invalid at least for the reasons described in ClearCorrect’s motion to dismiss pursuant to 12(b)(6) with regard to § 101. Dkt. 31 at 18-20. ClearCorrect will also provide invalidity contentions, which are incorporated herein by reference, consistent with the schedule ordered by the Court and following Align’s infringement contentions.

472. ClearCorrect desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties.

473. Therefore, ClearCorrect counterclaims against Align pursuant to the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[redacted]

474. ClearCorrect is entitled to a declaratory judgment that the claims of the '936 patent are invalid including, without limitation, under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Counterclaim-plaintiff ClearCorrect demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, ClearCorrect denies that Align is entitled to any relief, including, without limitation, as described in the "Prayer for Relief" section of Align's Complaint.

ClearCorrect prays for:

1. Dismissal of Align's Complaint in its entirety with prejudice;
2. A judgment in favor of ClearCorrect and against Align on all aspects of Align's Complaint and denying the relief requested therein;
3. A judgment in favor of ClearCorrect and against Align on each of ClearCorrect's claims;
    a. A judgment in favor of ClearCorrect that Align has engaged in violations of Sherman Act § 2.
    b. A judgment in favor of ClearCorrect requiring Align to pay (1) ClearCorrect's trebled damages pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15 and (2) ClearCorrect's cost of suit and attorneys' fees pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.
    c. A judgment in favor of ClearCorrect that Align has violated Texas antitrust law.
    d. A judgment in favor of ClearCorrect requiring Align to pay (1) ClearCorrect's trebled damages pursuant to Tex. Bus. & Com. Code § 15.21(a)(1) and (2)

[redacted]

ClearCorrect's cost of suit and attorneys' fees pursuant to Tex. Bus. & Com. Code § 15.21(a)(1).

e. A judgment in favor of ClearCorrect that Align has engaged in false advertising under 15 U.S.C. § 1125(a) and unfair competition.

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

g. A judgment in favor of ClearCorrect that Align's damages and profits be trebled under 15 U.S.C. § 1117 and awarded to ClearCorrect.

h. A declaration that ClearCorrect has not engaged in false advertising;

i. A declaration that ClearCorrect has not engaged in unfair competition;

j. A declaration that ClearCorrect has not engaged in a civil conspiracy against Align;

k. A declaration that ClearCorrect has not infringed and does not infringe any claims of the Asserted Patents;

l. A declaration that the claims of the Asserted Patents are invalid, patent ineligible, and/or unenforceable;

m. A finding that this is an exceptional case under 35 U.S.C. § 285 and an award to ClearCorrect of attorneys' fees, costs, and disbursements incurred in defending this action, including but not limited to under 35 U.S.C. § 285; and

[redacted]

4. An order preliminarily and permanently enjoining Align, its affiliates, officers, agents, servants, employees, attorneys, dealers, confederates, privies, subsidiaries, divisions, successors, and assigns, and all persons acting for, with, by, through, under, or in active concert, participation or combination with any of the foregoing from engaging in the unlawful sales practices alleged herein.
5. An order preliminarily and permanently enjoining Align, its affiliates, officers, agents, servants, employees, attorneys, dealers, confederates, privies, subsidiaries, divisions, successors, and assigns, and all persons acting for, with, by, through, under, or in active concert, participation or combination with any of the foregoing from making false and/or misleading statements suggesting superiority of its aligners, including overstating the efficacy of its aligners.
6. An order that Align:
    a. Recall and/or remove all promotional materials that contain the false statements set forth above;
    b. Provide corrective advertising on Align's website and social media platforms informing customers of its misrepresentations; and
    c. Provide notice to all customers of Align about the false statements and Align's plans to correct them.
7. [redacted]
8. [redacted]

[redacted]

9. [redacted]

10. [redacted]

11. [redacted]

12. Such other and further relief as the Court deems just and proper.

[redacted]

Dated: July 9, 2024

Respectfully submitted,

/s/ Melissa R. Smith

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Plaintiff's counsel of record was served with a true and correct copy of the foregoing document by electronic mail on July 9, 2024

/s/ Melissa R. Smith
Melissa R. Smith