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12 UNITED STATES DISTRICT COURT  
13 NORTHERN DISTRICT OF CALIFORNIA  
14 SAN JOSE DIVISION

16 ALIGN TECHNOLOGY, INC.,

17 Plaintiff,

18 vs.

19 SMILECARECLUB, LLC, CAMELOT SI,  
20 LLC D/B/A SHARPERIMAGE.COM, and  
BROOKSTONE, INC.,

21 Defendants.

CASE NO. 3:15-cv-04864

**COMPLAINT FOR DAMAGES AND  
INJUNCTIVE RELIEF**

**JURY TRIAL DEMANDED**

1 For its Complaint against Defendants SmileCareClub, LLC (“SmileCareClub”), Camelot  
2 SI, LLC d/b/a SharperImage.com (“Sharper Image”), and Brookstone, Inc. (“Brookstone”)  
3 (collectively, “Defendants”), Plaintiff Align Technology, Inc. (sometimes hereinafter referred to  
4 as “Align”) hereby alleges, by and through its attorney, on personal knowledge as to its own  
5 actions and on information and belief as to the actions of others, as follows:

6 **THE PARTIES**

7 1. Plaintiff Align Technology, Inc. (“Align”) is a corporation organized under the  
8 laws of Delaware having its principal place of business in Santa Clara, California.

9 2. Upon information and belief, at all relevant times mentioned below, Defendant  
10 SmileCareClub, LLC has been a corporation organized under the laws of Tennessee with a  
11 principal place of business at 27725 Stansbury Blvd. Ste. 175, Farmington Hills, Michigan.

12 3. Upon information and belief, at all relevant times mentioned below, Defendant  
13 Camelot SI, LLC d/b/a SharperImage.com has been a corporation organized under the laws of  
14 Michigan with a principal place of business at 27725 Stansbury Blvd. Ste. 175, Farmington Hills,  
15 Michigan.

16 4. Upon information and belief, at all relevant times mentioned below, Defendant  
17 Brookstone Inc. has been a corporation organized under the laws of Delaware with a principle  
18 place of business at One Innovation Way, Marrimack, New Hampshire.

19 **JURISDICTION AND VENUE**

20 5. This lawsuit is an action for patent infringement rising under the patent laws of the  
21 United States, 35 U.S.C. §§ 101 et seq. The Court has subject matter jurisdiction over this action  
22 pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a), and 1367.

23 6. On information and belief, Defendants regularly conduct business in this judicial  
24 district, and certain of the acts complained of herein occurred in this judicial district.

25 7. Accordingly, the Court has personal jurisdiction over SmileCareClub, Sharper  
26 Image, and Brookstone, and venue is proper in this judicial district pursuant to 28 U.S.C.  
27 §§ 1391(b) and 1400(b).

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**THE PATENTS-IN-SUIT**

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2 8. On November 2, 1999, United States Patent No. 5,975,893 (“the ‘893 patent”),  
3 entitled “Method and System for Incrementally Moving Teeth,” was issued to Align. At all  
4 relevant times, Align owned the ‘893 patent with full and exclusive right to bring suit to enforce  
5 it. A true and correct copy of the ‘893 patent is attached as **Exhibit A**.

6 9. On April 17, 2001, United States Patent No. 6,217,325 (“the ‘325 patent”), entitled  
7 “Method and System for Incrementally Moving Teeth,” was issued to Align. At all relevant  
8 times, Align owned the ‘325 patent with full and exclusive right to bring suit to enforce it. A true  
9 and correct copy of the ‘325 patent is attached as **Exhibit B**.

10 10. On April 25, 2001, United States Patent No. 6,602,070 (“the ‘070 patent”), entitled  
11 “Systems and Methods for Dental Treatment Planning,” was issued to Align. At all relevant  
12 times, Align owned the ‘070 patent with full and exclusive right to bring suit to enforce it. A true  
13 and correct copy of the ‘070 patent is attached as **Exhibit C**.

14 11. On May 8, 2001, United States Patent No. 6,227,850 (“the ‘850 patent”), entitled  
15 “Teeth Viewing System,” was issued to Align. At all relevant times, Align owned the ‘850 patent  
16 with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘850 patent  
17 is attached as **Exhibit D**.

18 12. On September 17, 2002, United States Patent No. 6,450,807 (“the ‘807 patent”),  
19 entitled “System and Method for Positioning Teeth,” was issued to Align. At all relevant times,  
20 Align owned the ‘807 patent with full and exclusive right to bring suit to enforce it. A true and  
21 correct copy of the ‘807 patent is attached as **Exhibit E**.

22 13. On October 29, 2002, United States Patent No. 6,471,511 (“the ‘511 patent”),  
23 entitled “Defining Tooth-Moving Appliances Computationally,” was issued to Align. At all  
24 relevant times, Align owned the ‘511 patent with full and exclusive right to bring suit to enforce  
25 it. A true and correct copy of the ‘511 patent is attached as **Exhibit F**.

26 14. On September 30, 2003, United States Patent No. 6,626,666 (“the ‘666 patent”),  
27 entitled “Method and System for Incrementally Moving Teeth,” was issued to Align. At all  
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1 relevant times, Align owned the ‘666 patent with full and exclusive right to bring suit to enforce  
2 it. A true and correct copy of the ‘666 patent is attached as **Exhibit G**.

3 15. On October 7, 2003, United States Patent No. 6,629,840 (“the ‘840 patent”),  
4 entitled “Method and System for Incrementally Moving Teeth,” was issued to Align. At all  
5 relevant times, Align owned the ‘840 patent with full and exclusive right to bring suit to enforce  
6 it. A true and correct copy of the ‘840 patent is attached as **Exhibit H**.

7 16. On March 2, 2004, United States Patent No. 6,699,037 (“the ‘037 patent”), entitled  
8 “Method and System for Incrementally Moving Teeth,” was issued to Align. At all relevant  
9 times, Align owned the ‘037 patent with full and exclusive right to bring suit to enforce it. A true  
10 and correct copy of the ‘037 patent is attached as **Exhibit I**.

11 17. On April 20, 2004, United States Patent No. 6,722,880 (“the ‘880 patent”), entitled  
12 “Method and System for Incrementally Moving Teeth,” was issued to Align. At all relevant  
13 times, Align owned the ‘880 patent with full and exclusive right to bring suit to enforce it. A true  
14 and correct copy of the ‘880 patent is attached as **Exhibit J**.

15 18. On November 14, 2006, United States Patent No. 7,134,874 (“the ‘874 patent”),  
16 entitled “Computer Automated Development of an Orthodontic Treatment Plan and Appliance,”  
17 was issued to Align. At all relevant times, Align owned the ‘874 patent with full and exclusive  
18 right to bring suit to enforce it. A true and correct copy of the ‘874 patent is attached as **Exhibit**  
19 **K**.

20 19. On August 25, 2009, United States Patent No. 7,578,674 (“the ‘674 patent”),  
21 entitled “Methods for Correcting Tooth Movements Midcourse in Treatment,” was issued to  
22 Align. At all relevant times, Align owned the ‘674 patent with full and exclusive right to bring  
23 suit to enforce it. A true and correct copy of the ‘674 patent is attached as **Exhibit L**.

24 20. On December 6, 2011, United States Patent No. 8,070,487 (“the ‘487 patent”),  
25 entitled “System and Method for Positioning Teeth,” was issued to Align. At all relevant times,  
26 Align owned the ‘487 patent with full and exclusive right to bring suit to enforce it. A true and  
27 correct copy of the ‘487 patent is attached as **Exhibit M**.

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1 takes molds, pictures, and/or digital scans of a patient's teeth and orders a system of progressively  
2 modified aligners that will gradually realign the patient's teeth from their original position to  
3 preferred final positions in accordance with the dentist's prescription. The system of  
4 progressively modified aligners is then manufactured, sold, and delivered to the dentist. The  
5 dentist provides the progressively modified aligners to the patient in sequence to gradually move  
6 the patient's teeth to the preferred positions over the course of treatment.

7 27. All dentists who treat patients using the Invisalign System must attend and  
8 complete specialized instructional sessions to become trained Invisalign Providers. Prior to  
9 beginning treatment, a dentist takes x-rays, impressions, pictures, and/or digital scans of a  
10 patient's teeth and evaluates their overall dental health to determine whether the patient is a  
11 suitable candidate for the Invisalign System. During the treatment process, dentists schedule  
12 regular appointments with their Invisalign patients to ensure that the treatment is progressing as  
13 planned and to provide subsequent sets of aligners.

14 28. Align's FDA clearance to market the Invisalign System specifies that a dentist will  
15 oversee each patient's treatment.

16 29. Defendant SmileCareClub competes with Align and recently became engaged in  
17 the business of marketing the SmileCareClub system, which also uses clear orthodontic  
18 appliances, or aligners, for use in treating malocclusion.

19 30. Under the SmileCareClub system, patients take and submit photographs of their  
20 teeth and fill out a medical questionnaire regarding their dental history. After the patients' photos  
21 have been reviewed and approved, SmileCareClub sends the patient an Impression Kit and a set  
22 of dental history forms to complete. The patient uses the Impression Kit to take impressions of  
23 their dentition and returns the impressions and the completed dental history forms to  
24 SmileCareClub's lab.

25 31. SmileCareClub's lab creates a custom treatment plan for each patient, which  
26 SmileCareClub sends to the patient for review prior to the start of treatment. The treatment plan  
27 shows how the patient's teeth are expected to move with each set of aligners and what the  
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1 patient's final teeth position is expected to be. Once the treatment plan is approved, the patient  
2 receives a series of aligners to be worn in a specific sequence.

3 32. Upon information and belief, SmileCareClub contracts with dental professionals  
4 licensed in the patient's state to oversee each patient's case and to approve the patient's treatment  
5 plan. The dental professional does not meet with the patient for an initial evaluation of the  
6 patient's dental history, does not take an x-ray of the patient's teeth, and does not meet with the  
7 patient in-person during their treatment to evaluate the patient's progress. In certain cases, the  
8 dental professional will conduct an Interproximal Reduction to remove enamel from between the  
9 patient's teeth to create the necessary space for the teeth to move to their ideal position.

10 33. Upon information and belief, SmileCareClub does not have a dental professional  
11 independently verify a patient's self-reporting of their medical or dental history.

12 34. Upon information and belief, SmileCareClub received FDA clearance as a  
13 Repackager/Relabeler of invisible aligners that are cleared by the FDA for manufacturing by a  
14 separate entity.

15 35. Upon information and belief, SmileCareClub does not develop the treatment plans  
16 or manufacture the aligners itself for SmileCareClub patients.

17 36. Defendant SmileCareClub markets and sells the SmileCareClub system directly to  
18 consumers on its website SmileCareClub.com.

19 37. Defendant Sharper Image markets and sells the SmileCareClub system directly to  
20 consumers on its website SharperImage.com.

21 38. Defendant Brookstone markets and sells the SmileCareClub system directly to  
22 consumers on its website Brookstone.com.

23 39. At all times material to this action, Defendants have marketed, distributed, offered  
24 for sale, and sold the SmileCareClub system to customers in the State of California, and  
25 throughout the United States, in competition with the Invisalign System that is marketed,  
26 distributed, offered for sale, and sold by Align.

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1 **COUNT ONE:**  
2 **INFRINGEMENT OF THE '893 PATENT**

3 40. Align realleges and incorporates herein the allegations contained in the preceding  
4 paragraphs of this Complaint as if fully set forth herein.

5 41. In violation of 35 U.S.C. § 271(a), Defendants have infringed and are still  
6 infringing, either literally and/or under the doctrine of equivalents, the '893 patent by making,  
7 offering to sell, and/or selling clear aligner therapy systems covered by at least claim 1 thereof.

8 42. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still  
9 infringing, either literally and/or under the doctrine of equivalents, the '893 patent by offering to  
10 sell and selling clear aligner therapy systems made by the processes covered by at least claim 12  
11 thereof.

12 43. Upon information and belief, Defendants have willfully infringed the '893 patent.

13 44. As a result of Defendants' infringement, Align has suffered and will suffer  
14 damages.

15 45. Upon information and belief, Defendants' acts of infringement of the '893 patent  
16 will continue after service of this Complaint unless enjoined by the Court.

17 46. Unless Defendants are enjoined by the Court from continuing their infringement of  
18 the '893 patent, Align will suffer additional irreparable damages and impairment of the value of  
19 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
20 infringement.

21 **COUNT TWO:**  
22 **INFRINGEMENT OF THE '325 PATENT**

23 47. Align realleges and incorporates herein the allegations contained in the preceding  
24 paragraphs of this Complaint as if fully set forth herein.

25 48. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed  
26 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of  
27 the '325 patent by performing in the United States in the United States and without authority  
28 every step of the patented invention by providing clear aligner therapy systems.





1 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
2 infringement.

3 **COUNT FOUR:**  
4 **INFRINGEMENT OF THE '850 PATENT**

5 60. Align realleges and incorporates herein the allegations contained in the preceding  
6 paragraphs of this Complaint as if fully set forth herein.

7 61. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed  
8 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of  
9 the '850 patent by performing in the United States in the United States and without authority  
10 every step of the patented invention by providing clear aligner therapy systems.

11 62. Upon information and belief, Defendants have willfully infringed the '850 patent.

12 63. As a result of Defendants' infringement, Align has suffered and will suffer  
13 damages.

14 64. Upon information and belief, Defendants' acts of infringement of the '850 patent  
15 will continue after service of this Complaint unless enjoined by the Court.

16 65. Unless Defendants are enjoined by the Court from continuing their infringement of  
17 the '850 patent, Align will suffer additional irreparable damages and impairment of the value of  
18 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
19 infringement.

20 **COUNT FIVE:**  
21 **INFRINGEMENT OF THE '807 PATENT**

22 66. Align realleges and incorporates herein the allegations contained in the preceding  
23 paragraphs of this Complaint as if fully set forth herein.

24 67. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed  
25 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of  
26 the '807 patent by performing in the United States in the United States and without authority  
27 every step of the patented invention by providing clear aligner therapy systems.  
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1 87. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed  
2 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of  
3 the '840 patent by performing in the United States in the United States and without authority  
4 every step of the patented invention by providing clear aligner therapy systems.

5 88. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still  
6 infringing, either literally and/or under the doctrine of equivalents, the '840 patent by offering to  
7 sell and selling clear aligner therapy systems made by the processes covered by at least claim 1  
8 thereof.

9 89. Upon information and belief, Defendants have willfully infringed the '840 patent.

10 90. As a result of Defendants' infringement, Align has suffered and will suffer  
11 damages.

12 91. Upon information and belief, Defendants' acts of infringement of the '840 patent  
13 will continue after service of this Complaint unless enjoined by the Court.

14 92. Unless Defendants are enjoined by the Court from continuing their infringement of  
15 the '840 patent, Align will suffer additional irreparable damages and impairment of the value of  
16 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
17 infringement.

18 **COUNT NINE:**  
19 **INFRINGEMENT OF THE '037 PATENT**

20 93. Align realleges and incorporates herein the allegations contained in the preceding  
21 paragraphs of this Complaint as if fully set forth herein.

22 94. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed  
23 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of  
24 the '037 patent by performing in the United States in the United States and without authority  
25 every step of the patented invention by providing clear aligner therapy systems.

26 95. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still  
27 infringing, either literally and/or under the doctrine of equivalents, the '037 patent by offering to  
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1 sell and selling clear aligner therapy systems made by the processes covered by at least claim 1  
2 thereof.

3 96. Upon information and belief, Defendants has willfully infringed the '037 patent.

4 97. As a result of Defendants' infringement, Align has suffered and will suffer  
5 damages.

6 98. Upon information and belief, Defendants' acts of infringement of the '037 patent  
7 will continue after service of this Complaint unless enjoined by the Court.

8 99. Unless Defendants are enjoined by the Court from continuing their infringement of  
9 the '037 patent, Align will suffer additional irreparable damages and impairment of the value of  
10 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
11 infringement.

12 **COUNT TEN:**  
13 **INFRINGEMENT OF THE '880 PATENT**

14 100. Align realleges and incorporates herein the allegations contained in the preceding  
15 paragraphs of this Complaint as if fully set forth herein.

16 101. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed  
17 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of  
18 the '880 patent by performing in the United States in the United States and without authority  
19 every step of the patented invention by providing clear aligner therapy systems.

20 102. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still  
21 infringing, either literally and/or under the doctrine of equivalents, the '880 patent by offering to  
22 sell and selling clear aligner therapy systems made by the processes covered by at least claim 1  
23 thereof.

24 103. Upon information and belief, Defendants have willfully infringed the '880 patent.

25 104. As a result of Defendants' infringement, Align has suffered and will suffer  
26 damages.

27 105. Upon information and belief, Defendants' acts of infringement of the '880 patent  
28 will continue after service of this Complaint unless enjoined by the Court.



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**COUNT TWELVE:**  
**INFRINGEMENT OF THE '674 PATENT**

114. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

115. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 17 of the '674 patent by performing in the United States in the United States and without authority every step of the patented invention by providing clear aligner therapy systems.

116. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still infringing, either literally and/or under the doctrine of equivalents, the '674 patent by offering to sell and selling clear aligner therapy systems made by the processes covered by at least claim 17 thereof.

117. Upon information and belief, Defendants have willfully infringed the '674 patent.

118. As a result of Defendants' infringement, Align has suffered and will suffer damages.

119. Upon information and belief, Defendants' acts of infringement of the '674 patent will continue after service of this Complaint unless enjoined by the Court.

120. Unless Defendants are enjoined by the Court from continuing their infringement of the '674 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

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**COUNT THIRTEEN:**  
**INFRINGEMENT OF THE '487 PATENT**

121. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

122. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 10



1 of the '487 patent by performing in the United States in the United States and without authority  
2 every step of the patented invention by providing clear aligner therapy systems.

3 123. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still  
4 infringing, either literally and/or under the doctrine of equivalents, the '487 patent by offering to  
5 sell and selling clear aligner therapy systems made by the processes covered by at least claim 10  
6 thereof.

7 124. In violation of 35 U.S.C. § 271, Defendants have infringed and continue to  
8 infringe the '487 patent by contributing to or actively inducing the infringement by others, such  
9 as Defendants' customers, of the '487 patent by providing clear aligner therapy systems.

10 125. Upon information and belief, Defendants have willfully infringed the '487 patent.

11 126. As a result of Defendants' infringement, Align has suffered and will suffer  
12 damages.

13 127. Upon information and belief, Defendants' acts of infringement of the '487 patent  
14 will continue after service of this Complaint unless enjoined by the Court.

15 128. Unless Defendants are enjoined by the Court from continuing their infringement of  
16 the '487 patent, Align will suffer additional irreparable damages and impairment of the value of  
17 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
18 infringement.

19  
20 **COUNT FOURTEEN:**  
**INFRINGEMENT OF THE '106 PATENT**

21 129. Align realleges and incorporates herein the allegations contained in the preceding  
22 paragraphs of this Complaint as if fully set forth herein.

23 130. In violation of 35 U.S.C. § 271(a), Defendants have infringed and are still  
24 infringing, either literally and/or under the doctrine of equivalents, at least claim 7 of the '106  
25 patent by performing in the United States in the United States and without authority every step of  
26 the patented invention by providing clear aligner therapy systems.

27 131. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still  
28 infringing, either literally and/or under the doctrine of equivalents, the '106 patent by offering to

1 sell and selling clear aligner therapy systems made by the processes covered by at least claim 7  
2 thereof.

3 132. Upon information and belief, Defendants have willfully infringed the ‘106 patent.

4 133. As a result of Defendants’ infringement, Align has suffered and will suffer  
5 damages.

6 134. Upon information and belief, Defendants’ acts of infringement of the ‘106 patent  
7 will continue after service of this Complaint unless enjoined by the Court.

8 135. Unless Defendants are enjoined by the Court from continuing their infringement of  
9 the ‘106 patent, Align will suffer additional irreparable damages and impairment of the value of  
10 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further  
11 infringement.

12 **COUNT FIFTEEN:**  
**FALSE AND MISLEADING ADVERTISING IN VIOLATION OF SECTION 43(A) OF**  
**THE LANHAM ACT, 15 U.S.C. § 1125(A)**

13 136. Align realleges and incorporates herein the allegations contained in the preceding  
14 paragraphs of this Complaint as if fully set forth herein.

15 137. SmileCareClub advertises on its website that “[b]y working with remote licensed  
16 dental professionals to prescribe treatment and oversee your case, we eliminate a majority of the  
17 costs associated with other invisible aligner systems . . . all without sacrificing quality.”

18 Additionally, SmileCareClub advertises that customers will receive “identical results for less than  
19 50% of the others.”

20 138. SmileCareClub further advertises that SmileCareClub Invisible Aligners are “FDA  
21 Approved.”

22 139. Sharper Image currently advertises on its website that the SmileCareClub system is  
23 “convenient, safe and affordable, and all under the care of a licensed dental professional who  
24 prescribes and oversees treatment virtually.” Sharper Image previously advertised that the  
25 SmileCareClub system is “easy, convenient and this consumer-friendly model lowers costs, and  
26 the savings are passed on to you. Smile Care Club has pioneered teledentistry by matching  
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1 patients with Smile Care Club dental professionals for virtual office visits to prescribe and  
2 oversee treatment.”

3 140. Brookstone advertises on its website that the SmileCareClub system is “easy,  
4 convenient and this consumer-friendly model lowers costs, and the savings are passed on to you.  
5 Smile Care Club has pioneered teledentistry by matching patients with Smile Care Club dental  
6 professionals for virtual office visits to prescribe and oversee treatment.”

7 141. Defendants’ advertising misleads customers into believing that the SmileCareClub  
8 product is of the same quality, and is just as safe, as the Invisalign System.

9 142. The SmileCareClub system is not identical to the Invisalign System because  
10 customers using the SmileCareClub system are not physically evaluated or monitored throughout  
11 treatment by a dentist. Oversight by a dentist is necessary to protect a patient’s dental health and  
12 monitor their treatment progress.

13 143. Dentists play an important role in determining a patient’s suitability for treatment  
14 and prescribing treatment, as well as in monitoring the patient’s dental health and treatment  
15 progress. For example, without oversight by a dentist to determine if they are good candidates for  
16 treatment, customers of the SmileCareClub system are at risk of undiagnosed tooth decay,  
17 periodontal disease, decalcification (permanent markings on the patient’s teeth), or inflammation  
18 of the gums. Customers are also at risk of existing dental restorations, such as crowns and  
19 bridges, becoming dislodged. Moreover, dentists monitor patients for extreme side effects such  
20 as root resorption, where the tooth’s roots become shorter, possibly leading to the loss of the  
21 tooth.

22 144. Defendants’ adoption of SmileCareClub’s claim that it is “FDA Approved” is  
23 deceptive and misleading for several reasons. First, SmileCareClub’s claim that SmileCareClub  
24 invisible aligners are “FDA Approved” is false. SmileCareClub aligners have not been subject to  
25 the FDA Premarket approval (PMA) process. SmileCareClub’s advertising misleads customers  
26 into believing that the FDA has analyzed the SmileCareClub clear aligner system and verified  
27 that it is a safe and effective product when no such scientific and regulatory review has occurred.  
28 Second, for this same reason, SmileCareClub’s use of the “FDA Approved” logo on its marketing

1 materials is improper, deceptive and misleading. Third, until very recently, SmileCareClub's  
2 purported "FDA approval" was only as a repackager/relabeler of dental positioners designed to  
3 prevent teeth from moving, not sequential aligners intended to move teeth. Thus, for that period  
4 of time, SmileCareClub was distributing a product that was not properly registered with the FDA,  
5 let alone "FDA Approved." Fourth, even now, SmileCareClub is only registered with the FDA as  
6 a repackager/relabeler, not as a manufacturer or specification developer, and is limited to the  
7 activities associated with this registration. SmileCareClub's fundamental alteration of the  
8 doctor/patient relationship renders SmileCareClub's comparison to other FDA cleared devices  
9 like the Invisalign System inapt. The existing FDA cleared devices contemplate dental  
10 professionals meeting in-person with patients to diagnose the patient, obtain accurate impressions  
11 of the patient's existing dentition, develop a treatment plan, and monitor the ongoing treatment  
12 through regular in-person contact. The elimination of these components changes the risk profile  
13 of the device and affects the safety and effectiveness of the device. SmileCareClub's product  
14 lacks all of these critical components of the current FDA cleared devices.

15 145. Defendants' advertising is literally false, deceptive, and misleading representations  
16 of fact in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

17 146. Upon information and belief, Defendants' false advertising is likely to influence  
18 purchasing decisions of customers by representing that customers can receive the same product as  
19 Align's Invisalign System for a reduced cost.

20 147. As a result of Defendants' false and misleading advertising, Align has suffered and  
21 will continue to suffer irreparable and monetary damages in an amount to be determined at trial.  
22 Align has and will suffer direct monetary damages from loss of sales from customers who select  
23 the SmileCareClub system instead of the Invisalign System. Align also has and will suffer  
24 reputational damage from instances in which customers have negative experiences with the  
25 SmileCareClub system that are attributed to problems with all clear aligner systems.

26 148. Upon information and belief, Defendants' acts of false and misleading advertising  
27 will continue after service of this Complaint unless enjoined by the Court.

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