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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

MISTY SNOW, individually and on behalf of
others similarly situated,

Plaintiffs,

v.

ALIGN TECHNOLOGY, INC.,

Defendant.

No. 3:21-cv-03269-VC

**THIRD AMENDED CLASS ACTION
COMPLAINT**

JURY TRIAL DEMANDED

Hon. Vince Chhabria

TABLE OF CONTENTS

	<u>Page</u>
I. NATURE OF THE CASE.....	1
II. JURISDICTION AND VENUE.....	9
III. PARTIES.....	10
A. Plaintiffs	10
1. Arizona – Celeste Hamilton	10
2. California – Jaime Gooch and Tracy Mound	10
3. Connecticut – Kelley Stevens.....	11
4. Florida – Darlena Strong	11
5. Maryland – Katie Campbell	11
6. Massachusetts – Jennifer Ezzio	11
7. Michigan – Angela Carnaghi.....	12
8. Minnesota – Adelaide Liedl and Elisabeth Skibba.....	12
9. Nebraska – Justin Hansen.....	13
10. Nevada – Cecelia Garay	13
11. North Carolina – Stephanie Rickenbaker	13
12. Oregon – Misty Snow.....	14
13. Federal Sherman Act Injunctive Relief Purchaser – Emily Vo.....	14
14. SmileDirectClub Purchaser – Dana Bozian	14
B. Defendant	15
C. Agents & Co-Conspirators	15
IV. FACTS.....	15
A. Align’s profits largely derive from its domination of the aligner market	15
B. The expiration of Align’s intellectual property exposed it to competition	20
C. Align implemented a closed system of scanners and aligners that would protect its monopolies in the respective markets.....	21

D. Align terminated its interoperability agreement with 3Shape, sacrificing short-term profits in order to gain long term profits from the anticompetitive effects of its refusal to deal.....25

E. Align signed exclusive dealing contracts with dental service organizations to entrench its monopoly power.....28

F. Align’s “Fusion Program” tied together iTero links, iTero prices and Invisalign sales.31

G. At the same time it was monopolizing the scanner market, Align entered into a set of anticompetitive agreements with SmileDirectClub that allocated the direct-to-consumer submarket (to SDC) and dentist-directed submarket (to Align).....32

H. Align’s set of actions substantially foreclosed competition in the aligner and scanner markets.45

V. INTERSTATE COMMERCE47

VI. CLASS ACTION ALLEGATIONS.....48

VII. RELEVANT MARKETS53

A. The aligner market.....53

B. The market for hand-held digital intra-oral scanners56

VIII. ANTITRUST INJURY61

A. SmileDirectClub purchasers paid inflated prices for SmileDirectClub aligners as a result of the anticompetitive agreements between Align and SmileDirectClub.61

B. Inflated prices of Invisalign aligners were passed on to consumer purchasers of Invisalign treatments.....62

IX. CAUSES OF ACTION.....66

VIOLATIONS OF THE SHERMAN ACT66

FIRST CLAIM FOR RELIEF: VIOLATION OF SECTION 2 OF THE SHERMAN ACT 15 U.S.C. §2 FOR MONOPOLIZATION OF THE ALIGNER MARKET (ON BEHALF OF THE NATIONWIDE INJUNCTIVE RELIEF CLASS)66

SECOND CLAIM FOR RELIEF: VIOLATION OF SECTION 1 OF THE SHERMAN ACT 15 U.S.C. §1 (ON BEHALF OF THE NATIONWIDE SMILEDIRECTCLUB PURCHASER CLASS).....67

THIRD CLAIM FOR RELIEF: VIOLATION OF ARIZONA’S UNIFORM STATE ANTITRUST ACT, ARIZ. REV. STAT. § 44-1401, ET SEQ. (ON BEHALF OF THE ARIZONA CLASS)68

FOURTH CLAIM FOR RELIEF: VIOLATIONS OF CALIFORNIA’S UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200, ET SEQ. (ON BEHALF OF THE CALIFORNIA CLASS).....69

FIFTH CLAIM FOR RELIEF: VIOLATION OF THE CONNECTICUT ANTITRUST ACT CONN. GEN. STAT § 35-24, ET SEQ. (ON BEHALF OF THE CONNECTICUT CLASS)70

SIXTH CLAIM FOR RELIEF: VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. § 501.201(2), ET SEQ. (ON BEHALF OF THE FLORIDA CLASS)71

SEVENTH CLAIM FOR RELIEF: VIOLATION OF THE MARYLAND ANTITRUST ACT, ANN. COM. LAW § 11-201, ET SEQ. (ON BEHALF OF THE MARYLAND CLASS)72

EIGHTH CLAIM FOR RELIEF: VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT, MASS. GEN. LAWS CH. 93A § 1, ET SEQ. (ON BEHALF OF THE MASSACHUSETTS CLASS)73

NINTH CLAIM FOR RELIEF: VIOLATION OF THE MICHIGAN ANTITRUST REFORM ACT MICH. COMP. LAWS § 445.771, ET SEQ. (ON BEHALF OF THE MICHIGAN CLASS)75

TENTH CLAIM FOR RELIEF: VIOLATION OF THE MINNESOTA ANTITRUST LAW, MINN. STAT. § 325D.49, ET SEQ. (ON BEHALF OF THE MINNESOTA CLASS).....75

ELEVENTH CLAIM FOR RELIEF: VIOLATION OF THE NEBRASKA CONSUMER PROTECTION ACT, NEB. REV. STAT. § 59-1602, ET SEQ. (ON BEHALF OF THE NEBRASKA CLASS)76

TWELFTH CLAIM FOR RELIEF: VIOLATION OF THE NEVADA UNFAIR TRADE PRACTICES ACT, NEV. REV. STAT. § 598A.010, ET SEQ. (ON BEHALF OF THE NEVADA CLASS).....77

THIRTEENTH CLAIM FOR RELIEF: VIOLATION OF THE NORTH CAROLINA GENERAL STATUTES, N.C. GEN. STAT. § 75-1, ET SEQ. (ON BEHALF OF THE NORTH CAROLINA CLASS).....78

FOURTEENTH CLAIM FOR RELIEF: VIOLATION OF THE OREGON ANTITRUST LAW, OR. REV. STAT. § 646.705, ET SEQ. (ON BEHALF OF THE OREGON CLASS).....79

REQUEST FOR RELIEF80

DEMAND FOR JURY TRIAL81

Plaintiffs bring this action on behalf of themselves individually and on behalf of plaintiff classes consisting of (1) a class of all persons and entities who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Invisalign-brand aligners acquired for personal use during the period beginning May 4, 2017 (“Class Period”), and sold by Align Technology, Inc. (“Align” or “Defendant”); and (2) a class of all persons and entities who purchased, paid, and/or provided reimbursement for some or all of the purchase price for SmileDirectClub aligners acquired for personal use during the period beginning October 22, 2017 (“SmileDirectClub Class Period”) and sold by SmileDirectClub (“SDC” or “Conspirator”). Plaintiffs have amended the complaint as follows:

- To add class two new substitute class representatives from California, and a substitute class representative from Florida.¹
- To narrow the claims and causes of action at issue in light of the Court’s February 16, 2022 orders [ECF Nos. 96, 97] by removing Plaintiffs’ claims under California’s Cartwright Act, as well Plaintiffs’ claims under New York, Tennessee, and Iowa law.

I. NATURE OF THE CASE

1. Aligners are orthodontic devices that, in essence, are a plastic form of dental braces. Over a course of treatment, a patient generally uses a successive series of aligners that slowly realign the teeth. Aligners possess several significant advantages over dental braces. Aligners, unlike braces, can be removed from the mouth for short periods of time, such as for eating, brushing, or flossing. Aligners, made out of clear plastic, are also more visually inconspicuous than dental braces that are usually made out of metal.

¹ In its Supplemental Order [ECF No. 97], the Court dismissed the claims of plaintiffs Cindy Ellis (California) and Marjorie Sandner (Iowa) for lack of standing because they purchased Invisalign before Align terminated its interoperability agreement with 3Shape. *See id.* at 3.



Braces



Invisalign

2. For decades, Align dominated the market for aligners with its Invisalign products. Align controlled more than 90 percent of the market and earned consistent, durable profit margins. Invisalign aligners are sold through dental offices. Full dental courses of treatment using Invisalign aligners are expensive, generally costing up to \$8,000.

3. Align used its intellectual property to protect its dominant market position. Align frequently filed litigation, such as patent infringement lawsuits, against potential competitors in the aligner market who threatened Align's dominance.

4. However, by 2017, Align's intellectual property that had helped drive its market dominance had begun to expire. Align publicly acknowledged the risk that "[w]hen patents expire, we lose the protection and competitive advantages they provided to us, which could negatively impact . . . operating results."

5. Align had been able to charge high prices and earn high profit margins on Invisalign because the product was protected by a thicket of hundreds of patents that Align wielded aggressively to protect its aligner monopoly. As Align CEO Joe Hogan stated in 2017: "We've been in business now for almost 20 years, and we've had so few competitors and people think it's because we have this great IP, it's true we have good intellectual property, but it took 15 years for people to

really believe that you can move teeth with plastics[.]. . . It gave us this period of time to really iterate and learn *without the outside influence of other competitors coming in.*²

6. Meanwhile, clear aligners are ascendent in the world of dentistry. According to one source, they result in fewer errors than traditional braces and can be used to treat between 50-70% of patients who need teeth correction. Competitors have taken note of this market opportunity: since 2017, a number of major companies—including Straumann, Henry Schein, and 3Shape—have entered the clear aligner market, which was estimated to be worth nearly \$3 billion in 2019. In fact, in late 2020, the multinational dental company Dentsply Sirona announced that it would exit the traditional orthodontic business altogether (i.e., the market for wire brackets) and focus on the digital aligner business instead—specifically, its “SureSmile” brand of clear aligners and “Primescan” brand of oral scanners.³

7. Faced with competition from the loss of patent exclusivity, Align implemented an anticompetitive Scheme to willfully acquire and maintain its monopoly position. Align’s Scheme centered around its efforts to foreclose competition in the linked markets of (1) aligners; and (2) hand-held digital intraoral scanners (“scanners”).

8. Dental offices use scanners to take digital images of the jaws, teeth, and bite of a patient. These digital images are then used by aligner manufacturers to create individualized aligners for patients. During the course of a treatment, patients will generally take regular scans and have a series of individual aligners manufactured for their usage.

9. Align sells a scanner product called the iTero. Align’s primary competitor in the scanner market is 3Shape, which sells its own scanner, the “Trios.” Digital scanners make it more convenient and efficient for dental practices to order aligners. Align has stated that “Invisalign doctors with an iTero scanner have notably higher utilization rates than non-iTero doctors,” i.e., Invisalign doctors with an iTero scanner order Invisalign aligners at significantly higher levels than

² Michela Tindera, *Out of Silicon Valley, A Billion-Dollar Orthodontics Business Built with Plastic and Patents*, Forbes (April 25, 2017) (emphasis added).

³ See Jeremy Booth, *Dentsply Sirona reshuffles as pandemic cuts sales in half*, Dental Tribune (August 12, 2020), available at <https://am.dental-tribune.com/c/dentsply-sirona/news/dentsply-sirona-reshuffles-as-pandemic-cuts-sales-in-half/>.

doctors without iTero scanners. Align itself has also emphasized that dental practices need a fast and accurate way to create digital scans that can be used to create aligners and to transfer those scans to the aligner manufacturer.

10. Align’s iTero and 3Shape’s Trios are the two primary scanners specifically designed for ordering aligners.⁴ However, the two scanners have an obvious difference. Trios allows for dentists to order aligners from a number of different aligner manufacturers, thus encouraging competition in the market for aligners. By contrast, iTero is a closed system because it imposes substantial costs on dentists who attempt to use the iTero for ordering aligners that are not manufactured by Align.

11. As a result of this distinction, the spread of iTero’s closed-system scanner across dentists drives sales towards Invisalign and excludes rival aligner manufacturers. For example, in 2019, Invisalign stated that the “use of the iTero scanners for Invisalign case submission continues to grow and remains a positive catalyst for Invisalign utilization” and that the “iTero scanner and services business has become an integral part of our business and is key to our end-to-end digital workflow.”

12. Align’s anticompetitive Scheme was designed to monopolize the scanner and aligner markets, creating a self-reinforcing cycle where Align’s dominance of the scanner market ensured continued dominance of the aligner market. Align’s Scheme contained several key components: (1) the economically irrational, unilateral termination of Align’s longstanding and profitable agreement with 3Shape that allowed the Trios scanner to be used to order Invisalign (hereafter the “Interoperability Agreement”)—a termination that sacrificed short-term profits and only made sense because of its later anticompetitive effects; (2) exclusive dealing contracts with two of the largest dental service organizations (“DSO”) that effectively prevented DSO members from dealing with Align’s competitors in the scanner and aligner markets; and (3) the “Fusion” program, which

⁴ As discussed in more detail below, while the company Sirona has recently launched its own intraoral scanner and clear aligner brands, it has yet to gain any significant share of either market. Furthermore, Sirona has so far allowed the use of Trios scanners to order its clear aligners, despite competing with Trios in the scanner market.

bundled iTero and Invisalign aligner sales together, effectively preventing dentists from ordering either aligners or scanners from rivals.

13. Align’s Scheme substantially foreclosed competition in the aligner and scanner markets. Align successfully tied Invisalign to iTero in order to monopolize both markets—with dentists that used iTero scanners effectively forced to use Invisalign because Align terminated its interoperability agreement with its primary rival, 3Shape.

14. A rival aligner manufacturer looking to compete against Invisalign would have to offer below-cost prices to offset the penalties and overcome the restrictions Align has placed on its customers through this Scheme. Likewise, Align has foreclosed Trios, its only true rival in the scanner market. Because Align controls approximately 90 percent of the aligner market, that has effectively foreclosed the ability for a rival scanner manufacturer to compete.

15. At approximately the same time, Align entered into a set of interlocking agreements in July 2016 with its strongest potential competitor, SmileDirectClub (“SDC”) that effectively allocated the aligner market between themselves. Prior to the agreements, Align had exclusively sold aligners wholesale through dental offices. Align sold Invisaligners to dentists and orthodontists, who then charged consumers for Invisaligner treatments that contained Invisaligners. Patients received the Invisaligner treatments through regular visits to dental offices. Founded in 2014, SmileDirectClub pioneered the practice of selling aligners directly to consumers. The two channels constituted distinct product submarkets, with Align repeatedly explaining that the varying complexity of treatment between the two channels meant there was little customer overlap. Nevertheless, SmileDirectClub posed a competitive threat to Align, especially since the first patents of Align to expire were focused in the lower end of the aligner market where SmileDirectClub had pioneered the direct-to-consumer channel.

16. Just as it had done to 3Shape, Align initiated patent infringement litigation against SDC in 2015. But, in July 2016, the two companies entered into an interlocking set of agreements that effectively allocated the direct-to-consumer product submarket to SDC while furthering Align’s monopolization of the wholesale dental office product submarket. There were two main agreements:

(1) an Operating Agreement; and (2) a Supply Agreement that accomplished this anticompetitive effect (attached hereto as Exhibits A and B, respectively).

17. First, Align and SDC entered into an Operating Agreement where Align purchased 17% of SDC for \$46.7 million [REDACTED]. The Operating Agreement included restrictive covenants that prevented Align from competing in the direct-to-consumer product submarket.

18. Second, Align and SDC entered into a Supply Agreement that provided that Align would supply a portion of SDC's aligner orders. [REDACTED]

[REDACTED]

19. The agreements between Align and SDC were highly effective in stifling competition in both of the aligner product submarkets. First, in 2017, Align attempted to encroach on SDC's direct-to-consumer channel by opening its own brick and mortar stores for consumers interested in Invisaligners. In response, SDC initiated arbitration against SDC for breach of the Operating Agreement and, in 2018, obtained an award that required Align to close its existing stores; prevented Align from opening new stores; required Align to sell back to SDC its ownership interest; and extended the parties' non-compete provisions until August 18, 2022. Thus, the agreements foreclosed competition in the consumer product submarket.

20. Second, the Supply Agreement ran until December 31, 2019. Immediately upon the Supply Agreement's expiration, SDC announced on January 14, 2020 its plans to "offer its clear aligners through the wholesale channel, providing dentists and orthodontists an in-office option in 2020." SDC specifically attributed its plans to the expiration of the supply agreement. In the press release, SDC stated that "With the December 31, 2019 expiration of its exclusive supply agreement with Align Technology, Inc., SmileDirectClub will expand access to its clear aligner therapy solutions and open its network to dentists and orthodontists in search of a premium and affordable teeth straightening solution for their patients." In the press release, SDC's co-founder, Alex Frenkel, directly attributed SmileDirectClub's entrance into this product submarket to the expiration of the supply agreement, stating that "We have seen increasing demand from the dentists and orthodontists in our network who wish to provide SmileDirectClub clear aligners to their in-office patients, and *with our agreement with Align Technology now expired, we are no longer obligated to stay in the direct-to-consumer channel.*"⁵

21. The costs of Invisalign aligners are incorporated into the prices that dentists charge for Invisalign aligner treatment. Dental insurance, if it is available, generally only covers a minority portion of the overall Invisalign aligner treatment, generally capping benefits at 25-50% of the overall cost of the Invisalign aligner treatment. Therefore, Plaintiff consumer purchasers of Invisalign aligners pay much or all of the cost of Invisalign aligners out-of-pocket.

⁵ Though this press release has since been removed from SDC's website, it remains available online. See <https://apnews.com/press-release/pr-globenewswire/ad9eb6c97db2ed0c94263c9356010f61>; a true and correct copy of which is attached hereto as Exhibit C. Frenkel's statement was widely reported at the time of its release by industry groups and market analysts. See, e.g., Jeremy Booth, "SmileDirectClub Aims to Change Tack in 2020," DDS World <https://www.dds.world/smiledirectclub-aims-to-change-tack-in-2020/> ("With our agreement with Align Technology now expired, we are no longer obligated to stay in the direct-to-consumer channel," Alex Frenkel, co-founder of SDC, said in a statement, "We're excited to expand our offering," he added. The expiry of the pact means that SDC can now compete directly with Align, which manufactures the leading Invisalign clear aligner brand, and it signals the end of a five-year entanglement between the two companies."); Scott Van Voorhis, "SmileDirectClub Beaming as Wholesale Dental Product Venture Boosts Shares," TheStreet (Jan. 14, 2020), available at <https://www.thestreet.com/investing/smiledirectclub-beaming-as-wholesale-dental-product-venture-boosts-shares>.

22. Align itself recognizes that Plaintiff consumers pay much of the cost for Invisalign aligner treatment. On its own website, Align describes various out-of-pocket payment options for consumers purchasing Invisalign aligners, including the usage of HSA or FSA spending accounts, or monthly payment plans:



The infographic features a central icon of a piggy bank with a dollar sign. Below it, the title reads "Paying for Invisalign treatment with tax-free dollars using an FSA or HSA". It is divided into two columns. The left column is titled "What is an FSA?" and describes it as a flexible savings account managed by an employer. The right column is titled "What is an HSA?" and describes it as a special savings account with a high-deductible health insurance plan. A central note states, "You don't pay taxes on the money you put in an FSA or HSA." Below this, a question asks "What is the advantage of an FSA or HSA?" and another asks "How can I use my FSA or HSA to pay for Invisalign treatment?".

What is an FSA?
A flexible savings account, or FSA, is an account you may be able to use to pay for certain medical, dental, and orthodontic costs, including Invisalign clear aligners. Your FSA is managed by your employer, and you pay money into the account throughout the year, usually through a deduction from your paycheck. You may set aside up to \$2,600 annually. Not all employers offer an FSA.

What is an HSA?
A health savings account, or HSA, is a special savings account designed for people with a high-deductible health insurance plan. You put money into the account and can use it to cover certain medical, dental, and orthodontic costs, including Invisalign clear aligners. You may set aside up to \$3,400 for an individual or \$6,750 for a family annually. To open an HSA, you must meet [IRS eligibility requirements](#).

You don't pay taxes on the money you put in an FSA or HSA.

What is the advantage of an FSA or HSA?

How can I use my FSA or HSA to pay for Invisalign treatment?
Before you begin your Invisalign treatment, talk to both your doctor's office and your benefits manager. You may be able to pay your doctor and be reimbursed from your FSA or HSA. Your benefits provider may also be able to pay your doctor directly.



The infographic features a central icon of a calendar with a dollar sign. Below it, the title reads "Paying for your Invisalign treatment with a monthly payment plan". It is divided into three columns. The first column asks "What is a monthly payment plan?". The second column asks "How can a monthly payment help me?". The third column asks "How can I arrange a monthly payment plan?".

What is a monthly payment plan?
A monthly payment plan is an arrangement between you and your doctor to spread the cost of your Invisalign clear aligners over the length of your treatment. Typically, doctors will request a down payment before treatment begins.

How can a monthly payment help me?
Making small payments throughout the course of your Invisalign treatment rather than all at once can make it easier to plan your monthly budget.

How can I arrange a monthly payment plan?
Many doctors offer flexible and affordable monthly payment plans. Before or during your consultation for Invisalign treatment, ask your doctor what options they offer.

23. Align has specifically emphasized that it works to arrange third party financing programs for end user consumers to shoulder the high cost of Invisalign aligners. For example, Align introduced a third-party financing program where the cost of Invisalign aligners would be specifically paid to Align. Invisalign's CEO, Joseph Hogan, explained the program as follows:

“When consumers finance their treatment through us, Invisalign providers no longer pay Align. Instead, they just receive payment for the treatment fee minus Align’s lab fee. By changing the financial relationship between the patient, Align and the provider, Invisalign treatment becomes a revenue source for the provider.” Align also specifically recognized that dentists otherwise pass through the cost of Invisalign aligners to patients, with Hogan stating that the new financing program “eliminates the need for [dentists] to pass on the high down payments to patients.”

24. Therefore, ultimately, whether they pay directly to Invisalign through financing or through payments for the cost of Invisalign aligner treatment provided by dentists, it is Plaintiffs, consumer purchasers of Invisalign aligners and SDC aligners, who have paid the price for Align’s anticompetitive Scheme through supracompetitive prices on aligners.

II. JURISDICTION AND VENUE

25. Plaintiffs bring this action under Section 16 of the Clayton Act (15 U.S.C. § 26) to secure injunctive relief against Defendant for violating Section 2 of the Sherman Act (15 U.S.C. § 2). Plaintiffs also bring these state law class claims on behalf of all the classes to recover actual and/or compensatory damages, double and treble damages as permitted, pre- and post-judgment interest, costs, and attorneys’ fees for the injury caused by Defendant’s conduct in monopolizing the aligner and scanner markets. Plaintiffs seek damages in excess of \$5,000,000. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26.

26. This Court also has jurisdiction over the instant matter pursuant to 28 U.S.C. § 1332(d) and the Class Action Fairness Act of 2005 (“CAFA”), 28 U.S.C. § 1711, *et seq.*, which vest original jurisdiction in the district courts of the United States for any multi-state class action where the aggregate amount in controversy exceeds \$5 million and where the citizenship of any member of the class of plaintiffs is different from that of any defendant. The \$5 million amount-in-controversy and diverse citizenship requirements of CAFA are satisfied in this case.

27. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 15 U.S.C. §§ 15 and 22, as Defendant resides, transacts business, committed an illegal or tortious act, has an agent, and/or can be found in this District.

28. This Court has personal jurisdiction over the Defendant, as it has corporate offices in the District, markets and distributes aligners and scanners in this District, had corporate headquarters in this District during the majority of the class period during which it engaged in anticompetitive acts, enters into contracts within this District, and otherwise transacts business within this District.

III. PARTIES

A. Plaintiffs

1. Arizona – Celeste Hamilton

29. Plaintiff Celeste Hamilton purchased Invisalign aligners in June 2021. At the time of her purchase, continuing into the present, Plaintiff Hamilton was and is a resident of Mesa, Arizona. Plaintiff Hamilton paid approximately \$4,000 for the aligners and financed the purchase with her credit card. Plaintiff Hamilton also received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Hamilton purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

2. California – Jaime Gooch and Tracy Mound

30. Plaintiff Jaime Gooch purchased Invisalign aligners in May 2021. At the time of her purchase, continuing into the present, Plaintiff Gooch was and is a resident of Clovis, California. Plaintiff Gooch received dental scans as part of the treatment. Plaintiff Gooch paid approximately \$5,000 for her Invisaligners, with no portion of the purchase covered by insurance. Plaintiff Gooch paid \$500 up front and the remaining through monthly payments to her orthodontist. Plaintiff Gooch purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

31. Plaintiff Tracy Mound purchased Invisalign aligners in September 2020. At the time of her purchase, continuing into the present, Plaintiff Mound was and is a resident of Santa Clarita, California. Plaintiff Mound received dental scans as part of the treatment. Plaintiff Mound paid approximately \$5,000 for her Invisaligners, with no portion of the purchase covered by insurance. Plaintiff Mound paid \$3000 on a care credit card and is still making monthly payments to her orthodontist. Plaintiff Mound purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

3. Connecticut – Kelley Stevens

32. Plaintiff Kelley Stevens purchased Invisalign aligners in February 2019. At the time of her purchase, continuing into the present, Plaintiff Stevens was and is a resident of North Haven, Connecticut. Plaintiff Stevens paid approximately \$6,000 for the aligners and financed the purchase through her orthodontist. Plaintiff Stevens received dental scans as part of the treatment in receiving Invisalign Aligners. Plaintiff Stevens purchased Invisalign aligners at prices that were artificially inflated because of Defendant’s anticompetitive Scheme, and thereby suffered antitrust injury.

4. Florida – Darlena Strong

33. Plaintiff Darlena Strong purchased Invisalign aligners around August 2020. At the time of her purchase, continuing into the present, Plaintiff Strong was and is a resident of Palmetto, Florida. Plaintiff Strong paid approximately \$7000 for the aligners and financed the purchase through Care Credit. Plaintiff Strong received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Strong purchased Invisalign aligners at prices that were artificially inflated because of Defendant’s anticompetitive Scheme, and thereby suffered antitrust injury.

5. Maryland – Katie Campbell

34. Plaintiff Katie Campbell purchased Invisalign aligners in July 2019. At the time of her purchase, continuing into the present, Campbell was and is a resident of Lusby, Maryland. Plaintiff Campbell paid approximately \$6,000 for the aligners. She paid half of the cost up front and financed the rest through her orthodontist. Plaintiff Campbell also received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Campbell purchased Invisalign aligners at prices that were artificially inflated because of Defendant’s anticompetitive Scheme, and thereby suffered antitrust injury.

6. Massachusetts – Jennifer Ezzio

35. Plaintiff Jennifer Ezzio purchased Invisalign aligners in July 2019. At the time of her purchase, continuing into the present, Plaintiff Ezzio was and is a resident of Pepperell, Massachusetts. Plaintiff Ezzio paid \$2000.00 immediately, then paid \$313.00 each month (with a final payment of \$310), ultimately paying a total of \$5,440.00 for her aligners. Plaintiff Ezzio received financing through OrthoBanc LLC. Plaintiff Ezzio also received dental scans as part of her

treatment in receiving Invisalign aligners. Plaintiff Ezio purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

7. Michigan – Angela Carnaghi

36. Plaintiff Angela Carnaghi purchased Invisalign aligners in August 2020. At the time of her purchase, continuing into the present, Plaintiff Carnaghi was and is a resident of Grosse Pointe, Michigan. Plaintiff Carnaghi paid approximately \$5,000 for the aligners. A portion of the cost was paid for by insurance, but Plaintiff Carnaghi was still individually responsible for paying the majority of the cost of Invisalign aligners. Plaintiff Carnaghi also received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Carnaghi purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

8. Minnesota – Adelaide Liedl and Elisabeth Skibba

37. Plaintiff Adelaide Liedl began making payments for Invisalign aligners in January 2017. At the time of her purchase, continuing into the present, Plaintiff Liedl was and is a resident of Eden Prairie, Minnesota. Plaintiff Liedl was quoted \$6320 for the aligners. Her orthodontist applied a \$500 coupon and insurance paid \$1500. For the remaining \$4320, Plaintiff Liedl put \$2200 down and paid remaining \$2120 over 17 months. Plaintiff Liedl received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Liedl purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

38. Plaintiff Elisabeth Skibba purchased Invisalign in August 2018. Plaintiff Skibba received dental scans as part of her treatment. At the time of her purchase, continuing into the present, Plaintiff Skibba was and is a resident of Minneapolis, Minnesota. Plaintiff Skibba was quoted approximately \$6,000 for her Invisaligners. Insurance did not cover any portion of the cost. Plaintiff Skibba financed her purchase through her dentist and paid approximately \$314 a month over a period of approximately 2 years. Plaintiff Skibba purchased Invisalign aligners at prices that were

artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

9. Nebraska – Justin Hansen

39. Plaintiff Justin Hansen purchased Invisalign aligners in December 2020. At the time of his purchase, continuing into the present, Plaintiff Hansen was and is a resident of Lincoln, Nebraska. Plaintiff Hansen paid approximately \$5000 for the aligners and financed the purchase through his orthodontist's office. Plaintiff Hansen received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Hansen purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

10. Nevada – Cecelia Garay

40. Plaintiff Cecilia Garay purchased Invisalign aligners in December 2019. At the time of her purchase, continuing into the present, Plaintiff Garay was and is a resident of North Las Vegas, Nevada. Plaintiff Garay paid approximately \$5750 for the aligners and financed the purchase through OrthoBank LLC, paying \$136 a month for 36 months. Plaintiff Garay received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Garay purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

11. North Carolina – Stephanie Rickenbaker

41. Plaintiff Stephanie Rickenbaker purchased Invisalign aligners in January 2019. At the time of her purchase, continuing into the present, Plaintiff Rickenbaker was and is a resident of Charlotte, North Carolina. Plaintiff Rickenbaker paid approximately \$7000 for the aligners. Plaintiff Rickenbaker received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Rickenbaker purchased Invisalign aligners at prices that were artificially inflated because of Defendant's anticompetitive Scheme, and thereby suffered antitrust injury.

12. Oregon – Misty Snow

42. Plaintiff Misty Snow purchased Invisalign aligners in January 2019, during which time she was a resident of Oregon.⁶ Plaintiff Snow initially paid for the entire cost of Invisalign aligners, approximately \$5,350, out-of-pocket through payments to her dental office. Plaintiff Snow was subsequently partially reimbursed by insurance for her purchase (in the amount of approximately \$2,500) but was still individually responsible for paying the majority of the cost (approximately \$2,850) of the Invisalign aligners. Plaintiff Snow purchased Invisalign aligners at prices that were artificially inflated because of Defendant’s anticompetitive Scheme, and thereby suffered antitrust injury.

13. Federal Sherman Act Injunctive Relief Purchaser – Emily Vo

43. Plaintiff Emily Vo purchased Invisalign aligners for her son in July 2019. At the time of her purchase, continuing into the present, Plaintiff Vo was and is a resident of Jamaica, New York. Plaintiff Vo paid approximately \$6000 for the aligners. A portion of the cost was paid for by insurance, but Plaintiff Vo was still individually responsible for paying the majority of the cost of Invisalign aligners. Plaintiff Vo’s son received dental scans as part of the treatment in receiving Invisalign aligners. Plaintiff Vo purchased Invisalign aligners at prices that were artificially inflated because of Defendant’s anticompetitive Scheme, and thereby suffered antitrust injury.

44. Plaintiff Vo has a minor child, age 12, for whom she intends to purchase Invisalign aligners in the future once they are financially ready to make the purchase. Plaintiff Vo will suffer imminent, concrete injury in the future by paying supracompetitive prices for Invisalign aligners on behalf of her minor child.

14. SmileDirectClub Purchaser – Dana Bozian

45. Plaintiff Dana Bozian purchased SmileDirectClub aligners in June 2020 on behalf of his minor child. Plaintiff Bozian was and is a resident of Florida. Plaintiff Bozian paid approximately \$2000 for the SmileDirectClub aligners. Plaintiff Bozian purchased the aligners

⁶ Snow has been an Idaho resident since August 2020.

directly from SmileDirectClub. No portion of the payment was covered by insurance. Plaintiff Bozian eventually returned a portion of the aligners and received a partial refund.

B. Defendant

46. Defendant Align Technology, Inc. is a Delaware corporation that had its corporate headquarters in San Jose, California for the majority of the class period until January 1, 2021. Defendant still maintains its primary research hub in San Jose, California. Upon information and belief, Defendant has corporate offices in the Northern District of California, has many Invisalign providers in the Northern District of California which are trained by Defendant to prescribe Invisalign and which purchase both iTero scanners and Invisalign aligners from Defendant for usage on Plaintiffs.

C. Agents & Co-Conspirators

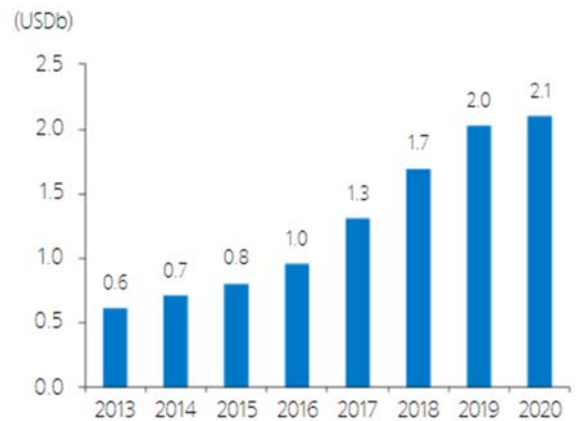
47. SmileDirectClub (“SDC”) is a Delaware corporation with its corporate headquarters in Nashville, Tennessee. During the Class Period, SDC and/or its predecessors, wholly owned or controlled subsidiaries, or affiliates sold Aligners in interstate commerce, directly or through its wholly owned or controlled affiliates, to purchasers in the United States.

IV. FACTS

A. Align’s profits largely derive from its domination of the aligner market

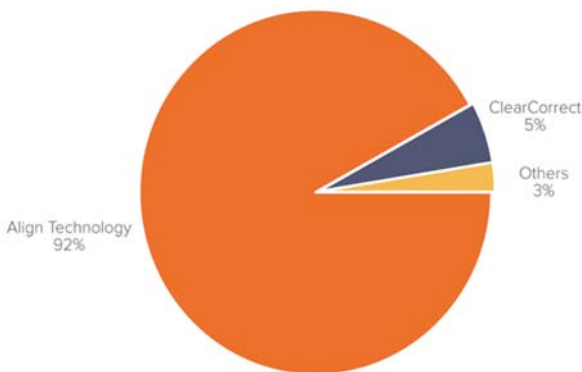
48. Align’s largest source of revenue comes from its Invisalign brand aligners, by far the dominant product in the aligner market, with an approximately 90-percent share of the aligner market. Align earns well over a billion dollars per year selling Invisalign products at gross margins exceeding 75 percent. Its revenues and profits continue to grow year after year, and it continues to raise prices, despite the (largely unsuccessful) efforts of other companies to break into the aligner market:

Align Technology: Clear aligner sales



Source: Bloomberg

Clear Aligners - Doctor-Directed Market Share, 2019



Source: Company Annual Reports, Credit Suisse Equity Research

49. Align also sells the iTero scanner. Align acquired the iTero technology through a corporate acquisition and then integrated it with the Invisalign system. The iTero scanner’s integration with Invisalign, as well as Align’s anticompetitive conduct described herein, have enabled iTero to become the dominant scanner. If the scanner market is defined to include Align’s iTero and 3Shape’s Trios—the only two scanners properly understood to comprise the relevant “scanner market”—Align now controls approximately 80 percent of that market, which earns Align hundreds of millions of dollars a year.⁷

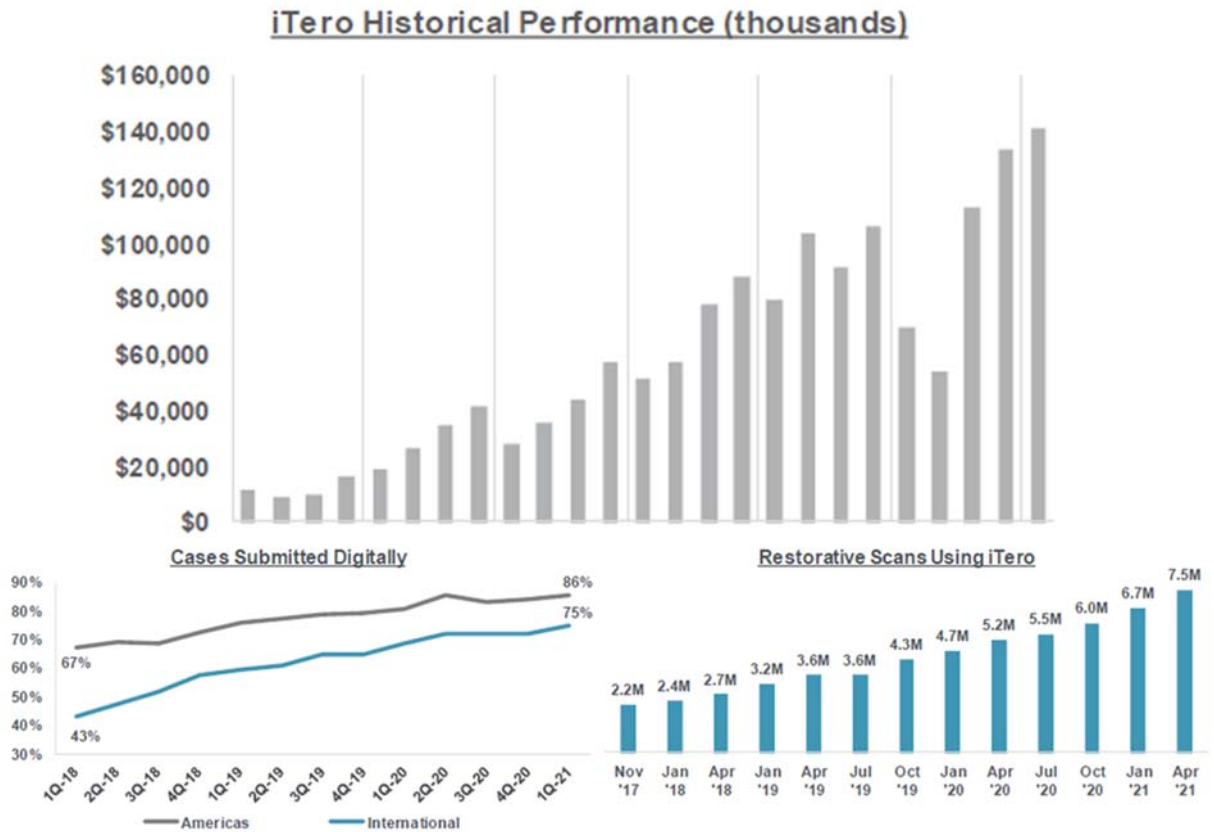
⁷ For reasons discussed in more detail below, while certain other scanners can be used to order clear aligners, including Invisalign aligners, these are not viable substitute for the iTero or Trios scanners because they are not well suited to provide full mouth scans for aligner orders—and are in fact rarely used by providers for this purpose.

50. An example of an iTero scanner is pictured below:



51. The iTero scanner is highly profitable, with profit margins above 60 percent. A May 2021 market analysis estimates the iTero install base at approximately 35,000.⁸ Meanwhile, Align has steadily increased the number of iTero units sold and number of restorative scans performed using iTeros as digital case submission increasingly becomes the norm—part of what one recent market analysis characterizes as “the megatrend towards digital dentistry workflows”:

⁸ A separate analysis notes that while iTero sales “were weak until 2015,” they have grown at a compound annual growth rate of 32% between 2016 and 2020.



52. Although there are new entrants to the scanner market (discussed *infra*), Align’s only real competitor in this market is 3Shape, which sells the Trios. The Trios, like iTero, is designed for ordering multiple brands of aligners.

53. Because of its dominance and consumer brand awareness, Invisalign is a “must have” for dental practices that offer aligner treatment to patients. When a patient seeks Invisalign treatment, that patient would visit a dental practice authorized by Align to prescribe the treatment. A dentist or staff member would then normally perform a scan of the patient’s jaws, teeth, and bite using a scanner, and the dentist would review the scan. If the dentist determines that Invisalign treatment is appropriate, the dental practice will then purchase a set of custom-made Invisalign aligners directly from Defendant for that patient’s treatment.

54. Align knew that the use of digital scanners, like iTero, would make it more likely that a dental practice would use aligners—because of the scanner’s design and “digital workflow,” because it provides a more accurate impression of a patient’s jaws, teeth, and bite for the improved design of that patient’s aligners, and because once a dental practice makes a large investment in a

digital scanner, that practice would be more likely to order more aligners as a way to pay for the scanner. In addition, as described below, dental practices are able to access non-penalty pricing on aligners as the number of Invisalign orders increases, thus making scanners—and in particular ones that can be used to order Invisalign—a critical piece of a dental practice’s business.

55. The primary focus of Align is selling more aligners at extremely high profit margins. As Align’s CEO, Joe Hogan, stated in a July 2017 investor call, “[W]e’re in the clear aligner business and anything that help us to sell more clear aligners directly . . . would be in our . . . range. So, that’s why we have a scanner business. We have a scanner business not from a diversification standpoint. We have a scanner business because it allows us to sell more clear aligners.”

56. The bottom line was (and is) that more iTero scanners equal more Invisalign orders for Align. As Hogan told investors in an April 2018 call, “So yeah, [iTero] is another component of growth in the company overall. What’s great is it’s synergistic growth, right. You have equipment growth, but it really leads to the growth of our core product line which is Invisalign.” And as Hogan reminded Wall Street analysts when discussing scanner sales in an October 2018 investor call: “[R]emember, it’s just a wonderful footprint for us for future Invisalign business once we have those scanners in place.” Most recently, during a June 2021 call, Align’s CFO, John Morici, emphasized: “[W]e know having an iTero at a doctor's office is going to drive more Invisalign sales. We see that lift within. So, great stand-alone business, very profitable. But the added synergies that we get from both iTero and Invisalign is significant.”

57. Align’s strategy is working: not only have iTero sales increased consistently since 2016 (specifically, at an average rate of 32% between 2016 and 2020), but the number of scans performed digitally—already an overwhelming majority of the total—continues to increase as well. On an April 2021 call, Hogan stated:

In terms of digital scans used for Invisalign case submissions in Q1, total digital scans increased to 80.9% from 75.8% in Q1 last year. International scans increased to 75.1%, up from 68.7% in the same quarter last year. For the Americas, 85.5% of the cases submitted digitally compared to 80.5% a year ago. Cumulatively, over 35.4 million orthodontic scans and 7.5 million restorative scans have been performed with iTero scanners.

58. With this dominance have come consistently extraordinary profits: in the fourth quarter of 2020, for instance, Align reported record sales of \$834 million, including \$700.7 million in aligner revenues and \$133.8 million in “Imaging Systems” and “CAD/CAM Services revenues” – year-over-year increases of 28.9% and 26.0%, respectively.⁹

59. The fact that competitor scanners make it easier to order aligners *could* have spelled trouble for Align’s market dominance in the aligner market *if* the two available scanners, the iTero and Trios, were able to send scans to any aligner manufacturer. Then dental practices could have offered Invisalign and competing aligners on equal footing, which would have engendered competition among aligner manufacturers that would have lowered prices and/or improved quality or innovation. Indeed, Trios is such an “open” platform—as a technological matter, Trios can be used to order aligners from a wide range of manufacturers, including competitor Sirona (which recently unveiled its own Primescan intraoral scanner and clear aligner brand, “SureSmile”). But Align has created a “closed” system for iTero, which limits the ability of dental practices to use it to order competing aligners. And Align has imposed contractual commitments to limit access to Trios and competing aligners and—after 3Shape refused Align’s demand to send scans for aligner orders only to Align—terminated the highly profitable Interoperability Agreement with 3Shape, all to create a bulwark to defend Invisalign from competition.

60. Thus, for Align, monopolizing the scanner market was not just about increasing price (and profits) in the scanner market—which it did—but also about maintaining its monopoly power in the aligner market, and thereby maintaining its supracompetitive prices and profits on aligners.

B. The expiration of Align’s intellectual property exposed it to competition

61. Defendant held hundreds of patents on its aligner technology. These patents, along with other high barriers to entry, largely deterred entrants into the aligner market until recently. Align has aggressively wielded those patents as well, filing patent and trade proceedings against potential competitors in the aligner market as necessary to maintain its monopoly position.

⁹ See <https://www.streetwisereports.com/article/2021/02/04/align-technology-shares-grind-12-5-higher-after-firm-posts-record-q4-revenue-of-834-5-million.html>.

62. Meanwhile, the Invisalign brand has become synonymous with aligners generally. As a result, dental practices engaged in the business of straightening teeth must carry Invisalign to satisfy the demands of customers. And as described below, for those dental practices who want to offer Invisalign, Align has essentially made it impossible to offer competing aligners or to use scanners that compete with Align's iTero.

63. Align's monopoly started to come under heightened threat beginning in 2017, due to the expiration of many of its key patents. Having enjoyed years of operating without "the outside influence of other competitors coming in," as patent expiry loomed, Align changed its message to investors from reliance on the patents to protect its monopoly, to concern that "[w]hen patents expires, we lose the protection and competitive advantages they provided to us, which could negatively impact . . . operating results." But instead of competing on the merits of its products and its pricing, Align responded to the emerging threat of competition by implementing the Scheme, described in detail below, to use its monopoly power in both the aligner and scanner markets to maintain and/or increase its monopoly power in each market and continue to charge supracompetitive prices for both aligners and scanners.

C. Align implemented a closed system of scanners and aligners that would protect its monopolies in the respective markets

64. One piece of the bulwark protecting Align's monopoly power is Align's "closed system" design of its scanner and aligner technology. For example, iTero is the only scanner with integration into the Align treatment system, including Align's "Invisalign Outcome Simulator." Because of the way iTero is integrated into the "digital workflow" a dental practice would use to order Invisalign, Align knew that placing its scanners in dental practices was going to drive those dental practices to use Invisalign exclusively.

65. Second, iTero is intentionally designed in such a way that it is expensive, inefficient, and impracticable to use it to order non-Invisalign aligners. For example, iTero does not create scans in the standard file format used by other aligner manufacturers, and thus, a dental practice wishing to order non-Invisalign aligners using iTero scans must either undertake an expensive and time-consuming process of converting iTero scans to a format that can be used for other aligners, or use

silicone-based molds to create a cast of a patient’s mouth and teeth, which is a messy, uncomfortable for the patient, time-consuming, and inefficient method. By contrast, 3Shape’s Trios scanner uses standard file formats and cloud technology to work with numerous aligner brands, including Invisalign (prior to Align’s termination of 3Shape’s Interoperability Agreement) and Sirona’s “SureSmile” aligners.¹⁰ For this reason, Trios represented a breach in Align’s bulwark protecting Invisalign from competition.

66. Third, Align intentionally does not accept scans from any scanner for Invisalign orders, but rather, only allows Invisalign orders from a limited group of authorized scanners. Until the termination of Align’s Interoperability Agreement with 3Shape, discussed below, the Trios scanner was one such authorized scanner.

67. Upon information and belief, Align has only allowed interoperability for scanners that are not designed for ordering aligners, that do not compete with iTero in the scanner market, and that do not represent a threat to Align’s dominance of the aligner market. According to 3Shape, at the Greater New York dental meeting in November 2017, Align executive Raphael Pascaud communicated to 3Shape that Align will no longer validate any non-iTero intraoral scanner for use with Invisalign. Given that Invisalign orders are highly profitable for Align, this decision by Align terminated a previously highly profitable course of conduct for Align for the sole reason of furthering Align’s exclusionary conduct.

68. For example, while Sirona Dental Systems (“Sirona”) launched “Primescan,” a new scanner that has a digital workflow to create Sirona’s SureSmile aligners, in early 2019,¹¹ Align has

¹⁰ Indeed, 3Shape and Sirona recently announced a partnership, as part of which Trios scanners will be more fully integrated into the SureSmile aligner order flow. *See* <https://www.3shape.com/en/press/2021/3shape-and-dentsply-sirona-announce-strategic-partnership> (“In the immediate term, the partnership will focus on a collaboration for better access of TRIOS users to SureSmile Clear Aligners. Opening the platforms to the 3Shape system allows dental professionals to benefit from greater choices, more flexibility, and smoother workflows in the future.”).

¹¹ *See Dentsply Sirona unveils new high-precision intra-oral scanner Primescan*, Dental Tribune (Feb. 4, 2019), available at <https://www.dental-tribune.com/c/dentsply-sirona/news/dentsply-sirona-unveils-new-high-precision-primescan-intra-oral-scanner/>.

not extended Invisalign interoperability to Primescan. Nor is Primescan qualified for Invisalign case submissions. Thus, Primescan cannot be used to send scans to Align.

69. In addition, on information and belief, while Align has interoperability agreements for ordering Invisalign cases with two other intraoral scanners—Midmark True Definition (formerly known as the 3M True Definition, hereafter “MTD”) and the Sirona CEREC Omnicam (hereafter “CEREC”)—neither agreement fosters an open ecosystem for ordering aligners that could meaningfully erode Align’s aligner dominance, nor were they intended to have that effect.¹²

70. Instead, on information and belief, Align entered into (and has maintained) interoperability with MTD and CEREC in order to access dental networks that use these intraoral scanners for restorative and other non-orthodontic applications (like crowns and bridges), rather than for aligner scans. The MTD and the CEREC scanners are not viable substitutes for the iTero or Trios scanners because neither scanner is well suited to provide full mouth scans for aligner orders. Neither the MTD nor the CEREC scanners are viable options for dental professionals seeking to send digital scans for Clear aligners.

71. More broadly, the iTero and 3Shape scanners occupy a unique and rapidly growing market segment for so-called “DI” (dental impression) scanners, which are used to generate dental impressions—and are thus distinct from so-called “full CAD/CAM” (computer-aided design & computer-aided manufacturing) scanners, which dentists use for a wider array of procedures. DI scanners appeal to dentists and orthodontists because they are considerably cheaper (often between \$25,000-40,000 for a DI unit vs. \$130,000 for a full CAD/CAM unit), used for specialized applications, and typically have quicker innovation cycles.¹³ A June 2020 research note estimates

¹² For example, a 2019 survey of dental professionals conducted by Credit Suisse found that Sirona’s Omnicam (CEREC) “was utilized by only 5% of the population (10% of digital impression users vs. 15% in 4Q), demonstrating still low penetration of XRAY’s most established [dental impression] offering[.]”

¹³ For example, a July 2019 survey by Credit Suisse states:

Sirona has chosen to forego its longstanding steadfast approach to promoting more comprehensive chairside CAD/CAM systems (scanner + mill). As of March 2018, it began an initiative geared more toward standalone digital impression, with also a dedicated lab strategy, where it has been lacking. At the Chicago Midwinter Show (Feb 21-23), XRAY launched its Primescan offering, its most meaningful product

that the global DI scanner market “was likely growing at a double-digit clip exiting 2019,” and estimates its size at between \$600 and \$700 million.¹⁴

72. Thus, DI scanners are essential for dental practices to offer and sell aligners (particularly Invisalign) to their patients, and dental practices typically do not purchase more than one scanner due to the expense. In the case where a dental practice buys more than one scanner, that practice nonetheless would tend to use only one *brand* of scanner due to the cost of maintaining multiple software subscriptions and the time and expense to train personnel to use different scanners and software programs. And like most such capital investments, a scanner is meant to last several years.¹⁵

73. Thus, the iTero scanner and Invisalign operate as a *de facto* product bundle by (a) making iTero the only viable option for dental practices seeking to sell the market-dominant Invisalign to their patients, and (b) preventing other scanners from becoming established in the market that would allow dentists to order competing aligners without undue burden. Indeed, an October 2018 research note emphasizes how iTero scanners drive Invisalign utilization and create barriers to entry for potential competition:

DSOs Meaningfully Scale iTero and Thus Invisalign; Huge Competitive Barrier as Well. We continue to write about how not only is iTero important from a revenue perspective but also as a driver

launch this year. Primescan is an open system that can connect with all labs, an important difference from its legacy Omnicam offering, with which data transfer to labs was a cumbersome process as it predominately promoted chairside systems. While it technically offered Omnicam for standalone digital impression, penetration was extremely low, with its salesforce not aligned with this strategy. However, we view XRAY is meaningfully better positioned to penetrate the digital impression and chairside markets with the Primescan launch, which should also offer the company a fresh approach to the market, more aligned with broader market demand trends.

¹⁴ While the MTD is a DI scanner, it is primarily used for scanning individual teeth for crowns and similar local dental restorative work—and not for comprehensive, full-mouth orthodontic treatments. It takes significantly longer to scan a patient’s entire mouth with a MTD or CEREC scanner than with a Trios or iTero scanner.

¹⁵ Indeed, the iTero website features a “ROI calculator” that prospective buyers can use to calculate the cost of scanner ownership over 1- and 5-year intervals. See <https://euitero-calc-prd-eu.herokuapp.com/na/total-cost-ownership>. For the iTero “Element” scanner, Align estimates the first-year cost of ownership at \$34,112 (\$33,000 for the scanner itself and an estimated \$1,112 for “scanner sleeves,” with a free year of subscription service), and the five year cost of ownership at \$55,840 (\$33,000 for the scanner, \$5,560 for sleeves, and \$17,280 in subscription fees – or approximately \$360 a month after the first year).

of Invisalign utilization, with a study showing Invisalign volumes increase 20% in the first year of introduction. That said, iTero is still <20% penetrated into the Invisalign customer base and <10% into GPs. While speculative, we estimate the Aspen agreement¹⁶ will contribute ~40M in revenue in '19 or ~200 bps to growth . . . so the North America business could surprise as a result. Importantly, given DSOs tend to use the same providers for equipment/supplies across all their practices, additional DSO agreements are significant barriers to entry for competition.

74. In order to cause the vast majority of dental practices to have long-term dependence on both the iTero scanner and Invisalign aligners, Align has engaged in the anticompetitive Scheme to entrench its monopoly power in the aligner and scanner markets.

D. Align terminated its interoperability agreement with 3Shape, sacrificing short-term profits in order to gain long term profits from the anticompetitive effects of its refusal to deal.

75. 3Shape has been selling the Trios scanner internationally since 2011, and in the United States since 2012. Unlike Align's iTero, the Trios can send scans to any manufacturer of aligners without any fees, delays, conversion process, or loss of image resolution. This was an advantage to Trios customers because it allowed for choice of aligners and would have benefitted dental practices had other aligner manufacturers been able to compete with Invisalign on the merits with lower prices and/or better quality for aligners.

76. Indeed, Align's then-Chief Operating Officer told industry analysts in an April 23, 2015 investor call (when its aligner market dominance was protected by patents), such open systems:

are better for our customers. No one wants to have to redesign, start over, buy multiple pieces of equipment if they can have greatest utility from a scanner. . . . So, we believe what we hear from our customers is they don't want to be forced to buy a system from you for the pleasure of offering Invisalign to their patients and other therapies we may have down the road. So we feel actually very strongly. . . . There's no reason for us not to act in complementary ways because it's good for the customer. So in our minds, we don't need to own the channel. we don't need to have exclusivity. *In fact, we want probably more high-quality scanners that can make it easier to do Invisalign and other chair-side procedures that we have the unique capabilities to fulfill.*

¹⁶ As discussed in more detail below, on July 25, 2018, Align announced that it had also secured a deal with Aspen Dental, another of the nation's largest dental service organizations ("DSOs") with nearly 700 locations (and approximately 750 dentists), to equip all Aspen locations with iTero scanners.

77. In December 2015, Align and 3Shape entered into the Interoperability Agreement, under which the parties worked together to build an interface so that dental professionals could send Trios scans into Align’s Invisalign workflow. According to 3Shape, Align executive Raphael Pascaud testified in prior litigation that Align had entered into this Interoperability Agreement to increase aligner sales, including from dental practices that were already using the Trios scanner.

78. But even as Align was preparing to enter into the Interoperability Agreement, according to 3Shape, Align was seeking to change the terms of its relationship with 3Shape by proposing an agreement whereby 3Shape would agree to make its Trios scanners send scans *exclusively* to Align for Invisalign aligners. Align also did not want 3Shape to promote or offer alternative software capable of staging treatments from non-Invisalign aligners. Align knew that 3Shape’s open system and popularity represented a breach in the bulwark it had erected around Invisalign, and thus, the purpose of this proposed exclusive arrangement was for Align to impair other aligner manufacturers.

79. 3Shape refused to make the Trios exclusive to Align, as Align had asked. Instead, 3Shape sought to continue to allow the Trios to send scans to any aligner manufacturer in the interests of open competition. 3Shape wanted to maintain 3Shape’s relationships with other aligner manufacturers, as well as to allow 3Shape to develop its own software to compete with Align. The Interoperability Agreement ultimately permitted 3Shape to provide scans to other aligner manufacturers as well as to continue to promote and offer its own software.

80. According to 3Shape, shortly after the Interoperability Agreement was signed, Align began again to seek to change the terms. In a February 2016 meeting, attended by top Align executives, Align made clear that as part of any further collaboration between the companies, 3Shape would need to treat Invisalign as the “preferred partner” for aligners. In a November 2016 meeting, Align asked 3Shape to enter into a joint venture that would allow Align to control Trios. 3Shape again refused.

81. According to 3Shape, throughout 2017, including at the International Dental Show in March 2017, Align executive Raphael Pascaud continued to demand that 3Shape agree to the joint venture that would exclude Invisalign competitors. During this time, 3Shape has alleged that it heard from resellers and distributors that Align had threatened that it would end interoperability with Trios.

82. On December 20, 2017, Align announced that it would terminate the Interoperability Agreement with 3Shape as of January 17, 2018, and the Trios would no longer be able to submit scans for Invisalign.

83. After many dental practices and the American Association of Orthodontists expressed dismay at the termination, Align extended the date of termination to January 31, 2018, and then terminated the Interoperability Agreement on that date, making Trios scanners no longer capable of ordering Invisalign.

84. This termination represented a sacrifice of revenue for Align, and it was economically irrational but for the market exclusion this profit sacrifice created. Indeed, according to 3Shape, Align had profited from the interoperability agreement with 3Shape that allowed Trios users to order Invisalign, and in fact received 40,000 Invisalign orders from Trios in the United States between October 2016 and January 2018. Upon information and belief, at an estimated consumer price of \$3,000 to \$8,000 per treatment with high profit margins, Align's termination of the interoperability agreement represented a profit sacrifice of many millions of dollars.

85. Because Align has not blocked Trios users outside of the United States from ordering its aligners, there are approximately 23,000 Invisalign orders per month from those Trios users, which is nearly 40 percent of all Invisalign global submissions to Align. Align sacrificed profits in the short run by refusing to allow the Trios or other potential scanners to order Invisalign in the United States, and Align engaged in this conduct solely to make the iTero the only viable scanner for dental professionals in the United States to purchase and use, which would allow it to enhance its monopoly power in the scanner market, and would allow it to maintain its monopoly power in the aligner market.

86. Although the Interoperability Agreement extends beyond the United States, Align terminated interoperability only with respect to the United States. In the rest of the world, where Align has a materially lower aligner market share, Align has continued to accept scans from the Trios scanner because it cannot effectively force customers to use iTero by threatening to withhold access to Invisalign, and because Align profits from interoperability there just as it did when Trios interoperability existed in the United States.

87. Interoperability had also been a benefit to dental practices who had increased choice of scanners and aligners, and who would have benefitted from increased competition in the form of lower prices but for Align’s conduct. Upon termination of the Interoperability Agreement, those dental practices with Trios scanners were forced either to quit offering Invisalign to patients (and many of those patients were in the middle of multi-month treatment programs with Invisalign), to order a new scanner (despite having spent thousands or tens of thousands of dollars on a Trios, which many dental practices find to be a superior scanner), or to go back to using silicone-based molds. According to 3Shape, for American dental practices seeking to order Invisalign aligners, termination of interoperability in the United States made the Trios “basically a paperweight,” as one dental professional complained.

88. In short, Align was willing to forego short-term profits on its aligners (from Trios owners ordering Invisalign), and to sacrifice customer goodwill, in order to engage in the anticompetitive Scheme described herein and thereby further its dominance in the aligner and scanner markets. By gaining and/or maintaining its monopoly power in the aligner and scanner markets, and foreclosing competition in both markets, Align would profit far more than it lost by terminating the Interoperability Agreement, all at the expense of Align’s customers.

E. Align signed exclusive dealing contracts with dental service organizations to entrench its monopoly power.

89. Beginning in mid-2018, Align entered into multiyear contracts with the two largest dental service organizations (“DSOs”) in the country, Heartland Dental and Aspen Dental, that effectively exclude 3Shape from their members’ dental offices. DSOs provide business support to independent dental practices, including by managing purchasing contracts with suppliers. Align has reported that DSOs – whose members are bound by the purchase decisions of the DSO – are an important “strategic part of [Align’s] overall strategy,” are a “force multiplier” for Align, and were a significant factor in Align’s 2018 “[r]ecord Q4 volumes [of sales].”

90. In line with its “Fusion Program,” described below, Align dramatically dropped the price of the iTero to major DSOs in exchange for multi-year Invisalign order commitments. Those commitments could practicably be achieved only if a DSO sent aligner scans exclusively to Align, and

not to its aligner competitors. As a result, sales of iTero scanners to DSOs increased dramatically, and sales of Invisalign were accordingly higher than they would have been absent these agreements.

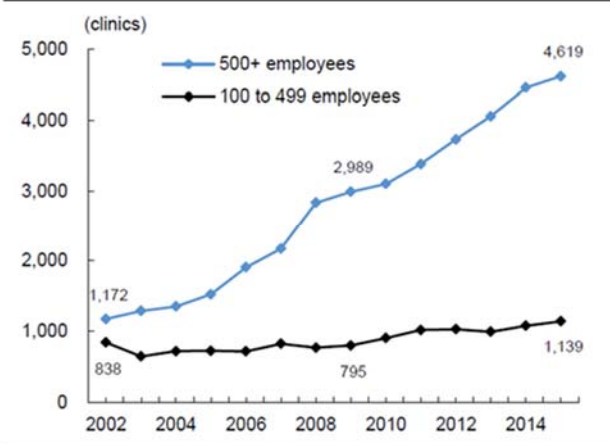
91. On July 25, 2018, Align announced a multi-year deal with Heartland Dental, the nation's largest DSO with more than 850 supported dental offices (and approximately 1,300 dentists) across 35 states, to place iTero scanners in member dental offices under a timeline that would place iTero in 90 percent of supported offices nationwide by the end of the year. As a result of the deal, Heartland Dental purchased 900 iTero scanners in 2018. The Heartland "endeavor represent[ed] the industry's single-largest scanner deployment." And as with Align's overall efforts to use iTero to lock practices into Invisalign, Heartland's "front-loading their businesses with iTero" will, in turn, "give them a very strong position in clear aligners."

92. On July 25, 2018, Align announced that it had also secured a deal with Aspen Dental, the nation's second largest DSOs with nearly 700 locations (and approximately 750 dentists) across 38 states, to equip all Aspen locations with iTero scanners.

93. 3Shape has stated that it bid for the Aspen Dental contract, and its Trios scanner scored the highest in Aspen Dental's evaluations, but Aspen Dental informed 3Shape that Aspen Dental did not select the Trios scanner because Align did not permit the Trios to interoperate with Invisalign. In other words, because of Align's dominant position in the aligner market, Aspen Dental was forced to select Align's less desirable iTero scanner.

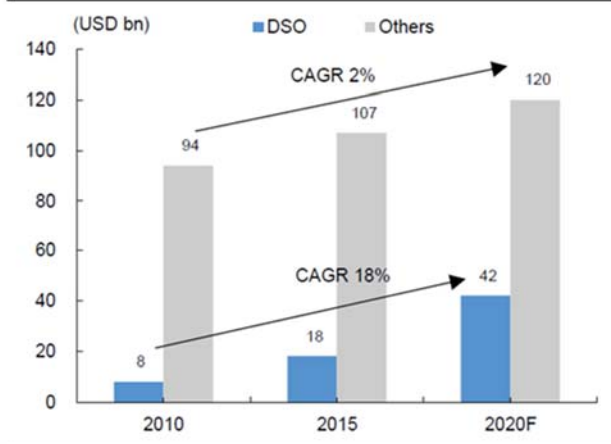
94. DSOs represent a large and growing part of the dental market in the United States. According to an October 2018 research note, DSOs then accounted for approximately 20% of the US dental market (and counted 8% of US dentists as members), a figure expected to grow given the superior profitability of DSOs. A separate September 2019 analysis of the digital dentistry market estimates that DSOs then made up 16% of the US dental care market and estimated that this figure would climb to 30% by 2021, noting a rapid trend in the market towards consolidation "aided by investment from private funds and M&A deals":

Figure 45. Large dental offices on the upswing



Source: Morgan Stanley, Korea Investment & Securities

Figure 46. DSOs feature brisk growth



Source: Align Technology, Korea Investment & Securities

95. Most recently, in June 2021, Align’s CFO estimated that DSOs now make up between 20% and 25% of “overall dentistry.”

96. These DSO contracts have enabled Align to rapidly increase its market share in the scanner market and, because of Align’s conduct as alleged herein, to use its increased monopoly power in the scanner market to maintain and enhance its monopoly power in the aligner market. Align reported an 84 percent growth in its scanner sales in North America in the first quarter of 2018. And in Q3 2018, Align saw “strong volume growth from the Dental Service Organizations (DSOs) channel which increased over 40% Y/Y in Q3.”

97. Align employees speak openly about the strategic (and synergistic) value of these DSO contracts. During a Q1 2021 earnings call, Align CEO Joe Hogan emphasized the importance of Align’s DSO partnerships as a “digital platform strategy” and driver of iTero adoption:

Q: One last one for me, just on the DSO, kind of the business model and strategy that you guys have for entrenching iTero systems in DSOs across all practices, kind of how do you approach that? And when you do see DSOs, where the large majority of their practices have adopt the iTero scanner, what's the sort of pickup that you guys see in terms of utilization? Thanks so much.

Hogan: Well, where you use iTero scanners, you train the doctors properly. You have the right products in the GP channel like iGo and different products like that. We get terrific uptake. I mean, you can’t measure it the way you do share a chair from orthodontic office. *But our DSO business is significant now. It’s meaningful in that way. And it’s one where that digital platform strategy, as you kind of outlined in your question, is what we employ.* But again, we employ it in different ways, depending on how a DSO really wants to engage with us.

98. Most recently, during a June 2021 call, Align's CFO explained:

Q: Got it. Okay. I just got a good question from the audience. I'll just throw that out now, which is talk about how your DSO relationships are working, have they evolved over time? And to be blunt, how are you trying to sort of counter the threat of alternatives, particularly sort of lower-cost alternatives coming into some of these higher-volume customers?

John F. Morici: Well, I think DSOs are something that's happening within the industry. I mean, some of these dental practices consolidate and companies going to consolidate these practices. And it's just a way of life within this industry. And for us, when we think about the benefits that this bring, our system, our platform, the way we want doctors to go-to-market is perfect for DSOs. You think about ADAPT is kind of individual practices. DSOs are ADAPT kind of on steroids from the standpoint that you sell into a DSO you're selling, many times you have an iTero that purchase and they purchase for their doctors. It's the platform that they're buying into; the digital platform that we have, the visualization, the training that goes in, the marketing that we do and all the local marketing that they do. It's a very good combination. And remember, a lot of these DSOs, they're private equity owned; they're all about return on investment, return on capital. And we can prove to them. And why we see success with those DSOs is they're seeing the returns. They're seeing the benefits.

And when we look at DSOs, I think sometimes it gets lost or makes the headline is, oh, that's at a lower price, it's a lower ASP. Don't think of it that way. Think of it as from a gross margin standpoint, it's very efficient for us to serve those customers. And certainly, from an up margin standpoint, it's also efficient where we get the economies of scale. Some of these DSOs are 500, 700 practices. And we get some economies when we help with training, with marketing, with other go-to-market activities that we don't have to spend, they're spending locally there. So, it's the way the industry is going. And we're definitely a part of that. But it really plays into our digital story, our digital conversion that we're trying to bring to this market, and DSOs are a way to do that.

F. Align's "Fusion Program" tied together iTero links, iTero prices and Invisalign sales.

99. In late 2017, as patent expiry loomed, Align launched the Fusion Program, a bundled pricing mechanism for iTero that further entrenched its dominance in the aligner and scanner markets.

100. Upon information and belief, under the Fusion Program, the price of the iTero scanner depended on a dental practice's purchases of Invisalign. Failure to meet a minimum threshold of Invisalign cases each year for a three-year period resulted in substantial annual back-end penalties.

Align set these targets in a manner that forced the dental practices either to stop sending cases to Align's aligner competitors or trigger the substantial penalties.

101. The penalties could total \$10,000 over three years, or 30 percent or more of the cost of the iTero scanner (approximately \$33,000 for the current iteration of the iTero, according to a pricing calculator available on Align's website, *see supra* note 15). A dental practice that incurred these penalties would be at a substantial disadvantage to other dental practices that avoided these penalties. Given Align's dominant position in the market for aligners, dental practices that wanted to offer aligner treatment could not forego Invisalign orders entirely.

102. The effect of Align bundling its scanner with its market dominant aligners is that dental practices are substantially foreclosed from ordering aligners from Align's rivals. Indeed, according to 3Shape, experts have described the Fusion Program as "a not-so-subtle effort on the part of management to lock these customers in for a fairly long time, in our view, just as Clear aligner competition is likely set to rise over the next 3-6+ months."

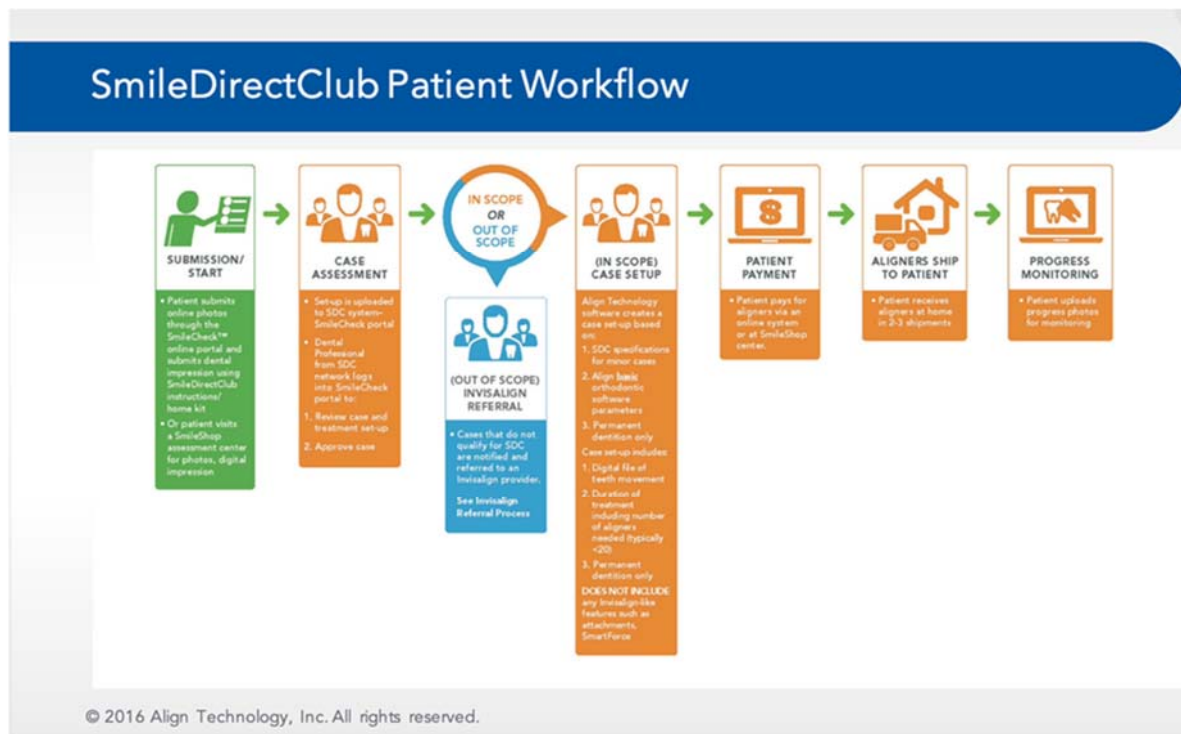
103. Absent the bundled pricing, the Trios and iTero scanners were sold at similar list prices. In the bundle, however, the effective price of the iTero (when incorporating the incentives for effectively agreeing not to purchase aligners from Align's competitors) was \$10,000 cheaper (as reflected in the penalty provisions of the program)—a discount of approximately 30% off the iTero's current sticker price of \$33,000.¹⁷ According to 3Shape, dropping the Trios price to offset the penalties on such sales would represent a loss of a third of the Trios scanner revenue, yet Align could make up the lost revenue with the sales of just a few cases of Invisalign per iTero scanner.

G. At the same time it was monopolizing the scanner market, Align entered into a set of anticompetitive agreements with SmileDirectClub that allocated the direct-to-consumer submarket (to SDC) and dentist-directed submarket (to Align).

104. SmileDirectClub ("SDC") is a teledentistry company founded in 2014 whose primary business is selling clear aligners directly to consumers. SmileDirectClub was a pioneer in the business of selling clear aligners directly to consumers. To order aligners from SDC, a person can

¹⁷ See <https://euitero-calc-prd-eu.herokuapp.com/na/total-cost-ownership> (last accessed June 22, 2021).

either visit an SDC “SmileShop” (a physical retail space) for an intraoral scan or use an at-home kit to create an impression. A 3D image of that person’s teeth is sent for review by an orthodontist or dentist, who also approves a customized treatment plan if the treatment is simple enough. After the treatment plan is approved, SDC ships its aligners directly to the customer.¹⁸ A customer using SmileDirectClub could conceivably go through the entire process of straightening their teeth without ever once having met with an orthodontist. The SmileDirectClub process is visualized below:¹⁹



105. SDC’s do-it-yourself approach is a significant departure from Align’s dentist-directed aligner offering. In 2016, Align CEO Joe Hogan explicitly assured Invisalign providers that SDC’s offering “is not Invisalign . . . What can be accomplished with SmileDirectClub aligners and protocols is not the same or equal to what doctors can accomplish with Invisalign aligners, features, and protocols.”²⁰ One analyst concurred, stating, “To be clear, this SDC product is a very simple

¹⁸ See https://smiledirectclub.com/how_it_works/.

¹⁹ Company Presentation, Financial Results Q2 2016 (July 28, 2016).

²⁰ Dr. Ben Burris’ Blog (July 28, 2016), available at <https://orthopundit.com/align-announces-supply-agreement-smiledirectclub/>.

aligner that does not have access to SmartTrack, SmartStage, or any other piece that elevates the Invisalign brand.”²¹

106. As discussed in more detail below, the product submarket for selling aligners directly to consumers is generally distinct from—and overlaps little with—the product submarket for selling aligners to dentists. Thus, these two submarkets each constitute distinct relevant product markets. SmileDirectClub has consistently held significant market share in the discrete product submarket of aligners sold directly to consumers. For example, a 2019 report by Jeffries, an investment bank, stated that Smile Direct Club had “pioneered the multi-billion dollar DTC (direct-to-consumer) clear aligner market and has maintained 90%+ market share.”

107. As explained above, Align has often filed lawsuits, including patent infringement lawsuits, against potential competitors in the aligner market who threaten Align’s dominance. Consistent with this pattern, in 2015, just one year after SDC was founded, Align filed a patent infringement lawsuit against SDC (then operating as SmileCareClub LLC), alleging that SmileCareClub infringed fourteen Align patents related to the manufacture and sale of SmileCareClub’s clear aligners, and that SmileCareClub, deliberately deceived and confused patients and unfairly competed with Align by making false and unsupported claims regarding the safety and effectiveness of SmileCareClub’s products (which are offered without any direct in-person contact with a dental professional).²² In an accompanying press release, Roger E. George, Align’s vice president and general counsel, stated:

Doctors play a necessary and integral role in any orthodontic treatment process, starting with a diagnosis and treatment prescription based on an in-person examination of the patient. This critical role continues with in-person consultations throughout treatment as the doctor monitors the patient's dental health and treatment progress. The SmileCareClub do-it-at-home system lacks this critical oversight and entirely eliminates the doctor’s role in treatment. It instead replaces the doctor with an unknown email address and no actual patient contact, thus impairing the ability to accurately diagnose and care for the patient during treatment.²³

²¹ Align Technology Company Note, Piper Jaffray (July 28, 2016).

²² See Complaint, *Align Techs. v. SmileCareClub et al.*, No. 15-cv-4864 (N.D. Ca., Oct. 22, 2015).

²³ See Align Press Release (Oct. 22, 2015), available at <https://investor.aligntech.com/news-releases/news-release-details/align-technology-files-patent-infringement-and-false-advertising>.

108. In July 2016, Align and SmileDirectClub entered into a simultaneous set of agreements that resolved the patent litigation and effectively allocated the aligner market between the two companies. Specifically, the effect of these agreements was to allocate the direct-to-consumer submarket to SDC, and the dentist-directed submarket to Align. The existence of this Scheme is evidenced by (1) the plain text of the parties' agreements; (2) subsequent litigation between the parties; and (3) a press release by SDC containing public statements from SDC's co-founder that the agreements "obligated" SDC to "stay" in the direct-to-consumer channel.

109. The agreements contained three main components: 1) Align purchased 17% of SDC for \$46.7 million and obtained a seat on SDC's board of directors; 2) Align and SDC entered into an operating agreement ("Operating Agreement") that placed restrictive covenants on Align competing in the direct-to-consumer channel; 3) Align and SDC entered into a supply agreement ("Supply Agreement") that lasted until December 31, 2019 and contained a number of specific restraints that restricted competition between Align and SmileDirectClub. The overall effect of these agreements was to restrain competition, allocate the two product submarkets, and further Align's monopolization of the dental product submarket.

110. As part of the Operating Agreement, Align purchased a 17% ownership stake in SDC. For purposes of the Operating Agreement, Align, as well as other owners of SDC, were defined as members of SDC Financial, LLC, the newly formed holding company for SDC. The Operating Agreement contained an extensive set of Restrictive Covenants that restricted members, including Align, from competing with SDC. In particular, the Agreement provided that no member could

[REDACTED]

[REDACTED]

111. Thus, on its clear terms, the Operating Agreement allowed Align to obtain an ownership interest in SDC, and in exchange, Align agreed not to compete in the direct-to-consumer product submarket.

112. At the same time they entered into the Operating Agreement, Align and SDC entered into a Supply Agreement. The Supply Agreement contained a number of restraints that restricted competition between the two competitors, effectively allocating the direct-to-consumer aligner submarket to SDC and strengthening Align’s monopoly in the dental office aligner submarket.

113. [REDACTED]

114. [REDACTED]

115. [REDACTED]

[REDACTED]

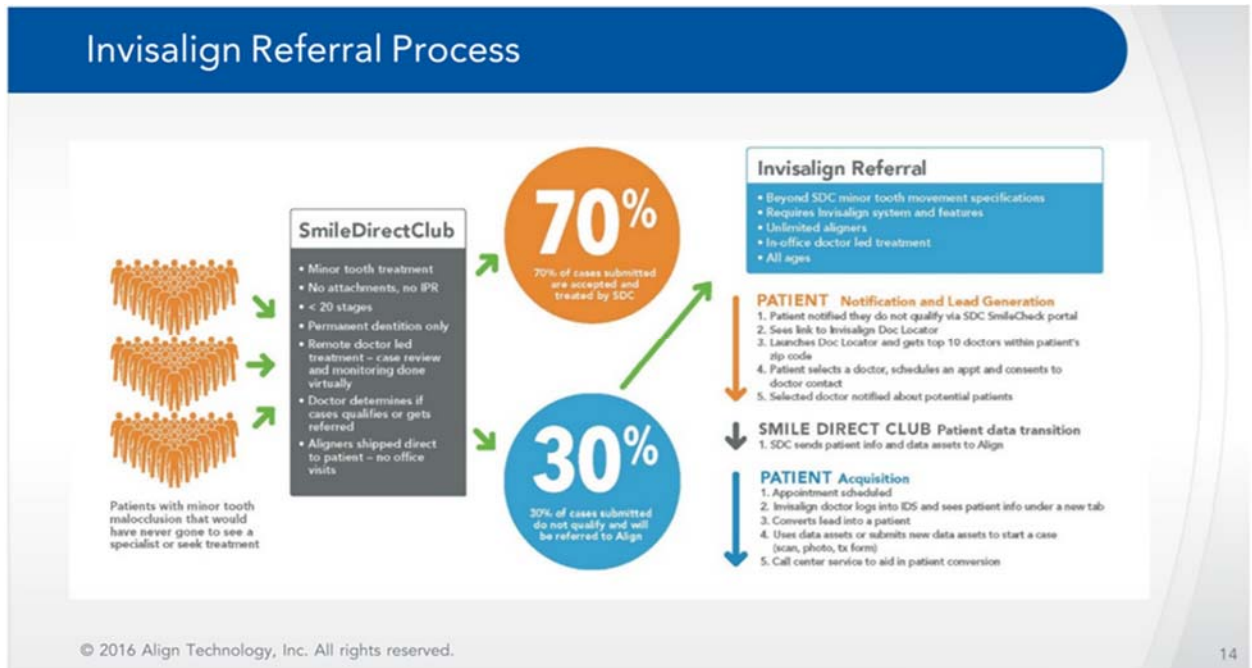
116. [REDACTED]

[REDACTED]

117. [REDACTED]

[REDACTED]

118. On a July 28, 2016 quarterly earnings presentation, Align emphasized the importance of this referral provision, stating that the 30% of SDC case submissions that do not qualify for SDC submission will be referred to Align.



119. On that same July 28, 2016 earnings call, Align’s CEO, Joseph Hogan, stated that he anticipated that under the new program, SDC would “systematically refer the approximately 30 percent of SmileDirectClub’s SMILECHECK case assessments that are too complex for their minor tooth movement product, to Invisalign providers in the patient's local area.”²⁴ Hogan assured concerned investors in an earnings call that “[W]e keep the Invisalign products . . . all the pieces of that Invisalign brand name, all that stays at the doctor’s office.”²⁵

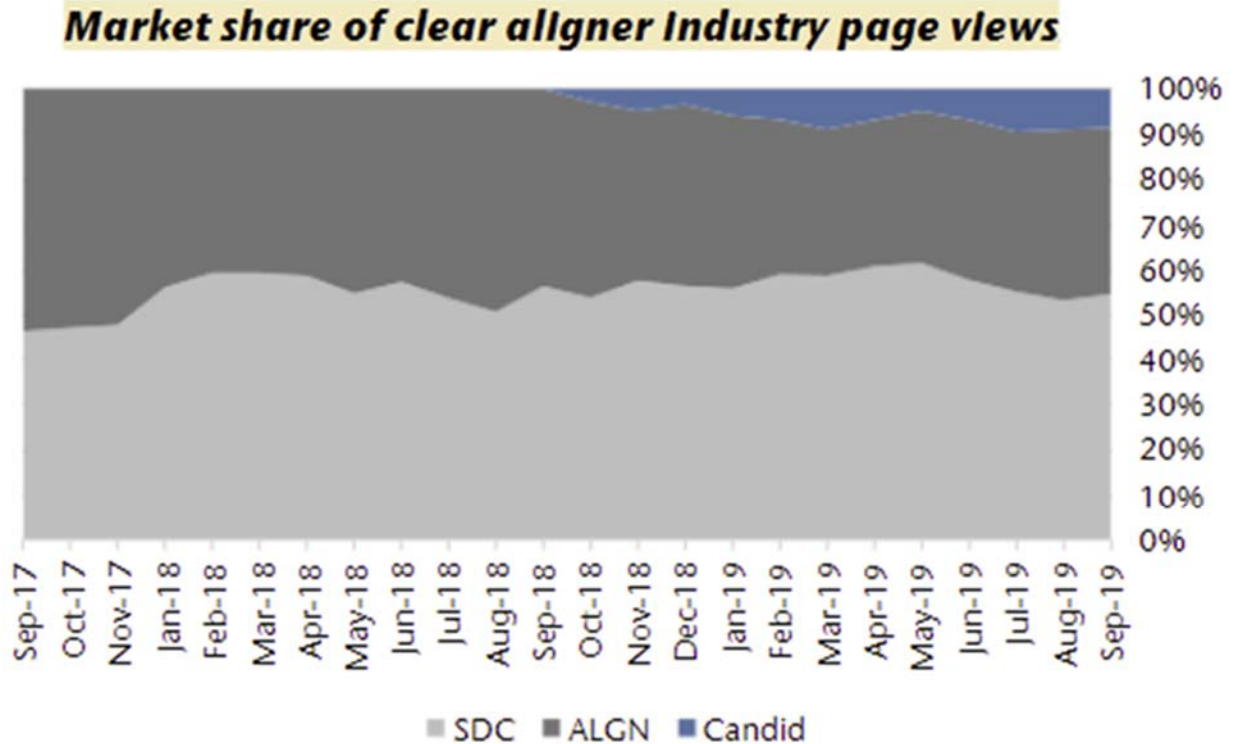
120. This referral program further strengthened Align’s monopolization of the dentist product submarket, with the agreement ensuring that intakes that SmileDirectClub received who were only suited for the dental channel submarket would be specifically directed to Align, as opposed to any potential competing aligners in the dentist product submarket.

121. The referral program was especially important for maintaining Align’s monopolization of the dental channel submarket because SDC, through its extensive consumer outreach, had a highly significant share of web page views for clear aligner websites across the industry. For example, one 2019 report by Jeffries, an investment bank, stated that SDC consistently

²⁴ Align, Press Release (July 28, 2016), *supra* note **Error! Bookmark not defined.**

²⁵ Align Earnings Call (July 28, 2016).

averaged above 50% share of clear aligner industry page views, with Align taking a smaller portion. Align reinforced its monopoly position in the dental channel submarket by ensuring that all patients that contacted SDC and were only suitable for treatment in the dental channel would be referred directly to Align.



122. [REDACTED]

123. [REDACTED]

[REDACTED]

[REDACTED]

124. [REDACTED]

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125. [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

126. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

127. Following execution of the agreements, investment analysts recognized that the agreements between Align and SmileDirectClub were effective in allowing Align to strengthen its

monopoly in the wholesale channel and limit competitive threat emanating from the lower end of the market and the consumer channel.

128. In a November 15, 2016 research note, Northcoast Research stated that surveys of orthodontists had indicated concern that “SDC could negatively impact their practices given that it costs 50-80% less than Invisalign.” But Northcoast Research reassured investors that Align’s CEO, Joseph Hogan, had addressed “these concerns head on,” regarding a lower priced competitor, at the 2016 North American Invisalign Ortho Summit. At the summit, according to Northcoast Research, Hogan had explained that because Align “has equity ownership in SDC, and a supply agreement, it can help *control how this market develops protecting the orthodontic community.*” Northcoast Research further emphasized the importance of the referral component of the agreement, stating that “Align expects 30% of SDC’s customers won’t fit its simplicity protocol and will therefore be referred to an Invisalign doctor.”

129. Piper Jaffray, in a November 14, 2016 research note, also reassured investors after the 2016 North American Invisalign Ortho Summit, about Align’s agreements with SmileDirectClub. Piper Jaffray stated that the agreements would benefit Align because:

ALGN will be the sole outside supplier of all clear aligners manufactured for SDC customers. Management emphasized to the orthos that these products are utilizing 10-year old technology (generic plastic, contains no IPR, and does not utilize attachments) since the cases being treated are very simple. To us, what is even more important is that ClearCorrect was SDC’s sole supplier prior to the ALGN investment and generated 30% of its revenue from the supply agreement. While contract manufacturing is not ClearCorrect’s core business, this will definitely impact the company’s financial profile going forward. 2) We view SDC as an extension of ALGNs marketing arm in the sense that patients who are not motivated to see a doctor and have a more complex case will be referred to an Invisalign provider. While still skeptical, this is where docs feel more comfortable about the arrangement as they may experience an increase in patient traffic without having to do much work. Management believes this could be a decent sized opportunity as they estimate ~30% of all patients in the SDC channel will be referred to an Invisalign provider. 3) In addition to a strategic move to take the legs out from one its competitors, we believe the SDC investment is a defensive play to reduce the risk of a future DTC model that drives pricing down and takes market share (e.g., Dollar Shave Club). As we learn more and more about the SDC relationship, we believe the company is strategically positioning itself ahead of future competition (various patents expire in late 2017) that will likely compete at the low end of the market initially.

130. Notably, Piper Jaffray identified a key anticompetitive benefit for Align from the supply agreement. By becoming the exclusive third-party aligner supplier for SDC, Align took away 30% of the revenues from ClearCorrect, a competitor aligner manufacturer. This aspect of the supply agreement helped further strengthen Align's monopoly of the aligner market by depriving revenues from a competitor aligner manufacturer.

131. In sum, when faced in 2015 with a potential competitor (SDC) in the clear aligner market, Align responded by first suing SDC, then by entering into a set of agreements that had the practical effects of allocating the market for aligners sold to consumers to SDC and strengthening Align's monopoly of the product submarket of aligners sold by dentists. Notably, Align, in 2015, stated that SDC's business had "attempted to deceive the public regarding the safety and effectiveness of its product" but then, nine months later, entered into a business agreement with SDC where it invested tens of millions of dollars to purchase a significant portion of the company's business model.

132. The binding nature of Align and SDC's agreement to allocate the direct-to-consumer market was vividly shown when Align decided to encroach on SDC's agreed-upon turf. As noted above, prior to the 2016 agreement, SDC operated several SmileShops, brick-and-mortar stores intended to familiarize consumers with clear aligners. By contrast, Align did not have brick-and-mortar stores, and marketed to consumers via its website and advertisements but depended entirely on the wholesale channel for selling aligners to consumers.

133. However, in November 2017, Align opened two Invisalign "Scan Shops" in California that mimicked SDC's "SmileShop" business model. In response, SDC sent a cease-and-desist letter to Align in which it claimed that Align violated the Operating Agreement's restrictive covenants and that SDC was exercising its right to repurchase Align's membership interest. It initiated arbitration against Align on April 2, 2018, alleging (1) that Align's Invisalign stores were competing businesses in violation the Operating Agreement; and (2) that Align breached its fiduciary duty by improperly using SDC's confidential information to design and launch its Invisalign stores.

134. On March 4, 2019, the arbitrator issued an award in favor of SDC, finding Align in breach of the parties' non-compete agreement and "permanently enjoin[ing] and prohibit[ing]" Align

from (1) conducting business at its Invisalign stores or from opening new stores; or (2) providing certain services at its “physical retail establishments” in connection with the marketing and sale of clear aligners. The arbitrator also found that Align misused SDC’s confidential information and violated its fiduciary duties to SDC, and: (1) prohibited Align from using SDC’s confidential information; (2) ordered it to close its physical store by April 3, 2019; (3) ordered that it tender its membership interest in SDC in exchange for payment; and (4) extended the parties’ non-compete provision to August 18, 2022.

135. Notably, in its last year of operation in 2019, the supply agreement involved almost no supply. Despite the minimum volume commitments in the supply agreement, both Align and SmileDirectClub confirmed that SmileDirectClub purchased minimal volumes of aligners from Align in 2019. Align, in its Q2 and Q3 2019 earnings calls, stated that it expected no purchases from SDC of aligners for the upcoming quarters. In its 2019 10-K, SmileDirectClub stated that it only purchased aligners from Align in the first quarter of 2019.

136. Nevertheless, even without actual supply, the supply agreement still effectively allocated the market by restraining SmileDirectClub from entering the “wholesale channel” of aligners sold through dental offices. For example, SmileDirectClub filed for an IPO in 2019. In its S-1 for its IPO filing, SmileDirectClub specifically identified restraints on its ability to hire Align employees, stemming from its supply agreement with Align, as a risk factor that may limit SmileDirectClub’s competitiveness: “Treatment planning, a key step leading to our manufacturing process, relies on sophisticated computer technology requiring new technicians to undergo an extensive training process. Training setup technicians takes several weeks, and it takes several months for a new technician to achieve his or her full capacity. The non-solicitation provisions of our supply agreement with Align prohibit us from soliciting Align's current employees in Costa Rica through the end of 2019, and we have also agreed that we will not solicit or hire any employee working at Align, which may restrict our ability to hire experienced team members through 2019.”²⁶

²⁶ Both Align and SmileDirectClub have treatment plan facilities in Costa Rica where technicians review scans and provide input on the appropriate aligner treatment plan for patients. SmileDirectClub explained the importance of placing facilities in Costa Rica, stating that “Initial

As a result, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained technicians to deliver our products within the time frame our members expect. Such a delay could cause us to lose existing members or fail to attract new members.”

137. As stated in Align’s 2019 10-K, the supply agreement “expired by its terms on December 31, 2019.” Immediately upon the supply agreement’s expiration, SmileDirectClub announced plans in a January 14, 2020 press release to “offer its clear aligners through the wholesale channel, providing dentists and orthodontists an in-office option in 2020,” stating: “[w]ith the December 31, 2019 expiration of its exclusive supply agreement with Align Technology, Inc., SmileDirectClub will expand access to its clear aligner therapy solutions and open its network to dentists and orthodontists in search of a premium and affordable teeth straightening solution for their patients.”²⁷

138. In the press release, SmileDirectClub’s co-founder, Alex Frenkel, directly attributed SmileDirectClub’s entrance into this product submarket to the expiration of the supply agreement, stating that “We have seen increasing demand from the dentists and orthodontists in our network who wish to provide SmileDirectClub clear aligners to their in-office patients, and *with our agreement with Align Technology now expired, we are no longer obligated to stay in the direct-to-consumer channel.*”²⁸ At the time the press release was published, Frenkel’s statements were widely reported in the media²⁹, and received particular attention from industry groups and market analysts.³⁰

treatment plan design is conducted primarily at our facilities in San Jose and Cartago, Costa Rica. Costa Rica’s status as one of the Americas’ leading nations for dental education and expertise enables us to recruit and employ highly qualified personnel in our treatment plan setup facilities.”. In its 2019 10-K, Align also stated that its digital dental modeling was primarily processed in its facility located in San Jose, Costa Rica.

²⁷ See Exhibit C (emphasis added).

²⁸ *Id.* (emphasis added).

²⁹ See, e.g., Sunny Kim, “SmileDirectClub stock rises 15% on news it will sell its aligners to orthodontists and dentists”, CNBC (Jan. 14, 2020), available at <https://www.cnbc.com/2020/01/14/smiledirectclub-stock-rises-15percent-on-plan-to-sell-aligners-to-orthodontists.html>.

³⁰ See *supra* note 5.

While SDC has since deleted this press release from its own website, it has not renounced, retracted, or otherwise corrected Frenkel's statement.

139. The set of agreements between SDC and Align are not only per se market allocation of the direct-to-consumer channel of the aligner market to SDC, but also served to further Align's monopolization Scheme by the foreclosure of competition in the aligner market—specifically, the distinct, lucrative product market of aligners sold through dental offices, *see infra* Section VII.A—which has enabled it to impose supracompetitive prices for aligners.

140. The anticompetitive market allocation of the direct-to-consumer channel of the aligner market to SDC lacked any procompetitive benefits. Notably, the primary engine for this market allocation was the Operating Agreement between SDC and Align. The main terms of the Operating Agreement were that Align purchased an ownership interest in SDC, and, in exchange, agreed not to compete with SDC in the direct-to-consumer channel. Thus, in essence, the sole purpose of the Operating Agreement was to allocate the direct-to-consumer channel to SDC and, in exchange, allocate a portion of the profits from supracompetitive prices to Align through its ownership interest in SDC. The Operating Agreement, on its own terms, contained no procompetitive benefits. Its sole purpose was to restrain competition between Align and SDC. Notably, enforcement of the Operating Agreement has acted to restrain competition even after Align terminated its ownership interest in SDC, with Align restrained from entering the direct-to-consumer channel until August 18, 2022. Indeed, the Operating Agreement continued to restrain competition in the direct-to-consumer channel even after the separate Supply Agreement ended on December 31, 2019.

H. Align's set of actions substantially foreclosed competition in the aligner and scanner markets.

141. Align's Scheme has substantially foreclosed competition in both the aligner and scanner markets and has enabled Align to impose supracompetitive prices for scanners and aligners.

142. Through this Scheme, Align ties Invisalign to iTero to maintain dominance in both the aligner and scanner markets. For example, because of the closed system architecture of Align's system, the dental practices using iTero scanners are effectively forced to use Invisalign or incur the expense and difficulty of using iTero to order rival aligners.

143. A dental practice that wants to offer Invisalign must, for all practical purposes, purchase and use an iTero. Since the implementation of the Scheme, the only true scanner option for these dental practices looking to offer Invisalign is the iTero. In effect, dental practices are coerced into purchasing the iTero if they want to offer Invisalign using digital scanning technology.

144. The DSO contracts themselves also represent long-term, exclusive commitments on the part of DSOs to deal only with Align for aligners and scanners. Likewise, the Fusion Program ties iTero discounts to such high levels of aligner commitments over a number of years that those customers are essentially locked into using both the iTero and Invisalign exclusively. All of this is compounded by Align's "closed system" design and the termination of the Interoperability Agreement with 3Shape, which means that any dental practice who wants to offer the dominant Invisalign product must use only an iTero scanner.

145. A rival aligner manufacturer looking to compete against Align would have to offer below-cost prices to offset the penalties and overcome the restrictions Align has placed on its customers through this Scheme. Likewise, Align has foreclosed Trios, its only true rival in the scanner market, and has, upon information and belief, not authorized interoperability for any other scanner manufacturer. Because Align controls approximately 90 percent of the aligner market, that has substantially foreclosed any ability for a rival scanner manufacturer to compete.

146. As discussed above, Align's scanner and aligner monopolies are self-reinforcing. Align sought to use its substantial market power to eliminate competition from the Trios and other competing scanners that are able to order aligners from other manufacturers, thereby making the iTero the only viable option for dental practices to purchase and use. Not only would that allow Align to enhance its monopoly power in the scanner market, but that would also allow Align to prevent other aligner manufacturers from becoming established and competing with Invisalign, allowing Defendant to enhance its monopoly power in the aligner market.

147. Indeed, these foreclosure effects and the harm to competition and consumers are not hypothetical. After the expiration of key patents, Align began to face the prospect of competition in the aligner market from large companies with substantial experience in the dental field, such as Straumann, a global tooth replacement and orthodontics manufacturer who had purchased Align's

largest (though still minimal) competitor ClearCorrect; Henry Schein, a worldwide distributor of medical and dental supplies that tried to introduce a competing aligner product; and 3M, a global manufacturer who tried to introduce a competing aligner product in May 2018. Yet despite the size and resources of the potentially competing aligner manufacturers, none of them have been able to gain a foothold in the aligner market, where Align has maintained an approximately 90 percent share. Indeed, according to 3Shape, Align’s CEO insisted that it could “still jack price in the marketplace” notwithstanding potential competitors, and indeed, Align did increase prices in 2019. Thus, because of Align’s Scheme, choice has been limited and prices have continued to be supracompetitive.

148. Additionally, according to 3Shape, since Align has engaged in this Scheme, 3Shape’s business has been injured. Its market share has dropped precipitously in the scanner market and Align has gained that market share due to the Scheme. This has not only allowed Align to gain a monopoly in the scanner market, but that scanner market monopoly has enabled Align to maintain its monopoly in the aligner market. As a result of the Scheme alleged herein, Defendant’s sales of the iTero grew 84% in the first quarter of 2018 and rose by another 50% from the first quarter of 2018 to the third quarter. In 2017, Defendant had over an 80% market share in the market for scanners in the United States. Were the scanner market competitive, purchasers would have benefited from greater choice and lower prices.

149. Align’s market allocation agreement with SDC furthered its overall Scheme to monopolize the aligner market by preventing an emerging competitor from infringing on Align’s dominant position in the most profitable product submarket—aligners sold through dental offices.

150. Defendant intended to harm, and indeed its anticompetitive actions have harmed competition in the aligner and scanner markets, resulting in higher prices, reduced competition, and reduced product choice. This is the type of injury that the antitrust laws were intended to prevent and is a direct and proximate result of Defendant’s anticompetitive Scheme, and therefore Defendant has caused antitrust injury to the Class.

V. INTERSTATE COMMERCE

151. The market for aligners in the United States is a national market.

152. Defendant has marketed its Invisalign aligners to dental practices and patients in all 50 states.
153. Defendant has sold its Invisalign aligners to dental practices in all 50 states.
154. Defendant has recruited and trained dental and orthodontic professionals to perform scans for Invisalign patients in all 50 states, and there are dental and orthodontic professionals who actively perform scans for Invisalign patients in all 50 states.
155. The market for scanners in the United States is a national market.
156. Defendant has marketed and sold its iTero scanner to dental practices in all 50 states.
157. Defendant's business in aligners and scanners involves a continuous and uninterrupted flow of commerce across state lines.
158. Defendant's anticompetitive actions have had a substantial effect on interstate trade and commerce in the markets for aligners and scanners.

VI. CLASS ACTION ALLEGATIONS

159. Plaintiffs bring this action under Federal Rule of Civil Procedure 23(b)(2) on their own behalf and on behalf of the following class (the "Nationwide Injunctive Relief Class") for claims arising under Federal law:

All persons or entities in the United States that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the "Class Period"). This class excludes the Defendant; the officers, directors or employees of the Defendant; and any subsidiary, affiliate or other entity in which Defendant has a controlling interest. The Class also excludes all federal, state or local governmental entities, all judicial officers presiding over this action and their immediate family members and staff, and any juror assigned to this action.

160. Plaintiff Bozian also brings this action under Federal Rule of Civil Procedure 23(b)(3) on his own behalf and on behalf of the following class (the "SmileDirectClub Purchaser Class") for claims arising under Federal law:

All persons or entities in the United States that purchased, paid and/or provided reimbursement for some or all of the purchase price for SmileDirectClub aligners acquired for personal use during the period beginning October 22, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the "Class Period"). This class

excludes the Defendant and the Conspirator; the officers, directors or employees of the Defendant and Conspirator; and any subsidiary, affiliate or other entity in which Defendant or Conspirator has a controlling interest. The Class also excludes all federal, state or local governmental entities, all judicial officers presiding over this action and their immediate family members and staff, and any juror assigned to this action.

161. Plaintiffs also seek certification under Federal Rule of Civil Procedure 23(b)(2) and 23(b)(3) of the following subclasses for claims arising under various antitrust, unfair competition, unjust enrichment, and consumer protection laws of the states listed below:

Arizona class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Arizona, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

California class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in California, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Connecticut class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Connecticut, acquired for personal use during the period beginning July 10, 2017³¹ until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Florida class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Florida, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Maryland class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Maryland, acquired for personal use during the period beginning May 27, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Massachusetts class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while

³¹ On July 10, 2017, Connecticut amended Conn. Gen. Stat. Ann. § 35-46a to authorize the assertion of claims by indirect purchasers for violations of state antitrust laws involving drugs, medicine, and medical devices. *See* <https://www.cga.ct.gov/2017/act/pa/pdf/2017PA-00241-R00SB-00445-PA.pdf>. On October 1, 2018, Section 35-46a was further amended to authorize suit by all indirect purchasers. *See* <https://www.cga.ct.gov/2018/ACT/pa/pdf/2018PA-00022-R00HB-05252-PA.pdf>.

residing in Massachusetts, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Michigan class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Michigan, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Minnesota class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Minnesota, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Nebraska class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Nebraska, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Nevada class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Nevada, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

North Carolina class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in North Carolina, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

Oregon class: All persons or entities that purchased, paid and/or provided reimbursement for some or all of the purchase price for Invisalign aligners, while residing in Oregon, acquired for personal use during the period beginning May 4, 2017 until such time as the anticompetitive conduct alleged herein has ceased (the “Class Period”).

162. The members of the Class are so numerous that joinder is impracticable. On information and belief, at least hundreds of thousands of individual consumers purchased aligners for personal use during the Class Period.

163. Common questions of law and fact exist as to all members of the Classes. Such questions of law and fact common to the Classes include, but are not limited to, the following:

a. Whether Defendant terminated its agreement with 3Shape in order to maintain and/or enhance its monopoly power in the market for aligners;

- b. Whether Defendant terminated its agreement with 3Shape in order to maintain and/or enhance its monopoly power in the market for scanners;
- c. Whether Defendant's practice of allowing only its iTero scanner to send scans directly to Defendant for Invisalign patients on commercially reasonable terms, and preventing 3Shape's Trios scanner and other potentially competing scanners from doing so, constitutes a violation of the antitrust laws;
- d. Whether Defendant's policy of requiring dentists who wish to prescribe Invisalign aligners, but who do not use Defendant's iTero scanner or another approved scanner, to create manual casts of patients' teeth from a silicone mold, involves imposing a burdensome and inefficient alternative;
- e. Whether Defendant's refusal to accept, for Invisalign orders, the standard file format used by other aligner manufacturers, has legitimate medical or technical reasons or is anticompetitive;
- f. Whether Defendant's agreements with SDC are anticompetitive;
- g. Whether Defendant's contractual restrictions and penalties imposed on customers for dealing with rivals are anticompetitive;
- h. Whether Defendant has substantial market power in the market for aligners sold in the United States;
- i. Whether Defendant has substantial market power in the market for scanners sold in the United States;
- j. Whether Defendant has substantially foreclosed competition in the markets for aligners and/or scanners;
- k. Whether Defendant's Scheme has artificially raised prices and reduced competition in the market for aligners;
- l. Whether Defendant's Scheme has a legitimate procompetitive justification;
- m. Whether the conduct alleged herein artificially maintained, preserved, or enhanced Defendant's market power in the market for aligners;

- n. Whether the conduct alleged herein artificially maintained, preserved, or enhanced Defendant's market power in the market for scanners;
- o. The operative time period and extent of Defendant's antitrust violations;
- p. Whether the conduct alleged herein caused damages to the members of the Class in the form of overcharges paid for Invisalign aligners, and the proper measure of such overcharge damages; and
- q. The appropriate injunctive and equitable relief for the Class.

164. Plaintiffs' claims are typical of, and not antagonistic to, the claims of the other Class members. By advancing their claims, Plaintiffs will also advance the claims of all Class members, because Defendant participated in activity that caused all Class members to suffer similar injuries. Fed. R. Civ. P. 23(a)(3).

165. Plaintiffs will fairly and adequately protect the interests of absent Class members. There are no material conflicts between Plaintiffs' claims and those of absent Class or Subclass members that would make class certification inappropriate. Counsels for Plaintiffs are experienced in complex class action litigation, including antitrust litigation, and will vigorously assert Plaintiffs' claims and those of absent Class members. Fed. R. Civ. P. 23(a)(4).

166. A class action is superior to other methods for the fair and efficient resolution of this controversy. The class action device presents fewer management difficulties, and provides the benefit of a single adjudication, economy of scale, and comprehensive supervision by a single court. Fed. R. Civ. P. 23(b)(3). The damages suffered by each Plaintiff and Class member is relatively small, given the expense and burden of individual prosecution of the claims asserted in this litigation. Thus, absent class certification, it would not be feasible for Plaintiffs and Class members to redress the wrongs done to them. Even if Plaintiffs and Class members could afford individual litigation, which is not the case, the court system could not. Further, individual litigation presents the potential for inconsistent or contradictory judgments and would greatly magnify the delay and expense to all parties and to the court system. Therefore, the class action device presents far fewer case management difficulties and will provide the benefits of unitary adjudication, economy of scale and comprehensive supervision by a single court.

167. Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Classes as a whole. Fed. R. Civ. P. 23(b)(2).

168. Plaintiffs know of no difficulty likely to be encountered in the maintenance of this action as a class action under Federal Rule of Civil Procedure 23.

VII. RELEVANT MARKETS

A. The aligner market

169. At all relevant times, Align had substantial market power in the market for aligners. It had the power to maintain the price of Invisalign at supracompetitive levels profitably without losing substantial sales to other products used for the same purposes as Invisalign.

170. To the extent Plaintiffs' claims require the definition of a relevant market for aligners, the relevant product market is the market for custom-manufactured, transparent, removable dental aligners made from clear plastic or similar materials.

171. Dental aligners sold through dental offices constitute a distinct product submarket that is itself a defined market. Align also possesses market power in this market, as reflected in a dominant market share of at least 90% for aligners sold through dental offices.

172. Dental aligners sold through dental offices feature more complex treatments than dental aligners sold through other distribution channels, such as dental aligners that are sold directly to consumers. Dental aligners sold through dental offices use specialized vendors, dental offices, as compared to dental aligners sold directly to consumers, that do not feature specialized vendors. Dental aligners sold through dental offices also feature a distinct set of customers – consumers who need complex treatment that cannot be addressed by aligners that are sold directly to consumers. For these consumers, only dental aligners sold through dental offices are able to meet their treatment needs, which cannot be satisfactorily addressed by dental aligners that are sold directly to consumers.

173. Dental aligners sold through dental offices also feature markedly higher prices than dental aligners sold directly to consumers. For example, the cost of Invisalign treatment generally ranges between \$3,000 to \$8,000. By contrast, currently, SmileDirectClub has a set price of \$1,950

if the customer pays at once.³² The significantly higher prices of dental aligners sold through dental offices versus other distribution channels shows that there is minimal cross-price elasticity between the dental office and direct-to-consumer submarkets.

174. Align itself has specifically explained that there is little overlap between the product submarkets of dental aligners sold through dental offices and dental aligners sold directly to consumers. On a June 2019 earnings call, Invisalign's CEO, Hogan, explained that "there is about a 10% with our adult demographic with SDC"—i.e., a 10% overlap between the aligner product submarkets targeted by the two companies. Hogan went on to explain that this competition is concentrated in the market for "simple" (that is, less expensive and less complex) cases:

First of all on the DTC piece is, look I think it's—there's light and dark in that. Right. I do feel that SmileDirectClub and Candid, they've raised the category awareness significantly. And we hear throughout our doctor base, whether the orthodontics side or GP side, the patients come in asking about clear aligners much more than they have before. So it forces that conversation. It gives us an opportunity to engage at a level that I feel it's just our advertising alone, it would have never gotten to that level. So that's a positive side.

The negative side is, it's—there are some price competition, that segment offers \$2,000 or less kind of the case for simple case and its push some of the doctor office models and its pushed our portfolio too. We're saying is that, we've always known as a 10% overlap and educating our customers, having customers to be able to which is our doctors, having this customers be able to use an iTero scanner to help to communicate and visualize exactly the treatment plan would be, giving patients some off ramp in the sense that they have issues during the treatment time that they can be addressed by a doctor directly.

All those things are things that we just have to make sure we take better advantage of—with our, with our doctors and the channels that we work with in order to take advantage of that increased interest that we see out there.³³

175. Dental aligners sold through dental offices also feature markedly higher prices than dental aligners sold directly to consumers. For example, the cost of Invisalign treatment generally ranges between \$3,000 to \$8,000. By contrast, currently, SmileDirectClub has a set price of \$1,950

³² <https://smiledirectclub.com/faq/>.

³³ See Align Q2 2019 Earnings Call Transcript (July 24, 2019), available at <https://www.fool.com/earnings/call-transcripts/2019/07/25/align-technology-inc-algn-q2-2019-earnings-call-tr.aspx> (emphasis added).

if the customer pays at once.³⁴ The significantly higher prices of dental aligners sold through dental offices versus other distribution channels shows that there is minimal cross-price elasticity between the dental office and direct-to-consumer submarkets. Align itself has specifically explained that there is little overlap between the product submarkets of dental aligners sold through dental offices and dental aligners sold directly to consumers.

176. Align has, in particular, exercised dominant market power in the distinct, definable product submarket of dental aligners sold through dentist offices.

177. To the extent Plaintiffs' claims require the definition of a relevant market for aligners, the relevant geographic market is the United States. The Food and Drug Administration has to approve medical devices such as aligners, and consumers in the United States cannot practically seek out alternative aligners from other countries that have not been approved for sale and use in the United States. Therefore, the price of aligners in other countries does not affect the market for aligners in the United States.

178. There are also high barriers to entry in the aligner market, due in part to the cost of establishing and running manufacturing facilities and the cost of regulatory approval.

179. At all relevant times, Align has had an approximately 90 percent share of the market for aligners in the United States. Moreover, there are substantial barriers to entry for potential competitors in the aligner market.

180. Metal braces are not a reasonable substitute for aligners. Aligners are used for patients with moderate tooth misalignment, or who cannot receive metal braces due to activities in which they are involved, such as certain sports. Metal braces are used for patients with severe tooth misalignment, for whom aligners would not be sufficient for proper treatment. Metal braces are also far more uncomfortable, typically take a longer period for treatment to complete, require patients to avoid certain foods, and require repeated visits to an orthodontist.

181. Furthermore, as explained above (*see supra* ¶¶ 132-137), the submarket for selling aligners directly to consumers is generally distinct from—and overlaps little with—the submarket for

³⁴ <https://smiledirectclub.com/faq/>.

selling aligners to (and/or through) dentists and orthodontists, given the fundamentally different types of cases these two distribution channels generally serve.

182. A small but significant and non-transitory artificial inflation of the price of aligners would not cause any significant number of consumers to purchase other potentially substitutable products, including metal braces, instead, so as to make such price inflation unprofitable. A small but significant and non-transitory artificial inflation of the price of metal braces would not cause any significant number of consumers to purchase aligners instead, so as to make the artificial price inflation unprofitable.

B. The market for hand-held digital intra-oral scanners

183. At all relevant times, Align had market power in the market for scanners. It had the power to maintain the price of iTero scanners at supracompetitive levels profitably without losing substantial sales to other products used for the same purposes as iTero scanners.

184. To the extent Plaintiffs' claims require the definition of a relevant market for scanners, the relevant product market is the market for hand-held digital intra-oral scanners designed for ordering aligners (hereafter "scanner market").

185. To the extent Plaintiffs' claims require the definition of a relevant market for scanners, the relevant geographic market is the United States. The Food and Drug Administration has to approve medical devices such as scanners, and dental professionals in the United States cannot practically seek out alternative scanners from other countries that have not been approved for sale and use in the United States. Therefore, the price of scanners in other countries does not affect the market for scanners in the United States.

186. There are also high barriers to entry in the scanner market, due in part to the cost of establishing and running manufacturing facilities and the cost of regulatory approval.

187. At all relevant times, Align has had an approximately 80 percent share in the market for scanners in the United States. Additionally, there are substantial barriers to entry for potential competitors in the scanner market.

188. As explained above, dental professionals use scanners to scan patients' mouths to obtain three-dimensional digital impressions of patients' dental structures (a "scan"), process and

evaluate it through task-specific software, and then submit the scans to aligner manufacturers that are customized to treat the patient's needs. Having the ability to access and receive scans is indispensable to competing in the aligner market.

189. Currently, the iTero and Trios are the only two viable scanners in the scanner market.

190. Specifically, iTero and Trios are the only two viable scanners for orthodontic treatment that easily and accurately scan a patient's upper and lower jaws, teeth, and bite to create and deliver a digital 3D impression for ordering aligners. They are also the only scanners that have the software and delivery systems to accommodate digital aligner workflow. And, they have been in the same price class: as explained above, both are so-called "DI" (dental impression) scanners, which are considerably cheaper (often between \$25,000-40,000 for a DI unit vs. \$130,000 for a full CAD/CAM unit), used for specialized applications, and typically have quicker innovation cycles.

190. Furthermore, compared to Trios, iTero is slower, more difficult to use, larger, lacks CAD integration, and is a closed system. One commentator, reviewing the latest intraoral scanners, explained that "[t]he iTero does, however, have one saving grace, and that is its association with Invisalign."

191. Following Align's termination of interoperability with 3Shape's Trios, iTero's market share has increased significantly in the United States. In the third quarter of 2019, Align's iTero scanner and services revenues increased 16.5 percent, year-over-year.³⁵ In the fourth quarter of 2020, Align reported a record year-over-year increase of 26.0 percent in the same revenue category.

192. 3Shape's growth in the scanner market effectively stopped in 2018.

193. As explained above (*see supra* ¶¶ 70-71), both 3M and Sirona manufacture intraoral scanners—the MTD and CEREC, respectively. But neither the MTD nor the CEREC scanner is a viable substitute for the iTero or Trios scanners, and they are not in the relevant scanner market. The MTD and CEREC scanners are not viable substitutes for the iTero or Trios scanners because they are

³⁵ See *Align Technology Announces Third Quarter 2019 Financial Results*, BioSpace (Oct. 23, 2019), available at <https://www.biospace.com/article/releases/align-technology-announces-third-quarter-2019-financial-results/> ("Q3'19 total revenues were \$607.3 million, up 20.2% year-over-year, and Q3'19 scanner and services revenues were \$91.1 million, up 16.5% year-over-year.").

not well suited to provide full mouth scans for aligner orders. As a result, the MTD and CEREC scanners are not a viable option for dental professionals seeking to send digital scans for aligners, and are rarely used for this purpose.³⁶

194. Specifically, unlike the iTero and Trios scanners, which were designed and manufactured to generate full mouth scans used to order aligners, both the MTD and CEREC scanners are focused on scanning individual teeth for crowns and similar local dental restorative work—and not on comprehensive, full-mouth orthodontic treatments. It takes significantly longer to scan a patient’s entire mouth with a MTD or CEREC scanner than with a Trios or iTero scanner.

195. The MTD and CEREC scanners are also technologically inferior to the iTero and Trios scanners. On information and belief, Align executive Raphael Pascaud has testified in International Trade Commission proceedings that Trios is better than the MTD and CEREC scanners, and that MTD and CEREC scanners “are outdated.”

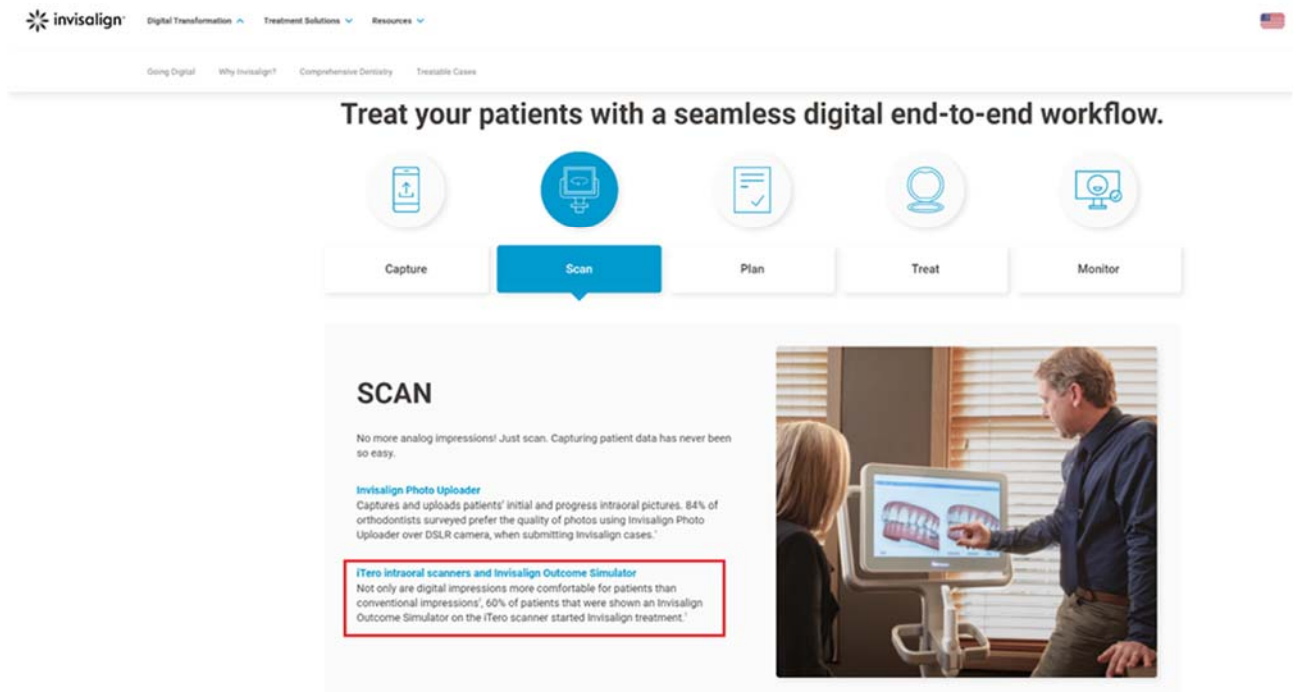
196. The MTD and CEREC scanners are not purchased by dental professionals to generate full mouth scans used for ordering aligners. The actual utilization rates for MTD’s and CEREC’s scanners to order aligners are low.

197. Furthermore, the MTD and CEREC scanners rely on outdated technology, and their utilization rates have been declining. The MTD scanner requires the use of a powder for scanning and generates a black-and-white scan. The CEREC scanner’s hardware is antiquated, having not been updated since 2012.

198. Invisalign’s advertising does not include MTD and CEREC as scanner options that can be used to order Invisalign—rather, the only scanner disclosed in its advertising is iTero. For

³⁶ For example, a July 2019 survey of dental practitioners by Credit Suisse found that, of 42 survey respondents, 60% used the iTero for “digital scanning,” while just 9% and 2% used the CEREC (or “Omnicam”) and MTD scanners, respectively, for this purpose. Commenting on Sirona’s then-recent launch of its “Primescan” scanner, the survey notes: “Primescan is an open system that can connect with all labs, an important difference from its legacy Omnicam offering, *with which data transfer to labs was a cumbersome process* as it predominately promoted chairside systems. While it technically offered Omnicam for standalone digital impression, *penetration was extremely low*, with its salesforce not aligned with this strategy.” (emphasis added); *see also* note 14 (explaining that the MTD scanner is “primarily used for scanning individual teeth for crowns and similar local dental restorative work—and not for comprehensive, full-mouth orthodontic treatments”).

example, the following page appears in the “going digital” section of the webpage Align makes available to doctors interested in becoming Invisalign providers:³⁷



199. The process for sending digital scans to Align from the MTD or CEREC scanners is also more cumbersome and time consuming than sending digital scans from the iTero scanner and requires an additional, manual quality approval step based on the poor quality of the scan from such scanners.

200. Other fringe scanners also do not competitively constrain Align. As explained above, Align has only allowed interoperability for scanners that are not designed for ordering aligners, that do not compete with iTero in the scanner market, and that do not represent a threat to Align's dominance of the aligner market. This in turn means the barriers to entry for a new supplier and scanner are insurmountable

201. Likewise, silicone molds are not part of the scanner market because they are not viable substitutes for iTero and Trios scanners.

202. Before the advent of digital intraoral scanners, dental professionals seeking to prescribe aligners were required to make manual dental impressions by inserting a metal or plastic

³⁷ See <https://www.invisalign.com/provider/digital-transformation/going-digital>.

tray containing impression material, such as silicone-based polyvinyl-siloxane or alginate, into a patient’s mouth to generate a cast of the patient’s teeth (“silicone mold”).

203. To take a dental impression using silicone molds, patients must bite into a rubbery and runny casting material for several minutes, waiting for it to set. During this process, patients are subject to unpleasant odor and taste, and may experience gagging. Patients may have to repeat this process more than once to get an adequate dental impression for aligners as manual impressions are often not accurate due to distortions and incomplete details.

204. Accordingly, silicone molds are less appropriate for use with aligners, which require extremely accurate full mouth scans (in contrast to silicone molds, scans also allow for real-time simulations of teeth movement to best plan a course of treatment). In particular, full mouth digital scans also offer flexibility and customization, because they allow dental professionals to use digital scans to simulate teeth movement and outcomes in software.

205. Neither dental professionals nor Align itself view silicone molds as substitutes for full mouth scans. In its Q1 2019 financial statement, Align reported that it expects that within a “year or two, nearly all Invisalign cases will be submitted digitally, primarily through an iTero scanner.” In a July 24, 2019 earnings call, Align’s CEO confirmed that “dental is going digital.” And as noted above, a recent research note estimates that 86% of cases were submitted digitally in the Americas in the first quarter of 2021, a number that will likely continue to increase:



206. Although Align accepts silicone molds for Invisalign orders, Align has itself admitted that these impressions are less accurate, more costly, and more stressful for the patient. In fact, Align has highlighted for those considering a silicone mold that the rejection rate for molds is 13 to 14 times higher than the rejection rate for an iTero digital scan.

207. Indeed, in its 2017 Annual Report, Align stated:

digital scanning is more efficient and precise and more comfortable for patients, compared to the mess, discomfort and subjective nature of taking physical impressions. The digitally scanned model is more accurate than a physical impression and substantially reduces the rate of restoration ‘remakes’ so 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.

208. 3Shape’s Trios and Defendant’s iTero are part of the relevant market for scanners.

209. A small but significant and non-transitory artificial inflation in the price of scanners would not cause any significant number of consumers to purchase other potentially substitutable products, including 3M’s True Definition and Dentsply Sirona’s CEREC Omnicam scanners, instead, so as to make the artificial price inflation unprofitable.

VIII. ANTITRUST INJURY

210. Defendant’s anticompetitive behavior resulted in antitrust injury to Plaintiffs and other members of the proposed Classes because it caused them to pay higher prices for either Invisalign aligners or SmileDirectClub Aligners than they otherwise would have paid if not for Defendant’s business practices.

A. **SmileDirectClub purchasers paid inflated prices for SmileDirectClub aligners as a result of the anticompetitive agreements between Align and SmileDirectClub.**

211. Defendant and Conspirator’s contract, combination and conspiracy, as set forth herein caused Plaintiffs to pay supracompetitive prices for aligners sold by SDC directly to Plaintiffs.

212. As a result of the anticompetitive agreements, price competition between Defendant and Conspirator in the sale, marketing, and distribution of aligners through the direct-to-consumer channel has been restrained.

213. Prices for aligners sold by Conspirator, SDC, during the Class Period to purchasers in the United States have been raised, fixed, maintained and/or stabilized at artificial and non-competitive levels.

214. The supplies of Defendant’s aligners available for sale during the Class Period to direct purchases by consumers in the United States has been artificially and unjustifiably restrained.

215. But for the agreements between Align and SDC that suppressed competition, the prices of SDC aligners sold directly to plaintiffs would have been lower.

216. Thus, Plaintiff and other members of the proposed SmileDirectClub purchaser class who purchased SDC aligners directly have suffered antitrust injury because they have been forced to pay supracompetitive prices for their SDC aligners.

B. Inflated prices of Invisalign aligners were passed on to consumer purchasers of Invisaligner treatments

217. Plaintiffs purchased Invisalign aligners as part of a course of treatment from dentist offices. Plaintiffs either paid for the cost of Invisalign aligners directly, through financing arranged by Align or indirectly, through dentist offices. When purchased indirectly, Plaintiffs were paying for an Invisalign aligner treatment whose sole product was the installation of Invisalign aligners. Invisalign aligners constitute a significant, material cost for Invisalign aligner treatment provided by Dentists.

218. The aligner market is subject to vigorous price competition between dentist offices offering to provide the Invisalign aligner treatment. As a result, increases in the prices of Invisalign aligners will lead to corresponding price raises for the cost of Invisalign aligner treatment provided by dentists.

219. Align has itself recognized that dentists pass through the cost of Invisalign aligners to patients. The CEO of Invisalign, Joseph Hogan, specifically touted a new financing program where patients paid Invisalign directly because it “eliminates the need for [dentists] to pass on the high down payments to patients.”

220. As a result, the inflated prices of Invisalign aligners have been passed on to the Plaintiffs who purchased Invisalign aligners indirectly from dentists.

221. Economic theory teaches that the only situations in which precisely zero pass through occurs is when an industry faces a perfectly elastic demand for its product (i.e., the price was fixed, with demand dropping to zero with an infinitesimal price increase, and expanding infinitely if price were to drop infinitesimally), or if supply was perfectly inelastic (i.e., if even a very large increase in price for a product was incapable of stimulating additional supply).³⁸ Therefore, at least a partial

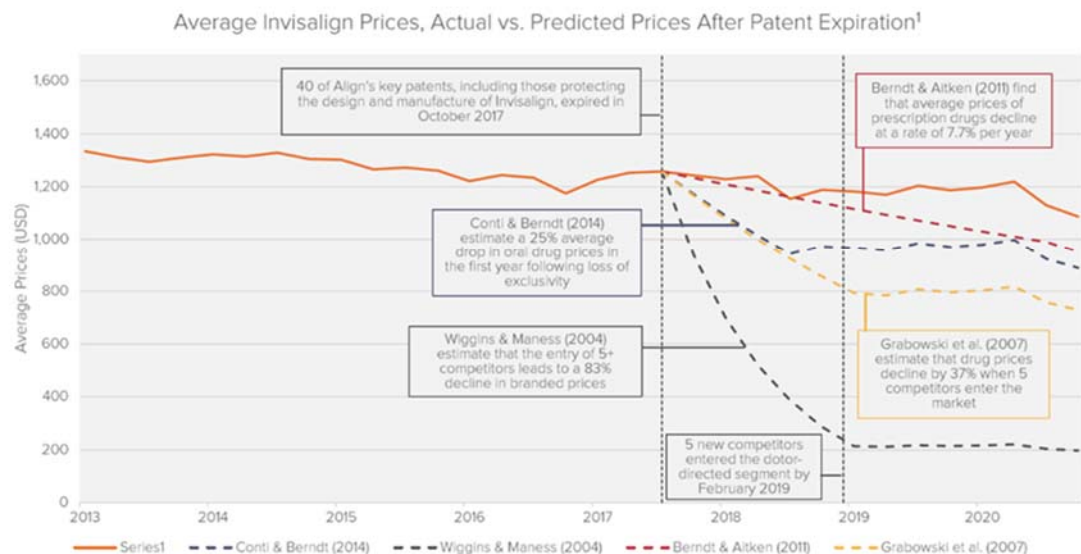
³⁸ The usual hypothesis that is commonly examined in empirical pass-through studies is whether pass through exceeds, falls short of or equals 100 percent.

pass through of an increase in the costs of Invisalign aligners onto the price of Invisalign aligner treatment – is the predicted outcome of successful monopolistic behavior.

222. Thus, the extent to which input cost increases are passed through into output prices is entirely an empirical issue, and it is an area in which methods of empirical analysis are well established. Based on both theory and the published studies in this area, it is likely that the pass-through rates of inflated costs on Invisalign aligners will exceed 100 percent, a situation known as “overshifting.”

223. Furthermore, academic literature on price dynamics in the pharmaceutical industry shows that prices decline between 7.7% and 83% following patent expiration. Meanwhile, although Align lost 40 key patents in October 2017—including patents protecting the design and manufacture of Invisalign³⁹—preliminary data indicates that its consumer-facing prices have declined by an average rate of only 1.6%. Invisalign prices would have declined by, at minimum, hundreds of dollars if they had followed the same decline in prices as other medical products that lost patent protection.

Invisalign Prices – Predicted Price Drop After Patent Expiration



³⁹ See *Align’s Dominance of Clear-Teeth-Straightener Market Challenged*, Bloomberg Law (Aug. 28, 2018), <https://news.bloomberglaw.com/business-and-practice/aligns-dominance-of-clear-teeth-straightener-market-challenged/>.

224. Aligners are the primary physical component, and a significant cost, for Aligner treatments purchased by Plaintiffs. Aligners remain essentially unchanged when they are incorporated into Aligner treatments. When Aligners are purchased as part of an Aligner Treatment, it is a distinct, physically discrete component that does not undergo physical alterations. Aligners are identifiable in a manner that permits tracing to Defendant. As a result, Aligners follow a traceable physical chain of distribution from the Defendant to Plaintiffs and members of the Class, and any costs attributable to Aligners can be traced through the chain of distribution to Plaintiffs and members of the Class.

225. Align itself understands the relationship between the prices of Invisaligners and the price of Invisaligner treatments. In particular, Align has repeatedly recognized in public statements the relationship between the number of aligners used in aligner treatments and the cost of Invisaligner treatments. In particular, Align has explained that less complicated Invisaligner treatments use fewer trays of Invisaligner aligners and therefore cost less. For example, on June 11, 2019, John Morici, CFO of Align, stated that “an easier case that doesn’t require as many stages of aligners” would be priced lower, and would “compete closer to some of the direct-to-consumers that are out there.”

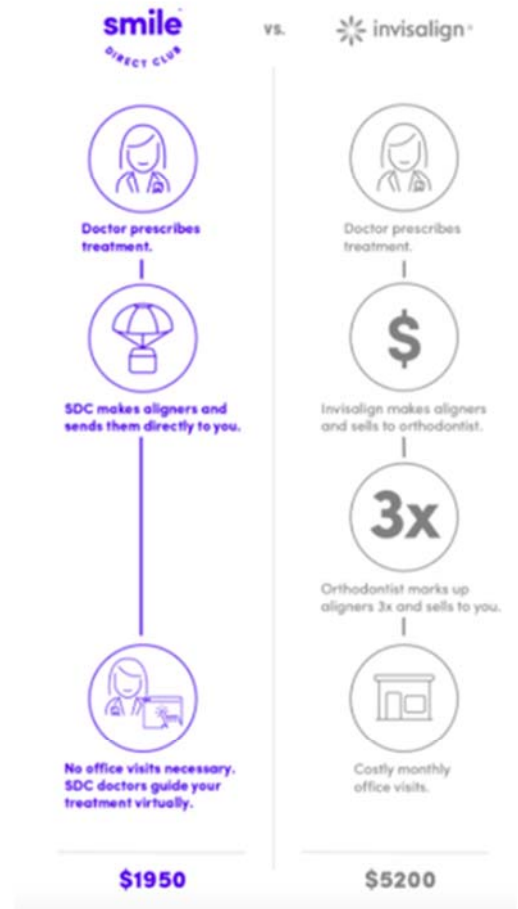
226. SDC has stated in publicly available materials, based on a 2021 national survey of practicing dentists and orthodontists, that “orthodontists mark up [Invisalign] aligners 3x and sells to” the consumer.⁴⁰

⁴⁰ <https://smiledirectclub.com/blog/smiledirectclub-vs-invisalign/>

What is your budget?

Your wallet is likely to be a lot happier with SmileDirectClub, which costs 60% less than Invisalign.¹ Our treatment is \$1950 USD, so you can get the smile you've always wanted without the 3x markup² of Invisalign. SmileDirectClub aligners are 100% made in America at our state-of-the-art 3D printing facility and are shipped directly to you all at one time.

When it comes to **payment**, you have the option to choose a one-time payment of \$1950 or SmilePay™. By choosing SmilePay, you can get started with just \$250 down followed by 24 monthly payments of less than \$89/month,³ a 100% approval rate financing option without the hassle of a credit check. We work directly with most **insurance providers** and accept HSA, FSA, and CareCredit. With that insurance savings, you can expect to pay less than \$975.⁴



227. Align itself indicated that many orthodontists have a standard markup of 3 times the cost of their lab fees for Invisaligners. On a May 3, 2011 investor meeting, Thomas Prescott, then CEO of Align, stated that for certain orthodontists, their invisaligner “lab fee is 3x,” indicating that the consumer price for Invisaligner treatments is approximately 3 times the cost that dental practices pay for Invisaligners.

228. Indeed, Align introduced a pricing program that specifically reflected an approximate 3 times markup between the cost of Invisaligners and Invisaligner treatments. At the beginning of 2020, Align introduced the Invisalign Swift program that featured a \$2,995 price point for consumers and a \$929 lab fee for dentists. The pricing of this program reflected an approximate 3x markup

between the lab fee paid by dentists for Invisaligners and the price paid by consumers for Invisaligner treatments.

229. A standard markup of 300% (or 3x) would mean that a \$1 increase in the price of Invisaligners purchased by dental practices would lead to a \$3 increase in the price of Invisaligner treatments purchased by Plaintiffs.

230. Thus, Plaintiffs and other members of the proposed Classes who purchased Invisalign aligners indirectly have suffered antitrust injury because they have been forced to pay supracompetitive prices for their Invisalign aligner treatments. These inflated prices have been passed on to them by direct purchasers, such as dental offices.

IX. CAUSES OF ACTION

VIOLATIONS OF THE SHERMAN ACT

FIRST CLAIM FOR RELIEF: VIOLATION OF SECTION 2 OF THE SHERMAN ACT 15 U.S.C. §2 FOR MONOPOLIZATION OF THE ALIGNER MARKET (ON BEHALF OF THE NATIONWIDE INJUNCTIVE RELIEF CLASS)

231. Plaintiffs repeat and reiterate each of the allegations contained in paragraphs above as if fully set forth herein.

232. The relevant product market is the aligner market, and the relevant geographic market is the United States.

233. As more fully alleged above, Align has willfully and intentionally engaged in conduct that has had the anticompetitive effects of allowing Align to unlawfully maintain and enhance its monopoly in the aligner market and preventing its rivals from competing for aligner sales. In particular, Align engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

234. Defendant's actions were carried out willfully and with the specific intent to maintain its monopoly power in the aligner market through anticompetitive conduct and not through a superior product, business acumen, or a historic accident.

235. The direct, foreseeable, and proximate result of Defendant's anticompetitive conduct was to increase prices and harm competition in the aligner market.

236. There is no legitimate procompetitive justification for Defendant's conduct, and even if there were, there would be less restrictive alternatives to achieve them.

237. As a direct, material, and proximate result of Defendant's violation of Section 2 of the Sherman Act, Plaintiffs and the Class have suffered injury to their business and property within the meaning of Section 4 of the Clayton Act throughout the Class Period because they have paid more for Invisalign aligner treatment than they otherwise would have paid in the absence of Defendant's unlawful conduct.

238. Plaintiff Vo intends to purchase Invisalign aligners in the future on behalf of her minor child. Plaintiff Vo will suffer concrete, future injury through the payment of supracompetitive prices for her future purchase of Invisaligners on behalf of her child.

239. These violations are continuing and will continue unless enjoined by this Court.

240. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, Plaintiffs and the Nationwide Class seek the issuance of an injunction against Defendant, preventing and restraining the violations alleged herein.

SECOND CLAIM FOR RELIEF:
VIOLATION OF SECTION 1 OF THE SHERMAN ACT 15 U.S.C. §1
(ON BEHALF OF THE NATIONWIDE SMILEDIRECTCLUB PURCHASER CLASS)

241. Plaintiffs repeat and reiterate each of the allegations contained in paragraphs above as if fully set forth herein.

242. Defendant Align and Conspirator SDC entered into and engaged in a continuing combination, conspiracy, or agreement to unreasonably restrain trade or commerce in violation of Section 1 of the Sherman Act by artificially reducing or eliminating competition with respect to the sale, marketing, and distribution of aligners sold directly to consumers in the United States and its territories.

243. As more fully alleged above, Defendant, Align, and Conspirator, SDC, have combined and conspired to divide and allocate the product submarket of aligners sold directly to

consumers by eliminating Align as a competitor, with the intended effect of raising, maintaining, or stabilizing the prices of aligners sold directly to consumer purchasers in the United States and its territories.

244. These violations of Section 1 of the Sherman Act consisted of the unlawful agreement between Align and SDC where Align agreed not to compete in the market of aligners sold directly to consumers and in exchange SDC gave Align an interest in SDC's business. The effect of this agreement was to raise, maintain or stabilize prices of aligners sold directly to consumers by SmileDirectClub and provide a portion of the resulting supracompetitive profits from the market allocation to Align through their ownership interest in SDC.

245. For the purpose of formulating and effectuating their combination or conspiracy, Defendant and Conspirator agreed to not compete and allocate or divide the market for aligners between them.

246. The direct, foreseeable, and proximate result of Defendant and Conspirator's anticompetitive conduct was to increase prices and harm competition in the aligner market.

247. Defendant's anticompetitive and unlawful conduct is per se illegal.

248. As a direct, material, and proximate result of Defendant's violation of Section 1 of the Sherman Act, Plaintiff Bozian and the SmileDirectClub Purchaser Class were injured in their business or property.

VIOLATIONS OF STATE ANTITRUST LAWS

249. Plaintiffs incorporate by reference the allegations in the preceding paragraphs.

250. The following claims for relief are pleaded under the antitrust laws of each jurisdiction identified below on behalf of the indicated classes.

THIRD CLAIM FOR RELIEF:
VIOLATION OF ARIZONA'S UNIFORM STATE ANTITRUST ACT,
ARIZ. REV. STAT. § 44-1401, ET SEQ.
(ON BEHALF OF THE ARIZONA CLASS)

251. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

252. By reason of the conduct alleged herein, Defendant has violated Arizona Rev. Stat. § 44-1401, *et seq.*

253. Defendant established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the aligner and scanner markets, a substantial part of which occurred within Arizona, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the aligner market. In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

254. Defendant's violations of Arizona law were flagrant.

255. Defendant's unlawful conduct substantially affected Arizona's trade and commerce.

256. As a direct and proximate cause of Defendant's unlawful conduct, plaintiffs and members of the Arizona Class have been injured in their business or property and are threatened with further injury.

257. By reason of the foregoing, plaintiffs and members of the Arizona Class are entitled to seek all forms of relief available under Arizona Revised Statute § 44-1401, *et seq.*

FOURTH CLAIM FOR RELIEF:
VIOLATIONS OF CALIFORNIA'S UNFAIR COMPETITION LAW,
CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.*
(ON BEHALF OF THE CALIFORNIA CLASS)

258. Plaintiffs incorporate by reference the allegations in the above paragraphs as if fully set forth herein.

259. By reason of the foregoing, Defendant has violated California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* Plaintiffs on behalf of the Indirect Purchaser State Subclass allege as follows.

260. Defendant has committed acts of unfair competition, as defined by section 17200, *et seq.*, by engaging in an anticompetitive Scheme to monopolize the aligner and scanner markets. Defendant acquired and maintained monopoly over the aligner and scanner markets through anticompetitive conduct. In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

261. The acts, omissions, misrepresentations, practices and non-disclosures of Defendant, as described above, constitute a common and continuing course of conduct of unfair competition by means of unfair, unlawful and/or fraudulent business acts or practices with the meaning of Section 17200, *et seq.*, including, but not limited to violations of Section 2 of the Sherman Act.

262. Defendant's acts or practices are fraudulent or deceptive within the meaning of section 17200, *et seq.*

263. Defendant's conduct was carried out, effectuated, and perfected within the state of California. During most of the class period, Defendant maintained headquarters in California where their employees engaged in communications, meetings and other activities in furtherance of Defendant's monopolization Scheme.

264. By reason of the foregoing, the Class is entitled to application of California law to a nationwide class and are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Defendant as result of such business acts and practices described above.

FIFTH CLAIM FOR RELIEF:
VIOLATION OF THE CONNECTICUT ANTITRUST ACT
CONN. GEN. STAT § 35-24, *ET SEQ.*
(ON BEHALF OF THE CONNECTICUT CLASS)

265. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this complaint.

266. The Connecticut Antitrust Act "expresses a public policy of promoting competition in the marketplace and prohibiting unreasonable restraints of trade, monopolies and attempts to monopolize a defined marketplace."

267. Members of the Class purchased Invisalign aligners within the State of Connecticut during the Class Period. But for Defendant's conduct set forth herein, the price of those aligners would have been lower, in an amount to be determined at trial.

268. Defendant made contracts or engaged in a combination or conspiracy for the purpose of fixing, controlling, or maintaining prices for scanners and aligners sold in Connecticut, and/or for

the purpose of substantially lessening competition and creating a monopoly in the aligner and scanner markets, in violation of Conn. Gen. Stat. Ann. § 35-24, *et seq.*

269. Defendant's unlawful conduct and practices have substantial anticompetitive effects in Connecticut, including increased prices and costs, reduced innovation, poorer customer service, and lowered output.

270. Members of the Class who purchased Invisalign aligners in Connecticut were harmed by Defendant's anticompetitive conduct in a manner that the Connecticut Antitrust Act was intended to prevent when they paid more for aligners than they would have paid in a competitive market. Members of the Class who purchased aligners in Connecticut have suffered and continue to suffer damages and irreparable injury, and such damages and injury will not abate until an injunction ending Defendant's anticompetitive conduct issues. Members of the Class who purchased Invisalign aligners in Connecticut are also entitled to all other forms of relief, including treble damages and reasonable attorneys' fees and costs.

SIXTH CLAIM FOR RELIEF:
VIOLATION OF THE FLORIDA DECEPTIVE AND
UNFAIR TRADE PRACTICES ACT,
FLA. STAT. § 501.201(2), *ET SEQ.*
(ON BEHALF OF THE FLORIDA CLASS)

271. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

272. The Florida Deceptive & Unfair Trade Practices Act, Florida Stat. §§ 501.201, *et seq.* (the "FDUTPA"), generally prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce," including practices in restraint of trade. Florida Stat. § 501.204(1).

273. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. § 501.202(2).

274. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

275. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint. Fla. Stat. § 501.211(a) (“anyone aggrieved by a violation of this [statute] may bring an action[.]”).

276. Plaintiffs purchased Invisalign aligners within the State of Florida during the Class Period. But for Defendant’s conduct set forth herein, the price of Invisalign aligners would have been lower, in an amount to be determined at trial.

277. Defendant established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the markets for aligners and scanners, for the purpose of excluding competition or controlling, fixing or maintaining prices in Florida at a level higher than the competitive market level, beginning at least as early as May 4, 2017 and continuing through the date of this filing. In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

278. Accordingly, Defendant’s conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Florida.

279. Defendant’s unlawful conduct substantially affected Florida’s trade and commerce.

280. As a direct and proximate cause of Defendant’s unlawful conduct, plaintiffs and the members of the Florida Class have been injured in their business or property by virtue of overcharges for Invisalign aligners and are threatened with further injury.

281. By reason of the foregoing, plaintiffs and the members of the Florida Class are entitled to seek all forms of relief, including injunctive relief pursuant to Florida Stat. §501.208 and declaratory judgment, actual damages, reasonable attorneys’ fees and costs pursuant to Florida Stat. § 501.211.

SEVENTH CLAIM FOR RELIEF:
VIOLATION OF THE MARYLAND
ANTITRUST ACT, ANN. COM. LAW § 11-201, *ET SEQ.*
(ON BEHALF OF THE MARYLAND CLASS)

282. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

283. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

284. Maryland's antitrust laws prohibit, *inter alia*, combinations that unreasonably restrain trade or commerce, and the monopolization or attempted monopolization of any part of the trade or commerce for the purpose of excluding competition or of controlling, fixing, or maintaining prices in trade or commerce.

285. Members of the Classes purchased Invisalign aligners within the state of Maryland during the Class Period. But for Defendant's conduct set forth herein, the price of aligners would have been lower, in an amount to be determined at trial. Defendant's unlawful conduct and practices have substantial anticompetitive effects in Maryland, including increased prices and costs for aligners and scanners, reduced innovation, poorer customer service, and lowered output.

286. Members of the Classes who purchased Invisalign aligners in Maryland were harmed by Defendant's anticompetitive conduct in a manner that the Maryland antitrust laws were intended to prevent when they paid more for those aligners than they would have paid in a competitive market. Members of the Classes who purchased Invisalign aligners in Maryland suffered and continue to suffer damages and irreparable injury, and such damages and injury will not abate until an injunction ending Defendant's anticompetitive conduct issues. Members of the Classes who purchased Invisalign aligners in Maryland are also entitled to all other forms of relief, including actual damages, treble damages, and reasonable attorneys' fees and costs.

EIGHTH CLAIM FOR RELIEF:
VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT,
MASS. GEN. LAWS CH. 93A § 1, *ET SEQ.*
(ON BEHALF OF THE MASSACHUSETTS CLASS)

287. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

288. By reason of the conduct alleged herein, Defendant has violated the Massachusetts Consumer Protection Act, Mass. Gen. Laws Ch. 93A § 2, *et seq.*

289. Plaintiffs purchased Invisalign aligners within the State of Massachusetts during the Class Period. But for Defendant's conduct set forth herein, the price of these aligners would have been lower, in an amount to be determined at trial.

290. Defendant established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the market for aligners and scanners, a substantial part of which occurred within Massachusetts, for the purpose of excluding competition or controlling, fixing, or maintaining prices in the aligner market.

291. Defendant's conduct was an unfair method of competition, and an unfair or deceptive act or practice within the conduct of commerce within the State of Massachusetts.

292. Defendant's unlawful conduct substantially affected Massachusetts' trade and commerce.

293. As a direct and proximate cause of Defendant's unlawful conduct, the plaintiffs and the members of the Massachusetts Class have been injured in their business or property and are threatened with further injury.

294. By reason of the foregoing, the plaintiffs and the Massachusetts Class are entitled to seek all forms of relief, including up to treble damages and reasonable attorney's fees and costs under Mass. Gen. Laws Ch. 93A § 9.

295. Based on Plaintiffs' information and belief, Align does not maintain a place of business in Massachusetts or have assets in Massachusetts.⁴¹

296. Plaintiffs bring this claim under Mass. Gen. Laws Ch. 93A *et seq.* Pursuant to Mass. Gen. Laws Ch. 93A § 9, plaintiffs served Defendant on July 30, 2021, via certified mail, return receipt requested, a Demand for Payment Letter. In accordance with the statute, these letters explained the unfair acts, the injury suffered, and requested relief from the Defendant within 30 days. Defendant did not respond to the Demand for Payment Letter.

⁴¹ See, e.g., Secretary of the Commonwealth of Massachusetts, Corporations Division, <https://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSummary.aspx?sysvalue=NyHXBpPR5Dua8EJUickDhHEcT14TNrAmxi2LuFZhYNY-> (last visited Sept. 1, 2021).

NINTH CLAIM FOR RELIEF:
VIOLATION OF THE MICHIGAN ANTITRUST REFORM ACT
MICH. COMP. LAWS § 445.771, *ET SEQ.*
(ON BEHALF OF THE MICHIGAN CLASS)

297. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

298. The Michigan Antitrust Reform Act aims “to prohibit contracts, combinations, and conspiracies in restraint of trade or commerce . . . to prohibit monopolies and attempts to monopolize trade or commerce . . . [and] to provide remedies, fines, and penalties for violations of this act.” Mich. Act 274 of 1984.

299. Plaintiffs purchased Invisalign aligners within the State of Michigan during the Class Period. But for Defendant’s conduct set forth herein, the price of Invisalign aligners would have been lower, in an amount to be determined at trial.

300. Under the Michigan Antitrust Reform Act, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. Mich. Comp. Laws. § 452.778(2).

301. Defendant contracted, combined or conspired to restrain or monopolize trade or commerce in the markets for aligners and scanners, in violation of Mich. Comp. Laws § 445.772, *et seq.* In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

302. Plaintiffs and members of the Michigan Class were injured with respect to purchases of Invisalign aligners in Michigan and are entitled to all forms of relief, including actual damages, treble damages for flagrant violations, interest, costs, reasonable attorneys’ fees, and injunctive or other appropriate equitable relief.

TENTH CLAIM FOR RELIEF:
VIOLATION OF THE MINNESOTA ANTITRUST LAW,
MINN. STAT. § 325D.49, *ET SEQ.*
(ON BEHALF OF THE MINNESOTA CLASS)

303. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

304. The Minnesota Antitrust Law of 1971 aims to prohibit any contract, combination or conspiracy when any part thereof was created, formed, or entered into in Minnesota; any contract,

combination or conspiracy, wherever created, formed or entered into; any establishment, maintenance or use of monopoly power; and any attempt to establish, maintain or use monopoly power, whenever any of these affect Minnesota trade or commerce.

305. Plaintiffs purchased Invisalign aligners within the State of Minnesota during the Class Period. But for Defendant's conduct set forth herein, the price of Invisalign aligners would have been lower, in an amount to be determined at trial.

306. Under the Minnesota Antitrust Act of 1971, indirect purchasers have standing to maintain an action based on the facts alleged in this Complaint. Minn. Stat. § 325D.56.

307. Defendant contracted, combined or conspired in unreasonable restraint of trade or commerce in the market for aligners and scanners within the intrastate commerce of and outside of Minnesota; and established, maintained, used or attempted to establish, maintains or uses monopoly power over the trade or commerce in the market for aligners and scanners within the intrastate commerce of and outside of Minnesota; and fixed prices and allocated markets for aligners and scanners within the intrastate commerce of and outside of Minnesota, in violation of Minn. Stat. § 325D.49, *et seq.* In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

308. Plaintiffs and members of the Minnesota Class were injured with respect to purchases of Invisalign aligners in Minnesota and are entitled to all forms of relief, including actual damages, treble damages, costs and disbursements, reasonable attorneys' fees, and injunctive relief necessary to prevent and restrain violations hereof.

ELEVENTH CLAIM FOR RELIEF:
VIOLATION OF THE NEBRASKA CONSUMER PROTECTION ACT,
NEB. REV. STAT. § 59-1602, *ET SEQ.*
(ON BEHALF OF THE NEBRASKA CLASS)

309. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

310. By reason of the conduct alleged herein, Defendant has violated Neb. Rev. Stat. § 59-1602, *et seq.*

311. Defendant established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the aligner and scanner markets, for the purpose of excluding or limiting competition or controlling or maintaining prices, a substantial part of which occurred within Nebraska. In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

312. Defendant's conduct was conducted with the intent to deceive Nebraska consumers regarding the nature of Defendant's actions within the stream of Nebraska commerce.

313. Defendant's conduct was unfair, unconscionable, or deceptive within the conduct of commerce within the State of Nebraska.

314. Defendant's conduct misled consumers, withheld material facts, and had a direct or indirect impact upon Plaintiffs and members of the Nebraska Class's ability to protect themselves.

315. Defendant's unlawful conduct substantially affected Nebraska's trade and commerce.

316. As a direct and proximate cause of Defendant's unlawful conduct, plaintiffs and the members of the Nebraska Class have been injured in their business or property and are threatened with further injury.

317. By reason of the foregoing, plaintiffs and members of the Nebraska Class are entitled to seek all forms of relief available under Neb. Rev. Stat. § 59- 1614.

TWELFTH CLAIM FOR RELIEF:
VIOLATION OF THE NEVADA UNFAIR TRADE PRACTICES ACT,
NEV. REV. STAT. § 598A.010, ET SEQ.
(ON BEHALF OF THE NEVADA CLASS)

318. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

319. The Nevada Unfair Trade Practice Act ("NUTPA") states that "free, open and competitive production and sale of commodities...is necessary to the economic well-being of the citizens of the State of Nevada." Nev. Rev. Stat. Ann. § 598A.030(1).

320. The policy of NUTPA is to prohibit acts in restraint of trade or commerce, to preserve and protect the free, open and competitive market, and to penalize all persons engaged in anticompetitive practices. Nev. Rev. Stat. Ann. § 598A.030(2). Such acts include, inter alia,

division of markets, allocation of customers, and monopolization of trade. Nev. Rev. Stat. Ann. § 598A.060.

321. Plaintiffs purchased Invisalign aligners within the State of Nevada during the Class Period. But for Defendant's conduct set forth herein, the price of these aligners would have been lower, in an amount to be determined at trial.

322. Under Nevada law, indirect purchasers have standing to maintain an action under NUTPA based on the facts alleged in this Complaint. Nev. Rev. Stat. Ann. §598A.210(2).

323. Defendant divided Nevada markets, allocated Nevada customers, monopolized or attempted to monopolize trade or commerce of aligners and scanners within the intrastate commerce of Nevada, constituting a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.* In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

324. Plaintiffs and members of the Nevada Class were injured with respect to purchases of Invisalign aligners in Nevada in that at least thousands of sales of Defendant's aligners took place in Nevada, purchased by Nevada consumers at supracompetitive prices caused by Defendant's conduct.

325. Accordingly, Plaintiffs and members of the Nevada Class are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, costs, and injunctive relief.

326. In accordance with the requirements of § 598A.210(3), notice of this action will be mailed to the Nevada Attorney General by plaintiffs.

THIRTEENTH CLAIM FOR RELIEF:
VIOLATION OF THE NORTH CAROLINA GENERAL STATUTES,
N.C. GEN. STAT. § 75-1, *ET SEQ.*
(ON BEHALF OF THE NORTH CAROLINA CLASS)

327. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

328. Defendant established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the scanner and aligner markets, for the purpose of affecting competition or controlling, fixing, or maintaining prices, a substantial part of which occurred within

North Carolina. In particular, Defendant engaged in a Scheme to monopolize the distinct product submarket of aligners sold through dental offices.

329. Defendant's unlawful conduct substantially affected North Carolina's trade and commerce.

330. As a direct and proximate cause of Defendant's unlawful conduct, plaintiffs and the members of the North Carolina Class have been injured in their business or property and are threatened with further injury.

331. By reason of the foregoing, Plaintiffs and members of the North Carolina Class are entitled to seek all forms of relief available, including treble damages, under N.C. Gen. Stat. § 75-1, *et seq.*

FOURTEENTH CLAIM FOR RELIEF:
VIOLATION OF THE OREGON ANTITRUST LAW,
OR. REV. STAT. § 646.705, *ET SEQ.*
(ON BEHALF OF THE OREGON CLASS)

332. Plaintiffs incorporate by reference the allegations in the above paragraphs as if fully set forth herein. The following claims for relief are pleaded under the antitrust laws of each jurisdiction identified below on behalf of the indicated class.

333. Chapter 646 of the Oregon Revised Statutes generally governs business and trade practices within Oregon. Sections 705 through 899 thereof govern antitrust violations, with the policy to "encourage free and open competition in the interest of the general welfare and economy of the state." Or. Rev. Stat. § 646.715.

334. Plaintiffs purchased Invisalign aligners within the State of Oregon during the Class Period. But for Defendant's conduct set forth herein, the price of aligners would have been lower, in an amount to be determined at trial.

335. Under Oregon law, indirect purchasers have standing under the antitrust provisions of the Oregon Revised Statutes to maintain an action based on the facts alleged in this Complaint. Or. Rev. Stat. § 646.780(1)(a).

336. Defendant contracted, combined, or conspired in restraint of trade or commerce of aligners and scanners, and monopolized or attempted to monopolize the trade or commerce of aligners and scanners, in violation of Or. Rev. Stat. § 646.705, *et seq.*

337. Plaintiffs and members of the Oregon Class were injured with respect to purchases of aligners within the intrastate commerce of Oregon, or alternatively to interstate commerce involving actual or threatened injury to persons located in Oregon, and are entitled to all forms of relief, including actual damages, treble damages, reasonable attorneys' fees, expert witness fees and investigative costs, and injunctive relief.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the classes of all others so similarly situated, respectfully requests judgment against Defendant as follows:

A. The Court determine that this action may be maintained as a class action under Rule 23(a) (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, appoint Plaintiffs as Class Representatives and their counsel of record as Class Counsel, and direct that notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to the Classes, once certified;

B. The unlawful conduct, conspiracy or combination alleged herein be adjudged and decreed in violation of Section 1 and Section 2 of the Sherman Act and listed state antitrust laws, unfair competition laws, state consumer protection laws, and common law;

C. Plaintiffs and the Classes recover damages, to the maximum extent allowed under the applicable federal and state laws, and that a joint and several judgments in favor of plaintiffs and the members of the Classes be entered against Defendant in an amount to be trebled to the extent such laws permit;

D. Defendant, its affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be permanently enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, conspiracy, or combination alleged herein, or from

entering into any other conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program, or device having a similar purpose or effect;

E. Defendant, its affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be permanently enjoined and restrained from in any manner continuing, maintaining, or renewing its anticompetitive acts in furtherance of its Monopolization.

F. Plaintiffs and the members of the classes be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of this Complaint;

G. Plaintiffs and the members of the Classes recover their costs of suit, including reasonable attorneys' fees, as provided by law; and

H. Plaintiffs and the members of the Classes have such other and further relief as the case may require and the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

DATED : March 2, 2022.

Respectfully submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

By /s/ Rio S. Pierce

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Counsel for Plaintiffs

**EXHIBIT A SUBMITTED
UNDER SEAL**

**EXHIBIT B SUBMITTED
UNDER SEAL**

STRATEGIC SUPPLY AGREEMENT

This Strategic Supply Agreement (the “Agreement”), by and between Align Technology Inc. (“Align”) and SmileCareClub, LLC d/b/a SmileDirectClub (“SDC,” and together with Align, the “Parties”), is entered into and is effective as of July 25, 2016 (the “Effective Date”).

RECITALS

WHEREAS, SDC and Align desire to set forth the terms and conditions pursuant to which Align will manufacture and sell Club Aligners (as defined herein) to SDC and SDC will purchase such Club Aligners from Align; and

NOW, THEREFORE, in consideration of the foregoing and the terms and conditions stated in this Agreement, the Parties agree as follows:

1. **Definitions.**

1.1 “Affiliate” of a company means any corporation or other entity that controls, is controlled by, or is under common control with that company, where “control” means either (i) direct or indirect ownership of at least fifty percent (50%) of the outstanding shares of stock entitled to vote for the election of directors (other than shares of stock whose voting rights are subject to restriction), or (ii) or in the case of an entity that does not have outstanding shares or securities (as may be the case in a partnership, joint venture or unincorporated association), direct or indirect ownership of at least fifty percent (50%) of the ownership interest representing the right to make the decisions for such entity, but such control will be deemed to exist only so long as such ownership or control exists.

1.2 “Applicable Law(s)” shall mean, with respect to a Party’s activities hereunder, individually and collectively, any and all applicable laws (including, without limitation, securities laws and healthcare laws), ordinances, orders, rules, rulings, directives and regulations of any kind whatsoever of any governmental authority or Regulatory Authority, final, binding and unappealable court orders and judgments, and rules of a stock exchange, in each case, including the then-current amendments thereto or any replacement thereof, and in each case, applicable to such Party’s activities hereunder.

1.3

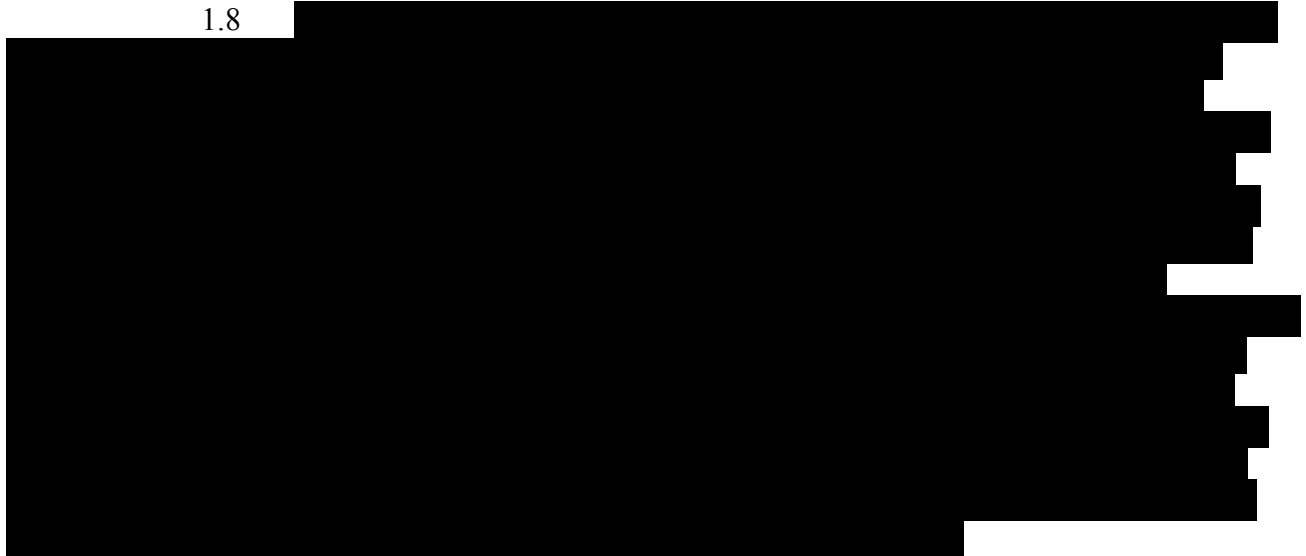
1.4

1.5 “Confidential Information” has the meaning specified therefor in Section 18.

1.6 “Delivery Date” means the date the Club Aligners are delivered by Align to the carrier at Align’s facility.

1.7 “DTC” means direct to patient.

1.8



1.9 “Label”, “Labeled”, or “Labeling” means, when used as a noun, (a) all labels and other written, printed or graphic matter upon a Club Aligner or any container or wrapper utilized with such Club Aligner, (b) any written material on or accompanying such Club Aligner, including, without limitation, package inserts, or (c) all primary and secondary containers, including cartons, shipping packages and other like matter used in packaging a Club Aligner. When used as verb, Label means to affix, insert or insert into a Label.

1.10 “Purchase Order” means a purchase order provided by SDC to Align that authorizes Align to manufacture and ship a definite quantity of Club Aligners to SDC.

1.11 “Regulatory Approval” means, with respect to a country or jurisdiction within the Territory, (a) any and all approvals, clearances, licenses, registrations or authorizations necessary to distribute a Club Aligner in such country or jurisdiction, and (b) where relevant, pricing approvals necessary to obtain reimbursement from a governmental entity with respect to such Club Aligner in such country or jurisdiction.

1.12 “Regulatory Authority” means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the distribution or manufacturing of, or granting of Regulatory Approval for, Club Aligners.

1.13 “Regulatory Documentation” means any filing, submission or application with any Regulatory Authority, including all applications for Regulatory Approvals and supplements thereto, and authorizations, approvals or clearances arising from the foregoing, as well as all correspondence with the relevant Regulatory Authority, in each case with respect to a Club Aligner.

1.14 “SDC Business Model” means SDC’s current business practice of providing certain services to SDC Endorsed Local Providers, as defined below, for the latter to deliver orthodontic treatment to patients. These services include, without limitation, marketing and advertising, logistic, treatment planning, practice management, billing and collection, records maintenance, case management, licenses for use of intellectual property and will include Club Aligners.

1.15 “SDC Direct Clear Aligner(s)” means clear aligner products manufactured directly by SDC pursuant to its 510(k) clearance using a material that is substantially similar to the Material, as defined below, that are substantially similar to Club Aligner(s) and do not (i) utilize attachments or optimized attachments, (ii) require IPR (interproximal reduction), (iii) require changes in velocity, (iv) utilize Align’s SmartStaging algorithms, Align’s SmartForce technology, or Align’s SmartTrack material or (iv) utilize gingiva cut technology.

1.16 “SDC Distribution Channels” means SDC’s current and currently proposed online DTC distribution channels in the Territory which can be further described/defined as supplying aligners for orthodontic treatment to patients’ address of choosing from SDC’s distribution centers as per the SDC Business Model.

1.17 “SDC Endorsed Local Provider” means a dentist or orthodontist who is (i) an independent third party who has contracted with SDC relating to services within the SDC Business Model, (ii) licensed to practice dentistry or orthodontia, as applicable, in the jurisdiction to which Club Aligners will be delivered, and (iii) has successfully completed the required Invisalign training for use of Align’s product.

1.18 “Term” has the meaning set forth in Section 13.1.

1.19

[REDACTED]

1.20

[REDACTED]

2. **Scope.**

2.1 **Manufacture, Sale and Distribution of Club Aligners.** Align will manufacture and sell Club Aligners to SDC for distribution by SDC only through SDC Distribution Channels, according to the terms and conditions of this Agreement. This Agreement is intended by Align and SDC to operate as a basic set of operating conditions regarding their respective business relationship.

2.2 **Project Managers.** Each Party will make available to the other a single point of contact (“Project Manager”) for managing the day-to-day relationship of the Parties under this Agreement and to assist in the escalation of issues. Notwithstanding any other provision herein, the Project Managers will have no authority to bind the Parties or to direct the activities of the other Party.

3. **Exclusivity.**

3.1

[REDACTED]

3.2

[REDACTED]

3.3

[REDACTED]

4. **Minimum Required Treatments.**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5. **Material and Manufacturing.**

5.1

[REDACTED]

5.2

[REDACTED]

[REDACTED]

5.3 [REDACTED]

[REDACTED]

5.4 Other Changes. Except for changes to the Material which require consent pursuant to Section 5.2 or use of third party manufacturers pursuant to Section 5.3, Align may make such changes to the Club Aligners or the manufacture thereof as it deems reasonable from time to time, provided that SDC approves changes to Club Aligners that would have an impact on the quality of the Club Aligners in writing, which approval will not be unreasonably withheld.

5.5 FDA Registration. Align shall permit SDC to register with the FDA as a relabeler for sequential tooth aligners. If the FDA requires Align's assistance for such registration, Align will provide reasonable cooperation as needed.

6. **Training, Material Review, and Treatment Planning**.

6.1 [REDACTED]

[REDACTED]

6.2 SDC Website Materials. SDC represents and warrants that each SDC Endorsed Local Provider, prior to issuing a Purchase Order, reviews and approves all patient (or prospective patient) educational or informational materials, including without limitation videos and impression kit instructions, made available on any website owned or operated by SDC.

6.3 Impression Kits. SDC represents and warrants that prior to sending a home impression kit to a patient, a SDC Endorsed Local Provider has provided a prescription or authorization to SDC for such patient's home use of the home impression kit and that the intended use of such impression kit is in compliance with all Applicable Laws.

6.4 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6.5

[REDACTED]

6.6 Customer Service. SDC will provide all customer service for Club Aligners. Align will have no direct contact with SDC's patients.

7. **Purchase Orders and Delivery Date Schedules; Cancellations and Rescheduling.**

7.1

[REDACTED]

7.2 Purchase Order Terms. All Purchase Orders will be governed solely by the terms and conditions of this Agreement, notwithstanding any preprinted terms or conditions on SDC's Purchase Order, Align's acknowledgement or invoice, or otherwise, and any such terms that conflict with, or are additional to, the terms and conditions of this Agreement will be void.

7.3 Cancellation. After Align has started to manufacture a Treatment, the Treatment may not be cancelled and all fees are owed for such Treatment. An order may be cancelled prior to manufacturing, subject to a cancellation charge per Treatment at the then current pricing for cancellations as set forth in the Align Pricing Terms and Conditions in effect upon the date the Purchase Order was placed.

8. **Labeling, Packaging and Shipment.**

8.1

[REDACTED]

8.2 Packaging. All Club Aligners will be packaged and prepared for shipment in a manner that is acceptable to common carriers for shipment, is in accordance with all Applicable Laws and within Align’s 510(k) clearance, and is adequate to ensure safe arrival. SDC at this time is not requesting standard aligner boxes but is working towards a model utilizing the Align plastic bags for each patient that are labeled and are placed into a standard shipping carton (“Standard Packaging”). Standard Packaging is included in the per Club Aligner Cost. SDC may request custom packaging beyond the Standard Packaging and expedited or additional shipping, which may result in additional fees to be mutually agreed by the parties. Align will mark all containers with necessary handling and shipping information and with Purchase Order numbers and date of shipment.

8.3 Labeling. Within two (2) months after the Effective Date, SDC will supply to Align its logo, the selected Club Aligner Trademark and any additional content for use on the Club Aligners or Labeling, which Align will (at Align’s sole expense) incorporate into the Club Aligners’ Labeling, provided the parties have agreed that the content of the label meets Align’s intended use under Align’s 510(k) and is in accordance with Applicable Laws. The parties must also agree that any instructions for use and other instructions to patients provided by SDC or SDC Endorsed Local Provider meet Align’s intended use under Align’s 510(k) and is in accordance with the Applicable Laws. In the event that SDC wishes to modify or change the Labeling, SDC will provide advance notice of such desired change to Align and forward such modifications or changes to Align for incorporation into the Labeling. Align will evaluate the request for compliance with Applicable Laws and provide SDC with an expected timeline for incorporating the change and an estimated cost for the change, however the obligation for compliance with Applicable Laws will reside with SDC and it should seek counsel as needed. Align will notify SDC if the change can’t be implemented. SDC will reimburse Align within forty-five (45) days following receipt of Align’s invoice, for all of Align’s reasonable direct costs and expenses incurred by Align in connection with implementing such label changes requested by SDC, including expenses of Labeling materials that are no longer useable by Align in the Labeling and were purchased or produced based on Purchase Orders and the next three (3) months’ worth of forecasts provided pursuant to Section 7.1 Align, at SDC’s direction, will make any changes to the Labeling that are required under Applicable Law or by any Regulatory Authority, at SDC’s expense; provided that Align will not make any changes to the Club Aligners’ Labeling without SDC’s prior written consent.

9. **Title, Risk of Loss and Acceptance.**

9.1

[REDACTED]

9.2

[REDACTED]

promptly replace any rejected Club Aligners, then, without limitation, SDC may cancel its Purchase Order for that Treatment without penalty or charge, for a credit or refund (at SDC's option). SDC's acceptance of Club Aligners is without prejudice to any other rights.

10. **Pricing and Payment.**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

11. [REDACTED]

treatments not suitable for Treatment with Club Aligners, service level updates, and number of those patients who utilized the Align Doc Locator site to locate an Invisalign trained doctor to work with, an average number of refinement aligners required per Treatment.

12. [REDACTED]

13. **Term and Termination.**

13.1 Term. Unless early terminated, the term of the Agreement will commence on the Effective Date and extend until December 31, 2019 (the "Term"). The agreement may be renewed by mutual agreement of the parties.

13.2 Termination for Breach. This Agreement may be terminated by a Party, upon written notice to the other Party, if such other Party breaches a material obligation thereunder and such failure is not cured within 45 days after the breaching Party receives a written notice alleging such breach, specifying its nature, and requesting its correction. The parties have agreed to SLA's as set forth on Exhibit A are for guidance purposes and Align will use commercially reasonable efforts to achieve such SLAs. Failure to meet such SLAs will not be a material breach of this Agreement and will not result in any financial penalties or fees. If Align fails to meet the SLAs the parties will meet and confer to decide how to resolve the issue and escalate to upper management as needed. If SLA delivery time becomes a substantial issue the parties may mutually decide that termination is required and can amend the Agreement as necessary.

13.3 Termination for Insolvency. Either Party may terminate this Agreement immediately upon notice if the other Party: (a) makes a general assignment for the benefit of creditors; (b) is adjudicated bankrupt or insolvent; (c) files a voluntary petition for bankruptcy, insolvency or reorganization, or has a petition filed against it for an adjudication in bankruptcy, insolvency or reorganization and such petition is not dismissed within 60 days; or (d) applies for or permits the appointment of a receiver, trustee or custodian for any of its property or assets.

13.4 [REDACTED]

13.4 [REDACTED]

[REDACTED]

13.5 Additional Termination. Align may also terminate this Agreement with respect only to the affected part of the Territory upon the enactment of any law, decree, or regulation by any governmental authority in any part of the Territory which would materially impair or restrict: (i) the right of Align to terminate or elect not to renew this Agreement as herein provided, (ii) Align's right, title or interest in the Club Aligners or the Intellectual Property Rights therein, (iii) Align's rights to receive the payments under this Agreement, or (iv) Align's right to manufacture, offer for sale, import, export, sell, or distribute the Club Aligners. If this Agreement is partially terminated in accordance with this paragraph, then the Minimum Required Treatments will be reduced proportionately based on the number of Treatments from the terminated area during the prior twelve month period.

13.6 No Termination Liability. In the event of termination by either Party in accordance with any of the provisions of this Agreement other than Section 13.2, neither Party will be liable to the other, because of such termination, for compensation, reimbursement or damages on account of the loss of prospective profits or anticipated sales or on account of expenditures, inventory, investments, leases or commitments in connection with the business or goodwill of SDC or Align. Termination will not, however, relieve either Party of obligations incurred prior to the termination.

[REDACTED]

[REDACTED]

14. **Representations and Warranties; Disclaimer; Recall**

14.1 General. Each Party represents and warrants that: (a) it has full power to enter into this Agreement and to grant to the other Party the rights granted to such other Party under this Agreement, (b) it has obtained all necessary corporate approvals to enter into and execute the Agreement, and (c) its execution of this Agreement and performance of the terms set forth herein will not cause be in conflict with or constitute a breach of any agreement or understanding with any third party.

14.2 Permits and Data. Each Party represents and warrants that: (a) subject to the terms of this Agreement, it has (or will timely obtain) and will maintain throughout the Term all permits, licenses, registrations and other forms of governmental authorization and approval as required by Applicable Laws in order for such Party to execute and deliver this Agreement and to perform its obligations hereunder (including the manufacture, relabeling, and distribution, as applicable of the Club Aligners) in accordance with all Applicable Laws; (b) any and all data and information provided by such Party to the other Party hereunder with respect to the Club Aligners, is accurate and complete in all material respects as of the date delivered or, in the case of dated information, as of the date thereof, was collected in accordance with Applicable Laws and is not subject to any material restriction on its use by Align or SDC, other than the confidentiality obligations in Section 18; and (c) neither such Party nor any current or former officer, employee or agent of such Party who has been or is involved in activities related to any Club Aligner has been convicted of any crime or engaged in any conduct that has resulted or would reasonably be expected to result in exclusion from any healthcare reimbursement program in the United States or the Territory.

14.3 Good Standing. SDC represents and warrants that all orders for Club Aligners submitted by SDC and received by Align during the term of the Agreement were ordered and will be ordered by currently licensed SDC Endorsed Local Providers that are in good standing with their applicable State Board(s) of Dentistry in the jurisdiction where they practice and where the patient prescribed the Club Aligners resides, and pursuant to valid prescriptions or authorizations.

[REDACTED]

[REDACTED]

14.6 Warranty Remedies. Where Align (i) cannot exclude any express or implied condition or warranty referenced below, or (ii) the Club Aligners fail to conform to the warranty above, then, to the extent permitted by applicable law, Align's sole and exclusive obligation and SDC's sole and exclusive remedy is at Align's discretion to (a) repair or replace the Club Aligners, or (b) pay the cost of having the Club Aligners repaired or replaced. No representative, employee or agent of Align is authorized to incur warranty obligations on behalf of Align or modify the limitations set forth herein. Aligners covered under this warranty section may be returned with a RMA number marked clearly on the outside of the package. Replacement Club Aligners will be warranted for the original warranty period set forth in Section 14.3 above. Costs of return transit to

SDC for replacement Club Aligners due to non-conformity to the warranty set forth in Section 14 will be borne by Align.

14.7 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH ABOVE IN THIS SECTION 14.6, ALIGN MAKES NO WARRANTIES OF ANY NATURE, DIRECTLY OR INDIRECTLY, EXPRESS OR IMPLIED, BY STATUTE OR OTHERWISE, INCLUDING WITHOUT LIMITATION (i) ANY WARRANTIES OF FITNESS OR SUITABILITY FOR ANY PURPOSE, QUALITY, CONDITION, MERCHANTABILITY, NON-INFRINGEMENT, OR OTHERWISE, OR (ii) ANY WARRANTY REGARDING THE OUTCOME OF TREATMENT USING THE CLUB ALIGNERS PROVIDED HEREUNDER OR THEIR SAFETY, AND ALL SUCH WARRANTIES ARE HEREBY EXCLUDED TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW.



15. Use of Trademarks.

15.1 Align Trademarks. During the Term, solely to the extent required by Applicable Law, SDC may indicate that Align manufactures its Club Aligners. In no event may SDC use any of Align's name, Trademarks or the Invisalign product name or logo in the advertising of its sale of Club Aligners. Any proposed representations and uses of the Align name will first be

submitted to Align for approval, which approval will be at Align's sole discretion. In addition, SDC will fully comply with all reasonable guidelines communicated by Align concerning the use of Align's name including without limitation any guidelines regarding quality control. In the event Align notifies SDC that any usage of the Align name is not acceptable to Align then SDC will immediately cease all such non-acceptable use including withdrawing all dissemination of embodiments of such usage where the withdrawal is within the reasonable control of SDC and any further unacceptable use by SDC will be deemed to be a material breach hereunder and the agreement may be terminated upon notice by Align.

15.2 SDC Trademarks. Align will include, to the extent reasonably requested by SDC and permitted under Applicable Law, the SDC trademarks, logos and trade names that SDC may designate for use on the Club Aligners from time to time on the Labeling intended for distribution in the Territory, provided that each such usage will be subject to Align's prior written consent, not to be unreasonably withheld. SDC hereby grants to Align, during the Term, a non-exclusive license to use SDC's Trademarks, to the extent they are included on Club Aligners or their Labeling in accordance with SDC's then-current guidelines for usage of SDC's Trademarks. SDC Trademarks will at all times remain the exclusive property of SDC, and all goodwill associated with the use of SDC's Trademarks will inure to the exclusive benefit of SDC.

16. Legal and Regulatory Matters; Insurance.

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

17. Limitation of Liability.

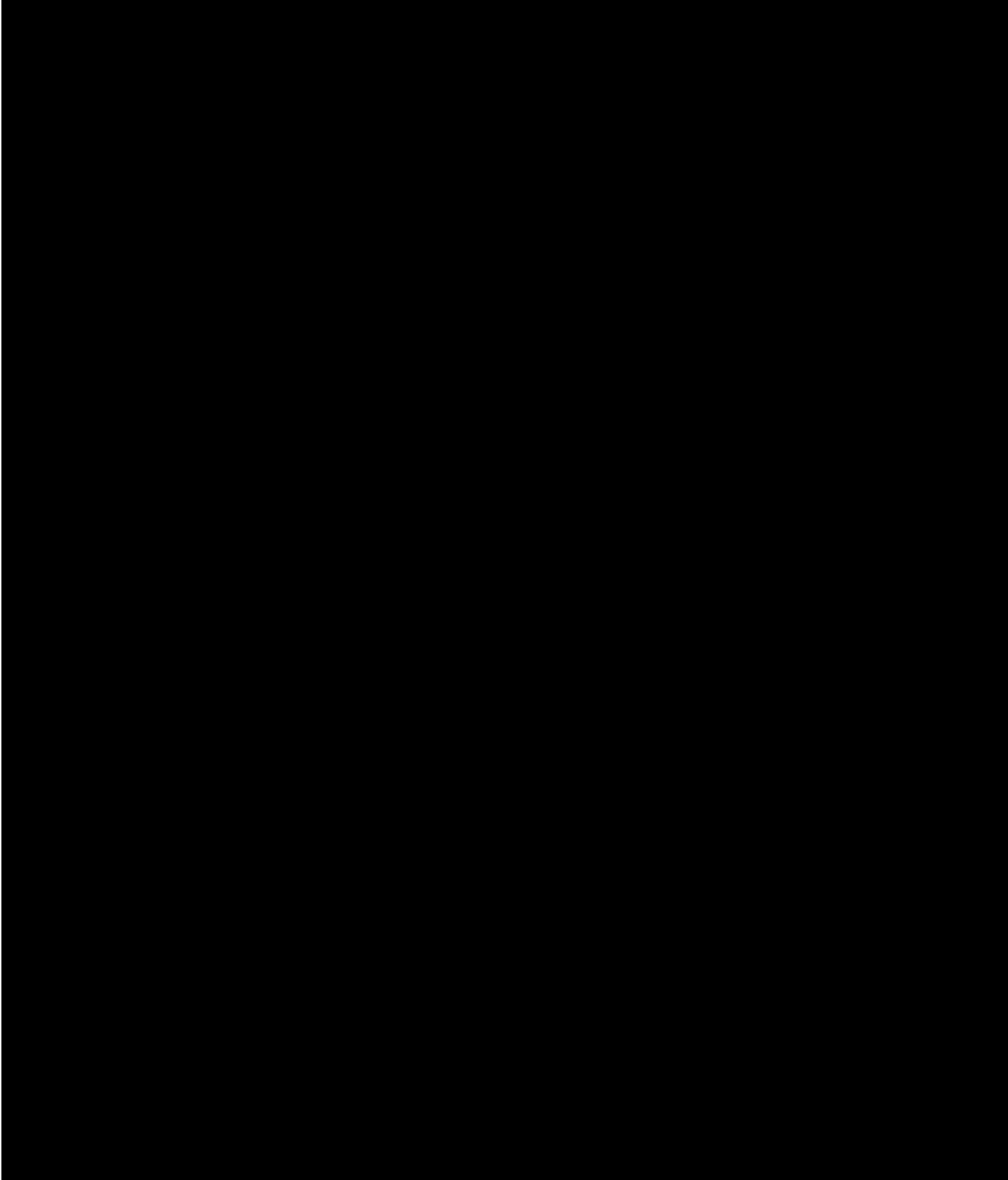
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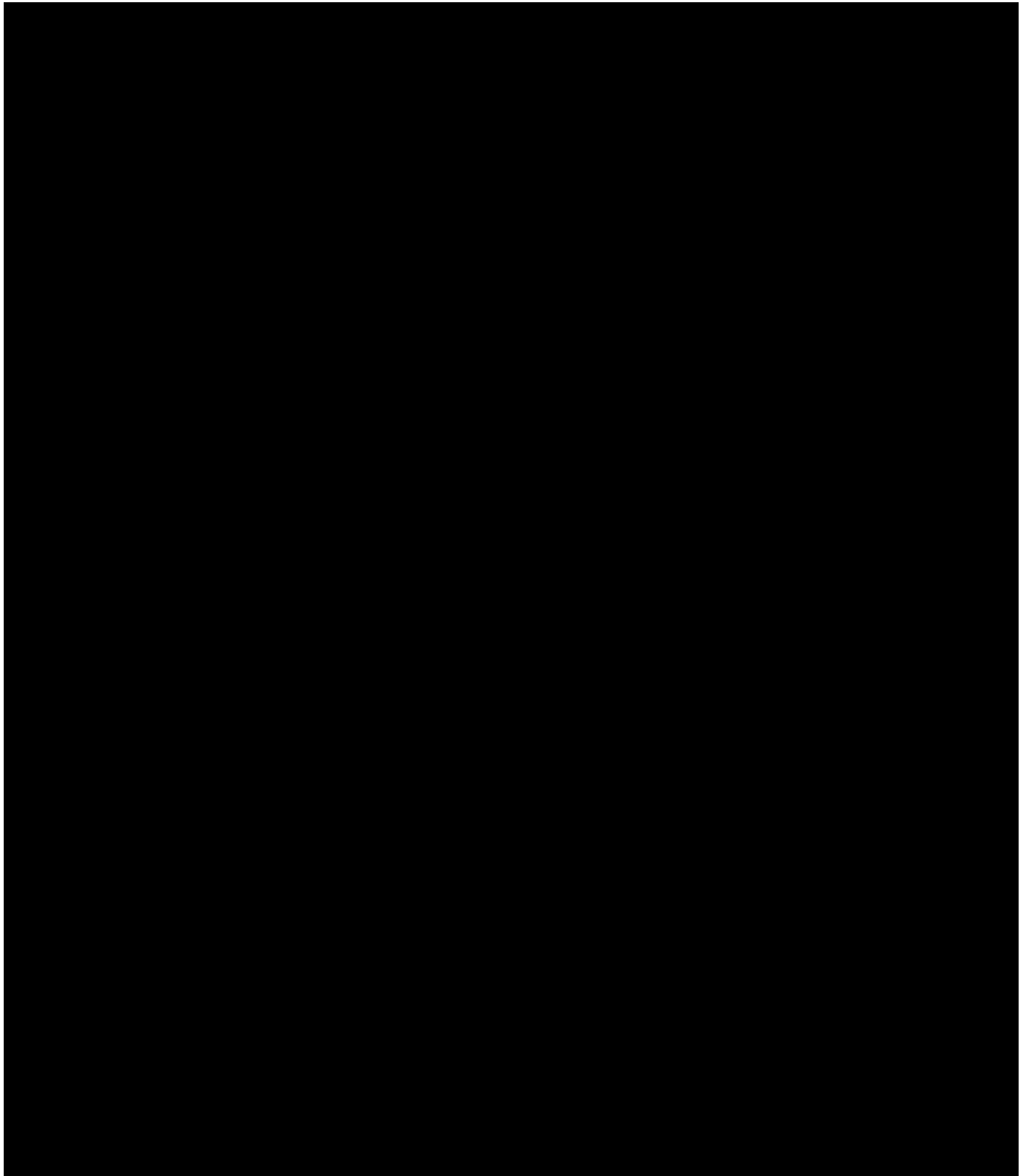
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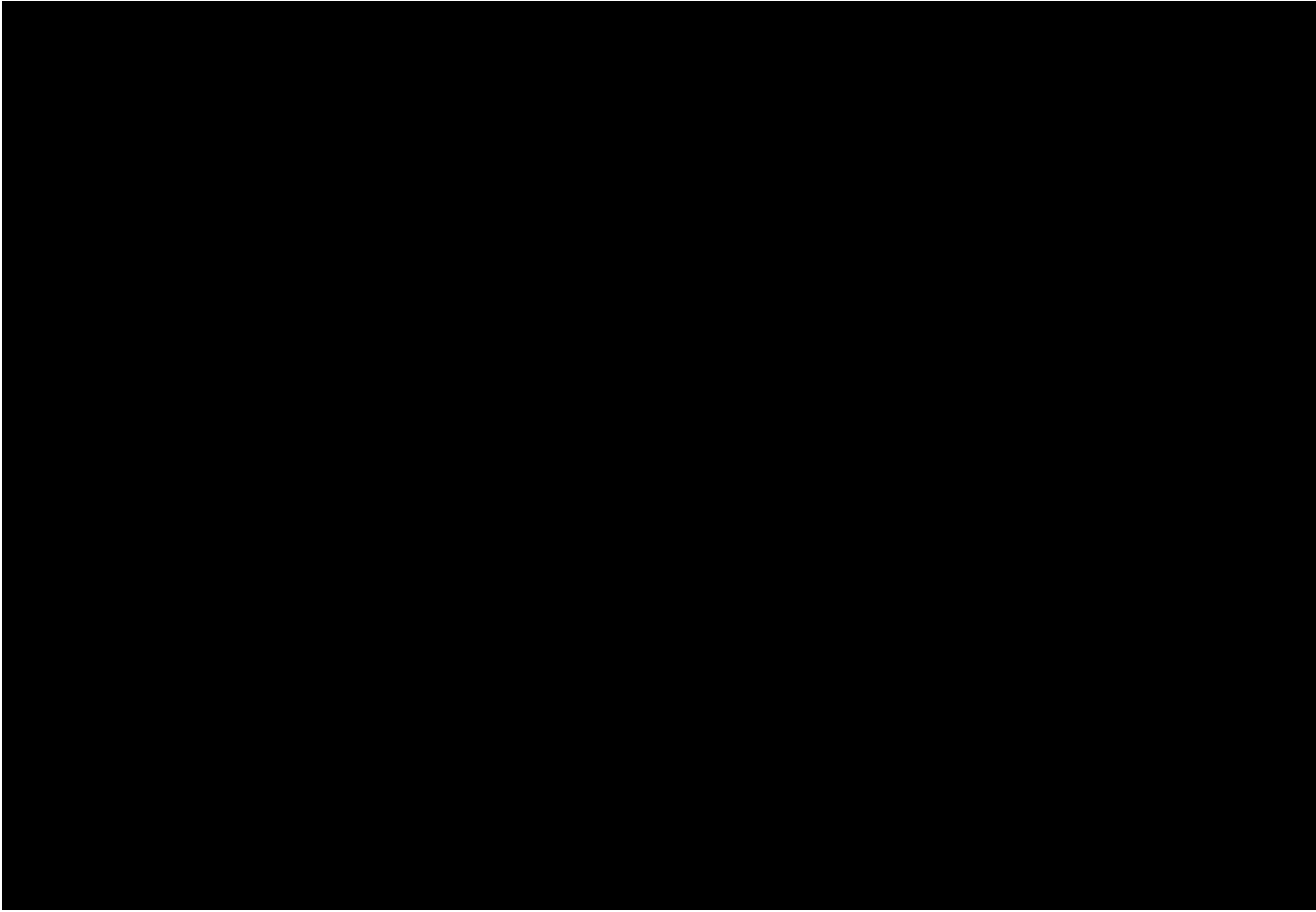
[REDACTED]

18. Confidentiality.

[REDACTED]







19. **Intellectual Property**. As between the Parties, Align retains all Intellectual Property Rights in and to the Club Aligners and all manufacturing processes, technology and documentation therefor other than SDC's Trademarks. Except as contemplated by this Agreement, no licenses are granted to SDC under this Agreement to any of Align's Intellectual Property Rights, expressly, by implication or otherwise, and all such rights are reserved by Align. Without limiting the generality of the foregoing, SDC will have no rights, expressly, by implication, or otherwise to manufacture, duplicate, translate, copy, reproduce, modify, improve, or reverse engineer any Club Aligners, any other Align products or services, or any materials provided by Align.

20. **Data Security and Privacy**.

20.1 **HIPAA**. Align acknowledges and accepts that SDC's Endorsed Local Providers provide SDC with Protected Health Information ("PHI"), as defined by the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder as they may be amended from time to time ("HIPAA"), therefore, to the extent that SDC provides Align access to such PHI in the course of its performance under this Agreement, Align, its directors, officers, affiliates, employees, contractors and consultants must not use or disclose the PHI other than as permitted in the sub-Business Associate Agreement executed by the parties. SDC is required to use appropriate safeguards to prevent use, reproduction or disclosure of PHI information. Such safeguards include but are not limited to training to protect PHI and education surrounding policies

and procedures to protect PHI. Without limiting the generality of Section 20.1, SDC to Align that SDC will at all times comply with HIPAA, all Applicable laws including without limitation and each state and local privacy law, rule, and regulation regarding the use and disclosure to Align of Personal Data (collectively, "Privacy Laws") including information received from SDC Endorsed Local Providers.

20.2 Security. Align and SDC will have in place and maintain throughout the Term reasonable technical, administrative and physical safeguards to protect the Personal Data against unauthorized destruction or loss, alteration, unauthorized disclosure or access, and against all other unlawful forms of processing (a "Data Breach"). Responding to Requests. The parties will provide all assistance reasonably required by either party to enable to respond to, comply with or otherwise resolve any request, question or complaint received by a party from (i) any individual whose Personal Data is processed or (ii) any applicable authority.

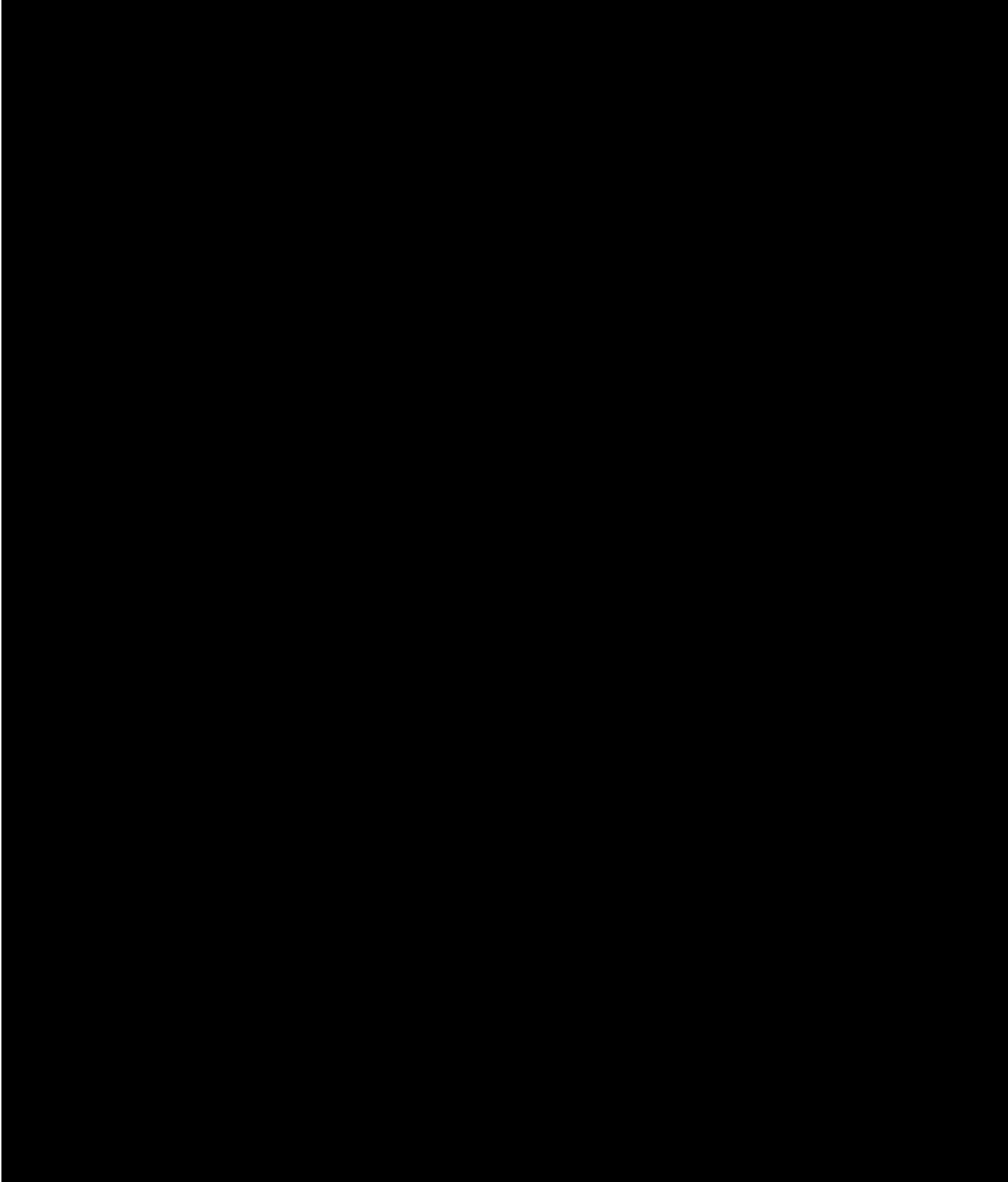
20.3 Notification. In the event of a Data Breach, a party will promptly in no event no later than within 48 hours notify the other party and do all such acts and things as such party considers reasonably necessary in order to remedy or mitigate the effects of the Data Breach and will continuously update the other party of developments relating to the Data Breach. In the event that any Personal Data is lost, damaged or destroyed as a consequence of a Data Breach, it will be promptly restored to the last available backup.

20.4 Audit. SDC will promptly: (i) procure an independent third party acceptable to Align to audit SDC's compliance with its HIPAA-related obligations; and (ii) deliver to Align an audit report from such independent third party documenting, to Align's satisfaction, SDC's substantial compliance with its HIPAA-related obligations, and (iii) provide to Align the report delivered to SDC regarding HIPAA compliance, and to the extent SDC does not comply with HIPAA, a gap assessment and remediation plan for compliance with HIPAA. Unless mutually agreed otherwise by the parties, an annual audit will be conducted by an independent third party acceptable to both parties to ensure SDC's compliance with this section and such report will be provided to Align. SDC shall pay for the cost of such audit. The first annual audit will take place no earlier than 30 days following SDC's initial launch date for offering the Club Aligners.

20.5 SDC and Align Vendors. SDC and Align will endeavor to obtain contractual assurances that any outsourcing service providers, vendors and suppliers will abide by All Applicable Laws with regards to privacy and information security, including without limitation HIPAA..

21. Indemnification.

[REDACTED]



[REDACTED]

22. **Litigation Dismissal and Covenant Not to Sue.**

[REDACTED]

[REDACTED]

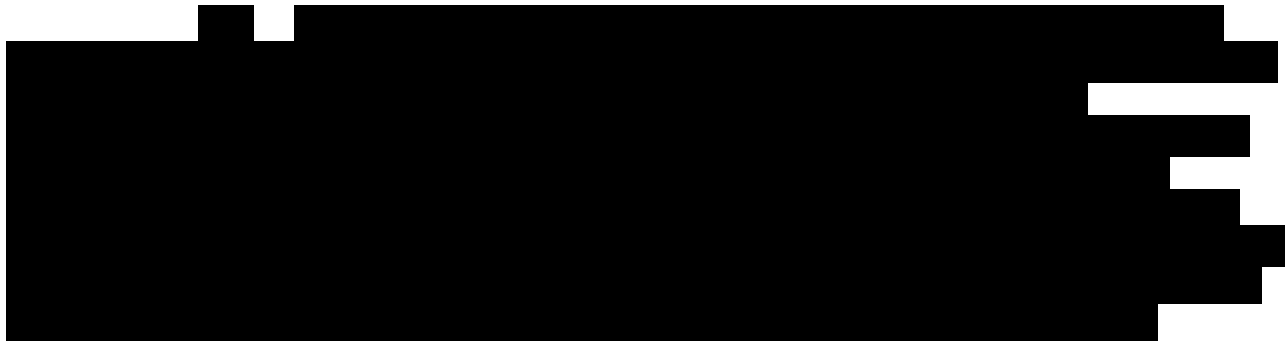
[REDACTED]

23. **Recordkeeping and Audit.** SDC agrees to maintain appropriate records (i) in accordance with a records retention policy which is consistent with generally accepted accounting principles and (ii) relating to local laws and regulations in the Territory. Upon written request from Align, SDC will provide (i) an third party audit report relating to SDC's system of internal auditing controls and SDC will allow Align or an independent third party to audit SDC's internal auditing controls, records, quality systems records and quality management system certifications, supporting regulatory documents like regulatory submission documents/dossiers/technical files or equivalent submitted to each country's local regulatory body and the clearances, licenses, certificates, approvals or equivalent documentation obtained for the Territory, provided that Align pays for such audit, it is completed during business hours, at a mutually convenient time, and the results of such audit are considered Confidential Information of SDC. Upon request, SDC will provide Align a copy of

clearances/approvals/licenses/certifications or equivalent, upon request and within forty-eight (48) hours of a request. Where a copy of the documentation is not required, SDC will provide Align written documentation within forty-eight (48) hours of a request stating that they have the appropriate regulatory documentation supporting distribution of Club Aligners under this Agreement.

24. **General.**

24.1 **Assignment.** The Agreement will not be assigned by either Party without the prior consent of the other Party; provided, however, that either Party may assign the Agreement without such consent to any Affiliate or in connection with a merger, acquisition, corporate reorganization or sale of all or substantially all of its relevant assets.



To SDC:

SmileDirectClub
701 Broadway
Nashville, TN 37203
Attn: CEO

With a copy to:

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
211 Commerce Street, Suite 800
Nashville, TN 37201
Attn: Chris Sloan, Esq.

To Align:

2560 Orchard Parkway
San Jose, CA 95131

Attn: General Counsel

All notices will be in English.

24.3 Force Majeure. Except for the obligation to pay money, neither Party will be liable to the other for any failure to perform due to acts of God, natural disasters, fire, floods, earthquakes, epidemics, quarantine, war or similar causes beyond such Party's control ("Force Majeure Event"). Each Party will promptly notify the other Party of any Force Majeure Event affecting its performance under this Agreement and will use diligent efforts to minimize the effect of the event and to recover and resume performance under this Agreement as soon as practicable. If Align is delayed by 30 days or more in the delivery of Club Aligners due to a Force Majeure Event, SDC may terminate or reschedule such delivery without charge or penalty.

24.4



24.5 Entire Agreement; Amendments. This Agreement constitutes the entire agreement between and final understanding of the Parties with respect to the subject matter of this Agreement and supersedes and terminates any and all prior or contemporaneous negotiations, representations, understandings, discussions, offers or agreements between the Parties, whether written or oral, express or implied, bilateral or unilateral, with respect to the subject matter of this Agreement. This Agreement is intended by the Parties to be a complete and wholly integrated expression of their understanding and agreement relating to the subject matter hereof, and this Agreement may not be altered, amended, modified or otherwise changed in any way except by a written instrument which specifically identifies the intended alteration, amendment, modification or other change and clearly expresses the intention to so change this Agreement, and is signed by a duly authorized representative of each of SDC and Align.

24.6 Waiver. Any waiver under this Agreement must be in writing and signed by the Party waiving its right; a failure by either Party to object to or enforce an instance of the other Party's noncompliance with any obligation or responsibility under this Agreement will not be deemed a waiver thereof. No waiver of any default hereunder or any terms or conditions of this

Agreement will be deemed to be a waiver of any other or subsequent default or of any other term or condition, but will apply solely to the instance to which such waiver is directed.

24.7 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid, illegal or unenforceable, the remaining provisions of this Agreement will remain in full force and effect and will be interpreted, to the extent possible, to achieve its purposes without the invalid, illegal or unenforceable provision, and the Parties will negotiate, in good faith, a substitute valid, legal and enforceable provision which most nearly effects the Parties' intent in entering into this Agreement.

24.8 Remedies. Unless explicitly specified in this Agreement as exclusive, the remedies set forth in this Agreement (including without limitation termination) will be nonexclusive and in addition to all other remedies, at law or in equity, except to the extent that any such other remedies are excluded by this Agreement.

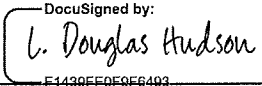
24.9 Disclaimer of Agency. The Parties hereto are independent contractors. This Agreement will not be construed as creating an agency, partnership or any other form of legal association between the Parties.

[Next page is signature page]

IN WITNESS WHEREOF, SDC's and Align's duly authorized representatives have executed this Agreement as of the Effective Date.

“SDC”

“Align”

By:  _____
Printed Name: L. Douglas Hudson _____
Title: CEO _____
Date: 7/25/2016 _____

By: _____
Printed Name: _____
Title: _____
Date: _____

IN WITNESS WHEREOF, SDC's and Align's duly authorized representatives have executed this Agreement as of the Effective Date.

"SDC"

"Align"

By: _____

By:  _____

Printed Name: _____

Printed Name: Joseph M. Hogan

Title: _____

Title: President and Chief Executive Officer

Date: _____

Date: _____

EXHIBIT C

PRESS RELEASE: Paid content from Globe Newswire

Smile Direct Club Clear Aligners Now Available at Dentist and Orthodontist Offices

SmileDirectClub January 14, 2020

NASHVILLE, Tenn., Jan. 14, 2020 (GLOBE NEWSWIRE) -- **SmileDirectClub**, the industry pioneer and first direct-to-consumer medtech platform for teeth straightening, today announced plans to offer its clear aligners through the wholesale channel, providing dentists and orthodontists an in-office option in 2020. With the December 31, 2019 expiration of its exclusive supply agreement with Align Technology, Inc., SmileDirectClub will expand access to its clear aligner therapy solutions and open its network to dentists and orthodontists in search of a premium and affordable teeth straightening solution for their patients.

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“We have seen increasing demand from the dentists and orthodontists in our network who wish to provide SmileDirectClub clear aligners to their in-office patients, and with our agreement with Align Technology now expired, we are no longer obligated to stay in the direct-to-consumer channel,” said SmileDirectClub Co-Founder Alex Fenkell. “We’re excited to expand our offering and welcome new providers to add an important and needed offering to their suite of services.”

SmileDirectClub will support this new distribution channel through its existing clear aligner manufacturing operation in Antioch, Tenn., which is the largest 3D printing facility in the United States. The company recently announced that it will add a second manufacturing facility located in Kyle, Texas in 2020 to meet increased demand for its products.

“Clear aligner therapy technology advances now enable patients who otherwise would not have been candidates in the past to avoid the discomfort and time commitment of traditional metal braces,” said Dr Jeffrey Sulitzer, SmileDirectClub Chief Clinical Officer. “Of the more than 200,000 licensed dentists and orthodontists in the United States, only an estimated 30% offer clear aligner therapy in their offices. We are looking forward to opening our network to providers who wish to join us in our mission to broaden access to premium care at an affordable price.”

Founded in 2014, SmileDirectClub has helped more than 750,000 people transform their smiles through remote doctor-directed clear aligner therapy.

SmileDirectClub's aligners can be used to correct mild to moderate malocclusion. All SmileDirectClub clear aligners are FDA-registered and produced at certified U.S. manufacturing facilities using BPA-free materials. With this new offering, licensed dentists and orthodontists can consult patients in-office and easily customize treatment plans and manage patient care, from initial diagnosis through to the conclusion of treatment. The average treatment plan for SmileDirectClub aligners is only six months.

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Dental providers interested in offering SmileDirectClub's clear aligner therapy at their practices may visit smiledirectclub.com/office-direct to learn more. About SmileDirectClub SmileDirectClub, Inc. (Nasdaq: SDC) ("SmileDirectClub"), is the industry pioneer as the first direct-to-consumer medtech platform for transforming smiles. Through our cutting-edge teledentistry technology and vertically integrated model, we are revolutionizing the oral care industry. SmileDirectClub's mission is to democratize access to affordable and convenient care, unleashing the power of a person's smile to positively impact their place in the world. SmileDirectClub was founded by Alex Fenkell and Jordan Katzman in partnership with Camelot Venture Group. Available in the U.S., Canada, Australia, New Zealand, United Kingdom, Ireland, Germany, and Hong Kong. SmileDirectClub is headquartered in Nashville, Tennessee. For more information, visit SmileDirectClub.com.

Contact:SmileDirectClub Media Relations: Press@SmileDirectClub.com