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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
WACO DIVISION

ALIGN TECHNOLOGY, INC.,

Plaintiff,

v.

CLEARCORRECT OPERATING, LLC, CLEARCORRECT HOLDINGS, INC., & INSTITUT STRAUMANN AG,

Defendants.

CLEARCORRECT OPERATING, LLC, CLEARCORRECT HOLDINGS, INC., & STRAUMANN USA, LLC

Counterclaim-Plaintiffs,

v.

ALIGN TECHNOLOGY, INC.,

Counterclaim-Defendant.

Case No. 6:24-cv-00187-ADA-DTG

DEFENDANTS' AND COUNTERCLAIM-PLAINTIFFS' PRELIMINARY INVALIDITY CONTENTIONS

[redacted]

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I. INTRODUCTION

Pursuant to the Court's August 5, 2024 Scheduling Order (D.I. 71) ("Scheduling Order"), Defendants ClearCorrect Operating LLC, ClearCorrect Holdings, Inc., and Institut Straumann AG (collectively "ClearCorrect") hereby provide the following Preliminary Invalidity Contentions with respect to U.S. Patent Nos. 10,973,613 (the "'613 patent"), 11,154,384 (the "'384 patent"), 11,648,090 (the "'090 patent"), and 11,648,091 (the "'091 patent"), referred to herein as the "Materials Patents"; 8,038,444 (the "'444 patent"), 10,456,217 (the "'217 patent"), 10,524,879 (the "'879 patent"), and 11,369,456 (the "'456 patent"), referred to herein as the "Treatment Planning Patents"; and 10,791,936 (the "'936 patent") referred to herein as the "Composite Image Patent." Together, these nine patents—which Plaintiff Align Technology, Inc. ("Plaintiff" or "Align") has asserted against ClearCorrect in this case and for which Plaintiff has served its July 18, 2024 Preliminary Infringement Contention Charts and Identification of Priority Dates ("Preliminary Infringement Contentions")—are referred to as the "Asserted Patents."

In its Preliminary Infringement Contentions served on July 18, 2024, Plaintiff provided infringement contentions for the 183 claims identified below (the "Asserted Claims"):

Patent	Asserted Claims
10,973,613	1, 3, 4, 6-10, 12-15, 17, 18, 20, 22
11,154,384	1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30
11,648,090	1-3, 5, 9-10
11,648,091	1, 4-7, 9-11, 13, 17-19, 21, 25, 26
8,038,444	1-42
10,456,217	1-20
10,524,879	1-24
11,369,456	1-19
10,791,936	1-20

ClearCorrect accordingly provides Preliminary Invalidity Contentions for the Asserted Claims of the Asserted Patents.

[redacted]

With respect to each asserted claim and based on its investigation to date, ClearCorrect's Preliminary Invalidity Contentions contain the following information pursuant to the Court's Scheduling Order and the Court's Standing Order Governing Proceedings ("OGP") Version 4.4:

(a) ClearCorrect's Preliminary Invalidity Contentions include claim charts labelled Exhibits 613-01 through 613-29, 384-01 through 384-29, 090-01 through 090-29, 091-01 through 091-29, 444-01 through 444-06, 444-08 through 444-12, 444-14 through 444-28, 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28, 879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28, 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28, 936-01 through 936-09, and 936-11 through 936-21, setting forth where in the prior art references or products each element of the Asserted Claims is found (at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions).

(b) ClearCorrect's Preliminary Invalidity Contentions identify limitations of the Asserted Claims that ClearCorrect contends are indefinite, lack written description, or lack enablement under 35 U.S.C. § 112.

(c) ClearCorrect's Preliminary Invalidity Contentions identify limitations of the Asserted Claims that ClearCorrect contends are directed to ineligible subject matter under 35 U.S.C. § 101.

Finally, with these Preliminary Invalidity Contentions, and based on its investigation to date, ClearCorrect produces (1) all prior art referenced in the Preliminary Invalidity Contentions, and (2) technical documents, including software where applicable, sufficient to show the operation of the accused products. This software is available for inspection per the terms set forth in ClearCorrect's September 26, 2024 letter to Align.

[redacted]

II. RESERVATION OF RIGHTS

Consistent with the Court's schedule setting Final Invalidity Contentions for April 17, 2025 (Dkt. 71 at 3), ClearCorrect reserves the right to supplement, modify, and/or amend these Preliminary Invalidity Contentions, including after the Court issues any claim construction ruling and/or if Plaintiff is permitted to clarify, modify, and/or amend its Infringement Contentions. ClearCorrect also expressly reserves the right to amend these disclosures and the accompanying document production (1) should Plaintiff provide any additional information that it failed to provide in its initial or amended contentions pursuant to the Court's schedule (Dkt. 71), including if Plaintiff amends its Complaint and/or (2) should Plaintiff clarify or amend its infringement allegations in any way.

Plaintiff's Infringement Contentions are deficient in several material respects, which has hampered ClearCorrect's ability to fully assess the scope of the Asserted Claims that Plaintiff is alleging in this case, thereby materially prejudicing ClearCorrect in connection with these Preliminary Invalidity Contentions. For example:

- Plaintiff's Infringement Contentions rely on "information and belief" to allege infringement of multiple limitations of the Asserted Claims. Such allegations are insufficient and fail to provide the required notice to ClearCorrect of Plaintiff's interpretation of the Asserted Claims. ClearCorrect reserves the right to revise, amend, and/or supplement the information provided herein if and when Plaintiff supplements its Preliminary Infringement Contentions with regard to those limitations for which Plaintiff has improperly relied on "information and belief" to allege infringement.

[redacted]

- For the at least 14 means-plus-function claims (MPF) that Plaintiff asserts, Plaintiff's infringement contentions merely cross-cite to contentions for other non-MPF claims, without doing any of the required analysis to show infringement of an MPF claim (i.e., identifying the claimed function, identifying the corresponding structure disclosed in the specification, and showing that the accused products perform the same function using an equivalent structure).
- Plaintiff's Infringement Contentions failed to identify "the earliest priority date (i.e., the earliest date of invention) for each asserted claim," as required by this Court's Standing Order Governing Proceedings. OGP Version 4.4 at 2. Instead, Plaintiff qualified its priority date disclosures by stating that "[t]he Asserted Claims are entitled to priority dates ***at least as early as***" certain dates. July 18, 2014 Prelim. Infr. Cont. at 2-3. This disclosure does not give ClearCorrect proper notice of Plaintiff's alleged priority dates. ClearCorrect notified Plaintiff of this deficiency in its September 5, 2024 correspondence and, still, Plaintiff refused to identify "the earliest priority date"; instead, it reserved the right to identify earlier dates should it later uncover support for them. This information is entirely within Plaintiff's possession, custody, and control and Plaintiff was obligated to disclose by the July 18 deadline. Plaintiff's refusal to commit to dates certain prejudices ClearCorrect's ability to prepare its invalidity contentions. ClearCorrect reserves the right to revise, amend, and/or supplement the information provided herein if and when Plaintiff supplements its Preliminary Infringement Contentions alleging earlier priority dates.

[redacted]

- Plaintiff's Infringement Contentions failed to include a complete production of documents evidencing conception and reduction to practice for each claimed invention, as the OGP requires. OGP Version 4.4 at 2. Among other deficiencies, Plaintiff's production does not appear to include support for its claimed May 12, 2011 priority date for the Materials Patents, including because it does not include [redacted]. ClearCorrect reserves the right to revise, amend, and/or supplement the information provided herein if and when Plaintiff supplements its production relating to conception and reduction to practice with the missing data and documents.[1]

Because Plaintiff's Infringement Contentions fail to include the required disclosures, ClearCorrect cannot fully assess the scope of the Asserted Claims that Plaintiff is alleging in this case with respect to its infringement allegations, which has impaired ClearCorrect's ability to fully formulate its Preliminary Invalidity Contentions.

ClearCorrect reserves the right to revise, amend, and/or supplement the information provided in these Preliminary Invalidity Contentions if Plaintiff is permitted to supplement or amend its Infringement Contentions, including as part of final contentions. ClearCorrect further reserves the right to present additional invalidity evidence and/or arguments if Plaintiff is permitted to present infringement evidence or provide additional specificity not contained in its Infringement Contentions.

[1]Further deficiencies in Plaintiff's Infringement Contentions are identified in ClearCorrect's September 5, 2024 letter. As of the date of these Invalidity Contentions, Plaintiff has not resolved the many deficiencies identified in ClearCorrect's letter.

[redacted]

Nothing in these Preliminary Invalidity Contentions shall be treated as an admission that ClearCorrect's accused technology meets any limitation of any Asserted Claim—to be clear, ClearCorrect denies that it infringes any Asserted Claim. In addition, nothing stated herein shall be construed as an admission or waiver of any particular construction of any claim term of the Asserted Claims. ClearCorrect expressly reserves the right to contest any claim construction asserted by Plaintiff and to advance additional claim constructions (including to the extent Plaintiff is permitted to amend or modify its infringement allegations and/or supplement its Infringement Contentions), and otherwise expressly reserves all noninfringement and claim construction arguments.

ClearCorrect's invalidity analysis applies the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, to the extent ClearCorrect can understand Plaintiff's positions given many deficiencies with those contentions. To the extent any prior art identified in these Preliminary Invalidity Contentions discloses a feature that is the same as or similar to an element in ClearCorrect's accused products, inclusion of that reference in ClearCorrect's Preliminary Invalidity Contentions is intended to show that the Asserted Claims are invalid at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions, and shall not be deemed a waiver by ClearCorrect of any claim construction, (pre-AIA Section 112 ¶¶ 1-2 or AIA Section 112(a)-(b), as applicable), or noninfringement position. Nothing stated herein shall be treated as an admission or suggestion that ClearCorrect agrees with Plaintiff regarding the alleged scope of any Asserted Claim (or interpretation of any claim term) or with any of Plaintiff's infringement theories.

Various positions put forth in these Preliminary Invalidity Contentions are predicated on Plaintiff's apparent incorrect, overbroad, and/or inconsistent interpretation of its claims as

[redacted]

evidenced by its Infringement Contentions provided to ClearCorrect. These Preliminary Invalidity Contentions are not intended to, and do not necessarily, reflect ClearCorrect's interpretation of the true and proper scope of the Asserted Claims. ClearCorrect objects to any attempt to infer any claim constructions from its identification of potential prior art. ClearCorrect reserves the right to adopt claim construction positions that differ from inferred positions from these Preliminary Invalidity Contentions. In those instances where ClearCorrect asserts that the Asserted Claims are invalid under 35 U.S.C. § 112 (e.g., no written description, not enabled, and/or indefinite), ClearCorrect has applied the prior art in accordance with Plaintiff's Infringement Contentions and the erroneous applications of the claim terms therein. As such, ClearCorrect's Preliminary Invalidity Contentions as to invalidity based on prior art do not represent its agreement or view as to the meaning, definiteness, written description support for, or enablement of any Asserted Claim. These Preliminary Invalidity Contentions and accompanying documents are not intended to reflect ClearCorrect's claim construction contentions, which will be disclosed in accordance with the Court's schedule.

The prior art discussed in these Preliminary Invalidity Contentions and in the claim chart exhibits attached hereto, or elsewhere identified, may disclose elements of the Asserted Claims explicitly and/or inherently, and also may be relied upon to show the state of the art in the relevant timeframe. Unless explicitly stated, the exemplary obviousness combinations identified in these Preliminary Invalidity Contentions are not to be construed to suggest that prior art included in the combinations does not itself disclose the limitation-at-issue.

The identification of any patent or patent publication herein shall be deemed to include any counterpart patent or application filed, published, or issued anywhere in the world. ClearCorrect further reserves the right to rely on (1) portions of the prior art identified in these

[redacted]

Preliminary Invalidity Contentions not specifically cited herein or in the attached claim charts, (2) additional publications, documents, testimony, and evidence that provide additional details regarding the prior art identified in these Preliminary Invalidity Contentions, and/or (3) information generally known to those skilled in the art and/or common sense, including as set forth in Section VI below.

References to the preamble of a claim in these Preliminary Invalidity Contentions shall not be treated as an admission that the preamble is limiting. ClearCorrect, however, reserves the right to assert that the preambles are limiting.

Discovery in connection with this lawsuit is ongoing, and these disclosures are based on information that ClearCorrect has obtained to date. To the extent it obtains additional information, ClearCorrect reserves the right to amend, revise, or supplement these Preliminary Invalidity Contentions in accordance with the Court's scheduling order and/or the Standing Order. For example, ClearCorrect reserves the right to revise, amend, and/or supplement these contentions with additional documentation, testimony, and other evidence, including obtained from one or more third parties, relating to the invention, availability, features, and operation of prior art products, including those specifically identified herein. Consistent with the Court's scheduling order, ClearCorrect reserves the right to revise, amend, and/or supplement the information provided herein, including to identify and rely on additional prior art should ClearCorrect's further search and analysis yield additional information or references, including in connection with any additional searching and analysis that ClearCorrect performs in response any attempt by Plaintiff to amend or supplement its Infringement Contentions.

In addition, ClearCorrect has requested discovery from Plaintiff on products that Plaintiff has identified as allegedly embodying the Asserted Claims but, to date, Plaintiff has not

[redacted]

produced that requested discovery. ClearCorrect therefore reserves the right to amend or supplement its Preliminary Invalidity Contentions to the extent Plaintiff subsequently produces additional discovery indicating that any such allegedly practicing product (or any other allegedly practicing product) is prior art to the Asserted Patents.

Prior art not included in this disclosure, whether known or unknown to ClearCorrect, may become relevant. In particular, ClearCorrect is currently unaware of the extent, if any, to which Plaintiff will contend that limitations of the Asserted Claims are not disclosed in the prior art identified by ClearCorrect, or will contend that any of the identified references do not qualify as prior art. If Plaintiff raises any such argument, ClearCorrect reserves the right to amend or supplement its Preliminary Invalidity Contentions to provide additional detail about prior art identified in these contentions and/or to identify additional prior art that addresses any such alleged deficiency.

ClearCorrect further reserves the right to assert that the Asserted Claims are invalid under 35 U.S.C. § 102(f) in the event discovery reveals that the named inventor of the Asserted Patents did not invent (either alone or in conjunction with others) the subject matter recited in the Asserted Claims. If ClearCorrect asserts invalidity under Section 102(f), ClearCorrect will provide the name of the person(s) from whom, and the circumstances under which, the alleged invention, or any part of it, was derived.

ClearCorrect further may rely on inventor admissions concerning the scope of the Asserted Claims or of prior art relevant to the Asserted Claims found in, *inter alia*: the patent prosecution history for the Asserted Patents and related patents and/or patent applications; any deposition testimony of a named inventor of the Asserted Patents; and/or the papers filed and any evidence submitted by Plaintiff in conjunction with this litigation. ClearCorrect reserves the

[redacted]

right to contend that the Asserted Claims are invalid for failure to name the correct inventor(s), and/or to contend that Plaintiff lacks standing to bring this litigation.

Moreover, ClearCorrect reserves the right to revise its Preliminary Invalidity Contentions, which may change depending upon the Court's construction of the Asserted Claims, any findings as to the priority or invention date of the Asserted Claims, and/or positions that Plaintiff or Plaintiff's experts may take concerning claim construction, infringement, and/or invalidity issues.

In addition to these Preliminary Invalidity Contentions and prior art identified herein, ClearCorrect relies on and incorporates by reference in their entirety, and expressly reserves the right to rely on, the invalidity reports of its experts, including all invalidity positions, invalidity charts, and all prior art cited therein.

ClearCorrect further reserves the right to assert that the Asserted Patents are unenforceable due to inequitable conduct, unclean hands, prosecution laches, ensnarement, and/or reverse doctrine of equivalents, among other grounds. Discovery is ongoing on these issues, and ClearCorrect reserves the right to assert those defenses and/or amend these contentions based on forthcoming discovery from Plaintiff and others.

III. PRIORITY DATES OF THE ASSERTED CLAIMS

A. Materials Patents

1. Plaintiff's Unsupported "Earliest Priority Date"

In its Preliminary Infringement Contentions, Plaintiff identifies "an earliest priority date" of May 12, 2011 for the Materials Patents. Plaintiff's allegation appears to be based on an alleged reduction to practice of a material named "LE-30."[2] *See* Plaintiff Preliminary

[2] ClearCorrect reserves the right to amend or supplement these disclosures to the extent Plaintiff

[redacted]

Infringement Contentions at 2-3; McClellen Ltr at 2, Sept. 13, 2024 ([redacted]

[redacted]

Actual reduction to practice requires a showing that the inventors (1) constructed an embodiment that ***met all of the limitations of the asserted claims***, and (2) recognized and appreciated the claimed invention. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998) (citing *Hybritech Inc. v. Monoclonal Antibodies*, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986)) ("In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the [claim]; and (2) he determined that the invention would work for its intended purpose."), 1331 ("[F]or an experiment to constitute an actual reduction to practice, there must have been contemporaneous appreciation of the invention at issue by the inventor. … Subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention."). Plaintiff has not established either requirement, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions. For example:

First, Plaintiff's evidence is insufficient to show that it actually constructed an embodiment of the asserted claims in May 2012. In fact, the materials produced by Plaintiff on July 18, 2024 and September 13, 2024 fail to show that Plaintiff was in possession of all

attempts to assert an earlier date or produces additional discovery relevant to the asserted patents' date(s) of priority or invention.

[redacted]

limitations of the asserted claims. According to Plaintiff's September 12, 2014 letter to ClearCorrect, Plaintiff's assertion of a May 12, 2011 date is based on [redacted] But, the produced documents do not show that SmartTrack (or any other material) meets all the limitations of the asserted claims, including but not limited to:

- A layer comprising a co-polyester and having a flexural modulus greater than 150,000 psi;
- A layer comprising a co-polyester and having an elongation at break of greater than 70%;
- A layer comprising a co-polyester and having an elongation at yield of greater than 4%;
- A layer comprising a co-polyester and having a tensile strength at yield of 4000-6500 psi;
- A layer comprising a co-polyester and having a tensile modulus greater than 150,000 psi;
- A layer comprising a co-polyester and having a stress relaxation of greater than about 10% at 24 hours testing in a wet environment;
- A layer comprising a polyurethane and having a flexural modulus greater than 35,000 psi;
- A layer comprising a polyurethane and having a hardness of 60A to 85D;
- A layer comprising a polyurethane and having an elongation at break of greater than 200%;
- A layer comprising a polyurethane and having an ultimate tensile strength of greater than 5000 psi; and
- A layer comprising a polyurethane and having a compression set at about 70° C of greater than 40% after 24 hours.

See ALGN00000001-ALGN00015088. In addition, the produced documents do not show that SmartTrack (or any of the materials) worked for its intended purpose—for use in a dental aligner. *Id*.

[redacted]

Second, Plaintiff's purported conception and reduction to practice evidence does not demonstrate inventor recognition—or even possession—of the claimed invention, to the extent Plaintiff alleges that it covers a hard-soft-hard material configuration or any other multi-layer material that is not a soft-hard-soft configuration. *See, e.g.*, Plaintiff's Preliminary Infringement Contentions, Ex. A at 1-2 ['613 patent, limitation 1[A]]. The SmartTrack material is a tri-layer product with a soft-hard-soft material configuration. This specific configuration was touted in a declaration filed with the PTO by inventor Chunhua Li. Li declared that, after testing 250 materials, Plaintiff found only the SmartTrack tri-layer material was suitable for the intended use in dental aligners. Sept. 16, 2019 Li Decl., ¶ 10 (ALGN00006843) ("[T]he over 250 materials tested by my team did not provide results meeting the desired criteria, while the SmartTrack material ***as described in the current claims*** was found to meet Align's criteria for a multilayer appliance"). In fact, Inventor Li emphasized the unpredictability of discovering a material that produced desirable results and acknowledged that "merely combining the materials into multiple layers was insufficient to improve performance." *Id.*

Consistent with Li's declaration, the only embodiment of the alleged invention described in the specification of the asserted patents is a soft-hard-soft configuration used in SmartTrack. No other permutations of the materials are described.

Contrary to this limited invention description and disclosure, the claims of the asserted patents are not—under Plaintiff's apparent interpretation put forth in its Infringement Contentions—limited to the specific soft-hard-soft configuration in the three-layer SmartTrack. *See, e.g.*, '613 patent at Abstract ("The appliance includes a hard polymer layer having a hard polymer layer elastic modulus disposed between a first soft polymer layer having a first soft

[redacted]

polymer layer elastic modulus and a second soft polymer layer having a second soft polymer layer elastic modulus."). Claim 1 of the '613 patent is representative:

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

As shown above, the claim describes a "sheet comprising three or more polymer layers" yet it defines specific material properties for only two of those layers, leaving the material properties of the additional layers and the order of the layers undefined under Plaintiff's apparent interpretation of the claims. Other asserted claims do not require a third layer at all, again under Plaintiff's apparent interpretation. '091 patent at claims 6, 10, 18, 25, 26. These claims are, thus, not supported by Plaintiff's narrower disclosure on which Plaintiff relies for its May 12, 2011 date. Sept. 13, 2024 McClellan Ltr. (identifying internal Align documents ALGN00000001, ALGN00000072, ALGN00000101, ALGN00000140, ALGN00000146, ALGN00000160, and ALGN00000223).

Third, Plaintiff's purported conception and reduction-to-practice evidence does not demonstrate inventor recognition—or possession—of the claimed invention to the extent Plaintiff alleges that it specifically covers a tri-layer material with a hard-soft-hard configuration. *See*, *e.g.*, Plaintiff's Preliminary Infringement Contentions, Ex. A at 1-4 (asserting that the claims

[redacted]

cover a material comprising (1) a layer of a thermoplastic polyurethane elastomer having an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D that is disposed between (2) two layers each comprising a co-polyester and having a flexural modulus greater than about 150,000 psi). As described above, Plaintiff's purported invention was much narrower. [redacted]

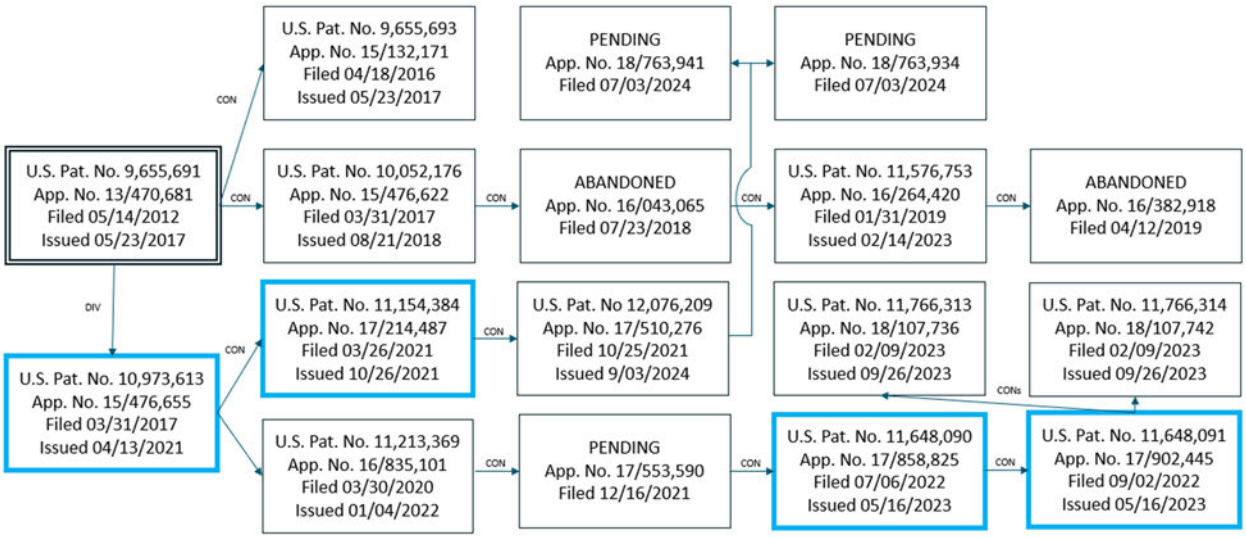
For at least these reasons, Plaintiff is not entitled to a May 12, 2011 date for the asserted claims.

2. Broken Chain of Priority

For a patent application to be entitled to claim priority to an earlier-filed application, the later claimed invention must have written description support in the earlier-filed application—i.e., the purported priority application must reasonably convey to a POSITA that the inventors were in possession of the later claimed invention. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) ("For a claim in a later-filed application to be entitled to the filing date of an earlier application under 35 U.S.C. § 120 (1994), the earlier application must comply with the written description requirement of 35 U.S.C. § 112. …"); *id*. ("A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations."); *Reiffin v. Microsoft Corp*., 214 F.3d 1342, 1346 (Fed. Cir. 2000) ("[C]laims to subject matter in a later-filed application not supported by an ancestor application in terms of § 112 ¶ 1 … do not receive the benefit of the earlier application's filing date.").

[redacted]

Here, the Materials Patents each claim priority to a common application, U.S. Patent Application No. 13/470,681 (the "'681 application").[3]



But the '681 application, inclusive of its originally filed claims, fails to provide written description support for the different multi-layered structures encompassed by the later claims of the Materials Patents, at least under the Plaintiff's apparent interpretation applied in its Infringement Contentions. For example, the '681 application fails to provide written description support for the hard-soft-hard layered structure, the soft-soft-hard layered structures, and other layered structures claimed in the Materials Patents under Plaintiff's apparent interpretation of the claims. *See PowerOasis, Inc. v. T–Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) ("[T]o satisfy the written description requirement, the missing descriptive matter must necessarily be present in the original application's specification such that one skilled in the art would recognize such a disclosure."). Instead, the '681 application discloses a single specific configuration of soft-hard-soft layers—it is the only embodiment disclosed. *See, e.g.*, '681 application at [0023] ("In general, structures, methods and systems of the present invention

[3] Blue outlining identifies the asserted patents in the instant case.

[redacted]

utilize a multilayer sheet for use in orthodontic appliances. The multilayer sheet can include three layers, in which a hard polymer layer is disposed between two soft polymer layers."), Abstract ("The appliance includes a hard polymer layer having a hard polymer layer elastic modulus disposed between a first soft polymer layer having a first soft polymer layer elastic modulus and a second soft polymer layer having a second soft polymer layer elastic modulus."). The figures included in the specifications disclose only soft-hard-soft Materials. For example, Figure 2 is a diagram of the multilayer structure of the claimed invention showing "an arrangement of polymer layers in a sheet having a hard polymer layer disposed between two soft polymer layers." '681 application at [0009]. Figure 3 and Figure 4 depict processes and methods for creating dental appliances from multilayer sheets having soft-hard-soft materials. *See id.* at [0010]-[0011], FIG. 2, FIG. 3, [0031] ("The multilayer sheet 32, as depicted [in Figure 3], can include three layers: a hard polymer layer disposed between two soft polymer layers."), *id.* at [0033] ("The method can include providing a multilayer sheet having a hard polymer layer disposed between two soft polymer layers (Step 42 [of Figure 4])."). The original claims of the '681 application likewise recite multilayered structures having only a soft-hard-soft material configuration.

In addition, a POSITA would have found that the prosecution history of the '681 application teaches away from any material other than a soft-hard-soft material configuration. During prosecution of the '681 application (which issued as the '691 patent, named inventor Chunhua Li represented to the Patent Office that her "team evaluated, in an iterative fashion, ***more than 250 distinct materials and/or material combinations*** for possible use in an improved appliance" and that "[a]fter years of development, Align produced the SmartTrack™ material (also referred to herein as "ST30"), which is a product according to the current claims

[redacted]

comprising a multilayered material with ***a hard polymer layer between two soft polymer layers***." Sept. 16, 2019 Li Decl., ¶ 4 (ALGN00006841). Dr. Li represented that "the effectiveness of the SmartTrack material was ***unpredictable and unexpected.***" *Id*., ¶ 5. Dr. Li also reported that "***merely combining the materials into multiple layers was insufficient to improve performance*** relative to the [single layer, thermoplastic polyurethane] EX30 material" and "many multilayer materials tested proved inferior to the EX30 material." *Id*., ¶ 6 (ALGN00006842); *see also id.* ¶ 10 (ALGN00006843) ("the ***over 250 materials tested by my team did not provide results meeting the desired criteria***, while the ***SmartTrack material as described in the current claims was found to meet Align' s criteria*** for a multilayer appliance"). In response to Dr. Li's representations, the '681 application issued as the '691 patent with claims directed to a soft-hard-soft material configuration.

Courts routinely reject priority claims where, as here, the later-filed continuation applications (i.e., issuing as the Materials Patents) attempt to enlarge the invention disclosed in the original, parent application (i.e., the '681 application), at least under Plaintiff's apparent interpretation put forth in its Infringement Contentions. *See, e.g.*, *Anascape, Ltd. v. Nintendo of America Inc*., 601 F.3d 1333, 1340 (Fed. Cir. 2010) ("[T]he description in the [parent] '525 specification is not reasonably read as describing a larger invention, of which the single input was only a preferred embodiment. … Whether or not the inventor could have described the '525 invention more broadly, 'it is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.' We conclude that the only reasonable reading of the '525 specification is that it is directed to and describes only a controller having a single input member operable in six degrees of freedom. In

[redacted]

contrast, the [continuation application] ’700 specification and claims were enlarged to cover more than single input members operable in six degrees of freedom. The district court erred in ruling that this subject matter is adequately described in the ’525 specification, for the statutory requirements are not met, on any reading of the’ 525 specification.”); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (“[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.”); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed. Cir. 1998) (“[C]laims may be no broader than the supporting disclosure.”).

a) Priority Dates of the Asserted Patents

(i) ’613 Patent[4]

U.S. Patent Application No. 15/476,655 (“the ’655 application”) issued as the ’613 patent and is a continuation of the ’681 patent. The specification of the ’655 application is substantively identical to the specification of the ’681 application and, consistent with the ’681 application, the originally filed claims of the ’655 application are directed to a multi-layered structure with a soft-hard-soft material configuration. Those claims were later amended. The resulting ’613 patent claims fail to recite a structure with the soft-hard-soft material configuration, at least under the Plaintiff’s apparent interpretation applied in its Infringement Contentions. And, as a result, the claims are not entitled to claim priority to the filing dates of either the ’681 or ’655 applications.

[4] In addition, the ’613 patent claims are invalid under 35 U.S.C. § 112. *See* Section XII.D.1 below.

[redacted]

Specifically, on September 16, 2019—more than seven years after the ’655 application was filed—Plaintiff amended the claims in the ’655 application purportedly to remove the requirement that the multi-layer sheet includes a hard layer disposed between two soft layers, at least under Plaintiff’s apparent interpretation of the claims in its Infringement Contentions:

> A method of making a dental appliance for positioning a patient’s teeth, the method comprising:
>
> providing a sheet comprising:
>
> a hard polymer layer of a hard polymeric material comprising a flexural modulus greater than about 150,000 psi; and
>
> a soft polymer layer of a soft polymeric material comprising an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D; ~~disposed between a first soft polymer layer and a second soft polymer layer;~~
>
> providing a positive model of the patient's teeth in a target position; and
>
> fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

’613 File History at ALGN00006866.

Since the originally filed ’618 and ’655 applications do not provide written description for these amended claims, which purportedly do not require a multi-layered structure with a soft-hard-soft material configuration, the ’613 patent claims are not entitled to a priority date before the date of the amendments—September 16, 2019. *See, e.g.*, *Muncie Gear Works, Inc. v. Outboard, Marine & Mfg. Co.*, 315 U.S. 759, 768 (1942) (claims are not entitled to a priority date preceding the date that the claimed subject matter was first submitted via claim amendment to the Patent Office); *cf. Eagle Comptronics, Inc. v. Tanner Elec. Sys. Tech., Inc.*, Nos. 79-CV-773, 80-CV-770, 1983 WL 51858, at *5 (N.D.N.Y. Dec. 6, 1983) (“If the applicant filed new

[redacted]

matter, then the date of that amendment is the operative date for purposes of determining whether devices embodying that new matter were on sale over one year previous to the filing."), *id*. at *4 ("Rather, their contention is that an 'inventive feature' was introduced into the application by amending the claim, and that that introduction was more than one year after the system with that inventive feature was offered for sale. This 'late-claiming' doctrine, first annunciated in Muncie Gear Works versus Outboard Marina Manufacturing Company, 315 U.S. 759 (1942) was well described by Judge Markey, now Chief Judge of the Federal Circuit: 'The holding in Muncie Gear that claims were invalid 'if there was public use or sale more than two years before the first disclosure thereof to the patent office,' is an application of the statutory prohibition against the introduction by amendment, after the filing date, of additional disclosure in an application and of claims directed thereto.' *Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981)."); *see also Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) (allowing applicants to use the "amendment process to update their disclosures" would defeat an "accurate accounting of the priority of invention.").

(ii) '384 Patent[5]

U.S. Patent Application No. 17/214,487 ("the '487 application") issued as the '384 patent and is a continuation of the '655 application (issued as the '613 patent), which is a continuation of the '681 application. The '487 application shares a substantively identical specification to the specifications of the '681 and '655 applications. As in the case of the '613 patent, the '618 and '655 applications do not provide written description support for the'384 patent claims to the extent the claims cover structures besides a multi-layered structure with a soft-hard-soft material

[5] In addition, the '384 patent claims are invalid under 35 U.S.C. § 112. *See* Section XII.D.1 below.

[redacted]

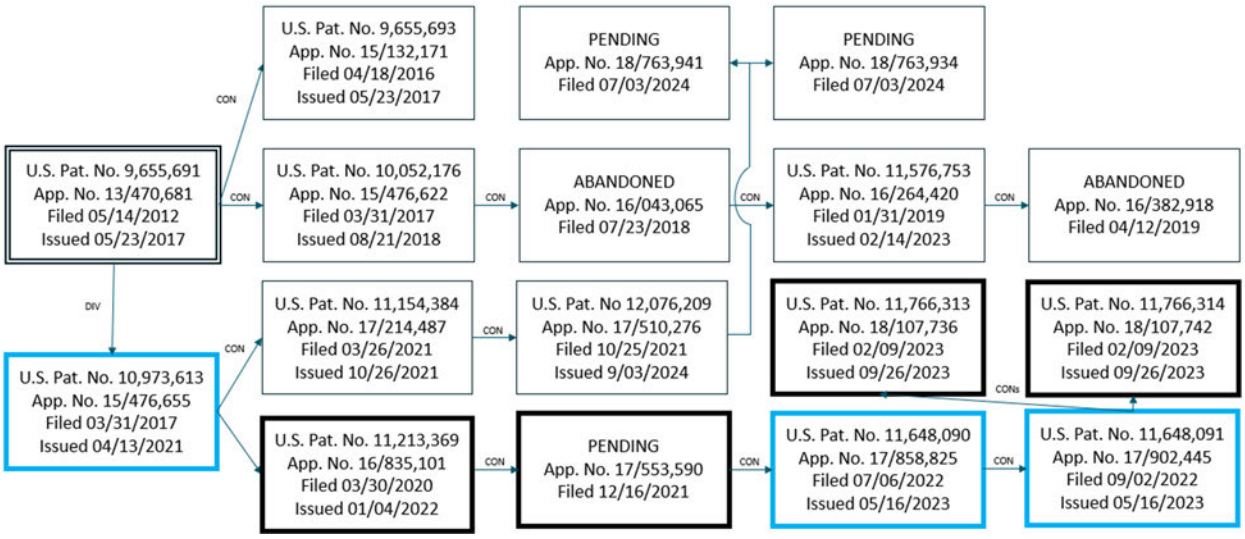
configuration, per the apparent interpretation of the asserted claims of the Materials Patents that Plaintiff applied in its Infringement Contentions. As a result, the '384 patent claims are not entitled to claim priority to the filing date of either the '618 application or the '655 application. Even though the Plaintiff amended the claims of the '655 application on September 16, 2019, to purportedly and impermissible remove the soft-hard-soft material configuration, under Plaintiff's apparent interpretation of the claims in its Infringement Contentions (as explained above), the '384 patent claims are not entitled to claim priority to the September 16, 2019 filing date of the amendment. As the Federal Circuit has explained, new matter introduced through claim amendments in a parent application "cannot contribute written description support" to a continuation application. *Anascape*, 601 F.3d at 1337.

Accordingly, the '384 patent is not entitled to a priority date any earlier than the March 26, 2021 filing date of the '487 application (which issued as the '384 patent).

(iii) '090 Patent[6]

U.S. Patent Application No. 17/858,825 ("the '825 application") issued as the '090 patent and is a continuation of U.S. Patent Application No. 17/553,590 ("the '590 application"), which is a continuation of U.S. Patent Application No. 16/835,101 ("the '101 application"), which is a continuation of the '655 application (issued as the '613 patent), which is a continuation of the '681 application. The '825 application shares a substantively identical specification to the '590, '101, '655, and '618 applications. The "family tree" of the '090 patent is shown below:

[6] In addition, the '090 patent claims are invalid under 35 U.S.C. § 112. *See* Section XII.D.1 below.



As in the case of the ’613 and ’384 patents, the ’618 and ’655 applications do not provide written description support for the’090 patent claims to the extent the claims cover structures besides a multi-layered structure with a soft-hard-soft material configuration, per the apparent interpretation of the asserted claims of the Materials Patents that Plaintiff applied in its Infringement Contentions. As a result, the ‘090 patent claims are not entitled to claim priority to the filing date of either the ‘618 application or the ‘655 application.

Moreover, even though the Plaintiff ultimately amended the claims of the ’655 application purportedly to remove the requirement that the multi-layer sheet includes a hard layer disposed between two soft layers, at least under Plaintiff’s apparent interpretation of the claims in its Infringement Contentions (as explained above), the ’090 patent claims are not entitled to claim priority to the September 16, 2019 date that the amendment was filed. As the Federal Circuit has explained, new matter introduced through claim amendments “cannot contribute written description support” to a continuation application. *Anascape*, 601 F.3d at 1337.

The specifications of the ’101 and ’590 applications also do not provide written description support for the ’090 patent claims. As a preliminary matter, the ’101 and ’590 applications share a substantially identical specification as the ’655 and ’618 applications and

[redacted]

thus do not provide written description support for the reasons set forth above. Furthermore, the originally filed claims of the '101 application recite the soft-hard-soft configuration because they are limited to an "outer" layer comprising a soft co-polyester and an "inner" layer comprising a hard thermoplastic polyurethane. Originally filed claim 1 is representative:

> A multilayer sheet comprising:
>
> a first outer polymer layer comprising co-polyester and a second outer polymer layer comprising co-polyester, each of the first and second outer polymer layers having a hardness of about 60 A to about 85 D; and
>
> an inner polymer layer comprising thermoplastic polyurethane.

'101 Application File History.

The '590 application is similarly limited, as shown in originally filed claim 1:

> A multilayer sheet comprising:
>
> a first outer polymer layer comprising co-polyester and a second outer polymer layer comprising co-polyester; and
>
> an inner polymer layer comprising thermoplastic polyurethane, wherein the multilayer sheet has a thickness from about 500 μm to about 900 μm.

'590 Application File History.

Accordingly, the '090 patent is not entitled to a priority date any earlier than the July 6, 2022 filing date of the '825 application (which issued as the '090 patent).

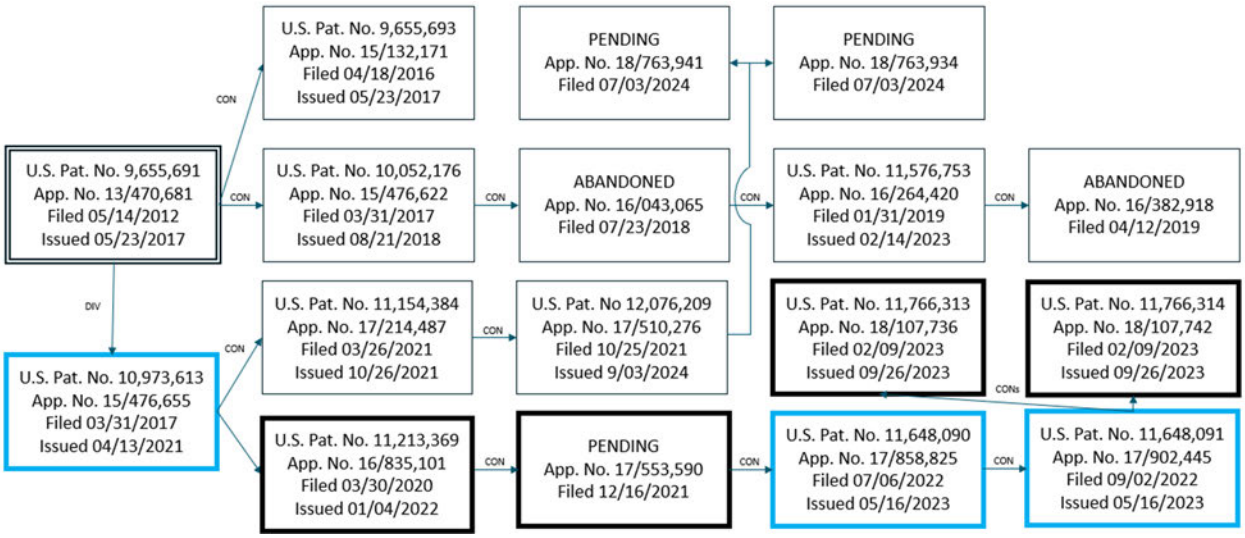
(iv) '091 Patent[7]

U.S. Patent Application No. 17/902,445 ("the '445 application") issued as the '091 patent and is a continuation of the '825 application (issued as the '090 patent), which is a continuation of the '590 patent, which is a continuation of the '101 application, which is a continuation of the

[7] In addition, the '091 patent claims are invalid under 35 U.S.C. § 112. *See* Section XII.D.1 below.

[redacted]

’655 application (issued as the ’613 patent), which is a continuation of the ’681 application. The ’445 application shares a substantively identical specification to the ’825, ’590, ’101, ’655, and ’618 applications. The “family tree” of the ’091 patent is shown below:



For the reasons explained above for the ’613, ’384, and ’090 patents, the ’618, ’655, ’101, and ’590 applications do not provide written description support for the’091 patent claims to the extent the claims cover structures besides a multi-layered structure with a soft-hard-soft material configuration, per the apparent interpretation of the asserted claims of the Materials Patents that Plaintiff applied in its Infringement Contentions. Accordingly, the ’091 patent is not entitled to a priority date any earlier that the July 6, 2022 filing date of the ’825 application (which issued as the ’090 patent).

B. Treatment Planning Patents

The earliest priority date alleged by Plaintiff for the Treatment Planning Patents is August 30, 2006, apparently based on the date of the two provisional applications cited on the face of the Treatment Planning Patents. ClearCorrect does not agree that the Treatment Planning Patents are entitled to that priority date based on the disclosure of the provisional applications. ClearCorrect also reserves the right to amend or supplement these disclosures if Plaintiff asserts

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an earlier priority date or invention date for the Treatment Planning Patents or produces additional discovery relevant to priority or invention dates.

C. Composite Image Patent

The earliest priority date alleged by Plaintiff for the Composite Image Patent is July 19, 2010, apparently based on the date of the provisional application cited on the face of the Composite Image Patent. ClearCorrect does not agree that the Composite Image Patent is entitled to that priority date based on the disclosure of the provisional application. ClearCorrect also reserves the right to amend or supplement these disclosures if Plaintiff asserts an earlier priority date or invention date for the Composite Image Patent or produces additional discovery relevant to priority or invention dates.

IV. IDENTIFICATION OF PRIOR ART

Subject to the reservation of rights above and based on ClearCorrect's present understanding of the Asserted Claims and the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, the prior art identified in these contentions anticipates and/or renders obvious all Asserted Claims under 35 U.S.C. § 102 and/or § 103, at least under Plaintiff's apparent infringement theories. The patents/applications, publications, devices, methods, and systems identified, are also relevant to show the state of the art and reasons and motivations for making improvements, additions, and combinations, including as set forth in Section VII and the attached claim charts.

As indicated below, for certain references, ClearCorrect has provided the claim charts in attached Exhibits 613-01 through 613-29, 384-01 through 384-29, 090-01 through 090-29, 091-01 through 091-29, 444-01 through 444-06, 444-08 through 444-12, 444-14 through 444-28, 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28,

[redacted]

879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28, 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28, 936-01 through 936-09, and 936-11 through 936-21 identifying where each element of the Asserted Claims can be found in the prior art, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions.

A. The Materials Patents

1. Prior Art Devices and Systems[8]

Subject to the reservation of rights above, ClearCorrect identifies herein prior art references that, under Plaintiff's apparent infringement theories and/or under any reasonable interpretation of the Asserted Claims, anticipate and/or render obvious one of more of the Asserted Claims.[9] The patents/applications, publications, devices, methods, and systems identified are also relevant for their showing of the state of the art and reasons and motivations for making improvements, additions, and combinations.

System(s) / Company[10]	Date[11]	Evidence	Exs.
Zendura FLX /	November 28,	Document No. 18-22: Process	613-29

[8] Because fact discovery in the case is ongoing, ClearCorrect reserves the right to rely upon additional evidence regarding these systems or other systems that are prior art to the Asserted Patents, consistent with the Court's scheduling order and the Local Rules.

[9] The prior art listed below shows that the Asserted Claims of the Materials Patents were anticipated or obvious as of the priority dates identified in Section III.A.2 above—namely, no earlier than September 16, 2019 for the '613 patent, March 26, 2021 for the '384 patent, and July 6, 2022 for the '090 and '091 patents. *See* Section III.A.2 [Broken Chain of Priority].

[10] The below-listed companies/producers are the entities that offered the below products for sale, used them publicly, and/or made them publicly known to U.S. consumers.

[11] Date refers to the date by which the system was known or used, in public use, and/or on sale in the United States, based on ClearCorrect's current knowledge. Discovery is ongoing, and ClearCorrect reserves the right to update or supplement these dates, if relevant additional facts come to light.

[redacted]

System(s) / Company[10]	Date[11]	Evidence	Exs.
Bay Materials	2018	Verification and Validation Report – Tri-laminate Rolls Process (August 28, 2018) ("Document 18-22"; Beginning Bates No. CC_ALGN_00005432); "Bay Materials Announces Zendura® FLX™ Thermoformable Material for Orthodontic Clear Aligner Therapy Appliances" (November 18, 2018) ("FLX Launch"; Beginning Bates No. CC_ALGN_00004955); Safety Data Sheet for Zendura FLX (March 14, 2021) ("FLX SDS" Beginning Bates No. CC_ALGN_00004961); Eastman Tritan™ Copolyester MP100 Product Data Sheet (January 29, 2010) ("Tritan MP100"; Beginning Bates No. CC_ALGN_00005473); Covestro Texin® RxT50D Product Data Sheet (September 27, 2017) ("Texin RxT50D"; Beginning Bates No. CC_ALGN_00005422); "Zendura FLX https://www.straightsmilesolutions.com/" (November 29, 2018), available at https://www.youtube.com/watch?v=Va0AcHS-IYs ("Zendura Youtube No. 1"); "What is Zendura FLX?" (June 13, 2019), available at https://www.youtube.com/watch?v=vQ_lrvLgv3I ("Zendura Youtube No. 2"); "Zendura FLX - A New Generation of Aligner Material" (November 29,	384-29 090-29 091-29

[redacted]

System(s) / Company[10]	Date[11]	Evidence	Exs.
		2018) ("FLX VIDEO1"), available at https://www.youtube.com/watch?v=CgpiDWEEJo0 ("Zendura Youtube No. 3"); Cavanaugh, "Silicon Valley firm touts new clear orthodontic material," Plastics News (May 15, 2019) ("Cavanaugh"; Beginning Bates No. CC_ALGN_00005075); Document 18-10: Zendura XL-1 Design Verification Report: Light Transmission and Haze (April 16, 2018) ("Document 18-10"; Beginning Bates No. CC_ALGN_00005467); U.S. Patent No. 10,549,511 to Stewart et al. ("Stewart"; Beginning Bates No. CC_ALGN_00002710), which was filed on December 15, 2018, and issued on February 4, 2020; Shipping Manifest of 1380 FT of Zendura FLX to ClearCorrect (January 28, 2019); Beginning Bates No. CC_ALGN_00004960; and Shipping Manifest of 2488 FT of Zendura FLX to ClearCorrect (July 16, 2019); Beginning Bates No. CC_ALGN_00004959.	

ClearCorrect's investigation of these devices is ongoing. ClearCorrect reserves the right to assert earlier dates for the prior art listed above. Additionally, ClearCorrect reserves the right to rely on the documents describing the features and operation of the above products as corroborating evidence of their functionality prior to the priority dates. ClearCorrect further contends that the above prior art devices and systems are prior art under 35 U.S.C. § 102(g). ClearCorrect further reserves the right to contend that the Asserted Patents are invalid in view of

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additional public knowledge and uses and/or offers for sale or sales of other products and services that are prior art under 35 U.S.C. § 102(a) and/or (b).

2. Prior Art Patent References

The following prior art anticipates and/or render obvious the Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrates the state of the art at the time of the alleged invention.[12] For published patent applications, ClearCorrect may identify the application and a patent that subsequently issued from that application. For any citation to a published application, ClearCorrect reserves the right to rely on the corresponding disclosure in the subsequently issued patent, and vice versa.

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	2011/0020761 ("Kalili"; Beginning Bates No. CC_ALGN_00000001)	Filed: June 14, 2010 Published: January 27, 2011	Kalili	613-08 384-08 090-08 091-08
WO	2010043419 ("Hinz"; Beginning Bates No. CC_ALGN_00000047[13])	Filed: October 19, 2009 Published: April 22, 2010	Hinz	613-02 384-02 090-02 091-02
US	2015/0374464 ("Stewart-'464"; Beginning Bates No. CC_ALGN_00000096)	Filed: February 27, 2013 Published: December 31, 2015	Stewart	613-03 384-03 090-03 091-03

[12] The prior art listed below shows that the Asserted Claims of the Materials Patents were anticipated or obvious as of the priority dates identified in Section III.A.2 above—namely, no earlier than September 16, 2019 for the '613 patent, March 26, 2021 for the '384 patent, and July 6, 2022 for the '090 and '091 patents. *See* Section III.A.2 [Broken Chain of Priority].
[13] Citations to Hinz are to the English translation. *See 3M Company v. Bay Materials, LLC*, IPR2022-01214, Exhibit No. 1015 (certified translation to English).

[redacted]

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	2005/0100853 ("Tadros"; Beginning Bates No. CC_ALGN_00000 111)	Filed: November 10, 2003 Published: May 12, 2005	Tadros et al.	613-01 384-01 090-01 091-01
US	6,077,075 ("Bedard"; Beginning Bates No. CC_ALGN_00000 132)	Filed: January 9, 1999 Issued: June 20, 2000	Bedard et al.	613-04 384-04 090-04 091-04
US	2009/0246724 ("Chen"; Beginning Bates No. CC_ALGN_00000 145)	Filed: March 25, 2008 Published: October 1, 2009	Chen et al.	613-05 384-05 090-05 091-05
WO	2006/096558A2 ("Wen-'558"; Beginning Bates No. CC_ALGN_00000 162)	Filed: March 3, 2006 Published: September 14, 2006	Wen et al.	613-06 384-06 090-06 091-06
US	2006/0078841 ("DeSimone-'841"; Beginning Bates No. CC_ALGN_00000 288)	Filed: October 12, 2004 Published: April 13, 2006	DeSimone et al.	613-07 384-07 090-07 091-07
US	2005/0082703 ("Wrosz"; Beginning Bates No. CC_ALGN_00000 310)	Filed: October 21, 2003 Published: April 21, 2005	Wrosz	613-12 384-12 090-12 091-12
WO	WO2013/171124 (Pudleiner-'124; Beginning Bates No. CC_ALGN_00004 837)	Filed: May 10, 2013 Published: November 21, 2013	Pudleiner et al.	613-13 384-13 090-13 091-13

[redacted]

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	10,549,511 ("Stewart-'511"; Beginning Bates No. CC_ALGN_00002710)	Filed: December 5, 2018 Issued: February 4, 2020	Stewart et al.	613-27 384-27 090-27 091-27
US	9,655,691 ("Li-'691"; Beginning Bates No. CC_ALGN_00000381)	Filed: May 14, 2012 Issued: May 23, 2017	Li et al.	613-25 384-25 090-25 091-25
WO	WO2007/110071 ("Paulus"; Beginning Bates No. CC_ALGN_00000401)[14]	Filed: March 29, 2007 Published: October 4, 2007	Paulus	613-22 384-22 090-22 091-22
US	9,022,903 ("Rafih"; Beginning Bates No. CC_ALGN_00000428)	Filed: March 11, 2011 Issued: May 5, 2015	Rafih et al.	613-23 384-23 090-23 091-23

3. Non-Patent Literature

The following prior art publications anticipate and/or render obvious the Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrate the state of the art at the time of the alleged invention.[15]

[14] Citations to Paulus are to certified translation to English included with the produced document.
[15] The prior art listed below shows that the Asserted Claims of the Materials Patents were anticipated or obvious as of the priority dates identified in Section III.A.2 above—namely, no earlier than September 16, 2019 for the '613 patent, March 26, 2021 for the '384 patent, and July 6, 2022 for the '090 and '091 patents. *See* Section III.A.2 [Broken Chain of Priority].

[redacted]

Title	Date	Publisher / Author	Exs.
Texin 990 Material Data Sheet ("Texin-990"; Beginning Bates No. CC_ALGN_00000472)	January 26, 2007	Covestro	613-15 384-15 090-15 091-15
Durasoft-PETG Data Sheet ("Durasoft-PETG"; Beginning Bates No. CC_ALGN_00000474)	August 23, 2018	Scheu Dental GmbH	613-28 384-28 090-28 091-28
Durasoft-PC Data Sheet ("Durasoft-PC"; Beginning Bates No. CC_ALIGN_00007720)	September 27, 2010	Scheu Dental GmbH	613-16 384-16 090-16 091-16
Imprelon S Data Sheet ("Imprelon"; Beginning Bates No. CC_ALGN_00004731)	April 2018	Scheu Dental GmbH	613-24 384-24 090-24 091-24
Hytrel 8238 Data Sheet ("Hytrel"; Beginning Bates No. CC_ALGN_00000477)	November 1, 2005	Celanese	613-17 384-17 090-17 091-17
Pellethane 2363-90AE Data Sheet ("Pellethane-AE"; Beginning Bates No. CC_ALGN_00000482)	March 1, 2016	Lubrizol	613-18 384-18 090-18 091-18
Eastar 6763 Data Sheet ("Eastar"; Beginning Bates No. CC_ALGN_00000484)	November 23, 2008	Eastman	613-20 384-20 090-20 091-20
Tritan EX401 Data Sheet ("Tritan EX401"; Beginning Bates No. CC_ALGN_00000494)	September 12, 2019	Eastman	613-21 384-21 090-21 091-21
Public Awareness Drives Market for Safer Alternatives ("Bailin"; Beginning Bates No. CC_ALGN_00000497)	September 15, 2008	Bailin	613-26 384-26 090-26 091-26
Dishwasher Safe: New Clear Copolyester Is Tougher, More Heat-Resistant, and Processes Easier, Too ("Beavers"; Beginning Bates No. CC_ALGN_00000534)	December 1, 2007	Beavers et al.	613-11 384-11 090-11 091-11

[redacted]

4. Additional Prior Art References

The following references may be relied upon to demonstrate the state of the art and/or the knowledge of a POSITA as it relates to the Materials Patents in the relevant timeframe.[16] These documents include all documents cited on the face of the Materials Patents and related patents, patent publications, file histories, and applications, all documents referenced elsewhere herein, as well as:

Title	Date	Publisher / Author	Exs.
Pellethane 2363-75D Data Sheet ("Pellethane-75D"; Beginning Bates No. CC_ALGN_00000483)	March 1, 2016	Lubrizol	613-19 384-19 090-19 091-19
Texin 245 Data Sheet ("Texin 245"; Beginning Bates No. CC_ALGN_00002702)	February 24, 2009	Bayer Material Science	
Texing 270 Data Sheet ("Texin 270"; Beginning Bates No. CC_ALGN_00002704)	February 22, 2007	Bayer Material Science	
Texin 285 Data Sheet ("Texin 285"; Beginning Bates No. CC_ALGN_00002706)	February 2, 2009	Bayer Material Science	
Eastman Tritan Copolyester ("Eastman Tritan"; Beginning Bates No. CC_ALGN_00002708)	October 2007	Eastman	
Wear comparison of thermoplastic materials used for orthodontic retainers ("Gardner"; Beginning Bates No. CC_ALGN_00000490)	November 2002	America Association of Orthodontists / Gardner et al.	
Bayer Materials Science NAFTA - Products: Texin® thermoplastic polyurethane (TPU) resin (Beginning Bates No. CC_ALGN_00002636)	July 26, 2011	Bayer Material Science	

[16] The relevant time frame for the Asserted Claims of the Materials Patents include the "earliest priority date" alleged by Plaintiff of May 12, 2011 and/or the priority dates identified in Section III.A.2 above—namely, September 16, 2019 for the '613 patent, March 26, 2021 for the '384 patent, and July 6, 2022 for the '090 and '091 patents. *See* Section III.A.2 [Broken Chain of Priority].

[redacted]

Title	Date	Publisher / Author	Exs.
Bayer Material Science NAFTA – Resources: Thermoplastic Part and Mold Design Guide (Beginning Bates No. CC_ALGN_00002639)	January 12, 2010	Bayer Material Science	
Bayer Material Science NAFTA – Resources: Multi-Component Molding for Medical Applications: Featuring PC, PC Blends, TPU, and LSR (Beginning Bates No. CC_ALGN_00002701)	August 26, 2011	Bayer Material Science	
Analysis of Chemical Leaching from Common Consumer Plastic Bottles Under High Stress Conditoins ("Dornath"; Beginning Bates No. CC_ALGN_00002646)	2010	Dornath	
ASTM D6272 Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials by Four-Point Bending1 ("ASTM D6272 2010"; Beginning Bates No. CC_ALGN_00002314)	2010	ASTM International	
ASTM D790 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials ("ASTM D790 2010"; Beginning Bates No. CC_ALGN_00002322)	2010	ASTM International	
ISO 178 Plastics – Determination of flexural properties ("ISO 178 2010"; Beginning Bates No. CC_ALGN_00002333)	2010	International Organization for Standardization	
ASTM D412 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension ("ASTM D412 2007"; Beginning Bates No. CC_ALGN_00002357)	2007	ASTM International	
ASTM D638 Standard Test Method for Tensile Properties of Plastics ("ASTM D638 2010"; Beginning Bates No. CC_ALGN_00002371)	2010	ASTM International	

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Title	Date	Publisher / Author	Exs.
ASTM D882 Standard Test Method for Tensile Properties of Thin Plastic Sheeting ("ASTM D882 2010"; Beginning Bates No. CC_ALGN_00002387)	2010	ASTM International	
ISO 37 Rubber, vulcanized or thermoplastic—Determination of tensile stress-strain properties ("ISO 37 2011"; Beginning Bates No. CC_ALGN_00002397)	2011	International Organization for Standardization	
ISO 527-1 Plastics — Determination of tensile properties —Part 1: General principles ("ISO 527-1 2012"; Beginning Bates No. CC_ALGN_00002429)	2012	International Organization for Standardization	
ISO 527-2 Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics ("ISO 527-2 2012"; Beginning Bates No. CC_ALGN_00002457)	2012	International Organization for Standardization	
ISO 527-3 Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets ("ISO 527-3"; Beginning Bates No. CC_ALGN_00002473)	1995	International Organization for Standardization	
ASTM D6147 Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomer—Determination of Force Decay (Stress Relaxation) in Compression ("ASTM D6147 2008"; Beginning Bates No. CC_ALGN_00002481)	2008	ASTM International	
ASTM E328 Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomer—Determination of Force Decay (Stress Relaxation) in Compression ("ASTM E328 2008"; Beginning Bates No. CC_ALGN_00002488)	2008	ASTM International	

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Title	Date	Publisher / Author	Exs.
ASTM D6048 Standard Practice for Stress Relaxation Testing of Raw Rubber, Unvulcanized Rubber Compounds, and Thermoplastic Elastomers ("ASTM D6048 2012"; Beginning Bates No. CC_ALGN_00002501)	2012	ASTM International	
ISO 13145 Rubber — Determination of viscosity and stress relaxation using a rotorless sealed shear rheometer ("ISO 13145 2012"; Beginning Bates No. CC_ALGN_00002516)	2012	International Organization for Standardization	
ISO 3384 Rubber, vulcanized or thermoplastic – Determination of stress relaxation in compression – Part 1: testing at constant temperature ("ISO 3384 2011"; Beginning Bates No. CC_ALGN_00002538)	2011	International Organization for Standardization	
ISO 6914 Rubber, vulcanized or thermoplastic — Determination of ageing characteristics by measurement of stress relaxation in tension ("ISO 6914 2008"; Beginning Bates No. CC_ALGN_00002558)	2008	International Organization for Standardization	
ASTM D395 Standard Test Methods for Rubber Property—Compression Set ("ASTM D395 2008"; Beginning Bates No. CC_ALGN_00002574)	2008	ASTM International	
ISO 815 Rubber, vulcanized or thermoplastic — Determination of compression set — Part 1: At ambient or elevated temperatures ("ISO 815 2008"; Beginning Bates No. CC_ALGN_00002580)	2008	International Organization for Standardization	
ASTM D8363 Standard Test Method for Rubber—Stress Relaxation in Tension Under Non-Isothermal Conditions ("ASTM D8363 2020"; Beginning Bates No. CC_ALGN_00002596)	2020	ASTM International	

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Title	Date	Publisher / Author	Exs.
ASTM D2240 Standard Test Method for Rubber Property—Durometer Hardness ("ASTM D2240 2010"; Beginning Bates No. CC_ALGN_00002600)	2010	ASTM International	
ASTM E2546 Standard Practice for Instrumented Indentation Testing ("ASTM E2546 2007"; Beginning Bates No. CC_ALGN_00002613)	2007	ASTM International	
ISO 527-3 Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets Technical Corrigendum 2 ("ISO 527-3 1995 Corr"; Beginning Bates No. CC_ALGN_00002700)	1995	International Organization for Standardization	

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
WO	2010043419 ("Hinz-Transperfect Translation"; Beginning Bates No. CC_ALGN_00004797[17])	Filed: October 19, 2009 Published: April 22, 2010	Hinz	613-02 384-02 090-02 091-02
US	2006/0275731 ("Wen-731"; Beginning Bates No. CC_ALGN_00000327)	Filed: April 13, 2006 Published: December 7, 2006	Wen et al.	
US	4,791,156 ("Hostettler"; Beginning Bates No. CC_ALGN_00000542)	Filed: August 12, 1982 Issued: December 13, 1988	Hostettler	613-10 384-10 090-10 091-10

[17] Citations to Hinz are to the English translation. See *3M Company v. Bay Materials, LLC*, IPR2022-01214, Exhibit No. 1015 (certified translation to English).

[redacted]

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	5,335,675 ("Wheeler"; Beginning Bates No. CC_ALGN_0000054 9)	Filed: October 11, 1991 Issued: August 9, 1994	Wheeler et al.	
US	2015/0140300 ("Pudleiner-'300"; Beginning Bates No. CC_ALGN_0000059 4)	Filed: May 10, 2013 Published: May 21, 2015	Pudleiner et al.	613-14 384-14 090-14 091-14
US	7,641,828 ("DeSimone-828"; Beginning Bates No. CC_ALGN_0000029 8)	Filed: October 12, 2004 Issued: January 5, 2010	DeSimone et al.	613-09 384-09 090-09 091-09
US	2019/0105881 ("Stewart-881"; Beginning Bates No. CC_ALGN_0000036 4)	Filed: December 5, 2018 Published: April 11, 2019	Stewart et al.	
DE	40 20 647 (Beginning Bates No. CC_ALGN_0000264 0)	Filed: June 29, 1990 Published: January 2, 1992	Horst	
US	2003/0198912 (Beginning Bates No. CC_ALGN_0000273 4)	Filed: April 23, 2002 Published: October 23, 2003	Mah	
US	US 2011/0091833 (Beginning Bates No. CC_ALGN_0000275 9)	Filed: January 20, 2010 Published: April 21, 2011	Farrell	
US	US 2012/0282565 (Beginning Bates No. CC_ALGN_0000278 7)	Filed: May 2, 2011 Published: November 8, 2012	Adell	
US	2013/0122447 (Beginning Bates No. CC_ALGN_0000279 4)	Filed: November 14, 2012 Published: May 16, 2013	Lemchen	

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Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	2018/0271620 (Beginning Bates No. CC_ALGN_0000280 3)	Filed: March 16, 2008 Published: September 27, 2018	Rodrigue z	
US	6,012,919 (Beginning Bates No. CC_ALGN_0000281 5)	Filed: Feb. 1, 1999 Issued: Jan. 11, 2000	Cross	
US	8,905,756 (Beginning Bates No. CC_ALGN_0000283 0)	Filed: Aug. 23, 2007 Issued: Dec. 9, 2014	Schwartz	
US	RE43,172 (Beginning Bates No. CC_ALGN_0000283 6)	Filed: December 31, 1997 Reissued: Feb. 14, 2012	Wu	
US	7,223,456 (Beginning Bates No. CC_ALGN_0000475 4)	Filed: March 18, 2004 Issued: May 29, 2007	Backman	
US	7,810,252 (Beginning Bates No. CC_ALGN_0000478 4)	Filed: February 9, 2007 Issued: October 12, 2010	Stone	
US	2004/0171766 (Beginning Bates No. CC_ALGN_0000473 3)	Filed: December 30, 2003 Published: September 2, 2004	Agrawal	
US	6,149,997 (Beginning Bates No. CC_ALGN_0000474 1)	Filed: January 30, 1992 Issued: November 21, 2000	Patel	
US	6,524,712 (Beginning Bates No. CC_ALGN_0000474 9)	Filed: April 4, 2001 Issued: February 25, 2003	Schledje wski	

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B. The Treatment Planning Patents

1. Prior Art Devices and Systems[18]

The following prior art devices and systems anticipate and/or render obvious one or more Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrate the state of the art at the time of the alleged invention.

System(s)/ Company[19]	Date[20]	Evidence	Exs.
Treat Software ("Treat") / Align Technologies, Inc.	November 2001	Form 10-K, Align Technology Inc., (Mar. 30, 2001) (Beginning Bates No. CC_ALGN_00003453). Wong, *Invisalign A to Z*, Am J Orthod Dentofacial Orthop, Vol. 121, No. 5, (Nov. 2001), 540-41 (Beginning Bates No. CC_ALGN_00003715). Bowen et al., *Align Technology, Inc.: Matching Manufacturing Capacity to Sales Demand*, Harvard	444-25 217-25 879-25 456-25

[18] Because fact discovery in the case is ongoing, ClearCorrect reserves the right to rely upon additional evidence regarding these systems or other systems that are prior art to the Asserted Patents, consistent with the Court's scheduling order and the Local Rules.
[19] The below-listed companies/producers are the entities that offered the below products for sale, used them publicly, and/or made them publicly known to U.S. consumers.
[20] Date refers to the date by which the system was known or used, in public use, and/or on sale in the United States, based on ClearCorrect's current knowledge. Discovery is ongoing, and ClearCorrect reserves the right to update or supplement these dates, if relevant additional facts come to light.

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System(s)/ Company[19]	Date[20]	Evidence	Exs.
		Business School (Sept. 24, 2002) (Beginning Bates No. CC_ALGN_00003431). Womack et al., *A new approach to correction of crowding*, Am J Orthod Dentofacial Orthop, Vol. 122, No. 3, (Sept. 2002), 310-16 (Beginning Bates No. CC_ALGN_00003424). Miller et al., *Validation of Align Technology's Treat III digital model superimposition tool and its case application*, Orthod Craniofacial Res 6 (Suppl. 1), (July 25, 2003), 143-49 (Beginning Bates No. CC_ALGN_00004478). *ClinCheck Evaluation Guide – Version 1.0*, Invisalign, available at https://cheninortho.com/wp-content/uploads/cover2.qxd_.pdf (Beginning Bates No. CC_ALGN_00004543). Beers et al., *Computer-assisted treatment planning and analysis*, Orthod Craniofacial Res 6 (Suppl. 1), (Aug. 11, 2003), 117-25 (Beginning Bates No. CC_ALGN_00003648). Form 10-Q, Align Technology, Inc., (May	

[redacted]

System(s)/ Company[19]	Date[20]	Evidence	Exs.
		6, 2004) (Beginning Bates No. CC_ALGN_00003498). Tuncay, *The Invisalign System*, Quintessence Publishing Co, Ltd, ISBN-10: 1850971277, (Mar. 2006) (Beginning Bates No. CC_ALGN_00003900). Kopczak et al., *Aligning the Supply Chain*, Center for Digital Strategies, Tuck School of Business at Dartmouth, (June 6, 2006) (Beginning Bates No. CC_ALGN_00003573).	
ClinCheck Software ("ClinCheck") / Align Technologies, Inc.	March 2001	Vlaskalic et al., *Orthodontic treatment of a mildly crowded malocclusion using the Invisalign System*, Australian Orthodontic Journal, Vol. 17, No. 1, (Mar. 2001), 41-46 (Beginning Bates No. CC_ALGN_00002728). Boyd, *Predictability of Successful Orthodontic Treatment Using Invisalign*, Greater Philadelphia Society of Orthodontists, (July 10, 2002), available at https://www.gpso.org/events/2003_outline.pdf (Beginning Bates No. CC_ALGN_00003004). *ClinCheck Evaluation Guide – Version 1.0*,	444-27 217-27 879-27 456-27

[redacted]

System(s)/ Company[19]	Date[20]	Evidence	Exs.
		Invisalign, available at https://cheninortho.com/wp-content/uploads/cover2.qxd_.pdf (Beginning Bates No. CC_ALGN_00004543). *Invisalign Clinical Monitoring Guide*, Invisalign (Aug. 8, 2003), available at https://cheninortho.com/wp-content/uploads/invisplanning.pdf (Beginning Bates No. CC_ALGN_00004653). Lau, *Computerised Imaging, Virtual Treatment Planning and Orthodontic Treatment of Dental Malocclusions Using the Invisalign Appliance*, Dental Bulletin, Vol. 9, No. 10, (Oct. 4, 2004) (Beginning Bates No. CC_ALGN_00003067). Kamatovic, *A Retrospective Evaluation of the Effectiveness of the Invisalign Appliance using the PAR and Irregularity Indices*, University of Toronto, (2004) (Beginning Bates No. CC_ALGN_00003732). U.S. Patent Pub. No.	

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System(s)/ Company[19]	Date[20]	Evidence	Exs.
		2005/0159986 A1. Shuman, *What Is Invisalign? An Introduction to the Technique*, ClinicalFeature, (Aug. 2005) (Beginning Bates No. CC_ALGN_00003604). U.S. Patent Pub. No. 2005/0192835 A1 (Beginning Bates No. CC_ALGN_00004275). Djeu et al., *Outcome assessment of Invisalign and traditional orthodontic treatment compared with the American Board of Orthodontics objective grading system,* American Journal of Orthodontics and Dentofacial Orthopedics, Vol. 128, No. 3 (Sept. 2005), 292-98 (Beginning Bates No. CC_ALGN_00004536). U.S. Patent Pub. No. 2005/0244791 A1 (Beginning Bates No. CC_ALGN_00004302). U.S. Patent Pub. No. 2005/0246154 A1 (Beginning Bates No. CC_ALGN_00004313). Tuncay, *The Invisalign System*, Quintessence Publishing Co, Ltd, ISBN-10: 1850971277,	

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System(s)/ Company[19]	Date[20]	Evidence	Exs.
		(Mar. 2006) (Beginning Bates No. CC_ALGN_00003900). Kopczak et al., *Aligning the Supply Chain*, Center for Digital Strategies, Tuck School of Business at Dartmouth, (June 6, 2006) (Beginning Bates No. CC_ALGN_00003573). U.S. Patent No. 7,074,038 B1 (Beginning Bates No. CC_ALGN_00004414). Boyd et al., *An Update on Present and Future Considerations of Aligners*, Journal of the California Dental Association, Vol. 34, No. 10, (Oct. 2006), 793-805 (Beginning Bates No. CC_ALGN_00003590).	

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SureSmile Treatment Planning Software ("SureSmile") / Dentsply Sirona Inc.	April 2001	Sachdeva, *SureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001), 245-53 (Beginning Bates No. CC_ALGN_00003083). Mah et al., *Computer-assisted orthodontic treatment: The SureSmile process*, Am J Orthod Dentofacial Orthop, Vol. 120, No. 1, (July 2001), 85-87 (Beginning Bates No. CC_ALGN_00003657). Tuncay, *The Invisalign System*, Quintessence Publishing Co, Ltd, ISBN-10: 1850971277, (Mar. 2006) (Beginning Bates No. CC_ALGN_00003900). *Moving Forward in Three Dimensions*, Orthodontic Products, (Apr. 1, 2006), https://orthodonticproductsonline.com/treatment-products/brackets-wires/wires/dan-de-silva-of-orametrix-inc-2006-04-19/ (Beginning Bates No. CC_ALGN_00003662). *SureSmile takes the trial-and-error out of braces*, SureSmile, (June 16, 2006), https://web.archive.org/web/20060616042924/http://www.suresmile.com/st/index.htm (Beginning Bates No.	444-26 217-26 879-26 456-26

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System(s)/ Company[19]	Date[20]	Evidence	Exs.
		CC_ALGN_00003689).	
Insignia 3D Interactive Approver Software ("Insignia") / Ormco Corp.	March 11, 2006	*Insignia*, Ormco Corp., (Mar. 11, 2006), https://web.archive.org/web/20060311180339/http://www.ormco.com/products/insignia/index.cfm (Beginning Bates No. CC_ALGN_00003714). *Orthodontics*, Ormco Corp., (Mar. 11, 2006), https://web.archive.org/web/20060311174857/http://www.ormco.com/ (Beginning Bates No. CC_ALGN_00003857). *Insignia: Increasing Clinical Performance with 3D Interactive Treatment Planning And Patient-Specific Appliances*, Ormco Corp., (Aug. 22, 2006), available at https://www.konsident.com/wp-content/files_mf/1295385693http___ormco.com_index_cmsfilesystemaction_fileOrmcoPDF_whitepapers.pdf (Beginning Bates No. CC_ALGN_00004486). *Insignia: The Perfect Fit for you and Your Patients*, Ormco Corp., (2006) (Beginning Bates No. CC_ALGN_00004647).	444-28 217-28 879-28 456-28

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ClearCorrect's investigation of these devices is ongoing. ClearCorrect reserves the right to assert earlier priority dates for the prior art listed above. Additionally, ClearCorrect reserves the right to rely on the documents describing the features and operation of the above products as corroborating evidence of its functionality prior to the priority dates. ClearCorrect further contends that the above prior art devices and systems demonstrate earlier invention by other parties under 35 U.S.C. § 102(g), and specifically, that the entities identified in the above table, their affiliates, and third parties, were entities involved in making and/or selling the alleged invention of the Asserted Patents before the patent applicants. ClearCorrect further reserves the right to contend that the Asserted Patents are invalid in view of additional public knowledge and uses and/or offers for sale or sales of other products and services that are prior art under 35 U.S.C. § 102(a) and/or (b).

Additionally, ClearCorrect is investigating the following products, devices, and/or systems as potentially anticipating and/or rendering obvious one or more Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrating the state of the art at the time of the alleged invention. ClearCorrect has served or will serve third-party subpoenas or requested discovery from Plaintiff in connection with various of these products, and ClearCorrect's investigation of the below products, devices, and/or systems is ongoing. ClearCorrect reserves the right to contend that the Asserted Patents are invalid in view of the following products, devices, and/or systems (or other products, devices, and/or systems that ClearCorrect becomes aware of) and to supplement its Invalidity Contentions and accompanying exhibits and documents accordingly.

System(s)	Entity
Aligner Software	Align Technologies, Inc.

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System(s)	Entity
Clipper Software	Align Technologies, Inc.
OrthoCAD Software	Align Technologies, Inc.
OrthoClear Software	Align Technologies, Inc.
Dolphin Imaging and Management Software	Dolphin Imaging Systems, LLC
J-Ortho Software	
Geomagic Software	3D Systems Corp.
Elan Software	Ormco Corp.
GeoDigm Software	National Dentex Labs LLC
IMS Digital Office Software	OrthoBanc LLC
VistaDent Software	Dentsply Sirona Inc.
Maestro 3D Software	Age Solutions s.r.l.
Carestream Treatment Planning Software (including software compatible with CS 3600)	Carestream Dental LLC
Medit USA Treatment Planning Software (including software compatible with the i500 digital intraoral scanner and/or i700 digital intraoral scanner)	Medit USA Inc.
Midmark Treatment Planning Software (including software compatible with the True Definition Scanner)	Midmark Corporation
Motion View Treatment Planning Software (inclusive of Ortho Insight 3D)	Motion View LLC
Orthocast Treatment Planning Software	Ortho Cast, Inc.

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System(s)	Entity
OrthoProof Treatment Planning Software (inclusive of DigiModel)	OrthoProof
Dandy Treatment Planning Software	Dandy Lab
Orthoselect Software	
Software Associated with Panda Scanner	
Planmeca Emerald and associated software	
RAY America RIOS Series and associated software	

2. Prior Art Patent References

The following prior art anticipates and/or render obvious the Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrates the state of the art at the time of the alleged invention. For published patent applications, ClearCorrect may identify the application and a patent that subsequently issued from that application. For any citation to a published application, ClearCorrect reserves the right to rely on the corresponding disclosure in the subsequently issued patent, and vice versa.

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	7,987,099 ("Kuo") (Beginning Bates No. CC_ALGN_00000607)	Filed: February 27, 2004 Issued: July 26, 2011	Kuo et al.	444-01 217-01 879-01 456-01

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Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	6,250,918 ("Sachdeva") (Beginning Bates No. CC_ALGN_00000634)	Filed: November 30, 1999 Issued: June 26, 2001	Sachdeva et al.	444-02 217-02 879-02 456-02
US	2002/0010568 ("Rubbert-'568") (Beginning Bates No. CC_ALGN_00000643)	Filed: April 13, 2001 Issued: January 24, 2002	Rubbert et al.	444-03 217-03 879-03 456-03
US	2004/0137400 ("Chishti-'400")[21] (Beginning Bates No. CC_ALGN_00000846)	Filed: January 5, 2004 Published: July 15, 2004	Chishti et al.	444-10 217-10 879-10 456-10
US	6,471,511 ("Chishti-'511") (Beginning Bates No. CC_ALGN_00001020)	Filed: October 8, 1998 Issued: October 29, 2002	Chishti et al.	444-21 217-21 879-21 456-21
WO	2000/019929A1 ("Chishti-'929")[22] (Beginning Bates No. CC_ALGN_00000754)	Filed: October 8, 1999 Published: April 29, 2000	Chishti et al.	444-22 217-22 879-22 456-22
US	2002/0072027 ("Chishti-'027") (Beginning Bates No. CC_ALGN_00000956)	Filed: December 13, 2000 Published: June 13, 2002	Chishti	444-14 217-14 879-14 456-14

[21] Chishti-'400 is a continuation of and shares a common specification with U.S. Patent No. 6,729,876 to Chishti et al., which the '444 patent specification describes as prior art. See '444 patent at 5:60-67.

[22] Chishti-'929 is a continuation-in-part of PCT/US98/12681, filed on June 19, 1998, which claims priority from U.S. patent application 08/947,080, filed on October 8, 1997, now U.S. Patent No. 5,975,893, which claims priority from U.S. provisional application 60/050,342, filed on June 20, 1997.

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Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	6,309,215 ("Phan") (Beginning Bates No. CC_ALGN_00000881)	Filed: December 3, 1999 Issued: October 30, 2001	Phan et al.	444-11 217-11 879-11 456-11
US	2007/0122592 ("Anderson") (Beginning Bates No. CC_ALGN_00000913)	Filed: August 16, 2006 Published: May 31, 2007	Anderson et al.	444-12 217-12 879-12 456-12
US	2002/0064746 ("Muhammad") (Beginning Bates No. CC_ALGN_00000921)	Filed: August 29, 2001 Published: May 30, 2002	Muhammad et al.	

3. Non-Patent Literature

The following prior art publications anticipate and/or render obvious the Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrate the state of the art at the time of the alleged invention.

Title	Date	Publisher	Author(s)	Exs.
The Orthodontic Treatment of Impacted Teeth ("Becker") (Beginning Bates No. CC_ALGN_00001054)	1998	Mosby	Becker	444-08 217-08 879-08 456-08
The Invisalign System ("Tuncay") (Beginning Bates No. CC_ALGN_00003900)	August 1, 2006	Quintessence	Tuncay	444-09 217-09 879-09 456-09

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Title	Date	Publisher	Author(s)	Exs.
Invisible Orthodontics: Current Concepts and solutions in Lingual Orthodontics ("Giuseppe") (Beginning Bates No. CC_ALGN_00001437)	2003	Quintessence	Giuseppe et al.	444-17 456-17
Orthodontics. Part 4: Treatment planning ("Roberts-Harry") (Beginning Bates No. CC_ALGN_00001450)	Dec. 20, 2003	British Dental Journal	Roberts-Harry et al.	444-18 217-18 879-18 456-18
Nonextraction treatment of upper canine-premolar transposition in an adult patient ("Kuroda") (Beginning Bates No. CC_ALGN_00001453)	May 2005	The Angle Orthodontics	Kuroda et al.	444-20 217-20 879-20 456-20
The Amalgamated Technique, a Mechanically and Biologically Efficient Method for Controlled Tooth Movement, ("DeAngelis") (Beginning Bates No. CC_ALGN_00001459)	Jan. 1980	Angle Orthod. 1980;50(1):1-15.	DeAngelis	444-23 217-23 879-23 456-23
Light Arch Wire Technique ("Begg") (Beginning Bates No. CC_ALGN_00002968)	1960	American Assoc. Orthodontists	Begg et al.	444-24 217-24 879-24 456-24

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Title	Date	Publisher	Author(s)	Exs.
Biomechanics and Esthetic Strategies in Clinical Orthodontics ("Nanda") (Beginning Bates No. CC_ALGN_00001405)	2005	Elsevier Saunders	Ravindra Nanda	444-16 217-16 879-16 456-16

4. Additional Prior Art References

The following references may be relied upon to demonstrate the state of the art and/or the knowledge of a POSITA as it relates to the Treatment Planning Patents in the relevant timeframe. These documents include all documents cited on the face of the Treatment Planning Patents and related patents, patent publications, file histories, and applications, all documents referenced elsewhere herein, as well as:

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	2004/0073417 ("Rubbert-'417") (Beginning Bates No. CC_ALGN_00000690)	Filed: October 9, 2003 Published: April 15, 2004	Rubbert et al.	444-04 217-04 879-04 456-04
US	2005/0244790 ("Kuperman") (Beginning Bates No. CC_ALGN_00000737)	Filed: April 30, 2004 Published: November 3, 2005	Kuperman	444-05 217-05 879-05 456-05
US	2007/0026358 ("Schultz") (Beginning Bates No. CC_ALGN_00000749)	Filed: July 26, 2005 Published: February 1, 2007	Schultz	444-06 217-06 879-06 456-06

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Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
EP	EP1119309 ("Chishti-309") (Beginning Bates No. CC_ALGN_00002847)	Filed: October 8, 1998 Published: April 13, 2000	Chishti et al.	
US	2006/0073435 ("Stark") (Beginning Bates No. CC_ALGN_00000980)	Filed: October 6, 2004 Published: April 6, 2006	Stark et al.	444-15 217-15 879-15 456-15
US	2006/0223023 ("Lai") (Beginning Bates No. CC_ALGN_00001006)	Filed: April 1, 2005 Published: October 5, 2006	Lai et al.	444-19 217-19 879-19 456-19
US	6,682,346 ("Chishti-'346") (Beginning Bates No. CC_ALGN_00001037)	Filed: August 26, 2002 Issued: January 27, 2004	Chishti et al.	
US	6,729,876 ("Chishti-'876") (Beginning Bates No. CC_ALIGN_00007637)	Filed: August 29, 2001 Issued: May 4, 2004	Chishti et al.	
ES	2 328 876 (Beginning Bates No. CC_ALIGN_00007189)	Filed: October 8, 1999 Published: April 3, 2002	Chishti et al.	
WO	2000/069356 (Beginning Bates No. CC_ALIGN_00007672)	Filed: October 8, 1999 Published: November 23, 2000	Chishti et al.	

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Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	6,616,444 ("Andreiko-444") (Beginning Bates No. CC_ALIGN_00007544)	Filed: June 11, 2001 Issued: September 9, 2003	Andreiko et al.	
US	6,244,861 ("Andreiko-861") (Beginning Bates No. CC_ALIGN_00007405)	Filed: November 1, 1999 Issued: June 12, 2001	Andreiko et al.	
US	5,683,243 ("Andreiko-243") (Beginning Bates No. CC_ALIGN_00007312)	Filed: June 2, 1995 Issued: November 4, 1997	Andreiko et al.	
US	5,447,432 ("Andreiko-432") (Beginning Bates No. CC_ALIGN_00007216)	Filed: November 9, 1992 Issued: September 5, 1995	Andreiko et al.	
US	6,398,548 ("Chishti-548") (Beginning Bates No. CC_ALIGN_00007502)	Filed: December 17, 1999 Issued: June 4, 2002	Chishti et al.	
US	7,555,403 ("Kopelman-'403") (Beginning Bates No. CC_ALGN_00004766)	Filed: February 8, 2006 Issued: June 30, 2009	Kopelman et al.	
US	60/777483 ("Andreiko-483") (Beginning Bates No. CC_ALGN_00003204)	Filed: February 28, 2006	Andreiko	

[redacted]

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Exs.
US	2006/0269896 (Beginning Bates No. CC_ALGN_00003244)	Filed: May 27, 2005 Published: November 30, 2006	Liu et al.	
US	2009/0098502 ("Andreiko-502") (Beginning Bates No. CC_ALGN_00003271)	Filed: February 28, 2007 Published: November 30, 2006	Andreiko	
US	3,128,553 ("Begg-553") (Beginning Bates No. CC_ALGN_00003313)	Filed: December 8, 1961 Issued: April 14, 1964	Begg	
US	5,064,370 ("Jones-370") (Beginning Bates No. CC_ALGN_00003320)	Filed: April 15, 1991 Issued: November 12, 1991	Jones	
US	7,134,874 ("Chishti-'874) (Beginning Bates No. CC_ALGN_00003328)	Filed: November 20, 2003 Issued: November 14, 2006	Chishti et al.	

Title	Date	Publisher / Author	Ex.
Group Distal Movement of Teeth Using Microscrew Implant Anchorage ("Park") (Beginning Bates No. CC_ALGN_00001481)	2005	Angle Orthodontist/ Park	

[redacted]

Title	Date	Publisher / Author	Ex.
Treatment Planning by Appliance Selection (Beginning Bates No. CC_ALGN_00002902)	1994	Twelftree	
Evaluation of Root Resorption Incident (Beginning Bates No. CC_ALGN_00002907)	June 1993	University of Connecticut / Costopoulos	
Varying Treatments of Class II malocclusions (Beginning Bates No. CC_ALGN_00002936)	2001	Australian Orthodontic Journal / Malek et al.	
The Economics of the Begg Technique (Beginning Bates No. CC_ALGN_00002948)	1972	Australian Orthodontic Journal / Abbott et al.	
Controlled Movement of Maxillary Incisors in the Begg Technique (Beginning Bates No. CC_ALGN_00002952)	September 1981	Am. J. Orthod. / Liu et al.	
Philosophies Distinguishing the Begg Technique (Beginning Bates No. CC_ALGN_00002987)	January 1973	Am. J. Orthod. / Baldridge	
A Comparison of Two Intraoral Molar Distalization Appliances: Distal Jet Versus Pendulum (Beginning Bates No. CC_ALGN_00003015)	September 2005	Am. J. Orthod. / Chiu et al.	
Static Anchorage in the Begg Technique (Beginning Bates No. CC_ALGN_00003028)	July 1969	The Angle Orthodontist / McDowell	
Simultaneous Intrusion and Retraction Using a Three-piece Base Arc (Beginning Bates No. CC_ALGN_00003037)	1997	The Angle Orthodontist / Shroff et al.	
A Study of Root Resorption in Treated Class II, Division I Malocclusions (Beginning Bates No. CC_ALGN_00003044)	October 1969	The Angle Orthodontist / DeShields	
Lower Incisor Extraction Treatment with the Invisalign System (Beginning Bates No. CC_ALGN_00003059)	February 2002	J. Clin Orthod. / Miller et al.	
Computerised Imaging, Virtual Treatment Planning and Orthodontic Treatment of Dental Malocclusions Using the Invisalign Appliance (Beginning Bates No. CC_ALGN_00003067)	October 2004	The Hong Kong Medical Diary / Lau et al.	

[redacted]

Title	Date	Publisher / Author	Ex.
Surgical-Orthodontic Treatment of Two Skeletal Class III Patients with Invisalign and Fixed Appliances (Beginning Bates No. CC_ALGN_00003069)	April 2005	J. Clin Orthod. / Boyd	
EIC0-1: An Orthodontist-Maintained Expert System in Clinical Orthodontics (Beginning Bates No. CC_ALGN_00003092)	April 1999	Australian Orthodontic Journal / Poon et al.	
Computerized Interactive Orthodontic Treatment Planning (Beginning Bates No. CC_ALGN_00003102)	June 1975	University of Connecticut / Faber	
Presentations with Dentofacial Planner Images (Beginning Bates No. CC_ALGN_00003181)	July 1999	Am. J. Orthod. & Dentofacial Orthopedics / Hegarty et al.	
Innovative Technologies to Support Positioning of Corrective Appliances in Orthodontic Treatments (Beginning Bates No. CC_ALGN_00003184)	June 2005	Raffaeli et al.	
Digital Models: An Introduction (Beginning Bates No. CC_ALGN_00003191)	2004	Peluso et al.	

C. The '936 Patent

1. Prior Art Devices and Systems[23]

The following prior art devices and systems anticipate and/or render obvious one or more Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrate the state of the art at the time of the alleged invention.

[23] Because fact discovery in the case is ongoing, ClearCorrect reserves the right to rely upon additional evidence regarding these systems or other systems that are prior art to the Asserted Patents, consistent with the Court's scheduling order and the Local Rules.

[redacted]

System(s)/ Company[24]	Date[25]	Evidence of Public Use, Sale, or Offer to Sell	Ex.
Cadent iTero / Align Technologies, Inc.	July 2005	Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) Berry et al., *New Technologies for Easier and More Accurate Impressions*, Inside Dentistry, Vol. 3, Iss. 9 (Oct. 2007). (Beginning Bates No. CC_ALGN_00003620) Palmer, *Close to open: new and expanding digital workflows broaden the CAD/CAM options available to labs and dentist*, Dental Lab Products, Vol. 33, Iss. 5 (May 2008). (Beginning Bates No. CC_ALGN_00003633) Ireland et al., *3D surface imaging in dentistry – what we are looking at*, British Dental Journal, Vol. 205, No. 7 (Oct. 11, 2008). (Beginning Bates No. CC_ALGN_00003415) Birnbaum et al., *Dental Impressions Using 3D Digital Scanners: Virtual Becomes Reality*, Digital Dentistry, Vol. 29, Iss. 8 (Oct. 2008). (Beginning Bates No. CC_ALGN_00003667) Cadent iTero Case Study: Predictable Precision With Digital Impressions, DentalCompare, (Jan. 9, 2009). (Beginning Bates No. CC_ALGN_00003617) Birnbaum et al., *3D Digital Scanners: A High-Tech Approach to More Accurate Dental Impressions*, Inside Dentistry, Vol. 5, Iss. 4 (Apr. 2009). (Beginning Bates No. CC_ALGN_00003405) Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010), 323-30. (Beginning Bates No. CC_ALGN_00003676)	936-17

[24] The below-listed companies/producers are the entities that offered the below products for sale, used them publicly, and/or made them publicly known to U.S. consumers.

[25] Date refers to the date by which the system was known or used, in public use, and/or on sale in the United States, based on ClearCorrect's current knowledge. Discovery is ongoing, and ClearCorrect reserves the right to update or supplement these dates, if relevant additional facts come to light.

[redacted]

3M Lava C.O.S. / Solventum Corp.	October 2007	Berry et al., *New Technologies for Easier and More Accurate Impressions*, Inside Dentistry, Vol. 3, Iss. 9 (Oct. 2007). (Beginning Bates No. CC_ALGN_00003620) Palmer, *Close to open: new and expanding digital workflows broaden the CAD/CAM options available to labs and dentist*, Dental Lab Products, Vol. 33, Iss. 5 (May 2008). (Beginning Bates No. CC_ALGN_00003633) Ireland et al., *3D surface imaging in dentistry – what we are looking at*, British Dental Journal, Vol. 205, No. 7 (Oct. 11, 2008). (Beginning Bates No. CC_ALGN_00003415) Birnbaum et al., *Dental Impressions Using 3D Digital Scanners: Virtual Becomes Reality*, Digital Dentistry, Vol. 29, Iss. 8 (Oct. 2008). (Beginning Bates No. CC_ALGN_00003667) Miyazaki et al., *A review of dental CAD/CAM: Current status and future perspectives from 20 years of experience*, Dental Materials Journal, (Feb. 2009). (Beginning Bates No. CC_ALGN_00003391) Birnbaum et al., *3D Digital Scanners: A High-Tech Approach to More Accurate Dental Impressions*, Inside Dentistry, Vol. 5, Iss. 4 (Apr. 2009). (Beginning Bates No. CC_ALGN_00003405) Farah et al., *3M ESPE Lava Chairside Oral Scanner C.O.S.*, The Dental Advisor, No. 10, (Apr. 2009). (Beginning Bates No. CC_ALGN_00003421) *Lava Chairside Oral Scanner C.O.S.: Technical Data Sheet*, 3M ESPE, (Aug. 2009), available at https://multimedia.3m.com/mws/media/632323O/lava-cos-technical-data-sheet.pdf. (Beginning Bates No. CC_ALGN_00004714) Schroder, *Moving Up With Digital Impression Technology*, DentistryToday.com, (Sept. 2009). (Beginning Bates No. CC_ALGN_00003896) Fasbinder, Digital Workflow for the Lava COS System, Inside Dentistry, Vol. 5, Iss. 9 (Oct. 2009). (Beginning Bates No. CC_ALGN_00003685) Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010), 323-30. (Beginning Bates No. CC_ALGN_00003676) Syrek et al., *Clinical evaluation of all-ceramic*	936-18

[redacted]

System(s)/ Company[24]	Date[25]	Evidence of Public Use, Sale, or Offer to Sell	Ex.
		crowns fabricated from intraoral digital impressions based on the principle of active wavefront sampling, Journal of Dentistry, Vol. 38, (July 2010), 553-59. (Beginning Bates No. CC_ALGN_00003626)	
CEREC / Dentsply Sirona Inc.	May 2008	Palmer, *Close to open: new and expanding digital workflows broaden the CAD/CAM options available to labs and dentist*, Dental Lab Products, Vol. 33, Iss. 5 (May 2008). (Beginning Bates No. CC_ALGN_00003633) Ireland et al., *3D surface imaging in dentistry – what we are looking at*, British Dental Journal, Vol. 205, No. 7 (Oct. 11, 2008). (Beginning Bates No. CC_ALGN_00003415) Birnbaum et al., *Dental Impressions Using 3D Digital Scanners: Virtual Becomes Reality*, Digital Dentistry, Vol. 29, Iss. 8 (Oct. 2008). (Beginning Bates No. CC_ALGN_00003667) Miyazaki et al., *A review of dental CAD/CAM: Current status and future perspectives from 20 years of experience*, Dental Materials Journal, (Feb. 2009). (Beginning Bates No. CC_ALGN_00003391) Birnbaum et al., *3D Digital Scanners: A High-Tech Approach to More Accurate Dental Impressions*, Inside Dentistry, Vol. 5, Iss. 4 (Apr. 2009). (Beginning Bates No. CC_ALGN_00003405) *CEREC – New Products 2009: Seeing CAD/CAM in a new light*, Sirona (Dec. 23, 2008). (Beginning Bates No. CC_ALGN_00003608) Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010), 323-30. (Beginning Bates No. CC_ALGN_00003676)	936-19

[redacted]

System(s)/ Company[24]	Date[25]	Evidence of Public Use, Sale, or Offer to Sell	Ex.
OraScanner and OraScan Image Processing Software ("OraScanner") / Dentsply Sirona Inc.	April 2001	Sachdeva, *SureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001), 245-53. (Beginning Bates No. CC_ALGN_00003083) Mah et al., *Computer-assisted orthodontic treatment: The SureSmile process*, Am J Orthod Dentofacial Orthop, Vol. 120, No. 1, (July 2001), 85-87. (Beginning Bates No. CC_ALGN_00003657) *SureSmile takes the trial-and-error out of braces*, SureSmile, (June 16, 2006), https://thermop.archive.org/web/20060616042924/http://www.suresmile.com/st/index.htm. (Beginning Bates No. CC_ALGN_00003689)	936-20
E4D Dental System ("E4D") / D4D Technologies, LLC	May 2008	Palmer, *Close to open: new and expanding digital workflows broaden the CAD/CAM options available to labs and dentist*, Dental Lab Products, Vol. 33, Iss. 5 (May 2008). (Beginning Bates No. CC_ALGN_00003633) Birnbaum et al., *Dental Impressions Using 3D Digital Scanners: Virtual Becomes Reality*, Digital Dentistry, Vol. 29, Iss. 8 (Oct. 2008). (Beginning Bates No. CC_ALGN_00003667) Birnbaum et al., *3D Digital Scanners: A High-Tech Approach to More Accurate Dental Impressions*, Inside Dentistry, Vol. 5, Iss. 4 (Apr. 2009). (Beginning Bates No. CC_ALGN_00003260) *E4D Dentist: Empowering Dentistry*, D4D Technologies, (Nov. 11, 2009). (Beginning Bates No. CC_ALGN_00003705) Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010), 323-30. (Beginning Bates No. CC_ALGN_00003676)	936-21

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ClearCorrect's investigation of these devices is ongoing. ClearCorrect reserves the right to assert earlier priority dates for the prior art listed above. Additionally, ClearCorrect reserves the right to rely on the documents describing the features and operation of the above products as corroborating evidence of their functionality prior to the priority dates. ClearCorrect further contends that the above prior art devices and systems demonstrate earlier invention by other parties under 35 U.S.C. § 102(g), and specifically, that the entities identified in the above table, their affiliates, and third parties, were entities involved in making and/or selling the alleged invention of the Asserted Patents before the patent applicants. ClearCorrect further reserves the right to contend that the Asserted Patents are invalid in view of additional public knowledge and uses and/or offers for sale or sales of other products and services that are prior art under 35 U.S.C. § 102(a) and/or (b).

Additionally, ClearCorrect is investigating the following products, devices, and/or systems as potentially anticipating and/or rendering obvious one or more Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrating the state of the art at the time of the alleged invention. ClearCorrect has served or will serve third-party subpoenas or requested discovery from Plaintiff in connection with various of these products, and ClearCorrect's investigation of the below products, devices, and/or systems is ongoing. ClearCorrect reserves the right to contend that the Asserted Patents are invalid in view of the following products, devices, and/or systems (or other products, devices, and/or systems that ClearCorrect becomes aware of) and to supplement its Invalidity Contentions and accompanying exhibits and documents accordingly.

System(s)	Entity
OrthoCAD Software	Align Technologies, Inc.

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System(s)	Entity
iTero Element	Align Technologies, Inc.
Dolphin Imaging and Management Software	Dolphin Imaging Systems, LLC
J-Ortho Software	
Geomagic Software	3D Systems Corp.
Insignia Software	Ormco Corp.
Elan Software	Ormco Corp.
GeoDigm Software	National Dentex Labs LLC
GeoDigm Scanner	National Dentex Labs LLC
IMS Digital Office Software	OrthoBanc LLC
VistaDent Software	Dentsply Sirona Inc.
iOS and iOS 2 Scanners	Ray America Inc.
IOS FastScan	Glidewell Laboratories
Maestro 3D Scanner	AGE Solutions Inc.
DigiModel	Orthoproof B.V.
Densys3d	Densys Ltd.
DPI/O and DPI-3D	Dimensional Photonics International, Inc.
3D Progress	Medical High Technologies S.p.A.
Maestro 3D Software	Age Solutions s.r.l.
Carestream Modeling Software and Scanner (including software compatible with CS 3600)	Carestream Dental LLC
Medit USA Modeling Software and associated scannes (including software compatible with the i500 digital intraoral scanner and/or i700 digital intraoral	Medit USA Inc.

[redacted]

System(s)	Entity
scanner)	
Midmark Modeling Software and associated scanner (including software compatible with the True Definition Scanner)	Midmark Corporation
Motion View Modeling Software and associated scanner (inclusive of Ortho Insight 3D)	Motion View LLC
Orthocast Modeling Software and associated scanner	Ortho Cast, Inc.
OrthoProof Modeling Software (inclusive of DigiModel) and associated scanner	OrthoProof
Dandy Modeling Software and associated scanner	Dandy
Orthoselect Modeling Software and associated scanner	
Panda Scanner and associated modeling software	
Planmeca Emerald and associated modeling software	
RAY America RIOS Series and associated modeling software	

ClearCorrect also reserves the right to contend that the Asserted Claims are invalid under 35 U.S.C. § 102(f). As detailed above, ClearCorrect has requested discovery from Plaintiff on products that Plaintiff has identified as allegedly embodying the Asserted Claims, *see* . ClearCorrect therefore reserves the right to amend or supplement these disclosures to the extent

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Plaintiff subsequently produces additional discovery indicating that any such allegedly practicing product (or any other allegedly practicing product) is prior art to the Asserted Patents. ClearCorrect also reserves the right to assert that the Asserted Claims are invalid under 35 U.S.C. § 102(f) if discovery from Plaintiff (or third parties) reveals that the named inventors of the Asserted Patents did not invent (either alone or in conjunction with others) the subject matter recited in the Asserted Clams. If ClearCorrect asserts invalidity under § 102(f), ClearCorrect will promptly provide the name of the person(s) from whom, and the circumstances under which, the alleged invention or any part of it was derived.

2. Prior Art Patent References

The following prior art anticipates and/or render obvious the Asserted Claims, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, and/or illustrates the state of the art at the time of the alleged invention. For published patent applications, ClearCorrect may identify the application and a patent that subsequently issued from that application. For any citation to a published application, ClearCorrect reserves the right to rely on the corresponding disclosure in the subsequently issued patent, and vice versa.

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Ex.
WO	2007/084727 ("Boerjes"; Beginning Bates No. CC_ALGN_00001867)	Filed: January 19, 2007 Issued: July 26, 2007	Boejies et al.	936-11
US	7,474,932 ("Geng"; Beginning Bates No. CC_ALGN_00004940)	Filed: October 25, 2004 Issued: January 6, 2009	Geng	936-15

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Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Ex.
US	2007/0236494 ("Kriveshko-'494"; Beginning Bates No. CC_ALGN_00001683)	Filed: January 20, 2006 Issued: October 11, 2007	Kriveshko	936-04
US	2002/0006217 ("Rubbert-'217"; Beginning Bates No. CC_ALGN_00001599)	Filed: April 13, 2001 Published: January 17, 2002	Rubbert et al.	936-03
US	2009/0316966 ("Marshall"; Beginning Bates No. CC_ALGN_00004889)	Filed: May 15, 2009 Published: December 24, 2009	Marshall et al.	936-16
US	6,227,850 ("Chishti-850"; Beginning Bates No. CC_ALGN_00001848)	Filed: May 13, 1999 Issued: May 8, 2001	Chishti et al.	936-09
US	2005/0283065 ("Babayoff-065"; Beginning Bates No. CC_ALGN_00001705)	Filed: June 17, 2005 Published: December 22, 2005	Babayoff	936-05
US	2007/0172112 ("Paley"; Beginning Bates No. CC_ALGN_00001579)	Filed: September 3, 2006 Published: July 26, 2007	Paley et al.	936-02
US	2004/0155975 ("Hart"; Beginning Bates No. CC_ALGN_00001742)	Filed: September 17, 2003 Published: August 12, 2004	Hart et al.	936-06

3. Additional Prior Art References

The following references may be relied upon to demonstrate the state of the art and/or the knowledge of a POSITA as it relates to the '936 patent in the relevant timeframe:

All documents cited on the face of the '936 patent and related patents, patent publications, file histories, and applications, all documents referenced elsewhere herein, as well as:

[redacted]

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Ex.
WO	2003094102A1 ("Rubbert-102"; Beginning Bates No. CC_ALGN_00001759)	Filed: March 27, 2003 Published: November 13, 2003	Rubbert et al.	936-07
WO	2000008415A1 ("Babayoff-415"; Beginning Bates No. CC_ALGN_00001819)	Filed: August 5, 1999 Published: February 17, 2000	Babayoff et al.	936-08
US	2003/0232302 ("Babayoff-'302"; Beginning Bates No. CC_ALGN_00004882)	Filed: June 18, 2002 Published: December 18, 2003	Babayoff et al.	936-13
WO	2007084647 ("Kriveshko-'647"; Beginning Bates No. CC_ALGN_00001482)	Filed: January 19, 2007 Published: July 26, 2007	Kriveshko et al.	936-01
WO	2009/085752 ("Cinader"; Beginning Bates No. CC_ALGN_00002005)	Filed: December 16, 2008 Published: July 9, 2009	Cinader	936-14
US	7,555,403 ("Kopelman-403"; Beginning Bates No. CC_ALGN_00004766)	Filed: February 8, 2006 Issued: June 30, 2009	Kopelman et al.	
US	6,405,071 ("Analoui"; Beginning Bates No. CC_ALGN_00004397)	Filed: February 10, 2000 Issued: June 11, 2002	Analoui	
US	7,796,811 ("Orth"; Beginning Bates No. CC_ALGN_00004436)	Filed: March 7, 2006 Issued: September 14, 2010	Orth	
US	9,861,457 ("Fisker"; Beginning Bates No. CC_ALGN_00004447)	Filed: March 18, 2010 Issued: January 9, 2018	Fisker et al.	
US	2010/0260405 (Beginning Bates No. CC_ALGN_00004377)	Filed: December 16, 2008 Published: October 14, 2010	Cinader	

[redacted]

Country/Patent or Application No.		Filing/Issue Dates	Inventor(s)	Ex.
US	2010/0260405 PCT Application (Beginning Bates No. CC_ALGN_00004328)	Filed: December 16, 2008	Cinader	

Title	Date	Publisher	Author(s)	Ex.
Contemporary Fixed Prosthodontics ("Rosenstiel"; Beginning Bates No. CC_ALGN_00002047)	2006	Mosby Elsevier	Rosenstiel et al.	936-12

V. IPR PROCEEDINGS

A. IPR for the '444 Patent

On July 20, 2017, ClearCorrect filed a petition for *inter partes* review of the '444 patent. *See* IPR2017-01829, Paper 1 (PTAB July 20, 2017). The IPR asserted that the '444 patent was unpatentable under 35 U.S.C. § 103 based on Chishti-'876 or based on Chishti-'511 in view of Chishti-'876. *Id.* at 5. On November 10, 2017, Plaintiff filed a Patent Owner Preliminary Response. *See* IPR2017-01829, Paper 7 (PTAB Nov. 10, 2017). On February 5, 2018, the PTAB denied institution of IPR. *See* IPR2017-01829, Paper 10 (PTAB Feb. 5, 2018).

In its Patent Owner Preliminary Response in IPR2017-01829 for the '444 patent, Plaintiff primarily focused on claim construction or procedural arguments. *See* IPR2017-01829, Paper 7 (PTAB Nov. 10, 2017). Plaintiff only contested whether the cited prior art disclosed the following limitations of the challenged claims:

Limitation	Claims
determining, by the host computer, an order of movement for each respective dental object such that the dental objects avoid colliding with or obstructing each other on their	1, 15, 29

[redacted]

Limitation	Claims
respective routes from said initial position to said desired final position through at least one of staggering and round-tripping of at least one dental object.	
receive an electronic representation of each dental object in relation to one another in an initial position	29
determining a total distance each respective dental object will move	6, 20, 34

IPR2017-01829, Paper 7 (PTAB Nov. 10, 2017). Plaintiff therefore conceded that all other limitations of the challenged claims in the '444 patent were known and disclosed by the prior art before the patent's priority date.

B. IPR for the '936 Patent

On July 26, 2021, 3Shape A/S and 3Shape Inc. filed a petition for *inter partes* review of the '936 patent. *See* IPR2021-01241, Paper 3 (PTAB July 26, 2021). The IPR asserted that the '936 patent was unpatentable under 35 U.S.C. §§ 102 and/or 103 in view of Rubbert-102; Rubbert-102 and Babayoff-415; or Rubbert-102 and Rosenstiel. *See id.* at 5-6. On November 9, 2021, Plaintiff filed a Patent Owner Preliminary Response. *See* IPR2021-01241, Paper 10 (PTAB Nov. 9, 2021). On January 26, 2022, the PTAB denied institution of IPR. *See* IPR2021-01241, Paper 15 (PTAB Jan. 26, 2022).

During IPR2021-01241 for the '936 patent, Plaintiff only contested whether the cited prior art disclosed the following limitations of the challenged claims:

Limitation	Claims
receive second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity;	1

[redacted]

Limitation	Claims
receiving second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity	9
after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner	17

IPR2021-01241, Paper 10 (PTAB Nov. 9, 2021). Plaintiff therefore conceded that all other limitations of the challenged claims in the '936 patent were known and disclosed by the prior art before the patent's priority date.

C. IPR for the '192 Patent

On November 9, 2018, 3Shape A/S and 3Shape Inc. filed a petition for *inter partes* review of U.S. Patent No. 9,299,192, to which the '936 patent claims priority and with which the '936 patent shares a specification. *See* IPR2019-00134, Paper 3 (PTAB Nov. 9, 2018). The IPR asserted that the '192 patent was unpatentable under 35 U.S.C. § 103 in view of Paley in view of Kriveshko-'494; Paley in view of Kriveshko-'494 and Babayoff-'302; or Paley in view of Kriveshko-'494 and Chishti-'850. *Id.* at 5. On April 24, 2019, Plaintiff filed a Patent Owner Preliminary Response. *See* IPR2019-00134, Paper 7 (PTAB Apr. 24, 2019). On July 22, 2019, the PTAB instituted IPR. *See* IPR2019-00134, Paper 8 (PTAB July 22, 2019). On October 15, 2019, Plaintiff filed a Patent Owner Response. *See* IPR2019-00134, Paper 12 (PTAB Oct. 15, 2019). On Jan. 12, 2020, 3Shape filed Petitioner's Reply. *See* IPR2019-00134, Paper 16 (PTAB Jan. 12, 2020). On Feb. 21, 2020, Plaintiff filed Patent Owner's Sur-Reply. *See* IPR2019-00134, Paper 18 (PTAB Feb. 21, 2020). On April 15, 2020, the PTAB held an oral hearing. *See* IPR2019-00134, Paper 27 (PTAB April 15, 2020). On July 20, 2020, the PTAB issued a Final Written Decision. *See* IPR2019-00134, Paper 29 (PTAB July 20, 2020). In the Final Written Decision, the PTAB found unpatentable claims 1-5 and 8-32 of the '192 patent. *Id.* at 59.

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ClearCorrect incorporates by reference the arguments made in the IPR proceeding and the PTAB's reasoning on the Institution Decision and Final Written Decision, and ClearCorrect reserves all rights to rely on similar arguments or reasoning in this proceeding.

VI. CORE CONCEPTS WERE WELL-KNOWN IN THE PRIOR ART

The Asserted Patents purport to cover a combination of basic concepts, all of which were well known in the prior art long before the Asserted Patents' alleged priority dates. ClearCorrect identifies below a non-exhaustive list of such concepts, including representative references showing that these concepts were well known in the prior art, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions. Additional concepts that were well known in the prior art are detailed in ClearCorrect's claim charts submitted as exhibits to these Preliminary Invalidity Contentions. The below descriptions are intended to be representative and to provide a high-level overview of the concepts that were well known. ClearCorrect reserves the right to supplement these disclosures as part of Final Invalidity Contentions and expert reports.

A. Materials Patents

1. Use of Dental Aligners to Reposition a Patient's Teeth

It was well known before the alleged invention date of the Materials Patents to use dental aligners to reposition a patient's teeth. For example:

- Tadros at [0007] ("Disclosed herein too is a method for maintaining or repositioning teeth in the oral cavity comprising placing an appliance in a patient's mouth, wherein the appliance comprises a polymeric shell that comprises a polymeric mixture, and further wherein the polymeric shell has cavities designed to receive teeth.").

[redacted]

- Stewart at [0100] ("If desired, one or more parts of the self-supporting shell can be offset from the natural position of one or more teeth, so that when the shell is in place, it exerts a force on one or more teeth which moves the teeth in a desired direction, for orthodontic purposes. In this use, the shell needs to be more rigid than is necessary, or even desirable, for a shell which has only a cosmetic purpose. For example, for orthodontic appliance, it is desirable to use a polymeric sheet which, before being thermoformed, is 0.5 to 0.8 mm thick and for the polymeric composition to have a flexural modulus between 1000 and 3000 MPa.").
- Chen at [0002] ("An alternative to braces includes the use of aligner-type dental appliances for realigning teeth. Such an appliance may be comprised of a thin concave trough of material that forms a receiving cavity geometry that generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the dental appliances over the teeth applies controlled forces in specific locations to gradually move the teeth into a new predetermined configuration. Repetition of this process with successive appliances comprising new configurations eventually moves the teeth through a series of predetermined intermediate arrangements along the most effective and efficient treatment path to a final predetermined arrangement.").
- Hinz at 1 ("The invention relates to a method for producing a multilayer dental splint in a deep-drawing tool. In addition, the present invention relates to a dental splint."), 1 ("Dental splints are used in orthodontics as occlusal splints, expansion plates, positioners, or retention splints for retention after completion of the active

[redacted]

treatment phase, for correcting minor dental misalignments or as other removable orthodontic treatment apparatuses.").

- Kalili at Abstract ("An invisible removable orthodontic repositioning appliance with a lower modulus inner lining for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement while minimizing propensity for root and bone resorption due to the lower modulus is disclosed. The aligning of the teeth may be accomplished by taking impressions at various intervals for greater accuracy in the event of a distorted impression. Patient impression and/or model may then be digitally scanned. Using 3D software, tooth position may be incrementally modified toward idealized position and associated stress analyzed. Final modified model and associated appliance may be fabricated for orthodontic movement using 3D printing. Each appliance may be numerically identified to maintain uniformity of application from start of treatment to completion. The forces required for the alignment may be from polymeric material used to fabricate the orthodontic appliances, the shape memory alloy, and/or micro-implants to accomplish optimal tooth movement.").

2. Fabricating a Dental Aligner from a Polymeric Sheet and a Model of a Patient's Teeth

It was well known before the alleged invention date of the Materials Patents to fabricate a dental aligner from a polymeric sheet and a model of a patient's teeth. For example:

- Tadros at [0080] ("In order to make a suitable appliance for repositioning the teeth, it is generally desirable to have the polymeric mixture in the form of a sheet. A polymeric mixture may generally be formed into a sheet by mixing the polymers in a device that can impart shear to the polymers. Suitable devices are

[redacted]

extruders such as single and twin-screw extruders, Buss kneaders, roll mills, helicones, and the like. It may be desirable to couple a twin screw extruder with a single screw extruder to mix the polymers prior to calendaring the mixture in a roll mill. The calendaring of the mixture facilitates the production of the sheet. In one embodiment, it is generally desirable to form the sheet on a roll mill wherein the mating surfaces of the rolls are both polished. Such a sheet is termed a polish/polish sheet. Sheets having a matte/polish finish may also be used. After the manufacture of the sheet, it may be formed into an appliance for repositioning the teeth as detailed below. The forming of the appliance may be accomplished by process such as thermoforming, molding, and the like, which are discussed in detail below.").

- Tadros at [0081] ("FIG. 2 is a schematic depicting the procedure by which the appliances may be manufactured in order to effect the repositioning of the teeth. As a first step, an initial digital data set (IDDS) representing the initial tooth arrangement is obtained. The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using methods such as x-rays, three-dimensional x-rays, computer-aided tomographic images or data sets, magnetic resonance images, and the like, as well as combinations comprising at least one of the foregoing methods. The IDDS may also be made after first obtaining a plaster cast of the patient's teeth. After the plaster cast is obtained, it can be digitally scanned using a laser scanner or another range acquisition system to produce the IDDS. The data set obtained by the range acquisition system may be converted to other formats so as to be compatible with the software which is

[redacted]

used for manipulating images within the data set, as described in more detail below.").

- Tadros at [0087] ("The rapid prototyping machine 200 may alternatively be used to produce molds, which are, in effect, positive tooth models (replicas) of each successive stage of the treatment. The positive tooth models may then be used to produce the appliance. The positive tooth models are generally made from plaster, epoxy, and the like. The appliance is generally manufactured by processes such as injection molding, compression molding, vacuum forming, blow molding, and the like. Suitable forming equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. The forming machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum forming machines are available from Raintree Essix, Inc. Metairie, La. These machines may operated in a batch or a continuous fashion.").
- Stewart at [0087] ("Any method can be used to make the selected polymeric composition into a shape which will fit over the teeth whose appearance is to be changed. Since the compositions cannot be shaped over the teeth themselves, the first step is to make a digital or physical image which corresponds to the teeth. A physical image can be made by forming an impression of the teeth, for example using an alginate composition, and then forming the physical image in the mold provided by the impression. A physical image can also be made from a digital image.").

[redacted]

- Stewart at [0100] ("If desired, one or more parts of the self-supporting shell can be offset from the natural position of one or more teeth, so that when the shell is in place, it exerts a force on one or more teeth which moves the teeth in a desired direction, for orthodontic purposes. In this use, the shell needs to be more rigid than is necessary, or even desirable, for a shell which has only a cosmetic purpose. For example, for orthodontic appliance, it is desirable to use a polymeric sheet which, before being thermoformed, is 0.5 to 0.8 mm thick and for the polymeric composition to have a flexural modulus between 1000 and 3000 MPa.").
- Chen at [0004] ("A dental appliance is described herein. In one embodiment, the dental appliance comprises a concave trough conforming to a plurality of teeth when placed over the plurality of teeth. The concave trough is configured to transition from a first shape to a second shape if a deforming force is applied. The concave trough comprises a shape memory material. The shape memory material is configured to restore the concave trough to an approximate first shape upon an application of an external stimulus. The first shape is configured to apply a first force on a tooth when the concave trough conforms.").
- Chen at [0031] ("The concave trough 102 may include a variable number of inner layers 132. For example, four, three or two inner layers 132, as shown in FIGS. 4A, 4B, and 4C, respectively. More than four inner layers (not depicted) may also be used. The inner layers 132, as well as the outer layers 134, may each have different thickness, such as 5 or 10 mils, and/or variable glass transition temperatures. The layers may be formed in various orientations and

[redacted]

configurations to suit the modulus and application requirements. The layers may be formed by a process, such as thermoforming or similar process, such as co-extrusion, lamination, or any other process where layers are formed. The layers may be formed with cavities and indentations used as repositioning forces on the teeth.").

- Hinz at 1 ("A deep-drawing technology known in the dental field can be used to produce the above-mentioned dental splints, in which thermoplastic films are heated in deep-drawing devices and formed over a jaw model made of plaster. Deep-drawing films are offered in greatly varying shapes and sizes and in different colors. The film shape is oriented to the deep-drawing device suggested for the processing, the thickness of the film to the desired structural form and the use of the splint and is often also dependent on the preferences of the dentist. The desired processing shape can be stamped out of the films, which is applied in the desired shape or to the respective model in the laboratory by heating and by means of pressure.").
- Hinz at 7-8 ("An alternative embodiment of a method for producing a multilayer dental splint is shown in Figure 2. In the embodiment shown in Figure 2, the deep-drawing film 1 from Figure 1 is bonded to a second deep-drawing film 7, which only has a soft layer 8 made of polyurethane. As in the method described in Figure 1, firstly the deep-drawing film 1 is deep drawn on the jaw model 3. Subsequently, this first splint thus obtained from the deep-drawing film 1 remains on the jaw model 3 and the second deep-drawing film 7 is deep drawn over the first layer on the jaw model 3, so that a two-layer splint is obtained. At least one

[redacted]

holding or auxiliary element can again be embedded between the deep-drawing film 1 and the deep-drawing film 7. To obtain the desired layered composite, subsequently a third deep-drawing film 9, which is single-layer and has a hard layer 10 made of polycarbonate, is deep drawn over the two-layer splint on the jaw model 3, so that a three-layer dental splint according to the invention is obtained. According to the method shown in Figure 1, the film excess of each splint obtained by forming the deep-drawing films 1, 7, 9 is severed before the deep drawing of the next following deep-drawing film 7, 9, without the splint being detached from the jaw model 3. Moreover, before the deep drawing of a next following deep-drawing film 7, 9, coating the previously obtained splint with an adhesion promoter can be provided.").

- Bedard at 2:27-38 ("The process includes steps of providing a cast, which reflects the regions to be contacted by the appliance. Undercut regions may be present in the patient and preferably are retained in the cast. In the process a laminate blank, with a soft layer and a hard, strengthening layer, is also provided. The blank is heated so that it is moldable, and then molded into contact with the study cast. The molded laminate is trimmed to form a try in base plate. A temporary wax layer, bearing artificial teeth, is formed on the try in base plate. The try in base plate, with wax layer and artificial teeth, is tested for fit and comfort in the patient's mouth.").
- Kalili at claim 12 ("12. A method of repositioning misaligned teeth comprising: a) taking an impression of the patient's teeth and forming a model based on the impression of the patient's teeth; b) adding at least one indentation to the model;

[redacted]

and c) creating a repositioning appliance from the model, wherein the repositioning appliance is formed with an inner layer having at least one raised surface corresponding in shape and size to the at least one indentation formed in the model").

- Kalili at [0009] ("In another aspect of the invention, a repositioning appliance may be constructed from polymers with a lower elastic modulus inner lining than the outer lining. The lower elastic modulus on the inner layer may allow for greater patient comfort, less tooth, bone and root damage, and longer duration of tooth movement by the repositioning appliance thereby requiring less number of appliances to achieve the same or similar orthodontic alignment.").
- Rafih at 5:6-20 ("For example, the channel 102 and the fins 120 can be formed of a thermo-plastic material such as ethylene vinyl acetate ('EVA'). Ethylene vinyl acetate is a thermo-plastic material that can be heated or boiled to soften the material and then the user can insert the appliance in his or her mouth, and bite down on the appliance in order to cause the softened appliance to permanently deform to the shape of the teeth and mouth of the user. In an embodiment, the thermoplastic material is ELVAX® 150 which has a melting point of 145° F. and a Shore A durometer of 73, or ELVAX® 250 which has a melting point of 158° F. and a Shore A durometer of 80. ELVAX® branded EVA copolymer resins are available from DUPONT®. In other embodiments, the thermo-plastic material can be some other EVA or non-EVA softenable material.").

[redacted]

3. Use of a Multilayer Polymeric Sheet with Three or More Layers in a Dental Aligner

It was well known before the alleged invention date of the Materials Patents to use a multilayer polymeric sheet with three or more layers in a dental aligner. For example:

- Bedard at 3:56-68 ("The inventors recognize that the laminate of the present invention dental appliance could alternatively include multiple thinner layers of strengthening material(s) which together form a strengthening layer equivalent; or multiple thinner layers of soft material(s) which together form a soft material layer equivalent; or groups of multiple thinner layers with each group working together to form a strengthening layer equivalent and a soft layer equivalent. The underlying concept remains that at least two layers of materials with different property are present in the laminate and working together to contribute to the final dental appliance product, with one layer proving flexible strength and the other layer providing a soft surface.).
- Bedard at claim 7: ("7. A laminated dental appliance comprising: a first layer for contact with gum tissue, the first layer having a first hardness; a second layer for strengthening the first layer and the appliance, the second layer laminated to the first layer and having a second hardness greater than the first hardness; a third layer laminated to the second layer, opposite the first layer.").
- Stewart at [0111] ("Statement 12. A shell according to any one of Statements 1-11 wherein the shell comprises two or more layers.").
- Tadros at [0016] ("In yet another embodiment, the polymeric shell comprises two or more layers, wherein one layer comprises an elastomer.").

[redacted]

- Chen at [0031] ("The concave trough 102 may include a variable number of inner layers 132. For example, four, three or two inner layers 132, as shown in FIGS. 4A, 4B, and 4C, respectively. More than four inner layers (not depicted) may also be used. The inner layers 132, as well as the outer layers 134, may each have different thickness, such as 5 or 10 mils, and/or variable glass transition temperatures. The layers may be formed in various orientations and configurations to suit the modulus and application requirements. The layers may be formed by a process, such as thermoforming or similar process, such as co-extrusion, lamination, or any other process where layers are formed. The layers may be formed with cavities and indentations used as repositioning forces on the teeth.").
- Hinz at Abstract ("A method is shown and described for producing a multilayer dental splint in a deep-drawing device. It is provided according to the invention that, in the deep-drawing device, a first deep-drawing film (1) and at least one second deep-drawing film (2, 7) and possibly at least one third deep-drawing film (9) are bonded to one another by deep drawing on a jaw model (3), wherein the first deep-drawing film (1) and the second deep-drawing film (2, 7) or the third deep-drawing film (9) have a hard layer (4, 5, 10) made of a first plastic material and at least one deep-drawing film (2, 7) has a soft layer (6, 8) made of a second plastic material, and wherein the deep-drawing films (1, 2, 7, 9) are bonded to one another in such a way that a layered composite having a hard outer layer (4, 5, 10) on each of the two outer sides and having a soft inner layer (6, 8) embedded between the hard layers (4, 5, 10) is obtained.").

[redacted]

- Hinz at 3-4 ("A deep-drawing film, which has an at least two-layer structure having at least one hard layer and having at least one soft layer, can be used to produce the dental splint according to the invention. The above-mentioned deep-drawing film can then be bonded to a further deep-drawing film, which has a preferably single-layer structure having a hard layer, by deep-drawing, so that a layered composite having two outside hard layers and a soft layer embedded between the hard layers results. For example, a first deep-drawing film can consist of polycarbonate and can have a single-layer structure. This deep-drawing film is first deep drawn on a jaw model, so that a single-layer splint is obtained. This splint than initially remains on the jaw model and is connected to a second deep-drawing film by deep-drawing, wherein the second deep-drawing film can have a two-layer structure having a hard layer made of polycarbonate and having a second soft layer made of polyurethane. To obtain the provided layer structure, the second deep-drawing film having the soft layer made of polyurethane is placed on the splint obtained from the first deep-drawing film made of polycarbonate and deformed over the first splint and deep drawn on the jaw model, so that a three-layer structure results. An adhesion promoter can possibly be applied to the first splint made of polycarbonate here, to ensure full surface bonding of the layers. In principle, of course, multiple films can be deep drawn simultaneously in one work step on the jaw model.").

[redacted]

4. Inclusion of One or More Thermoplastic Polyurethane Elastomer Layers in a Multilayer Dental Aligner

It was well known before the alleged invention date of the Materials Patents to include one or more thermoplastic polyurethane elastomer layers in a multilayer dental aligner. For example:

- Hinz at 3 ("In a further preferred embodiment, a deep-drawing film having a soft layer made of a thermoplastic polyurethane (TPU) or ethylene vinyl acetate (EVA) is selected. The above-mentioned plastic materials result in a sufficiently high elasticity of the dental splint according to the invention, so that breakage of the dental splint during insertion and removal and while it is worn does not have to be a concern.").
- Stewart at [0111] ("A shell according to Statement 1 wherein the polymeric composition is based on a polymer selected from the group consisting of polyolefins, e.g. polyethylene, polyesters, including for example copolymers such as polyethylene terephthalate glycol resins (PETG), polyurethanes including rigid polyurethanes, thermoplastic polyurethanes (TPU), polypropylene and propylene copolymers, acrylic and methacrylic resins and co-polymers, polystyrene and co-polymers including random and block co-polymer and elastomers and fluoropolymers.").
- Chen at claim 14 ("14. The method of claim 13, wherein the shape memory material comprises a material selected from the group consisting of shape memory polymers, methacrylate containing polymers, acrylate containing polymers, elastomer polymers, thermoplastic polymers, thermoplastic elastomer polymers, thermoset polymers, thermoplastic polymer blends, cross-linked

[redacted]

thermoplastic polymers, cross-linked thermoplastic polymer blends, metal alloys, and shape memory metals.").

- Kalili at [0069] ("FIGS. 15 and 16 illustrate the benefits of having an inner layer with a lower elastic modulus than the outer layer. The elastic modulus of a material is the ratio of the increment of unit stress to an increment of unit deformation within the elastic limit. When a material is deformed within the elastic limit, the coiled polymer chains are stretched reversibly. The magnitude of the elastic modulus may be indicative of the atomic and molecular bonding forces. When the stress is relieved, the material returns to its original shape and therefore the deformation is nonpermanent. Different materials may have different elastic moduli based on their molecular structures. Some materials, such as certain polymers including polycarbonates, polyacetates, polyolefins, polyamides, polystyrenes and epoxy resins among others, may be specially produced to have different elastic moduli while retaining similar chemical compositions by using additives such as silicates, other polymers or fillers among other materials. In an embodiment, the liner may be a polymer such as Thermoplastic Polyurethane that is an aromatic polyether based grade, such as TEXIN® 990R resin with a shore hardness of approximately 90A. The TEXIN® 990R resin may offer outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility. Furthermore, the resin may also provide good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics. Although in one embodiment a polycarbonate outer layer and a polyurethane inner layer is used,

[redacted]

the composition could consist of any type of polymers with higher modulus outer layer and a lower modulus inner layer.").

5. Inclusion of One or More Co-polyester Layers in a Multilayer Dental Aligner

It was well known before the alleged invention date of the Materials Patents to include one or more co-polyester layers in a multilayer dental aligner. For example:

- Stewart at [0111] ("A shell according to Statement 1 wherein the polymeric composition is based on a polymer selected from the group consisting of polyolefins, e.g. polyethylene, polyesters, including for example copolymers such as polyethylene terephthalate glycol resins (PETG), polyurethanes including rigid polyurethanes, thermoplastic polyurethanes (TPU), polypropylene and propylene copolymers, acrylic and methacrylic resins and co-polymers, polystyrene and co-polymers including random and block co-polymer and elastomers and fluoropolymers.").
- Tadros at [0073] ("In one embodiment, the appliance may comprise additional layers disposed upon the sheet comprising the polymeric mixture. The additional layers may comprise a first layer disposed upon a surface of the sheet comprising the polymeric mixture, and an optional second layer disposed upon a surface of the sheet opposite the surface in contact with the first layer. The additional layers generally comprise an organic polymer having a tensile modulus of less than or equal to about 1,000 N/mm^2. Preferred organic polymers for the additional layers are elastomers. Suitable examples of elastomers for the first layer and/or second layer include silicones, fluoroelastomers, styrene-butadienes, styrene-isoprenes, polybutadienes, polyisobutylenes, polyurethanes,

[redacted]

chlorosulfonates, butyls, neoprenes, nitrites, polyisoprenes, plasticized nylons, polyesters, polyvinyl ethers, polyvinyl acetates, polyisobutylenes, ethylene vinyl acetates, copolyester ethers, polyolefins, and polyvinyl chlorides, copolymer rubbers such as ethylene-propylene (EPR), ethylene-propylene-diene monomer (EPDM), copolyester ethers, styrene-isoprene-styrene (SIS), styrene-butadiene-styrene (SBS), nitrile-butadienes (NBR) and styrene-butadienes (SBR), mixtures such as ethylene propylene diene monomer (EPDM), EPR, or NBR, and mixtures and copolymers thereof. A preferred elastomer for the first layer is a copolyester ether. Another preferred organic polymer for the first layer and/or second layer is PCCD. When the appliance comprises only one additional layer, (e.g., a first layer), it is generally desirable to place the appliance in the mouth of the patient in such a manner so that the first layer contacts the gums of the patient. Since the first layer generally comprises a softer material than the polymeric mixture it can be used effectively to alleviate pain, discomfort and bleeding gums. A preferred elastomer is ECDEL 9966 commercially available from Eastman Chemical Company at Kingsport, Tenn.").

- Rafih at 10:43-54 ("Further, the frame 350 can comprise a material having sufficient stiffness to resist excessively and/or permanently deforming when placed in the mouth of a user and the user places the oral appliance in the mouth and additionally when the user clenches his or her jaws. In an embodiment, the frame can comprise a copolymer material that does not include bisphenol-A (BPA). For example, in an embodiment the frame can comprise a polymer such as TRITAN™ copolyester from EASTMAN® Chemical Company. TRITAN™

[redacted]

EX 401 has a melting temperature of approximately 515-535° F. and a stiffness of 1500 MPa.").

B. Treatment Planning Patents

1. Staging of tooth movements

It was well known before the alleged invention date of the Treatment Planning Patents that the teeth movements during orthodontic treatment could be staged using a computer or other appliance. For example:

- Chishti '511 at 2:1-41 ("[T]he invention provides methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate substeps for repositioning the teeth of a patient. The methods include providing a digital finite element model of the shape and material of each of a sequence of appliances to be applied to a patient; providing a digital finite element model of the teeth and related mouth tissue of the patient; computing the actual effect of the appliances on the teeth by analyzing the finite elements models computationally; and evaluating the effect against clinical constraints.").
- Chishti '511 at claim 1 ("1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising: . . . calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation.").
- Chishti '929 at 4:6-10 ("In one aspect, the invention relates to the computer-automated creation of a plan for repositioning an orthodontic patient's teeth. A computer receives an initial digital data set representing the patient's teeth at their

[redacted]

initial positions and a final digital data set representing the teeth at their final positions. The computer uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.").

- Kuo '099 at 1:31-39 ("The present invention provides methods and apparatus for mining relationships in treatment outcome and using the mined data to enhance treatment plans or enhance appliance configurations in a process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The invention can operate to define how repositioning is accomplished by a series of appliances or by a series of adjustments to appliances configured to reposition individual teeth incrementally.").
- Kuo '099 at 1:66-2:2 ("In general, in one aspect, the invention provides methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate substeps for repositioning the teeth of a patient.").
- Rubbert '568 at [0013] ("In a first aspect of the invention, apparatus for treatment planning for an orthodontic patient is provided. The apparatus can be considered an interactive, computer-based computer aided design and computer aided manufacturing (CAD/CAM) system for orthodontics. The apparatus is highly interactive, in that it provides the orthodontist with the opportunity to both observe and analyze the current stage of the patient's condition and develop and specify a target or desired stage. A shortest direct path of tooth movement to the target stage can also be determined. Further, the apparatus provides for simulation of tooth movement between current and target stages.").

[redacted]

- Muhammad at ¶ [0011]-[0012] ("In one aspect, a computer-implemented method to prepare a malocclusion treatment plan includes Selecting a tooth treatment pattern from a library of predetermined tooth treatment patterns, and generating the malocclusion treatment plan implementing the Selected tooth treatment pattern. Implementations of the above aspect may include one or more of the following. The generating the malocclusion treatment plan includes determining one or more tooth paths based on the selected tooth treatment pattern."); *id.* at ¶¶ [0018]-[0019].
- Muhammad at Claim 6 ("The method of claim 1, wherein generating the malocclusion treatment plan comprises specifying a series of treatment stages for one or more teeth.").

2. Use of Collision Avoidance Techniques in Staging

It was well known before the alleged invention date of the Treatment Planning Patents that collision avoidance techniques could be used in staging teeth movements. For example:

- Chishti '511 at 4:7-23 ("Having both a beginning position and a final position for each tooth, the process next defines a tooth path for the motion of each tooth. The tooth paths are optimized in the aggregate so that the teeth are moved in the quickest fashion with the least amount of round-tripping to bring the teeth from their initial positions to their desired final positions. (Round-tripping is any motion of a tooth in any direction other than directly toward the desired final position. Round-tripping is sometimes necessary to allow teeth to move past each other.) The tooth paths are segmented. The segments are calculated so that each tooth's motion within a segment stays within threshold limits of linear and

[redacted]

rotational translation. In this way, the end points of each path segment can constitute a clinically viable repositioning, and the aggregate of segment end points constitute a clinically viable sequence of tooth positions, so that moving from one point to the next in the sequence does not result in a collision of teeth.").

- Chishti '929 at 27:1-6 ("As the virtual articulator simulates the motion of a patient's teeth, a collision detection process, such as one implementing the oriented bounding box (OBB) algorithm described below, determines whether and how the patient's teeth will collide during the normal course of oral motion. Visual indicators, such as red highlights, appear on a displayed image of the teeth to indicate collision points. The final tooth positions are adjusted, automatically or manually, to avoid collisions detected by the collision detection algorithm.").
- Chishti '929 at 31:4-19 ("FIG. 16 is a flow chart of a computer-implemented process for generating non-linear treatment paths along which a patient's teeth will travel during treatment. The non-linear paths usually are generated automatically by computer program, in some cases with human assistance. The program receives as input the initial and final positions of the patient's teeth and uses this information to select intermediate positions for each tooth to be moved (step 1600). The program then applies a conventional spline curve calculation algorithm to create a spline curve connecting each tooth's initial position to the tooth's final position (step 1602). In many situations, the curve is constrained to follow the shortest path between the intermediate positions. The program then samples each spline curve between the intermediate positions (step 1604) and applies the collision detection algorithm to the samples (step 1606). If any

[redacted]

collisions are detected, the program alters the path of at least one tooth in each colliding pair by selecting a new position for one of the intermediate steps (step 1608) and creating a new spline curve (1602). The program then samples the new path (1604) and again applies the collision detection algorithm (1606). The program continues in this manner until no collisions are detected. The routine then stores the paths, e.g., by saving the coordinates of each point in the tooth at each position on the path in an electronic storage device, such as a hard disk (step 1610).").

- Chishti '929 at 32:26-33:3 ("In selecting the intermediate positions for each tooth, the path-generating program invokes the collision detection program to determine whether collisions will occur along the chosen paths. The program also inspects the patient's occlusion at each treatment step along the path to ensure that the teeth align to form an acceptable bite throughout the course of treatment. If collisions or an unacceptable bite will occur, or if a required constraint cannot be satisfied, the program iteratively alters the offending tooth path until all conditions are met. The virtual articulator described above is one tool for testing bite occlusion of the intermediate treatment positions.").
- Chishti '929 at 33:4-13 ("As shown in FIG. 17, once the path-generating program has established collision-free paths for each tooth to be moved, the program calls an optimization routine that attempts to make the transformation curve for each tooth between the initial and final positions more linear. The routine begins by sampling each treatment path at points between treatment steps (step 1702), e.g., by placing two sample points between each treatment step, and calculating for

[redacted]

each tooth a more linear treatment path that fits among the sample points (step 1704). The routine then applies the collision detection algorithm to determine whether collisions result from the altered paths (step 1706). If so, the routine resamples the altered paths (step 1708) and then constructs for each tooth an alternative path among the samples (step 1710). The routine continues in this manner until no collisions occur (step 1712).").

- Rubbert '568 at [0103] ("The brackets are represented in the software as virtual three-dimensional objects, and the surface of all the brackets and the teeth are known in three dimensional spatial coordinates. Accordingly, collision detection algorithms are employed to detect when simulated tooth or bracket movement would result in a collision between brackets and teeth. Similar collision algorithms are provided to prevent the adhesion surface of the bracket from migrating into the body of the virtual tooth object and to keep the brackets located on the surface of the teeth. If the user wishes to move the location of the brackets, the movement of the teeth follows the movement of the bracket.").
- Rubbert '568 at claim 22 ("22. The method of claim 14, further comprising the step of determining whether a collision of teeth occurs during the movement of the virtual model of the teeth from the current situation to the target situation.").
- Muhammad at ¶ [0012] ("The determining a tooth path includes finding a collision free shortest path between an initial position and a final position for one or more teeth.").
- Muhammad at ¶ [0021] ("A Set of rules can be applied to detect any collisions that will occur as the patient's teeth move along the treatment paths. Collisions

[redacted]

can be detected by calculating distances between a first tooth and a Second tooth by establishing a neutral projection plane between the first tooth and the Second tooth ….")._

- Muhammad at ¶¶ [0029], [0032]-[0034], [0041], [0043]-[044], [0117]-[0129], [0143]-[0149], [0177]-[0184] (discussing figures, including those that describe collision avoidance).
- Muhammad at ¶¶ [0138]-[0142] (discussing use of collision or interference detection algorithm); *id.* at ¶¶ [0143]-[00149] (discussing additional collision avoidance techniques).
- Muhammad at Claim 5 ("The method of claim 2, wherein determining a tooth path comprises finding a collision free shortest path between an initial position and a final position for one or more teeth.").

3. Use of Removable Teeth Aligners to Facilitate the Staging of Tooth Movements

It was well known before the alleged invention date of the Treatment Planning Patents that removable teeth aligners could be used to facilitate the staging of tooth movements. For example:

- Chishti '511 at 1:33-39 ("The present invention provides methods and apparatus for defining appliance configurations at the steps of a process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The invention can operate to define how repositioning is accomplished by a series of appliances or by a series of adjustments to appliances configured to reposition individual teeth incrementally.").

[redacted]

- Chishti ’511 at 1:44-58 (“A patient’s teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments using appliances specified in accordance with the invention. In one implementation, the invention is used to specify shapes for the above-mentioned polymeric shell appliances. The first appliance of a series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. The appliance is intended to be worn until the first intermediate arrangement is approached or achieved, and then one or more additional (intermediate) appliances are successively placed on the teeth. The final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to a desired final tooth arrangement.”).
- Chishti ’511 at 4:35-50 (“The invention can be used to augment a computational or manual process for defining tooth paths in orthodontic treatment by confirming that proposed paths can be achieved by the appliance under consideration and within user-selectable constraints of good orthodontic practice.”).
- Chishti ’929 at 9:1-9 (“One tool for a incrementally repositioning the teeth in a patient's jaw is a set of one or more adjustment appliances. Suitable appliances include any of the known positioners, retainers, or other removable appliances which are used for finishing and maintaining teeth positions in connection with conventional orthodontic treatment. As described below, a plurality of such appliances can be worn by a patient successively to achieve gradual tooth repositioning. A particularly advantageous appliance is the appliance 100, shown in FIG. 1C, which typically comprises a polymeric shell having a cavity shaped to

[redacted]

receive and resiliently reposition teeth from one tooth arrangement to another tooth arrangement. The polymeric shell typically fits over all teeth present in the upper or lower jaw.").

- Kuo '099 at 1:43-57 ("A patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments using appliances specified in accordance with the invention. In one implementation, the invention is used to specify shapes for the above-mentioned polymeric shell appliances. The first appliance of a series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. The appliance is intended to be worn until the first intermediate arrangement is approached or achieved, and then one or more additional (intermediate) appliances are successively placed on the teeth. The final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to a desired final tooth arrangement.").
- Muhmad at ¶ [0012] ("The generating the malocclusion treatment plan includes specifying a series of treatment Stages for one or more teeth. The method can include dividing a path for one or more teeth into the Series of Stages while keeping the movement of teeth in each Stage below a predetermined range. The method can include generating an appliance for each treatment Stage. The appliance can be either a removable appliance or a fixed appliance.").
- Muhammad at ¶¶ [0118]-[0119], [0127] ("The collision detection process determines if any of the geometries describing the tooth Surfaces intersect. If there are no obstructions, the Space is considered free; otherwise it is obstructed.

[redacted]

Suitable collision detection algorithms are discussed in more detail below. If a collision occurs, a "push" vector is created to shift the path of the planned movement (step 315). Based on the push vector, the current tooth "bounces" from the collision and a new tooth movement is generated (step 316).").

4. Automation of Staging Using a Computer

It was well known before the alleged invention date of the Treatment Planning Patents that the staging of teeth could be automated using a computer. For example:

- Chishti '511 at 2:35-41 ("The apparatus of the invention can be implemented as a system, or it can be implemented as a computer program product, tangibly stored on a computer-readable medium, having instructions operable to cause a computer to perform the steps of the method of the invention.").
- Chishti '511 at claim 1 ("1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising … calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation.").
- Chishti '929 at 4:6-10 ("In one aspect, the invention relates to the computer-automated creation of a plan for repositioning an orthodontic patient's teeth. A computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.").

[redacted]

- Chishti ’929 at 4:27-30 (“Other embodiments allow the computer to render a three-dimensional (3D) graphical representation of the teeth at any selected treatment step. The computer also can be used to animate the graphical representation of the teeth to provide a visual display of the movement of the teeth along the treatment paths.”).
- Kuo ’099 at 22:13-17 (“30. The method of claim 29, where the computer providing the dental treatment plan includes one or more of providing a dental appliance design, providing a dental appliance manufacturing protocol, and providing a treatment approach for dental appliance usage.”).
- Rubbert ’568 at [0013] (“In a first aspect of the invention, apparatus for treatment planning for an orthodontic patient is provided. The apparatus can be considered an interactive, computer-based computer aided design and computer aided manufacturing (CAD/CAM) system for orthodontics. The apparatus is highly interactive, in that it provides the orthodontist with the opportunity to both observe and analyze the current stage of the patient's condition and develop and specify a target or desired stage. A shortest direct path of tooth movement to the target stage can also be determined. Further, the apparatus provides for simulation of tooth movement between current and target stages.”).
- Muhammad at [0003] (“The invention relates generally to the field of orthodontics and, more particularly, to computer-automated development of an Orthodontic treatment plan and appliance”).
- Muhammad at ¶ [0013] (“In another aspect, a computer-implemented method prepares a malocclusion treatment plan by: Selecting one tooth treatment pattern

[redacted]

from a library of predetermined tooth treatment patterns, generating the malocclusion treatment plan in accordance with the Selected treatment pattern; and producing a plurality of data Sets representing a Series of Successive tooth arrangements progressing from a first tooth arrangement to a Second tooth arrangement. Implementations of this aspect may include generating an appliance for each tooth arrangement.").

- Muhammad at ¶ [0014] ("In another aspect, a computer-readable medium executable by a computer to prepare a malocclusion treatment plan includes code to Select one tooth treatment pattern from a library of predetermined tooth treatment patterns, and code to generate the malocclusion treatment plan in accordance with the Selected treatment pattern.").
- Muhammad at ¶ [0019] ("In another aspect, a computer system to prepare a malocclusion treatment plan includes a processor, a display coupled to the processor, and a data Storage device coupled to the processor and containing code to Select a tooth treatment pattern from a library of predetermined tooth treatment patterns, and code to generate the malocclusion treatment plan implementing the Selected tooth treatment pattern.").
- Muhammad at ¶ [0022] ("Advantages of the system may include one or more of the following. The System facilitates automated Staging after final Setup. The System eliminates manual Staging, Saves time and is convenient to use.").
- Muhammad at ¶ [0058] ("In one embodiment, the prescription is entered into a computer, which automatically computes the final positions of the teeth. In alternative other embodiments, a user moves the teeth into their final positions by

[redacted]

independently manipulating one or more teeth while Satisfying the constraints of the prescription. Various combinations of the above described techniques may also be used to arrive at the final tooth positions.").

- Muhammad at ¶ [0130] (discussing figures, including those describing automation of staging using a computer).
- Muhammad at ¶¶ [0135]-[0136] ("In some embodiments, as alluded to above, the Software automatically computes the treatment path, based upon the IDDS and the FDDS. This is accomplished using a path Scheduling algorithm which determines the rate at which each component, i.e., each tooth, moves along the path from the initial position to the final position. The path Scheduling algorithm determines the treatment path while avoiding "round-tripping, i.e., while avoiding moving a tooth along a distance greater than absolutely necessary to Straighten the teeth. Such motion is highly undesirable, and has potential negative effects on the patient.").
- Muhammad at ¶¶ [0090]-[0112] (discussing automation in movement stages).
- Muhammad at ¶ [0130] ("FIG. 6 is a flow chart of a computer-implemented process for generating non-linear treatment paths along which a patient's teeth will travel during treatment. The non-linear paths usually are generated automatically by computer program, in some cases with human assistance').
- Muhmmad at Claim 1 ("A computer-implemented method to prepare a malocclusion treatment plan, comprising: selecting a tooth treatment pattern from a library of predetermined tooth treatment patterns; and generating the malocclusion treatment plan implementing the selected tooth treatment pattern.").

[redacted]

- Muhammad at Claim 28 ("A computer-implemented method to automatically stage a series of tooth movements, comprising: …").
- Muhammad at claims 31-33 (reciting "A computer system to prepare a malocclusion treatment plan, comprising …").

5. Producing Removable Teeth Aligners Based on Results of Automated Staging

It was well known before the alleged invention date of the Treatment Planning Patents that removable teeth aligners could be produced based on results of automated staging. For example:

- Chishti '511 at 1:33-42 ("The present invention provides methods and apparatus for defining appliance configurations at the steps of a process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The invention can operate to define how repositioning is accomplished by a series of appliances or by a series of adjustments to appliances configured to reposition individual teeth incrementally. The invention can be applied advantageously to specify a series of appliances formed as polymeric shells having the tooth-receiving cavities.").
- Chishti '511 at 2:50-58 ("Use of the invention to design aligners allows the designer (human or automated) to finely tune the performance of the aligners with respect to particular constraints. Also, more precise orthodontic control over the effect of the aligners can be achieved and their behavior can be better predicted than would otherwise be the case. In addition, computationally defining the aligner geometry facilitates direct aligner manufacturing under numerical control.").

[redacted]

- Chishti ’511 at claim 1 (“1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising: . . . generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.”)
- Chishti ’511 at 4:52-65 (“The segmented tooth paths and associated tooth position data are used to calculate clinically acceptable appliance configurations (or successive changes in appliance configuration) that will move the teeth on the defined treatment path in the steps specified by the path segments (step 170). Each appliance configuration represents a step along the treatment path for the patient. The steps are defined and calculated so that each discrete position can follow by straight-line tooth movement or simple rotation from the tooth positions achieved by the preceding discrete step and so that the amount of repositioning required at each step involves an orthodontically optimal amount of force on the patient's dentition. As with the path definition step, this appliance calculation step can include interactions and even iterative interactions with the clinician (step 160).”).
- Chishti ’511 at 6:10-17 (“A finite element model of the initial configuration of the teeth and tissue is created (step 310) and optionally cached for reuse in later iterations of the process (step 320). As was done with the teeth and tissue, a finite element model is created of the polymeric shell aligner (step 330). The input data

for this model includes data specifying the material of which the aligner is made and the shape of the aligner (data input 304).").

- Chishti '929 at 44:2-4 ("Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in FIG. 10. Common fabrication methods employ a rapid prototyping device 200 such as a stereolithography machine.").
- Chishti '929 at 55:29-56:2 ("62. The program of claim 49, wherein the computer delivers data representing the positions of the patient's teeth at selected points along the treatment paths to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final positions.").
- Kuo '099 at 1:31-42 ("The present invention provides methods and apparatus for mining relationships in treatment outcome and using the mined data to enhance treatment plans or enhance appliance configurations in a process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The invention can operate to define how repositioning is accomplished by a series of appliances or by a series of adjustments to appliances configured to reposition individual teeth incrementally. The invention can be applied advantageously to specify a series of appliances formed as polymeric shells having the tooth-receiving cavities, that is, shells of the kind described in U.S. Pat. No. 5,975,893.").
- Kuo '099 at claim 30 ("30. The method of claim 29, where the computer providing the dental treatment plan includes one or more of providing a dental

[redacted]

appliance design, providing a dental appliance manufacturing protocol, and providing a treatment approach for dental appliance usage.").

- Rubbert '568 at claim 14 ("14. A method of digital treatment planning for an orthodontic patient on a workstation having a processing unit, a user interface including a display and software executable by said processing unit, comprising the steps of: . . . whereby parameters for an orthodontic appliance to move the patient's teeth from the current situation to the target situation can be derived from the virtual model and/or the target situation.").
- Muhammad at ¶ [0015] ("Implementation of this aspect may include one or more of the following. The medium can include code to fabricate an appliance for each tooth arrangement. The code to fabricate appliances can include code to control a fabrication machine to produce Successive positive models of the tooth arrangements, and code to produce the appliance as a negative of the tooth model. The code to control a fabrication machine includes code to provide a Volume of nonhardened polymeric resin; and code to Scan a laser to Selectively harden a resin to produce the positive model. The medium can include code to control a fabrication machine to produce Successive appliances for the tooth arrangements."), ¶ [0017].
- Muhammad at ¶¶ [0045], [0191] (describing figures, including how dental appliances may be prepared).
- Muhammad at ¶¶ [0050]-[0055] (discussing the use of "adjustment appliance" and how appliance may be made).

[redacted]

- Muhammad at Claims 8 ("The method of claim 1, further comprising generating an appliance for each treatment stage.").
- Muhammad at Claim 9 ("The method of claim 8, wherein the appliance is either a removable appliance or a fixed appliance.").
- Muhammad at Claims 24-29, 31 (discussing fabrication of an appliance).

6. Use of Treatment Patterns to Order Teeth Movement

It was well known before the alleged invention date of the Treatment Planning Patents to order the movement of teeth in various patterns, including, for example, an all-equal pattern, A pattern, M pattern, V pattern, or mid-line pattern. For example:

- Tuncay at 109 ("A low-anchorage staging pattern, also known as an equal staging pattern or an "X" pattern, occurs when all the teeth move concurrently throughout the sequence (Figs 12-9a and 12-9b). The maximum velocity for tooth movement is 0.25 mm/stage, and usually all or most of the teeth are moving through all the stages at various speeds, depending on the total distance each tooth has to move. Low-anchorage patterns are usually used in Type I space closure cases, mandibular incisor extraction cases, and expansion and crowding cases where no distalization is needed. To avoid intra-arch collisions throughout the sequence of movements, intermediate key frame points can be used to manage any overlap between the teeth that may develop; these are usually added every five stages or so to ensure that the collisions remain within the protocol guidelines throughout the whole sequence. Rotations should be kept under 2 to 3 degrees per stage.").
- Tuncay at 109–10 ("A high-anchorage pattern, sometimes referred to as a "V" pattern, is used when intra-arch anchorage needs to be maximized (Figs 12-10a).

[redacted]

High-anchorage patterns are used in any case where the posterior teeth need to be distalized. It could be for Class II correction or when the relief of crowding on the anterior teeth requires that the space is created by the distal movement of the posterior teeth. This is also the case in Type II space closure cases where no mesial movement of the molars is desired. Additionally, reciprocal space closure cases where the space is closed by mesial movement of the posterior teeth (not to be confused with equal staging—minimal anchorage where no posterior mesialization is staged), and cases where a midline shift is desired, fall into this category (Fig 12-10b). In high-anchorage patterns, only two posterior teeth can move concurrently, with the second one starting to move when the first one is halfway through its movement. The maximum speed is 0.33 mm/stage. In bilateral cases, both sides are staged symmetrically, with the number of stages determined by the teeth that are moving the most. The maximum speed for the anterior teeth remains 0.25 mm/stage.").

- Chishti-'876 at 2:20-49 ("Implementations of the above aspect may include one or more of the following. The generating the malocclusion treatment plan includes determining one or more tooth paths based on the selected tooth treatment pattern. . . . The method can include generating a three dimensional model for the teeth for each treatment stage. The method also can include generating dental diagnostic information from the three-dimensional model. Interproximal reduction, tooth size discrepancy information, and Bolton information, among others can be generated from the 3D model. The library of treatment patterns includes at least one or more of the following: all equal movement pattern, A-shaped movement pattern, V-

[redacted]

shaped movement pattern, M-shaped movement pattern, W-shaped movement pattern, symmetric staircase pattern, asymmetric staircase pattern, and equal equal movement pattern.").

- Chishti-'400 at [0012] ("In one aspect, a computer-implemented method to prepare a malocclusion treatment plan includes selecting a tooth treatment pattern from a library of predetermined tooth treatment patterns; and generating the malocclusion treatment plan implementing the selected tooth treatment pattern.").
- Chishti-'400 at claim 15 ("The method of claim 2, wherein the library of treatment patterns comprises at least one or more of the following: all equal movement pattern, A-shaped movement pattern, V-shaped movement pattern, M-shaped movement pattern, W-shaped movement pattern, symmetric staircase pattern, asymmetric staircase pattern, and equal equal movement pattern.").
- Muhammad at ¶ [0012] ("The library of treatment patterns includes at least one or more of the following: all equal movement pattern, A-shaped movement pattern, V-shaped movement pattern, M-shaped movement pattern, W-shaped movement pattern, Symmetric Staircase pattern, asymmetric Staircase pattern, and equal equal movement pattern. For the all equal movement pattern, the method includes Subdividing paths while Satisfying one or more constraints. The constraint can be minimizing tooth oscillation and tooth movement distance. For the equal equal pattern, the method includes dividing the teeth into a prestage movement group and a post stage movement group; and applying the all equal movement to the prestage movement group and Subsequently applying the all equal movement to the prestage movement group. For the A-shaped movement pattern, the method

[redacted]

includes Sequen tially moving each tooth from an incisor tooth toward a molar tooth. For the V-shaped movement pattern, the method includes Sequentially moving each tooth from a molar tooth toward an incisor tooth."); *id*. at ¶ [0020].

- Muhammad at ¶¶ [0027]-[0044] (describing figures, including how figures show use of treatment patterns).
- Muhammad at ¶¶ [0117]-[0129] (discussing "tooth movement plan").
- Muhammad at ¶ [0130] ("FIG. 6 is a flow chart of a computer-implemented process for generating non-linear treatment paths along which a patient's teeth will travel during treatment. The non-linear paths usually are generated automatically by computer program, in some cases with human assistance').
- Muhammad at ¶¶ [0148]-[0152] (discussing use of movement patterns including X-type, A-type, XX-type, V-type, all equal, and others).
- Muhammad at ¶ [0167] (describing Figure 15, and how it shows an all equal path).
- Muhammad at ¶ [0174] (describing Figure 18 and how it shows an A-shaped movement).
- Muhammad at ¶¶ [0180], [0185] (describing Figure 20A, and how it shows a V shaped movement).
- Muhammad at Claims 15 (describing movement patterns, including A-, V- M- W- equal, and others).
- Muhmmad at Claim 1 ("A computer-implemented method to prepare a malocclusion treatment plan, comprising: selecting a tooth treatment pattern from

a library of predetermined tooth treatment patterns; and generating the malocclusion treatment plan implementing the selected tooth treatment pattern.").

- Muhammad at Claim 2 ("The method of claim 1, wherein generating the malocclusion treatment plan comprises determining one or more tooth paths based on the selected tooth treatment pattern.").
- Muhammad at Claims 18-20 (discussing use of equal partner, A-shaped pattern, V-shaped pattern).
- Muhammad at Claim 23 ("A computer-readable medium executable by a computer to prepare a malocclusion treatment plan, comprising: code to select one tooth treatment pattern from a library of predetermined tooth treatment patterns; and code to generate the malocclusion treatment plan in accordance with the selected treatment pattern.").

C. Composite Image Patent

1. Intraoral Scanning

Intraoral scanning was well known before the alleged invention date of the Composite Image Patent. For example:

- Boerjes at [0007] ("A method disclosed herein includes acquiring a three-dimensional representation of one or more intraoral structures of a dental patient using an intraoral scanner; and providing the three-dimensional representation to a dental fabrication facility.").
- Boerjes at [0010] ("A computer program product disclosed herein includes computer executable code embodied in a computer readable medium that, when executed on one or more computer devices, may perform the steps of: acquiring

[redacted]

one or more images of one or more intraoral structures of a dental patient from an intraoral scanner; converting the one or more images into a three-dimensional representation of the one or more intraoral structures; and transmitting the three-dimensional representation to a dental fabrication facility.").

- Boerjes at [0162] ("The dental office may include a three-dimensional scanner, such as any of the scanners described above, which the dentist may use to capture a three-dimensional digital representation of the dental patient's dentition including scans both before and after one or more tooth surfaces have been prepared for a dental object such as a restoration or the like.").
- Paley at [0030] ("In one embodiment, the scanner 102 is a handheld, freely positionable probe having at least one user input device, such as a button, lever, dial, thumb wheel, switch, or the like, for user control of the image capture system 100 such as starting and stopping scans. In an embodiment, the scanner 102 may be shaped and sized for dental scanning. More particularly, the scanner may be shaped and sized for intraoral scanning and data capture, such as by insertion into a mouth of an imaging subject and passing the imaging plane 106 over one or more intraoral structures at a suitable distance to acquire surface data from teeth, gums, and so forth.").
- Rubbert at 2:8-15 ("Hand-held scanners for in-vivo scanning of dentitions have now become available. One such scanner is described in the PCT Patent Application of OraMetrix, Inc. WO 01/80761. Because a hand-held scanner allows for scans of the dentition in a relatively short time frame, the scanner can be used to perform an original scan of the patient's dentition. Based on this

[redacted]

original scan, an original 3-D virtual model of the patient's dentition can be derived, including a virtual model of each individual tooth. This information is then digitally recorded in some fashion, preferably in a patient record stored in a memory of a scanning node in the scanner system or in an orthodontic workstation.").

2. Virtual Modeling of an Oral Cavity Using Data from an Intraoral Scanner

It was well known before the alleged invention date of the Composite Image Patent that an oral cavity could be virtually modeled using data from an intraoral scanner. For example:

- Boerjes at [0012] ("A system disclosed herein includes an intraoral scanner for acquiring a three-dimensional representation of one or more intraoral structures of a dental patient; and a transmission means for transmitting the three-dimensional representation to a dental fabrication facility.").
- Boerjes at [0010] ("A computer program product disclosed herein includes computer executable code embodied in a computer readable medium that, when executed on one or more computer devices, may perform the steps of: acquiring one or more images of one or more intraoral structures of a dental patient from an intraoral scanner; converting the one or more images into a three-dimensional representation of the one or more intraoral structures; and transmitting the three-dimensional representation to a dental fabrication facility.").
- Boerjes at [0162] ("The dental office may include a three-dimensional scanner, such as any of the scanners described above, which the dentist may use to capture a three-dimensional digital representation of the dental patient's dentition

[redacted]

including scans both before and after one or more tooth surfaces have been prepared for a dental object such as a restoration or the like.").

- Paley at [0054] ("FIG. 4 depicts a view of a user interface for an image capture system during an acquisition of three-dimensional data. The user interface 400 may include a window 402 including range-finding visual cues 404, 406, all as generally described above. Within the window 402, a video image may be displayed, such as a video image from a current point of view of a scanner, such as the scanner 102 described above. As depicted, the video image may include a plurality of teeth 410 and other intraoral structures visible during an intraoral scan. It will be noted that three-dimensional points acquired from the surface, i.e., the current digital surface representation, may be rendered within the user interface 400, and more particularly, may be rendered from the point of view of the scanner and superimposed on the current video image. Although not depicted, it will be understood that in other embodiments, the current digital surface representation may be rendered from a fixed point of view.").
- Rubbert at 2:8-15 ("Hand-held scanners for in-vivo scanning of dentitions have now become available. One such scanner is described in the PCT Patent Application of OraMetrix, Inc. WO 01/80761. Because a hand-held scanner allows for scans of the dentition in a relatively short time frame, the scanner can be used to perform an original scan of the patient's dentition. Based on this original scan, an original 3-D virtual model of the patient's dentition can be derived, including a virtual model of each individual tooth. This information is then digitally recorded in some fashion, preferably in a patient record stored in a

[redacted]

memory of a scanning node in the scanner system or in an orthodontic workstation.").

- Rubbert at 10:3-11 ("Figure 1B is an illustration of an orthodontic care system 10 incorporating a scanner system 12. The scanner system 12 includes a hand-held scanner 14 that is used by the orthodontist or his assistant to acquire three-dimensional information of the dentition and associated anatomical structures of a patient. The images are processed in a scanning node or workstation 16 having a central processing unit, such as a general-purpose computer. The scanning node 16, either alone or in combination with a back-office server 28, generates a three-dimensional computer model 18 of the dentition and provides the orthodontist with a base of information for diagnosis, planning treatment, and monitoring care for the patient. The model 18 is displayed to the user on a monitor 20 connected to the scanning node 16.").

3. Editing a Virtual Model

It was well known before the alleged invention date of the Composite Image Patent that a virtual model could be edited. For example:

- Boerjes at [0194] ("Where the dental laboratory can quickly generate an accurate or rough model for a restoration or other dental object according to any fabrication or end use constraints, the rough model may, in digital form, be virtually fit to the prepared surface, and feedback may be provided to a dentist such as an identification of regions requiring further reduction.").
- Boerjes at [0199] ("After one or more quality control steps 406-410, a determination may be made as to whether a scan and/or surface preparations are

[redacted]

satisfactory. If the data is not satisfactory, the process 400 may proceed to step 414 where the digital model may be supplemented or replaced with new scan data. This may include, for example, new scanning to replace apparently erroneous or inadequate scan data, or a new scan of the dental subject matter following, e.g., additional surface preparation consistent with errors identified during quality control.").

- Kriveshko-'494 at [0097] ("In other embodiments, a landing mode may be provided in which a user attempts to initiate a new scan registered or connected to an existing three-dimensional model. In the landing mode, the system may optionally create a supplemental three-dimensional model by fitting sequential frames to one another before a successful fit to the original three-dimensional model. In various embodiments, the landing mode may also be distinguished by a user's ability to select a point on the original three-dimensional model for re-acquisition of a scan.").
- Kriveshko-'494 at [0066] ("As shown in step 212, the incremental three-dimensional image data may be fitted or stitched to the existing three-dimensional model. In one embodiment, this process is performed by deriving scanner motion between positions or points of view for successive image captures. However, other techniques may be employed, such as direct fitting of features from the new three-dimensional image to the previously acquired three-dimensional model. All such techniques that might usefully be employed to register new three-dimensional data to existing three-dimensional data are intended to fall within the

[redacted]

scope of this disclosure. Once a fit has been attempted in step 212, the process 200 may proceed to step 214.").

- Paley at [0060] ("Using the navigation controls 504, a user may rotate, pan, zoom in, or otherwise navigate around and within the digital model to more closely inspect areas of interest, or to view the model from a number of perspectives to visually inspect otherwise occluded features. One user control (not shown) may permit a user to return to data acquisition, e.g., the scanning mode of FIG. 4, to acquire additional data where a void or deviation is detected (either automatically or through human visual inspection). This control, or another control, may permit a user to select a specific point on the surface of the digital model (or the scan subject, although the distinction becomes trivial for highly detailed and accurate digital models) where the continuous scan is to be reacquired from the subject, as described for example in commonly-owned U.S. application Ser. No. 11/337,182, filed on Jan. 20, 2006, the entire content of which is incorporate herein by reference.").
- Geng at 7:38-51 ("The editor (312) can include general-purpose 3D model editing software that allows operators to modify 3D data files interactively and conveniently. The editor (312) allows operators to modify and/or eliminate any undesirable area(s) on the original 3D image obtained from the camera (104; FIG. 1), remove abnormal data point(s), and clean up the acquired image data to reduce the sizes of image data files. 3D objects can be edited, including triangular regions, vertices, local areas, and an entire data set. Known editing functions can be employed, including typical editing functions that provide for deleting,

creating, and modifying objects. The editor (312) can also provide various filtering functions (e.g., smoothing and noise removal) that can be applied to entire 3D data sets or to selected local areas.").

- Rubbert at 20:1-10 ("Generally, after a monitoring scan is performed, a registration process is used such that new scanned data relative to the existing virtual tooth model may be registered to the original virtual model derived during the original scan. By way of subsequent monitoring scans, the registration process may derive a current or an updated three-dimensional virtual model of the dentition at the point in time of treatment. For more details on these aspects of generating such a three-dimensional virtual model, the interested reader is directed to the commonly assigned patent application of Rubbert et al. entitled "Methods for Registration of Three-Dimensional Frames to Create Three-Dimensional Virtual Models of Objects," Serial No. 09/835,007 and filed April 13, 2001, the entire contents of which are incorporated by reference herein.").

4. Forming a Composite Image

It was well known before the alleged invention date of the Composite Image Patent that a composite image could be formed. For example:

- Boerjes at [0144] ("In an example of general operation of a three-dimensional image capture system 100, the scanner 102 may acquire two-dimensional image sets at a video rate while the scanner 102 is passed over a surface of the subject. The two- dimensional image sets may be forwarded to the computer 108 for derivation of three-dimensional point clouds.").

[redacted]

- Boerjes at [0040] (“In another aspect, a system disclosed herein includes a scanning device configured to intraorally capture surface image data from a surface within a mouth of a dental patient; a computer coupled to the scanning device and receiving the surface image data therefrom, the computer configured to resolve the surface image data into a digital surface reconstruction, the computer further configured to generate a visualization of the digital surface reconstruction and provide the visualization as a display signal; and a display coupled to the computer and receiving the display signal therefrom, the display converting the display signal into a viewable image of the visualization.”).
- Kriveshko-’494 at [0061] (“As shown in step 206, three-dimensional data may be derived from the candidate frame. Stated alternatively, the two-dimensional data, such as an image set, may be converted into three-dimensional data or a three-dimensional image.”).
- Paley at [0028] (“The scanner 102 may include suitable processing for deriving a three-dimensional point cloud from an image set or a number of image sets, or each two-dimensional image set may be transmitted to an external processor such as contained in the computer 108 described below.”).
- Paley at [0054] (“FIG. 4 depicts a view of a user interface for an image capture system during an acquisition of three-dimensional data. The user interface 400 may include a window 402 including range-finding visual cues 404, 406, all as generally described above. Within the window 402, a video image may be displayed, such as a video image from a current point of view of a scanner, such as the scanner 102 described above. As depicted, the video image may include a

[redacted]

plurality of teeth 410 and other intraoral structures visible during an intraoral scan.").

5. Using New Scan Data to Form a Composite Image

It was well known before the alleged invention date of the Composite Image Patent that new scan data could be used to form a composite image. For example:

- Boerjes at [0199] ("After one or more quality control steps 406-410, a determination may be made as to whether a scan and/or surface preparations are satisfactory. If the data is not satisfactory, the process 400 may proceed to step 414 where the digital model may be supplemented or replaced with new scan data. This may include, for example, new scanning to replace apparently erroneous or inadequate scan data, or a new scan of the dental subject matter following, e.g., additional surface preparation consistent with errors identified during quality control. The process 400 may then return to step 404 where a new digital model is obtained.").
- Kriveshko-'494 at [0096] ("FIG. 9 depicts a view of a user interface for an image capture system, such as described above with reference to FIGS. 4-8, after reacquiring a scan. In this figure, a user has realigned the current video image 404 so that a newly acquired three-dimensional image could be successfully fitted to one of the reference images.").
- Paley at [0036] ("In an example of general operation of a three-dimensional image capture system 100, the scanner 102 may acquire two-dimensional image sets at a video rate while the scanner 102 is passed over a surface of the subject. The two-dimensional image sets may be forwarded to the computer 108 for

[redacted]

derivation of three-dimensional point clouds. The three-dimensional data for each newly acquired two-dimensional image set may be derived and fitted or "stitched" to existing three-dimensional data using a number of different techniques.").

- Paley at [0065] ("A process of preparing a tooth surface, scanning the tooth surface, and analyzing the tooth surface may be applied iteratively to refine a surface preparation. In an iterative process, a dentist may repeat steps of tooth removal and scanning until a satisfactory surface preparation is achieved.").

VII. CONTENTIONS UNDER 35 U.S.C. §§ 102 AND 103

Subject to the reservation of rights above, and based on ClearCorrect's present understanding of the Asserted Claims, the below prior art references anticipate and/or render obvious the Asserted Claims, at least under the apparent interpretation of the claims that Plaintiff applied for its Infringement Contentions. As explained above, the charts provided in Exhibits 613-01 through 613-29, 384-01 through 384-29, 090-01 through 090-29, 091-01 through 091-29, 444-01 through 444-06, 444-08 through 444-12, 444-14 through 444-28, 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28, 879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28, 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28, 936-01 through 936-09, and 936-11 through 936-21 identify examples of where each element of each Asserted Claim can be found in each item of prior art, on a limitation-by-limitation basis.

A. Anticipation Under 35 U.S.C. § 102

Subject to the reservation of rights above and based on ClearCorrect's present understanding of the Asserted Claims, the prior art references identified below and charted in the corresponding Exhibits identified in the tables below anticipate the Asserted Claims identified

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below under 35 U.S.C. § 102 (pre-AIA) and/or 35 U.S.C. § 102 (AIA), at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions. Alternatively, to the extent Plaintiff argues that an anticipatory prior art reference fails to disclose one or more limitations of an Asserted Claim, the claim still would be anticipated and/or obvious under 35 U.S.C. § 103 (pre-AIA) and/or 35 U.S.C. § 103 (AIA) based on the reference in view of the knowledge of a person of ordinary skill in the art, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions—given that the Asserted Claims simply combine well-known concepts to achieve known and predictable results and merely present a design choice between a finite number of clear alternatives known to those of skill in the art.

1. Anticipation Under 35 U.S.C. § 102 for the Materials Patents

Subject to the reservation of rights above and based on ClearCorrect's present understanding of the Asserted Claims, the following reference(s) anticipate the Asserted Claims of the '613 patent identified below under 35 U.S.C. § 102 (pre-AIA) and/or 35 U.S.C. § 102 (AIA), at least under the apparent interpretation of the claims that Plaintiff applied for its Infringement Contentions and as of the priority dates established by ClearCorrect, namely no earlier than September 16, 2019 for the '613 patent, March 26, 2021 for the '384 patent, and July 6, 2022 for the '090 and '091 patents. *See* Section III.A.2 [Broken Chain of Priority].

[redacted]

Reference	Anticipated Claims	Exs.
Li-'691	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-7, 9-11, 13, 17-19, 21, 25, 26	613-25 384-25 090-25 091-25
WO2013/171124	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-7, 9-11, 13, 17-19, 21, 25, 26	613-13 384-13 090-13 091-13
Zendura FLX	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-7, 9-11, 13, 17-19, 21, 25, 26	613-29 384-29 090-29 091-29

2. Anticipation Under 35 U.S.C. § 102 for the Treatment Planning Patents

Subject to the reservation of rights above and based on ClearCorrect's present understanding of the Asserted Claims, the following reference(s) anticipate the Asserted Claims of the Treatment Planning Patents identified below under 35 U.S.C. § 102, at least under the apparent interpretation of the claims that Plaintiff applied for its Infringement Contentions.

[redacted]

Reference	Anticipated Claims	Exs.
Kuo	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-01 879-01 217-01 456-01
Rubbert-'568	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-03 879-03 217-03 456-03
Chishti-'511	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-21 879-21 217-21 456-21
Chishti-'400	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-10 879-10 217-10 456-10
Chishti-'929	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-22 879-22 217-22 456-22
Tuncay	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-09 879-09 217-09 456-09
Treat	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-25 879-25 217-25 456-25
ClinCheck	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-27 879-27 217-27 456-27
SureSmile	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-26 879-26 217-26 456-26

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Reference	Anticipated Claims	Exs.
Insignia	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19	444-28 879-28 217-28 456-28

3. Anticipation Under 35 U.S.C. § 102 for the Composite Image Patent

Subject to the reservation of rights above and based on ClearCorrect's present understanding of the Asserted Claims, the following reference(s) anticipate the Asserted Claims of the '936 patent identified below under 35 U.S.C. § 102, at least under the apparent interpretation of the claims that Plaintiff applied for its Infringement Contentions.

Reference	Anticipated Claims	Exs.
Boerjes	1, 4-6, 9-11, 12, 14-17, 19	936-11
Paley	1, 4-6, 8-12, 14-16	936-02

B. Obviousness Under 35 U.S.C. § 103

Subject to the reservation of rights above and based on ClearCorrect's present understanding of the Asserted Claims, the prior art references identified below render the Asserted Claims identified below obvious under 35 U.S.C. § 103, at least under the apparent interpretation of the claims that Plaintiff applied for its Infringement Contentions. The claim charts set forth in Exhibits 613-01 through 613-29, 384-01 through 384-29, 090-01 through 090-29, 091-01 through 091-29, 444-01 through 444-06, 444-08 through 444-12, 444-14 through 444-28, 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28, 879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28, 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28, 936-01 through 936-09, and 936-11 through 936-21 identify how prior art renders the Asserted Claims obvious on a limitation-by-limitation basis, either alone or in combination with one or more other prior art references and/or the knowledge of a person of ordinary skill in the art, including as described

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in Section VI above, at least under the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions.

As explained in the attached claim charts and in Section VI above, each core concept recited in the Asserted Claims was well known long before the alleged priority date of the Asserted Patents, and no Asserted Claim goes beyond combining these well-known elements in known ways to achieve known and predictable results, or otherwise reflects more than a basic design choice between a finite number of clear alternatives already known to persons of ordinary skill in the art, each with known and predictable outcomes and that could be implemented with a reasonable expectation of success. Further, to the extent Plaintiff argues that a prior art combination fails to disclose a specific limitation of the Asserted Claims, at a minimum, it would have been obvious to adapt the cited prior art to include the allegedly missing limitation or to combine the cited prior art with one or more other prior art references that disclose the concept, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions.

The Asserted Claims accordingly are obvious, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions, when considered in view of: (1) information known to persons of ordinary skill in the art at the time of the alleged invention, including as detailed in Section VI above; (2) the prior art references and combinations identified in the claim charts accompanying these contentions; (3) any of the additional prior art identified in these contentions; and/or (4) statements in the intrinsic record of the Asserted Patents, including but not limited to applicant-admitted prior art, representations made by or on behalf of the applicants during prosecution and post-grant proceedings, and prior art identified during prosecution and post-grant proceedings. ClearCorrect's claim charts identify disclosures in prior

art references that may be combined with any other prior art references identified in the claim charts that render the Asserted Claims obvious, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions. The reasons for modifying or combining references include those identified in Section V above, which is incorporated by reference into this section, as well as those further described below.

Below and in its attached claim charts, ClearCorrect identifies an exemplary list of prior art references and exemplary combinations of prior art references that, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions, the Asserted Claims obvious. To the extent ClearCorrect has identified a prior art reference as anticipatory that it also has included in an obviousness combinations, these obviousness contentions are not to be construed to suggest that the reference is not anticipatory, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions.

Each of the references cited in these contentions is analogous art to the claimed invention of the Asserted Patents: (1) each reference is from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses the field of orthodontics, and more particularly to the design of multilayer dental positioning appliances, and/or (2) each reference is reasonably pertinent to one or more supposed problems identified by the named inventors of the Asserted Patents (even if the reference is not in the identical field of endeavor as the alleged invention and even though that alleged problem had already been recognized and solved by others), including the supposed need for materials that improve properties of the appliances/aligners used for orthodontic treatment, for example to produce more continuous force and better bring a patient's teeth into a desired occlusion. It therefore would have been

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obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

The Supreme Court identified in *KSR International Co. v. Teleflex, Inc*., 550 U.S. 398 (2007), a number of rationales that would support a finding that the Asserted Claims are obvious, including where:

- The claims combine prior art elements according to known methods to yield predictable results;
- The claims involve the simple substitution of one known element for another to obtain predictable results;
- The claims involve the use of a known technique to improve similar devices (methods, or products) in the same way;
- The claims apply a known technique to known device (method, or product) ready for improvement to yield predictable results;
- The claims involve combinations of prior art references that would have been "obvious to try"—i.e., a person of ordinary skill in the art could have reached the Asserted Claims by choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and/or
- The claims are simply variations of work from one field of endeavor or a different one that would have been prompted based on design incentives or other market forces because the variations were predictable to one of ordinary skill in the art.

Id. at 414-18 (rejecting Federal Circuit's "rigid" application of motivation-to combine test, and instead espousing "expansive and flexible" approach); *see also* Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc*., 72 Fed. Reg. 57,526 (Oct. 10, 2007). The Supreme Court has also held that a person of ordinary skill in the art is "a person of ordinary creativity, not an automaton," that a motivation to combine may be simply "common sense," and that "familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a

puzzle." *KSR*, 550 U.S. at 420-21; *PAR Pharm., Inc. v. TWI Pharms., Inc*., 773 F.3d 1186, 1197-98 (Fed. Cir. 2014) ("Our precedent … does not require that the motivation be the ***best*** option, only that it be a *suitable* option from which the prior art did not teach away."). The Supreme Court has further held that a prior art combination can render a claim obvious if the combination was "obvious to try" because "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421.

As discussed above and in the attached claim charts, all elements of the Asserted Claims were well known in the prior art at the time of the priority date, and the use of these features in combination merely: (a) combines prior art elements according to known methods to yield predictable results; (b) involves the simple substitution of one known element for another to obtain predictable results; (c) involves the use of a known technique to improve similar devices (methods or products) in the same way; (d) applies a known technique to a known device, method, or product ready for improvement to yield predictable results; (e) involves combinations of prior art references that would have been "obvious to try"—i.e., a person of ordinary skill in the art could have reached the Asserted Claims by choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (f) would have been prompted by known work in the field based on design incentives or other market forces (including the miniaturization of hardware components coupled with increased processing and sensing capabilities, and the proliferation of battery-powered devices), because such variations were predictable to one of ordinary skill in the art. *See Lincoln Engineering Co. v. Stewart-Warner Corp*., 303 U. S. 545, 549 (1938) ("The mere aggregation of a number of old parts or

elements which, in the aggregation, perform or produce no new or different function or operation than that theretofore performed or produced by them, is not patentable invention."); *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp*., 340 U.S. 147, 152 (1950) ("The conjunction or concert of known elements must contribute something; only when the whole in some way exceeds the sum of its parts is the accumulation of old devices patentable. Elements may, of course, especially in chemistry or electronics, take on some new quality or function from being brought into concert, but this is not a usual result of uniting elements old in mechanics."); *id*. at 152-53 ("Courts should scrutinize combination patent claims with a care proportioned to the difficulty and improbability of finding invention in an assembly of old elements. The function of a patent is to add to the sum of useful knowledge. Patents cannot be sustained when, on the contrary, their effect is to subtract from former resources freely available to skilled artisans. A patent for a combination which only unites old elements with no change in their respective functions, such as is presented here, obviously withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men. This patentee has added nothing to the total stock of knowledge, but has merely brought together segments of prior art and claims them in congregation as a monopoly.").

A determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements. In other words, the test is not whether the references actually could be physically combined, but whether the claimed invention is rendered obvious by the teachings of the prior art as a whole. Likewise, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of a primary reference. Rather, the test for obviousness is what the combined teachings of the references would have suggested to those having ordinary skill in the art.

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The Court's order Governing Procedures (OGP) for Patent Cases requires defendants to serve preliminary invalidity contentions providing a chart setting forth where in the prior art references each element of the asserted claims is found. Although not required by the OGP, ClearCorrect below identifies certain motivations to combine various teachings in the prior art. These examples are given to illustrate various motivations to combine and are not intended to provide motivations to combine for every cited reference, or to identify an exhaustive set of every possible motivation to combine the references listed below. ClearCorrect reserves its right to identify additional motivations to combine and contends that the motivations described below apply to additional combinations.

1. Materials Patents

Prior art references rendering the asserted claims of the Materials Patents obvious under 35 U.S.C. § 103 (pre-AIA) and/or 35 U.S.C. § 103 (AIA), at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions, alone or in combination with other references, are discussed below and included in Exhibits 613-01 through 613-08, 613-11, 613-12, 613-15 through 613-18, 613-20 through 613-24, 613-26 through 613-28, 384-01 through 384-08, 384-11, 384-12, 384-15 through 384-18, 384-20 through 384-24, 384-26 through 384-28, 090-01 through 090-08, 090-11, 090-12, 090-15 through 090-18, 090-20 through 090-24, 090-26 through 090-28, 091-01 through 091-08, 091-11, 091-12, 091-15 through 091-18, 091-20 through 091-24, and 091-26 through 091-28. Further reasons to combine the references identified in Exhibits 613-01 through 613-08, 613-11, 613-12, 613-15 through 613-18, 613-20 through 613-24, 613-26 through 613-28, 384-01 through 384-08, 384-11, 384-12, 384-15 through 384-18, 384-20 through 384-24, 384-26 through 384-28, 090-01 through 090-08, 090-11, 090-12, 090-15 through 090-18, 090-20 through 090-24, 090-26 through 090-28, 091-01 through 091-08, 091-11, 091-12, 091-15 through 091-18, 091-20

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through 091-24, and 091-26 through 091-28 include the nature of the problem being solved, the express, implied and inherent teachings of the prior art, the knowledge of persons of ordinary skill in the art, that such combinations would have yielded predictable results, and that such combinations would have represented known alternatives to a POSITA.

Non-limiting illustrative obviousness combinations are listed below (it should be understood that each listed combination can also include the knowledge of a POSITA).

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Invalidity Grounds	Asserted Claims of the Materials Patents
Kalili Grounds: Kalili alone or combined with one or more of Bailin, Rafih, Stewart-'464, DeSimone-'841, Tritan EX401, Durasoft-PETG, Imprelon, Hytrel, and Eastar (the "Co-Polyester References") and further combined with one or more of Paulus, Bedard, Chen, and Wen-'558 (the "Third-Layer References")	'613 Patent: 1, 3, 4, 6-10, 12-15, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '091 Patent: 1, 4, 6, 7, 9-11, 17-19, 25, 26
Stewart-'464 Grounds: Stewart-'464 alone or combined with one or more of the Third-Layer References	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-7, 9-11, 13, 17-19, 21, 25, 26
Tadros Grounds: Tadros alone or combined with one or more of the Co-Polyester References and one of Texin-990 and Pellethane-AE (the "Polyurethane References")	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-, 9-11, 13, 17-19, 21, 25, 26
Hinz Grounds: (a) Hinz alone or combined with one or more of the Co-Polyester References (b) Hinz alone or combined with one or more of the Co-Polyester References and one or more of the Polyurethane References	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-7, 9-11, 13, 17-19, 21, 25, 26

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Stewart-'511 Grounds: (a) Stewart-'511 combined with one or more of the Polyurethane References (b) Stewart-'511 combined with one or more of the Co-Polyester References and one or more of the Co-Polyester References	'613 Patent: 1, 3, 4, 6-10, 12-15, 17, 18, 20, 22 '384 Patent: 1, 2, 4, 6-8, 10-12, 14, 16-18, 20-22, 24, 26-28, 30 '090 Patent: 1-3, 5, 9-10 '091 Patent: 1, 4-7, 9-11, 13, 17-19, 21, 25, 26
Co-Extrusion Grounds: Kalili Grounds alone or combined with one or more of Chen and Wen-'558 (the "Co-Extrusion Reference")	'613 Patent: 17
Trim Grounds: (a) Kalili Grounds alone or combined with Wrosz (the "Trim Reference") (b) Tadros Grounds alone or combined with the Trim Reference	'090 Patent: 1-3, 5, 9, 10

a) Combinations with the Co-Polyester References

The Materials Patents recite a dental appliance comprising a polymer layer that comprises or consists of a co-polyester having a flexural modulus greater than about 150,000 psi. *See, e.g.*, '613 patent, claim 1 limitation 1[B] ("a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi"), claim 20 limitation 20[B] ("a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi"); '384 patent, claim 1 limitation 1[C] ("a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi"), claim 11 limitation 11[B] ("a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi"), claim 21 limitation 21[A][iv] ("a first hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi) and limitation 21[B][iv] ("a second hard

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polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi"); '090 patent, claim 1 limitation 1[B] ("A first layer consisting of a co-polyester, the co-polyester having a flexural modulus greater than 150,000 psi. …"); '091 patent, claim 1 limitation 1[A] ("a first layer containing a single polymer, wherein the single polymer of the first layer is a co-polyester, and wherein the first layer has a flexural modulus greater than 150,000 psi"), claim 6 limitation 6[B] ("a first layer containing a single polymer, wherein the single polymer of the first layer is a co-polyester, and wherein the first layer has a flexural modulus greater than 150,000 psi"), claim 10 limitation 10[B] ("a first layer consisting of a co-polyester, the co-polyester having a flexural modulus of greater than 150,000 psi"), claim 18 limitation 18[B] ("a first layer consisting of a co-polyester, the co-polyester having [] a flexural modulus of greater than 150,000 psi").

A POSITA would have been motivated to combine (1) the teachings of any of the prior art references cited in these invalidity contentions that disclose a polymer layer, including without limitation, Kalili, Hinz, Stewart-'464, Stewart-'511, and Tadros, with (2) the knowledge of a POSITA and/or teachings of any of the cited prior art references that describe a layer as comprising or consisting of a co-polyester having a flexural modulus greater than about 150,000 psi.

(i) Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros Alone

(1) **Kalili**

As an illustrative, non-limiting example, a POSITA would have been motivated to combine the teachings of Kalili with the knowledge of a POSITA to select a co-polyester having a flexural modulus greater than about 150,000 psi. For example, Kalili recites "an inner layer configured to engage a portion of a patient's teeth" and an "an outer layer secured to the inner

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layer" (Kalili, Claim 1) wherein the inner layer may comprise a thermoplastic polyurethane such as Texin® 990R and "the composition could consist of any type of polymers with higher modulus outer layer and a lower modulus [polyurethane] inner layer." Kalili at [0069]. A POSITA was aware of co-polyesters with a higher modulus than a polyurethane such as Texin-990R, e.g., Tritan EX401 and numerous others. *See, e.g.*, Rafih at 5:57-61. Furthermore, a POSITA knew that Tritan EX401 and numerous other co-polyesters were biocompatible and preferrable for use in appliances that contact the human oral cavity. *See, e.g.*, *id*. at 1:50-56, 5:51-64; Bailin at 7. Thus, a POSITA would have been motivated to select such a co-polyester. Moreover, a POSITA would have known, based on a product sheet for Tritan EX401 or other co-polyester, that Tritan EX401 (or other co-polyester) has a flexural modulus greater than 150,000 psi. In addition, Tritan was the most popular brand of co-polyester (*see, e.g.*, Bailin, 12), and there were only a small number of known alternatives to co-polyesters. *See, e.g.*, Bailin at 27. Thus, implementing Kalili's outer layer using a co-polyester would have been obvious to try. *See* Section VII.B.

At least under Plaintiff's apparent infringement theories, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying Kalili to include a layer comprising or consisting of a co-polyester having a flexural modulus greater than about 150,000 psi. For example, Kalili teaches that the outer layer may be laminated to the inner layer. *See, e.g.*, Kalili at Claim 20 at [0063], [0091]. Doing so would consist of nothing more than using a known material in a known device to yield predictable results.

(2) **Hinz**

As an illustrative, non-limiting example, a POSITA would have been motivated to combine the teachings of Hinz with the knowledge of a POSITA to select a co-polyester having a

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flexural modulus greater than about 150,000 psi. For example, Hinz teaches a multilayer dental splint made in a deep-drawing device. Hinz at Abstract. Hinz further teaches that the dental device can have three different film layers, wherein there is a hard layer made of a first plastic material and a soft layer made of a second plastic material. Hinz at Abstract. Hinz teaches that "[i]n one preferred embodiment of the invention, a deep-drawing film having a hard layer made of a polyester plastic, preferably made of polycarbonate (PC) or polyethylene terephthalate (PET), is selected to produce the dental splint. The external hard layers made of the polyester plastic in the layered composite are stable against discoloration and enable a crystal-clear appearance of the dental splint according to the invention. In addition, the hard layer is sufficiently break-resistant so that breaking off of holding or auxiliary elements, such as anchoring parts for advancing or guide rods of intraoral protrusion devices, does not have to be a concern." Hinz at 3. Hinz identifies Durasoft as a suitable material. *See, e.g.*, Durasoft-PC (comprising a polycarbonate). A POSITA reading Hinz would understand that a co-polyester is a reasonable polymer to select based on the teaching of a "polyester plastic," and would be a good alternative to the teaching of a polycarbonate. As discussed above, a POSITA would have been aware of the Tritan EX401 (or other co-polyester) material and would have understood that such a co-polyester had a flexural modulus over 150,000 psi. Further, a POSITA would have known that Tritan EX401 (along with other co-polyesters) is stable against discoloration and sufficiently break-resistant consistent with Hinz's teachings. Thus, implementing Hinz's outer layer using a co-polyester would have been obvious to try. *See* Section VII.B.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying Hinz to include a layer comprising or consisting of a co-polyester having a flexural modulus greater than about 150,000 psi. For example, Hinz teaches that the

[redacted]

outer layer can comprise a hard plastic material, preferably a polyester, and teaches methods of deep-drawing the plastic layers together to form a dental aligner. *See, e.g.*, Hinz at Abstract.

Doing so would consist of nothing more than using a known material in a known device to yield predictable results.

(3) **Stewart-'464**

As an illustrative, non-limiting example, a POSITA would have been motivated to combine the teachings of Stewart-'464 with the knowledge of a POSITA to select a co-polyester having a flexural modulus greater than about 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. For example, Stewart-'464 teaches "a self-supporting shell which fits over one or more teeth and which is composed of a polymeric composition comprising a polymer and one or more optical additives." Stewart-'464 at [006]. Stewart-'464 then teaches that the "polymer [can be] a polyester, for example a polyethylene terephthalate glycol polymer (PETG), e.g. one of the polyesters sold by Eastman Chemical under the trade names Eastar and Durastar." Stewart-'464 at [0038], [0041]. A POSITA would thus be guided to Eastar 6373 (among other materials), which is a co-polyester having a flexural modulus of 300,000 psi (i.e., greater than 150,000 psi). *See* Eastar 6373 Data Sheet. Therefore, a POSITA would have understood that the polymer used in Stewart-'464's shell could be a co-polyester with a flexural modulus over 150,000 psi.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying Stewart-'464 to include a layer comprising or consisting of a co-polyester having a flexural modulus greater than about 150,000 psi. For example, Stewart-'464 teaches that the shell can be a laminate with two or more layers, including a laminate with a first layer in contact with the teeth and a second layer that faces outwardly. *See, e.g.*, Stewart-'464 at

[redacted]

[0066]. Stewart-'464 also teaches that the shell can be a three-layer laminate. *Id*. Thus, a POSITA would have understood a co-polyester is a material for an outer layer in the shells that Stewart-'464 teaches. Doing so would consist of nothing more than using a known material in a known device to yield predictable results.

(4) **Stewart-'511**

As an illustrative, non-limiting example, a POSITA would have been motivated to combine the teachings of Stewart-'511 with the knowledge of a POSITA to select a co-polyester having a flexural modulus greater than about 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. For example, Stewart-'511 teaches outer layers that may comprise a co-polyester such as Eastar 6763 or Tritan. Stewart-'511 at Tables 1, 3. A POSITA would thus be guided to Eastar 6373 (among other materials), which is a co-polyester having a flexural modulus of 300,000 psi (i.e., greater than 150,000 psi). *See* Eastar 6373 Data Sheet. Therefore, a POSITA would have understood that the polymer used in Stewart-'511's shell could be a co-polyester with a flexural modulus over 150,000 psi.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying Stewart-'511 to include a layer comprising or consisting of a co-polyester having a flexural modulus greater than about 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. For example, Stewart-'511 teaches that the shell can be a laminate with two or more layers, including a laminate with a first layer in contact with the teeth and a second layer that faces outwardly. *See, e.g.*, Stewart-'511 at [0066]. Stewart-'511 also teaches that the shell can be a three-layer laminate. *Id*. Thus, a POSITA would have understood a co-polyester is a material for an outer

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layer in the shells that Stewart-'511 teaches. Doing so would consist of nothing more than using a known material in a known device to yield predictable results.

(5) **Tadros**

As an illustrative, non-limiting example, a POSITA would have been motivated to combine the teachings of Tadros with the knowledge of a POSITA to select a co-polyester having a flexural modulus greater than about 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. For example, Tadros discloses that "[t]he appliance 100 of FIG. 3 preferably contains at least one layer manufactured from a sheet of a polymeric mixture. Polymeric mixtures used for such appliances, are generally physical mixtures of two or more thermoplastic polymers. Thermoplastic polymers that may be used in the polymeric mixture may be… polyesters… and the like, as well as combinations comprising at least one of the foregoing polymers." Tadros at [0022]. Tadros further discloses that "[p]referred polymeric mixtures are those derived from a polycarbonate, polyesters such as cycloaliphatic polyesters and polyarylates, and polycarbonate-polydimethylsiloxane copolymers." *Id*. Given Tadros's teaching of that various polyesters were suitable, a POSITA would have understood that a co-polyester would have been a suitable polymer to use for the appliance as well. Further, Tadros teaches that "the appliance may comprise additional layers disposed upon the sheet comprising the polymeric mixture. The additional layers may comprise a first layer disposed upon a surface of the sheet comprising the polymeric mixture, and an optional second layer disposed upon a surface of the sheet opposite the surface in contact with the first layer. The additional layers generally comprise an organic polymer having a tensile modulus of less than or equal to about 1,000 N/mm^2." Tadros at [0073]. A POSITA was aware of co-polyesters such as Tritan EX401 and numerous others. *See,*

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e.g., Rafih at 5:57-61. Furthermore, a POSITA knew that Tritan EX401 and numerous other co-polyesters were preferred for use in appliances that contact the human oral cavity. *See, e.g.*, *id*. at 1:50-56, 5:51-64; Bailin, 7. Thus, a POSITA would have been motivated to select such a co-polyester. Moreover, a POSITA would have known, based on a product sheet for Tritan EX401 (*see* EX401) or other co-polyester, that Tritan EX401 (or other co-polyester) has a flexural modulus greater than 150,000 psi. In addition, Tritan was the most popular brand of co-polyester (*see, e.g.*, Bailin at 12), and there were only a small number of known alternatives to co-polyesters. *See, e.g.*, Bailin at 27.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying Tadros to include a layer comprising or consisting of a co-polyester having a flexural modulus greater than about 150,000 psi. For example, Tadros teaches a shell with two or more layers, and a POSITA would have understood that a co-polyester material could be included in the shell as the outer layer. *See, e.g.*, Tadros at [0016]. Tadros further teaches the polymeric mixture can be made via extrusion, which was a well-known procedure at the time. *See*, *e.g.*, Tadros at [0080]. Doing so would consist of nothing more than using a known material in a known device to yield predictable results.

(ii) Bailin

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Bailin with Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros to select a co-polyester having a flexural modulus greater than about 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. For example, a POSITA would have been motivated to combine (1) the teachings of Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros to use a

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polycarbonate in a multilayer dental positioning appliance with (2) the teachings of Bailin that polycarbonates posed a health risk to humans due to the presence of Bisphenol-A ("BPA") and should be substituted for polymer alternatives that do not contain BPA and with (3) the teachings of Bailin that a co-polyester having a flexural modulus of greater than 150,000 psi was a suitable substitute.

Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros and Bailin are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses the field of polymer appliances that contact the intraoral cavity. Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros and Bailin are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

As noted above, Bailin teaches that BPA present in polycarbonates poses a health risk to humans. *See, e.g.*, Bailin, 4. As a result, a POSITA would have seen a benefit (a safer dental positioning appliance) to replacing the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros with a suitable alternative. A POSITA would have consulted the prior art for suitable substitutes. Bailin teaches that co-polyesters were a known alternative. *Id*., 20-26. As a nonlimiting example, Bailin specifically teaches that Tritan co-polyesters are a suitable substitute. *Id*. Moreover, Bailin specifically recommends a Tritan co-polyester with a flexural modulus greater than 150,000 psi and the other features of the co-polyester recited in the asserted claims of the Materials Patents. Bailin at 21 (citing Beavers); *see* Beavers at 5 (flexural modulus 225,000 psi). Therefore, a POSITA would have been motivated to replace the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros with a copolyester layer made of a

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co-polyester described in Beavers other copolyester with a flexural modulus of greater than 150,000 psi.

Replacing the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros in an orthodontic appliance with Bailin's co-polyester layer having a flexural modulus of greater than 150,000 psi (and the other features of the co-polyester recited in the asserted claims of the Materials Patents) would merely have involved the simple substitution of one known element for another to obtain predictable results. *See* Section VII.B. As noted, Bailin expressly teaches the substitution of a polycarbonate use in an oral appliance with a co-polyester. The features and functionality of co-polyesters (including co-polyesters in a multilayer sheet) were known in the art. *See, e.g.*, Rafih at 5:55-61 ("In an embodiment, the frame can comprise a copolymer material that does not include bisphenol-A (BPA). For example, in an embodiment the frame can comprise a polymer such as TRITAN™ copolyester from EASTMAN® Chemical Company. TRITAN™ EX 401 has a melting temperature of approximately 515-535° F. and a stiffness of 1500 MPa."); Tritan EX401. The ability to combine a layer of co-polyester with a layer of polyurethane in an orthodontic appliance was known to a POSITA. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

Replacing the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros in an orthodontic appliance with Bailin's co-polyester layer having a flexural modulus of greater than 150,000 psi would have also used a known technique (replacing a polycarbonate layer with a co-polyester layer) to improve a similar method (providing a sheet comprising a polycarbonate) in the same way. *See* Section VII.B. It would have also amounted to applying a known technique (replacing a polycarbonate layer with a co-polyester layer) to a known method (Kalili,

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Hinz, Stewart-'464, Stewart-'511 or Tadros method) ready for improvement to yield predictable results (BPA-free dental appliance).

Using the Tritan co-polyester recommended by Bailin to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available co-polyesters with which to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros for a POSITA to select from among, and a POSITA would have tested the recommended Tritan co-polyester with a reasonable expectation of success for the reasons given above.

The resulting combination would have included at least a multilayer sheet and an orthodontic appliance made from the multilayer sheet comprising a copolyester layer and a polyurethane layer, for example a co-polyester layer in contact with a polyurethane layer.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

(iii) Rafih

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Rifah with Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros to select a co-polyester having a flexural modulus greater than about 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. For example, a POSITA would have been motivated to combine (1) the teachings of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros to use a polycarbonate layer in a multilayer dental positioning appliance with (2) the teachings of Rafih

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that Tritan EX401 (a co-polyester with a flexural modulus greater than 150,000 psi) is a suitable substitute for polycarbonate and that does not contain BPA.

Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros and Rafih are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses the field of polymer appliances that contact the intraoral cavity. Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros and Rafih are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

As noted above, Rafih teaches that Tritan EX401 does not include BPA. *See, e.g.*, Rafih at 5:52–64 ("Further, the frame 150 can comprise a material having sufficient stiffness to resist excessively and/or permanently deforming when placed in the mouth of a user and the user clenches his or her jaws. In an embodiment, the frame can comprise a copolymer material that does not include bisphenol-A (BPA). For example, in an embodiment the frame can comprise a polymer such as TRITAN™ copolyester from EASTMAN® Chemical Company. TRITAN™ EX 401 has a melting temperature of approximately 515-535° F. and a stiffness of 1500 MPa. The frame 150 and additional feature(s) can be visible through the over-molded material 101 where the thermo-plastic over-molded material 101 is a translucent or transparent material."). The POSITA knew that BPA posed health risks. As a result, a POSITA would have seen a benefit (a safer dental positioning appliance) to replacing the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros with a suitable alternative. A POSITA would have consulted the prior art for suitable substitutes. Bailin teaches that co-polyesters were a known alternative. *Id*. As a nonlimiting example, Rafih specifically teaches that Triton EX401 is a

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suitable substitute. *Id*. Therefore, a POSITA would have been motivated to replace the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros and Rafih with a copolyester layer of Triton EX401 or other copolyester with a flexural modulus of greater than 150,000 psi.

Replacing the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros in an orthodontic appliance with Rafih's co-polyester layer having a flexural modulus of greater than 150,000 psi (and the other recited claim features of the co-polyester) would merely have involved the simple substitution of one known element for another to obtain predictable results. *See* Section VII.B. As noted, Rafih expressly teaches the substitution of a polycarbonate use in an oral appliance with a co-polyester. The features and functionality of co-polyesters (including co-polyesters in a multilayer sheet) were known in the art. *See, e.g.*, Rafih at 5:55-61; Tritan EX401. The ability to combine a layer of copolyester with a layer of polyurethane in an orthodontic appliance was known to a POSITA. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

Replacing the polycarbonate layer of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros in an orthodontic appliance with Rafih's co-polyester layer having a flexural modulus of greater than 150,000 psi would have also used a known technique (replacing a polycarbonate layer with a co-polyester layer) to improve a similar method (providing a sheet comprising a polycarbonate) in the same way. *See* Section VII.B. It would have also amounted to applying a known technique (replacing a polycarbonate layer with a co-polyester layer) to a known method (Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros method) ready for improvement to yield predictable results (BPA-free dental appliance).

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Using the Tritan EX401 co-polyester recommended by Rafih to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available co-polyesters with which to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros for a POSITA to select from among, and a POSITA would have tested the Tritan EX401 co-polyester with a reasonable expectation of success for the reasons given above.

The resulting combination would have included at least a multilayer sheet and an orthodontic appliance made from the multilayer sheet comprising a copolyester layer and a polyurethane layer, for example a copolyester layer in contact with a polyurethane layer.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

(iv) Hytrel, Eastar, Tritan EX401, or Imprelon

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine the teachings of Hytrel, Eastar, Tritan EX401, or Imprelon with Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros. For the reasons given above with respect to Kalili, Hinz, Stewart-'464, Stewart-'511 and Tadros alone, it was obvious to select a co-polyester for use in a layer of the aligner material. For example, Hytrel, Eastar, and Tritan EX401 each teach a suitable co-polyester having a flexural modulus greater than about 150,000 psi. Hytrel (flexural modulus of 1116 MPa (162,000 psi)); Eastar (flexural modulus of 290,000 psi); Tritan EX401 (flexural modulus of 1521 MPa (222,000 psi)).

Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros, Hytrel, Eastar, Tritan EX401, and Imprelon are from the same or an overlapping field of endeavor of the Asserted Patents' alleged

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invention, which encompasses use of polymer sheets including a co-polyester layer. Kalili, Hinz, Tadros, Hytrel, Eastar, Tritan EX401, and Imprelon are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

With respect to Tadros, a POSITA would have been motivated to select the co-polyester disclosed by Hytrel, Eastar, Tritan EX401, or Imprelon because, *inter alia*, (1) Tadros discloses that a co-polyester is a suitable choice but does not identify a specific co-polyester to use; (2) Hytrel, Eastar, Tritan EX401, and Imprelon are biocompatible co-polyesters; and (3) Hytrel, Eastar, Tritan EX401, and Imprelon have properties similar to the Tadros's exemplary hard layer. Thus, a POSITA would have seen a benefit to selecting Hytrel, Eastar, or Tritan EX401.

Tadros discloses a co-polyester layer and further discloses a multilayer sheet in which the hard layer has a specified tensile modulus, tensile strength at yield, tensile strength at break, and elongation at yield. Tadros, Table 2 (tensile modulus: 1743.94 N/mm^2 (252,900 psi); tensile strength at yield: 63.53 N/mm^2 (8,400 psi), tensile strength at break: 63.53 N/mm^2 (9,200 psi); and elongation at yield: 69.14%). Hytrel, Eastar, Tritan EX401, and Imprelon have similar properties to the exemplary hard layer in Table 2. *See, e.g.*, Hytrel (tensile modulus: 1180 MPa (171,000 psi); stress at break: 50 MPa (7,200 psi); strain at break: 400%); Eastar (tensile modulus: 1900 MPa (280,000 psi); tensile strength at yield: 52 MPa (7,500 psi); tensile strength at break: 59 MPa (8,600 psi); elongation at yield: 4.0%); Tritan EX401 (tensile modulus: 1624 MPa (235,500 psi); tensile strength at yield: 45 MPa (6,500 psi); tensile strength at break: 49 MPa (7,100 psi); and elongation at yield: 7%).

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With respect to Stewart-'511, it specifically identifies Eastar 6763 and Tritan co-polyesters as suitable. Stewart-'511 at Tables 1, 3.

Using Hytrel, Eastar, Tritan EX401, or Imprelon to implement Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros's multilayer dental appliance would have merely combined prior art elements (Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer appliance including a co-polyester layer of Hytrel, Eastar, or Tritan EX401) to yield predictable results (a multilayer dental appliance).

Starting from an embodiment of Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer dental appliance comprising Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's harder layer, replacing that layer with Hytrel, Eastar, or Tritan EX401 would have been a simple substitution of one known element (Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's harder layer) for another (Hytrel or Eastar) to obtain predictable results (multilayer dental appliance). A POSITA would have been motivated to make the substitution for the reasons given above, including because a Tadros discloses that a co-polyester is a suitable choice and co-polyesters were available with similar properties to Tadros's exemplary embodiment.

Using Hytrel, Eastar, Tritan EX401, or Imprelon to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available co-polyesters with which to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros for a POSITA to select from among, and a POSITA would have tested Hytrel, Eastar, or Tritan EX401 with a reasonable expectation of success for the reasons given above.

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The resulting combination would have included at least a multilayer sheet and an orthodontic appliance made from the multilayer sheet comprising a copolyester layer and a polyurethane layer, for example a co-polyester layer in contact with a polyurethane layer.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

(v) Stewart-'464

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Stewart-'464 with Kalili, Hinz, Stewart-'511, or Tadros into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Kalili, Hinz, Stewart-'511 or Tadros to use a polycarbonate layer in a multilayer dental positioning appliance with (2) the teachings of Stewart-'464 that Eastar (a co-polyester with a flexural modulus greater than 150,000 psi) is a suitable substitute for polycarbonate.

Kalili, Hinz, Tadros, Stewart-'511 and Stewart-'464 are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention and are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents for the reasons given above. *See* Sections B.1.a.i-iv.

As a nonlimiting example, Stewart-'464 specifically teaches that Eastar (*see* Section VII.B.1.a.iv) is a suitable polyester. Stewart-'464 at [0037] ("The polymer is a polyester, for example a polyethylene terephthalate glycol polymer (PETG), e.g. one of the polyesters sold by Eastman Chemical under the trade names Eastar and Durastar, or one of the polyesters sold by DuPont under the trade name Hytrel.") *id*. at [0110] ("PETG resin (Eastar 6763) is combined

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with ultramarine blue and ultramarine violet pigment master batch and extruded into a sheet of thickness 0.07 mm the amount of the pigment being such that the sheet has LAB color values measured on a white color tile of L=94, A=1.3, B=−2.5.").

Replacing the polycarbonate layer of Kalili, Hinz, Stewart-'511 or Tadros in an orthodontic appliance with Stewart-'464's co-polyester layer having a flexural modulus of greater than 150,000 psi (and the other recited claim features of the co-polyester) would merely have involved the simple substitution of one known element for another to obtain predictable results. *See* Section VII.B. The features and functionality of co-polyesters (including co-polyesters in a multilayer sheet) were known in the art. *See, e.g.*, Rafih at 5:55-61; Eastar. The ability to combine a layer of copolyester with a layer of polyurethane in an orthodontic appliance was known to a POSITA. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

Replacing the polycarbonate layer of Kalili, Hinz, Stewart-'511 or Tadros in an orthodontic appliance with Stewart-'464's co-polyester layer having a flexural modulus of greater than 150,000 psi would have also used a known technique (replacing a polycarbonate layer with a co-polyester layer) to improve a similar method (providing a sheet comprising a polycarbonate) in the same way. *See* Section VII.B. It would have also amounted to applying a known technique (replacing a polycarbonate layer with a co-polyester layer) to a known method (Kalili, Hinz, Stewart-'511, or Tadros's method) ready for improvement to yield predictable results.

Using Stewart-'464's co-polyester layer to implement Kalili, Hinz, Stewart-'511, or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available co-polyesters with which to implement Kalili, Hinz, Stewart-

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’511, or Tadros for a POSITA to select from among, and a POSITA would have tested Stewart-’464’s co-polyester with a reasonable expectation of success for the reasons given above.

The resulting combination would have included at least a multilayer sheet and an orthodontic appliance made from the multilayer sheet comprising a copolyester layer and a polyurethane layer, for example a copolyester layer in contact with a polyurethane layer.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-’464, Stewart-’511 or Tadros Alone].

(vi) DeSimone-’841

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine the teachings of DeSimone-’841 with Kalili, Hinz, Stewart-’464, Stewart-’511 or Tadros. For example, DeSimone-’841 teaches that a co-polyester having a flexural modulus greater than about 150,000 psi is preferrable its dental positioning device, at least under Plaintiff’s apparent interpretation of the claims as shown in its Preliminary Infringement Contentions. DeSimone-’841 at [0005] (“According to embodiments of the present invention, the polymeric shell of a removable dental positioning appliance is formed from, or coated with, transparent polymeric materials such as liquid crystalline polymeric materials, styrenics, and/or ion-containing polymers. These transparent polymeric materials preferably have a tensile strength at yield of greater than 6,000 pounds per square inch (psi), preferably have an elongation at yield of greater than 4%, an elongation at break of greater than 80%, preferably have a tensile modulus greater than 200,000 psi, preferably have a flexural modulus greater than 200,000 psi, stress relaxation over time of not more than 50%, and preferably have a transmissivity of light between 400 nm and 800 nm greater than 75%.”), [0017] (“A single

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polyester material need not be used, and copolyesters, blends, etc. may alternatively be used."), [0027] ("Other exemplary transparent materials having high glass transition temperatures include SUNTUF®, PALSUN® and PALTUF™ polycarbonate sheets, PALGLAS® acrylic sheets; PAL-G™ co-polyester sheets, and PALRUF® PVC sheets, all available from Suntuf, Inc. Kutztown, Pa."). Thus, a POSITA would have seen a benefit to selecting a co-polyester with a flexural modulus greater than 150,000 psi, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions.

Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros, and DeSimone-'841 are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses use of polymer sheets including a co-polyester layer for use in a dental appliance. Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros, and DeSimone-'841 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

With respect to Tadros, a POSITA would have also been motivated to select the co-polyester disclosed by DeSimone-'841 because, *inter alia*, (1) Tadros discloses that a co-polyester is a suitable choice but does not identify a specific co-polyester to use; (2) DeSimone-'841 discloses a co-polyester specifically for use in dental appliances; and (3) DeSimone-'841 has properties similar to the Tadros's exemplary hard layer. Thus, a POSITA would have seen a benefit to implementing the teachings of DeSimone-'841.

Tadros discloses a co-polyester layer and further discloses a multilayer sheet in which the hard layer has a specified tensile modulus, tensile strength at yield, tensile strength at break, and

[redacted]

elongation at yield. Tadros, Table 2 (tensile modulus: 1743.94 N/mm^2 (252,900 psi); tensile strength at yield: 63.53 N/mm^2 (8,400 psi), tensile strength at break: 63.53 N/mm^2 (9,200 psi), and elongation at yield: 69.14%). DeSimone-'841 discloses similar properties to the exemplary hard layer in Table 2. DeSimone-'841 at [0005] (tensile modulus: greater than 200,000 psi, tensile strength at yield: greater than 6,000 psi, elongation at yield: greater than 4%).

Starting from an embodiment of Tadros's multilayer dental appliance comprising Tadros's exemplary hard layer (Table 2), replacing that layer with a layer of DeSimone-'841's co-polyester would have been a simple substitution of one known element (Tadros's hard layer) for another (a layer of DeSimone-'841's co-polyester) to obtain predictable results (multilayer dental appliance). A POSITA would have been motivated to make the substitution for the reasons given above, including because Tadros discloses that a co-polyester is a suitable choice.

Using DeSimone-'841's co-polyester to implement Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros's multilayer dental appliance would have merely combined prior art elements (Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer appliance including DeSimone-'841's co-polyester layer) to yield predictable results (a multilayer dental appliance).

Using a layer of DeSimone-'841's co-polyester to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available co-polyesters with which to implement Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros's multilayer dental appliance for a POSITA to select from among, and a POSITA would have tested a layer of DeSimone-'841's co-polyester with a reasonable expectation of success for the reasons given above.

[redacted]

The resulting combination would have included at least a multilayer sheet and an orthodontic appliance made from the multilayer sheet comprising a copolyester layer and a polyurethane layer, for example a co-polyester layer in contact with a polyurethane layer.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros Alone].

(vii) Durasoft-PETG

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine the teachings of Durasoft-PETG with Kalili, Hinz, Stewart-'464, Stewart-'511 or Tadros. For example, Durasoft-PETG comprises a polyurethane layer and a co-polyester layer having an elastic modulus of 2,200 MPa (319,000 psi). Durasoft. A POSITA understood that the copolyester layer was an isotropic material that would have substantially the same flexural modulus (319,000 psi).

Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros, and Durasoft-PETG are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses use of polymer sheets including a co-polyester layer. Kalili, Hinz, Stewart-'464, Stewart-'511, Tadros, and Durasoft-PETG are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

With respect to Tadros, a POSITA would have been motivated to select the co-polyester disclosed by Durasoft. With respect to Tadros, *inter alia*, (1) Tadros discloses that a co-polyester is a suitable choice but does not identify a specific co-polyester to use; (2) Durasoft-PETG

[redacted]

comprises biocompatible co-polyester layer combined with a polyurethane layer; (3) Durasoft-PETG has properties similar to the Tadros's exemplary hard layer. Thus, a POSITA would have seen a benefit to selecting Durasoft-PETG for at least the same reasons given above with respect to Hytrel and Easter.

Tadros discloses a co-polyester layer and further discloses a multilayer sheet in which the hard layer has a specified tensile modulus, tensile strength at yield, tensile strength at break, and elongation at yield. Tadros, Table 2 (tensile modulus: 1743.94 N/mm^2 (252,900 psi); tensile strength at yield: 63.53 N/mm^2 (8,400 psi), tensile strength at break: 63.53 N/mm^2 (9,200 psi), and elongation at yield: 69.14%). Durasoft-PETG has similar properties to the exemplary hard layer in Table 2. Durasoft-PETG (tensile modulus: 2,200 MPa (319,000 psi).

Starting from an embodiment of Tadros's multilayer dental appliance comprising Tadros's exemplary hard layer (Table 2), replacing that layer with Durasoft-PETG would have been a simple substitution of one known element (Tadros's hard layer) for another (Durasoft) to obtain predictable results (multilayer dental appliance). A POSITA would have been motivated to make the substitution for the reasons given above, including because a Tadros discloses that a co-polyester is a suitable choice.

Using Durasoft-PETG to implement Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros's multilayer dental appliance would have merely combined prior art elements (Kalili, Hinz, Stewart-'464, or Tadros's multilayer appliance including a co-polyester layer of Durasoft) to yield predictable results (a multilayer dental appliance).

Using Durasoft-PETG to implement Kalili, Hinz, Stewart-'464, Stewart-'511, or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available co-polyesters with which to implement Tadros for a POSITA

[redacted]

to select from among, and a POSITA would have tested Durasoft-PETG with a reasonable expectation of success for the reasons given above.

The resulting combination would have included at least a multilayer sheet and an orthodontic appliance made from the multilayer sheet comprising a copolyester layer and a polyurethane layer, for example a co-polyester layer in contact with a polyurethane layer.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Kalili, Hinz, Stewart-'464, or Tadros Alone].

b) Combinations with the Third-Layer References

The Materials Patents recite a dental appliance comprising three or more layers. *See* '613 patent, claim 1 limitation 1[A] ("providing a sheet comprising three or more polymer layers"), claim 20 limitation 20[A] ("providing a sheet comprising three or more polymer layers…"); '384 patent, claim 1 limitation 1[B] ("three or more polymer layers"), claim 11 limitation 11[A] ("three or more polymer layers"), claim 21 limitation 21[A][iii] ("first three or more polymer layers…"), limitation 21[B][iii] ("a second three or more polymer layers"); '090 patent, claim 1 limitation 1[A] ("providing a multilayer sheet comprising three polymer layers"); '091 patent, claim 1 limitation 1[C] ("a third layer"), claim 6 limitation 6[A] ("a multilayer sheet"), claim 10 limitation 10[D] ("a third layer"), claim 18 limitation 18[Pre] ("a multilayer dental aligner").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated to combine (1) the teachings of any of the prior art references cited in these invalidity contentions that disclose a dental appliance, including without limitation, Kalili and Stewart-'464, with (2) the knowledge of a POSITA and/or teachings of any of the cited prior art references that describe a dental appliance comprising three or more layers.

[redacted]

(i) Kalili or Stewart-'464 Alone

As an illustrative, non-limiting example, a POSITA would have been motivated to combine the teachings of Kalili or Stewart-'464 with the knowledge of a POSITA to obtain a dental appliance comprising three or more layers. For example, Kalili discloses a third layer consisting of compressible "raised surfaces" disposed between an inner layer and the teeth and that may be "composed of the lower modulus inner layer material [e.g., polyurethane]" in order to apply force to exert greater control over the patient's teeth. *See, e.g.*, Kalili at [0082], [0083]. Kalili renders it obvious, for example, by combining Kalili's teachings that (1) an inner low modulus layer can be added in order to redistribute the load on a patient's teeth (*id.* at [0072]) and (2) the raised surfaces further modulate the load. It would therefore have been obvious to include a third layer (e.g., a third layer consisting of the low modulus polyurethane) over portions of Kalili's inner layer where greater control over the patient's teeth was desired. Such a configuration would have resulted in a soft-soft-hard configuration. Alternatively, Kalili teaches that the low modulus inner layer can increase the life of an intraoral appliance. *Id*. To further increase the life of the intraoral appliance, it would have been obvious to add a third layer to the opposite side of the higher modulus layer, resulting in a hard-soft-hard configuration.

Stewart-'464 also discloses this feature or at least renders it obvious. Stewart-'464 teaches a sheet, used for thermoforming a dental shell, that has "two or more layers." Stewart-'464 at [0066], [0111]. Indeed, Stewart-'464 teaches that the dental shell can be made from a "three layer laminate." Stewart-'464 at [0066]. Thus, it would have been obvious to a POSITA to make a dental appliance comprising three or more layers.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying Kalili or Stewart-'464 to obtain a dental appliance comprising three or

more layers. Doing so would consist of nothing more than applying known techniques to a known device to yield predictable results.

(ii) Paulus

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings from the systems and methods described in Paulus with Kalili or Stewart-'464 into one method. For example, a POSITA would have been motivated to combine (1) the teachings of Kalili or Stewart-'464 to use at least a low modulus inner layer with a higher modulus outer layer with (2) the teachings of Paulus that the number of layers can be adjusted, including by addition of a third layer, between stages in order to fine-tune and adjust the force against a tooth.

Kalili, Stewart-'464, and Paulus are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses the field orthodontics, and more particularly to the design of multilayer dental positioning appliances. Kalili, Stewart-'464, and Paulus are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

As noted above, Kalili teaches the desirability (e.g., through its "raised surfaces") of controlling force on a tooth. Stewart-'464 also teaches the need to apply force to teach. Stewart-'464 at [0003] ("One orthodontic procedure makes use of one or more rigid polymeric shells each of which fits over the teeth and, when in place, does not fit precisely to one or more of the teeth and, therefore, imparts a displacing force to the teeth and over the course of time changes the relative positions of two or more teeth."). Similarly, Paulus discloses the need to fine-tune

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and adjust the force against a tooth in different stages of treatment. *See, e.g.*, Paulus at 3 ("For further adjustment of the desired tooth correction forces occurring between the hard plastic elements 3, the orthodontic device 1 can be reworked step by step and one or more further soft plastic elements 4 (e.g., as a film-like soft plastic element 4b) can be subsequently attached to the soft plastic element 4a in a further processing step. This means that the orthodontic device 1 can be extended cost-effectively and the desired corrective forces can be gradually built up via the "growing" soft plastic element connection depending on the desired correction process over time. In contrast to the state of the art, it is therefore unnecessary to offer a large number of orthodontic devices consisting purely of hard plastic elements, which gradually map the respective tooth correction process. Rather, the novel orthodontic device 1 makes it possible to realize this by gradually applying further foil layers and additional soft plastic elements 4 with correspondingly modified corrective forces (with low corrective forces at the beginning and with greater corrective forces at the end)."), Fig. 3. Thus, a POSITA would have considered Paulus to provide a benefit. Paulus provides a way to control force on a tooth by the addition of a third layer to fine-tune and adjust the force against a tooth. *Id*. Moreover, like Kalili or Stewart-'464, Paulus's third layer can be the same material as the low modulus (or soft) layer. *Id*. As a result, a POSITA would have seen a benefit (force control) to adding a third layer to Kalili's method.

Furthermore, adding a third layer such as an additional polyurethane layer to Kalili's or Stewart-'464's method would have merely combined prior art elements (Paulus's third layer with Kalili's dental appliance) according to known methods to yield predictable results. *See* Section VII.B. For example, techniques for forming multilayer sheets comprising a polyurethane layer were known. *See* Section VII.B.1.a.i [Co-Polyester Limitations – Kalili, Hinz, Stewart-'464, or Tadros Alone]. Similarly, the known technique (Paulus's adding a third layer to make a dental

[redacted]

appliance) would improve a similar method (Kalili's method of making a dental appliance) in the same way (adding the third layer), and would have yielded predictable results (ability to fine tune force on a tooth).

The resulting combination would have been a three-layer sheet comprising a third layer based on the teachings of Paulus.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a.i [Co-Polyester Limitations – Kalili, Hinz, Stewart-'464, or Tadros Alone].

(iii) Bedard, Chen, or Wen-'558

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings from the systems and methods described in Paulus with Kalili or Stewart-'464 into one method. For example, a POSITA would have been motivated to combine (1) the teachings of Kalili or Stewart-'464 to use at least a low modulus inner layer with a higher modulus outer layer with (2) the teachings of Bedard, Chen, and Wen-'558 that multiple adjacent sublayers of the same or different material can be used improve strength, conformability, and/or comfort of a dental aligner.

Kalili, Stewart-'464, Bedard, Chen, and Wen-'558 are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention for the same reasons given above with respect to Paulus. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

As noted above, Kalili or Stewart-'464 teaches the desirability (e.g., through its "raised surfaces) of controlling force on a tooth. *See, e.g.*, Kalili at [0082], [0083]. Similarly, Bedard, Chen, and Wen-'558 teach that multiple adjacent sublayers of the same or different material can

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be used improve conformability and/or comfort of a dental aligner. *See, e.g.*, Bedard at 3:55-67 ("The inventors recognize that the laminate of the present invention dental appliance could alternatively include multiple thinner layers of strengthening material(s) which together form a strengthening layer equivalent; or multiple thinner layers of soft material(s) which together form a soft material layer equivalent; or groups of multiple thinner layers with each group working together to form a strengthening layer equivalent and a soft layer equivalent. The underlying concept remains that at least two layers of materials with different property are present in the laminate and working together to contribute to the final dental appliance product, with one layer proving flexible strength and the other layer providing a soft surface."); Chen at [0031] ("The concave trough 102 may include a variable number of inner layers 132. For example, four, three or two inner layers 132, as shown in FIGS. 4A, 4B, and 4C, respectively. More than four inner layers (not depicted) may also be used. The inner layers 132, as well as the outer layers 134, may each have different thickness, such as 5 or 10 mils, and/or variable glass transition temperatures. The layers may be formed in various orientations and configurations to suit the modulus and application requirements."), Wen at [00212]-[00214] ("The different dental-aligner layers in the multi-layer dental aligner 1700 can also comprise the same material. That is, rather than forming a dental aligner by a thick layer of the same aligner-making material, the aligner is formed by a plurality of thinner layers of aligner-making material using vacuum forming. The thinner layers can be more easily conformed to the physical tooth models than a single thick layer…. Further, a wider array of polymers may be utilized where thinner layers are used to form an appliance. Polymers of disparate properties may delaminate from one another where thicker films are used. Thinner films allow more intimate contact between polymer sheets

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and therefore help bond the films to one another. [00214] A dental aligner may also be formed so that it has sections or portions of different properties.").

A POSITA would have considered Bedard, Chen, and/or Wen's multiple layers (for example multiple soft layers or multiple hard layers) to greater strength, ability to conform to the shape of teeth, and/or comfort. Moreover, like Kalili and Stewart-'464, Bedard, Chen, and Wen's additional layer can be the same material. As a result, a POSITA would have seen the foregoing benefits to adding a third layer to Kalili's method.

Furthermore, adding a third layer such as an additional polyurethane layer to Kalili's or Stewart-'464's method would have merely combined prior art elements (*e.g.*, Paulus's or Stewart-'464 third layer with Kalili's dental appliance) according to known methods to yield predictable results. *See* Section VII.B. For example, techniques for forming multilayer sheets comprising a polyurethane layer were known. *See* Section VII.B.1.a [Co-Polyester Limitations – Kalili, Hinz, Stewart-'464, or Tadros Alone]. Similarly, the known technique (Paulus's adding a third layer to make a dental appliance) would improve a similar method (Kalili or Stewart-'464's method of making a dental appliance) in the same way (adding the third layer), and would have yielded predictable results (ability to fine tune force on a tooth).

The resulting combination would have been a three-layer sheet comprising a third layer based on the teachings of Bedard, Chen, or Wen.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.a [Co-Polyester Limitations – Kalili, Hinz, Stewart-'464, or Tadros Alone].

[redacted]

c) Combinations with the Polyurethane References

The Materials Patents recite a dental appliance comprising a polymer layer that comprises or consists of a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D. *See, e.g.*, '613 patent at claim 1 limitation 1[C] ("a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60A to about 85D "), claim 20 limitation 20[C] ("a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60A to about 85D "); '384 patent at claim 1 limitation 1[D] ("a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60A to about 85D"), claim 11 limitation 11[C] ("a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60A to about 85D"), claim 21 limitation 21[A][v] ("a first soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60A to about 85D"), limitation 21[B][v] ("a second soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60A to about 85D"); '090 patent at claim 1 limitation 1[C] ("[a] second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D"); '091 patent at claim 1 limitation 1[B] ("A second layer containing a single polymer, wherein the single polymer of the second layer is a thermoplastic polyurethane elastomer, and wherein the second layer has an

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ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D"), claim 6 limitation 6[C] ("a second layer containing a single polymer, wherein the single polymer of the second layer is a thermoplastic polyurethane elastomer, and wherein the second layer has an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D"), claim 10 limitation 10[C] ("a second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D"), claim 18 limitation 18[C] ("a second layer consisting of a thermoplastic polyurethane elastomer having an elongation at break of greater than 200%, an ultimate tensile strength of greater than 5000 psi, and a hardness of 60A to 85D").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated to combine (1) the teachings of any of the prior art references cited in these invalidity contentions that disclose a polymer layer, including without limitation, Tadros and Stewart-'511, with (2) the knowledge of a POSITA and/or teachings of any of the cited prior art references that describe a dental appliance comprising a polymer layer that comprises or consists of a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D.

(i) Stewart-'511, Hinz or Tadros Alone

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Stewart-'511, Hinz, or Tadrosto include these features. For example, Stewart, Hinz and Tadros explains that a multilayer sheet may comprise a polyurethane. *See, e.g.*, Stewart-'511 at 1:48-67 ("In one embodiment, the A and C layers are

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comprised of one of more of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide or a polyolefin. In another embodiment, the middle B layer is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane."); Tadros at [0073] ("Preferred organic polymers for the additional layers are elastomers. Suitable examples of elastomers for the first layer and/or second layer includes…polyurethanes…. A preferred elastomer is ECDEL 9966 [co-polyester] commercially available from Eastman Chemical Company…"). While Tadros discloses the use of a polyurethane, Tadros does not disclose a specific polyurethane. A POSITA would have therefore consulted the prior art to identify a suitable polyurethane. To identify a suitable polyurethane, a POSITA would have been guided by Tadros's disclosure that ECDEL 9966 [polyester] was a preferred embodiment. A POSITA would have therefore sought a polyurethane with similar properties to ECDEL 9966. Having done so, a POSITA would have observed that certain polyurethanes were softer than ECDEL 9966 and could therefore provide increased patient comfort compared to ECDEL 9966. Moreover, once identified, implementing the polyurethane doing so would be mere substitution of one known element for another to yield predictable results. In addition, there were a limited number of such polyurethanes that were commercially available, and it would have been obvious to try for a POSITA to compare the performance of polyurethane substitutes with ECDEL 9966. A manufacturer's product sheet for ECDEL 9966 specifies an elongation at break of 400% (greater than about 200%), a Shore A hardness of 95 (greater than about 60 A) and a Shore D hardness of 55 (less than about 85 D). ECDEL. For example, it would have been routine for a

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POSITA to search for and test commercially available polyurethanes such as Texin 990R, which has an elongation at break of 450% and a Shore A hardness of 90. Texin-990, 1.

A POSITA would have had a reasonable expectation of success, given Stewart-'511 and Tadros's disclosure that polyurethanes were suitable, and because it was known to include polyurethane as a layer in a multilayer sheet. Thus, a POSITA would have had a reasonable expectation of success implementing Tadros using a polyurethane with the claimed properties.

(ii) Texin-990, Pelletane 2363-90AE

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine the teachings of Texin-990 and/or Pellethane-AE with Stewart-'511 or Tadros. For example, Texin-990 and Pellethane-AE each teach a suitable polyurethane having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D. Texin-990, 1 (elongation at break: 400%; Shore A hardness: 90; Shore D hardness: 55); Pellethane-AE (elongation at break: 550%; Shore A hardness: 90).

Stewart-'511, Tadros, Texin-990 and Pellethane-AE are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses use of polymer sheets including a polyurethane layer. Stewart-'511, Tadros, Texin-990 and Pellethane-AE are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

As noted above, each of Stewart-'511 and Tadros teach that suitable polymer layers include polyurethane. With respect to Tadros, a POSITA would have been motivated to select the polyurethane disclosed by Texin-990 or Pellethane-AE because, *inter alia*, (1) Tadros

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discloses that a polyurethane is a suitable choice but does not identify a specific polyurethane to use; (2) each of Texin-990 and Pellethane-AE are biocompatible; (3) each of Texin-990, and Pellethane-AE have properties similar to the Tadros's preferred embodiment, ECDEL 9966; and (4) each of Texin-990 and Pellethane-AE have a lower Shore A hardness than ECDEL 9966 and therefore more comfortable for the patient. Thus, a POSITA would have seen a benefit to selecting Texin-990 or Pellethane-AE.

Using Texin-990 or Pellethane-AE to implement Stewart-'511 or Tadros's multilayer dental appliance would have merely combined prior art elements (Stewart-'511 or Tadros's multilayer appliance including a polyurethane with Texin-990 or Pellethane-AE) to yield predictable results (a multilayer dental appliance).

Starting from an embodiment of Tadros's multilayer dental appliance comprising ECDEL 9966, replacing ECDEL 9966 with Texin-990 or Pellethane-AE would have been a simple substitution of one known element (ECDEL 9966) for another (Texin-990 or Pellethane-AE) to obtain predictable results (multilayer dental appliance). A POSITA would have been motivated to make the substitution for the reasons given above, including because Texin-990 and Pellethane-AE are softer than ECDEL 9966 and therefore more comfortable for a patient.

Using Texin-990 or Pellethane-AE to implement Stewart-'511 or Tadros's multilayer dental appliance would have been obvious to try. There were a finite number of commercially available polyurethanes with which to implement Stewart-'511 or Tadros for a POSITA to select from among, and a POSITA would have tested Texin-990 and/or Pellethane-AE with a reasonable expectation of success for the reasons given above.

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A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination. *See* Section VII.B.1.c.i [Stewart-'511, Hinz, or Tadros Alone].

d) Combinations with the Co-Extrusion Reference

The '613 patent recites preparation of a multilayer polymer sheet comprising co-extruding different layers. '613 patent at claim 17 ("The method of claim 1, wherein the appliance comprises a co-extruded material.").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated to combine (1) the teachings of any of the prior art references cited in these invalidity contentions that disclose a multilayer polymer sheet, including without limitation, Kalili, with (2) the knowledge of a POSITA and/or teachings of any of the cited prior art references that describe preparation of a multilayer polymer sheet comprising co-extrusion.

(i) Kalili Alone

As an illustrative, non-limiting example, Kalili discloses this feature or at least render it obvious. For example, Kalili discloses laminating an inner and an outer layer. Kalili at [0074] ("The second repositioning appliance was fabricated from a polycarbonate sheet laminated with lower modulus polyurethane."). A POSITA understood that there are a limited number of ways to form a multilayer sheet, and that a commonly-practiced way to do so was co-extrusion. It would have been obvious to try forming Kalili's multilayer sheet via co-extrusion.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the multilayer sheet by co-extrusion. For example, a POSITA understood that co-extrusion was a widely practiced technique adapted for use with a variety of polymers.

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(ii) Chen

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings from the systems, methods, or articles described in Chen into one system, method, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Chen to use co-extrusion to form a multilayer sheet with (2) the teachings of Kalili of the need for a multilayer polymer sheet.

As explained above, Chen and Kalili are from the same field of endeavor of the Asserted Patents' alleged invention and are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references.

Chen and Kilili both teach the need to join a plurality of polymer sheets to form a multilayer sheet. *See, e.g.*, Chen at [0035] ("FIG. 5 illustrates cross-sectional view of a dental appliance 148 transforming shapes, in accordance with embodiments. The cross section view of the dental appliance 148 shows several layers, such as inner layers 150 and an outer layer 152."), [0021] ("The concave trough 102 may include a single or a plurality of polymeric material layers. In some embodiments, each layer may have shape memory materials, as discussed further herein. The layers may consist of similar and/or different materials. The shape memory materials may undergo a property change independent of one another or simultaneously. The layer or layers may also be made of a cross-linked polymer capable of undergoing a joint change in shape."); Kalili at claim 20 ("an outer layer laminated to the inner layer"), [0075] ("However, the level of stress was significantly lower using the laminated repositioning appliance 1702 as compared to the un-laminated repositioning appliance 1704."). Kalili describes laminated sheets,

[redacted]

but does not describe techniques for making laminated sheets. Accordingly, a POSITA would have been motivated to consult the prior art for techniques to form laminated sheets. Chen provides such a teaching. *See, e.g.*, Chen at [0031] ("The layers may be formed in various orientations and configurations to suit the modulus and application requirements. The layers may be formed by a process, such as thermoforming or similar process, such as co-extrusion, lamination, or any other process where layers are formed. The layers may be formed with cavities and indentations used as repositioning forces on the teeth.").

Combining Chen's teaching of co-extrusion to form Kalili's multilayer would have been obvious because it would have merely consisted of combining prior art elements according to known methods (co-extrusion) to yield predictable results (multilayer sheet). Doing so would have also been an application of a known technique (co-extrusion) to a known method, system, or article ready for improvement to yield predictable results. It would have also been obvious to try because there are a limited number of ways to form a sheet comprising multiple layers of polymers, and co-extrusion was a well-known technique for doing so.

To the extent that Plaintiff argues that Kalili's laminated sheet must be formed by a lamination process instead of co-extrusion, replacing lamination with co-extrusion would have been a simple substitution of one known technique (lamination) for another technique (co-extrusion) to obtain a predictable result (multilayer sheet).

A POSITA would have had a reasonable expectation of success in forming Kalili's multilayer sheet by co-extrusion. The technique was widely practiced and Chen shows that the technique is effective.

[redacted]

(iii) Wen-'558

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings from the systems, methods, or articles described in Wen-'558 into one system, method, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Wen-'558 to use co-extrusion to form a multilayer sheet with (2) the teachings of Kalili of the need for a multilayer polymer sheet.

As explained above, Wen-'558 and Kalili are from the same field of endeavor of the Asserted Patents' alleged invention and are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references.

Wen-'558 and Kilili both teach the need to join a plurality of polymer sheets to form a multilayer sheet. *See, e.g.*, Wen-'558 at [0189] ("Dental aligners may also be made having multiple layers (e.g., 2 or more layers). Multiple layers may allow the aligner to resist wear, and to be more comfortably (and accurately) worn by a user. Each layer may comprise a material (or a region of material) having different properties, (e.g., such as stiffness, elasticity, hardness, surface friction, hydrophobicity, etc.). Examples of aligners having such different layers are described below."); Kalili at claim 20 ("an outer layer laminated to the inner layer"), [0075] ("However, the level of stress was significantly lower using the laminated repositioning appliance 1702 as compared to the un-laminated repositioning appliance 1704."). Kalili describes laminated sheets, but does not describe techniques for making laminated sheets. Accordingly, a POSITA would have been motivated to consult the prior art for techniques to form laminated sheets. Wen-'558 provides such a teaching. *See, e.g.*, Wen-'558 at [0207]

[redacted]

("Figure 15 is a top view of a multilayer dental aligner 1610 comprising a first aligner layer 1620 and a second aligner layer 1630. The individual arch-shaped aligners maybe separated from one another. In some variations, the second layer is formed by a different method than the first layer. For example, the second layer maybe formed by extruding, dipping, coating, depositing, etc. onto the pre-formed first layer. In some variations, the first and second layer may be combined prior to forming over the tooth model and then (together) formed over the tooth model as described.").

Combining Wen's teaching of co-extrusion to form Kalili's multilayer would have been obvious because it would have merely consisted of combining prior art elements according to known methods (co-extrusion) to yield predictable results (multilayer sheet). Doing so would have also been an application of a known technique (co-extrusion) to a known method, system, or article ready for improvement to yield predictable results. It would have also been obvious to try because there are a limited number of ways to form a sheet comprising multiple layers of polymers, and co-extrusion was a well-known technique for doing so.

To the extent that Plaintiff argues that Kalili's laminated sheet must be formed by a lamination process instead of co-extrusion, replacing lamination with co-extrusion would have been a simple substitution of one known technique (lamination) for another technique (co-extrusion) to obtain a predictable result (multilayer sheet).

A POSITA would have had a reasonable expectation of success in forming Kalili's multilayer sheet by co-extrusion. The technique was widely practiced and Wen-'558 shows that the technique is effective.

[redacted]

e) Combinations with the Trim Reference

The Materials Patents recite a method of making a multilayer dental aligner comprising "trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner." *See, e.g.* '090 patent at claim 1. At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated to combine (1) the teachings of any of the prior art references cited in these invalidity contentions that disclose a method of making a multilayer dental aligner, including without limitation, Kalili and Tadros, with (2) the knowledge of a POSITA and/or teachings of any of the cited prior art references that describe trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner.

(i) Kalili or Tadros Alone

As an illustrative, non-limiting example, Kalili and Tadros disclose this feature or at least render it obvious. For example, Kalili and Tadros disclose forming a dental aligner by thermoforming a plastic sheet over a model of a patient's teeth. Kalili at [0053] ("These materials may range in thickness from 0.020 inch to 0.20 inch, depending upon the material's physical characteristics. In an aspect of the invention, repositioning appliance 300 may be 0.030 inch thick polycarbonate with a lower modulus inner lining which has been thermo vacuum-formed over a model 406 of a patient's teeth."); Tadros at [0069] ("After the manufacture of the sheet, it may be formed into an appliance for repositioning the teeth as detailed below. The forming of the appliance may be accomplished by process such as thermoforming, molding, and the like, which are discussed in detail below."), [0077]. A POSITA understood that thermoforming typically resulted in an excess portion of the polymer sheet that did not contribute to the appliance that needed to be cut away. Therefore, it would have been obvious to a POSITA

[redacted]

to trim such excess material, for example by cutting the excess material from the thermoformed sheet to form the dental aligner.

A POSITA would have had a reasonable expectation of success, and would have succeeded, in trimming the material by cutting it away. For example, a POSITA understood that the aligner materials described in Kalili and Tadros are thin polymer sheets comprising polymer layers that could be readily cut, for example by scissors, a milling machine, or by a laser.

(ii) Wrosz

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings from the systems, methods, or articles described in Wrosz with Kalili or Tadros into one system, method, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Wrosz to trim excess aligner material to form an aligner appliance with (2) the teachings of Kalili or Tadros to thermoform a multilayer sheet over a model of a patient's teeth.

Kalili, Tadros, and Wrosz are from the same or an overlapping field of endeavor of the Asserted Patents' alleged invention, which encompasses the field orthodontics, and more particularly to the design of dental positioning appliances. Kalili, Tadros, and Wrosz are reasonably pertinent to one or more supposed problems identified by the named inventors of the Materials Patents, including the supposed need for improved dental positioning appliances. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and devices.

As noted above, Kalili and Tadros teach the need for improved dental aligners and techniques including thermoforming a multilayer polymer sheet as part of a process for making dental aligners. A POSITA would therefore have been motivated to consult the prior art for

techniques to form finished dental aligners. Similar to Kalili and Tadros, Wrosz describes a process based on thermoforming and explains that a trimming system may be used to form a finished dental aligner. Wrosz at [0013] ("The apparatus may further include a laser-marking system to mark the workpiece following its removal from the workpiece operation chamber, and a trimming system, such as a multiple-axis CNC system, and preferably a 5-axis one, to trim the workpiece following its removal from the workpiece operation chamber."), [0015] ("Implementations of the method may include one or more of the following. The preparation of the first or second workpiece may include preheating or heating the first or second workpiece, respectively. This heating may occur at a temperature of between about 525 and 595° F. The same is true for the first or second mold. The method may further include moving a plug and the first workpiece into cooperative engagement. The method may further include marking the workpiece, such as by a laser-marking device, or trimming the workpiece."), [0034] ("The trimmer 54 removes the excess plastic from the aligner 136, and is typically a 5-axis CNC (computer-numerical-control) machine. Generally, a 5-axis machine is used although in some circumstances less may be employed. The CNC machine reads data from the NC file corresponding to the aligner, this NC file generated as noted above by the initial three-dimensional digitization and subsequent software analysis. [0035] After the plastic is trimmed, the mold is removed from the finished workpiece or aligner 136. This step generally requires human intervention, as the removal process is particularly difficult to achieve via automation. However, in some instances, this may also be performed. To assist in the removal, the mold and/or the aligner may be made with a release agent so as to ease separation. Such release agents may be, e.g., soap, Teflon®, or silicon, or other similar agents."). As a result, a POSITA would have seen a benefit (finished dental aligner) to utilizing Wrosz's method.

[redacted]

Furthermore, combining Wrosz's teaching of trimming with Kalili or Tradros's process for making dental aligners would have merely amounted to combining prior art elements (*inter alia*, thermoforming followed by trimming) according to known methods to yield predictable results (finished dental aligner). Doing so would have also amounted to simply using a known technique (trimming) to improve a similar process for making dental aligners in the same way. Combining Wrosz's teaching of trimming with Kalili or Tadros's process for making dental aligners would have also applied a known technique (trimming) to a Kalili or Tadros's process which was improvement to yield predictable results (finished dental aligner). It would have also been obvious to try, given that the excess material consisted of a thin polymer sheet that a POSITA would have known could be trimmed by cutting, for example.

The resulting combination would have been a finished dental aligner. A POSITA would have had a reasonable expectation of success, and would have succeeded, in forming the combination at least because cutting techniques were well-known and Wrosz specifically describes a cutting system used to prepare dental aligners following thermoforming.

2. Treatment Planning Patents

Prior art references rendering the asserted claims of the Treatment Planning Patents obvious, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions, alone or in combination with other references, are discussed below and included in Exhibits 444-01 through 444-06, 444-08 through 444-12, 444-14 through 444-28; Exhibits 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28; Exhibits 879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28; Exhibits 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28.. *See* Section VIII [Claim Charts]. Further reasons to combine the references identified in Exhibits 444-01 through 444-06, 444-08 through 444-12, 444-14

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through 444-28; Exhibits 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28; Exhibits 879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28; Exhibits 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28 include the nature of the problem being solved, the express, implied and inherent teachings of the prior art, the knowledge of persons of ordinary skill in the art, that such combinations would have yielded predictable results, and that such combinations would have represented known alternatives to a POSITA.

Non-limiting illustrative obviousness combinations are listed below (it should be understood that each listed combination can also include the knowledge of a POSITA).

[redacted]

Invalidity Grounds	Asserted Claims of the Treatment Planning Patents
Sachdeva Grounds: One or more of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia, alone or in combination with Sachdeva	'444 patent: 1, 12, 15, 26, 29, 40 '879 patent: 1, 9, 15, 20 '217 patent: 1, 11 '456 patent: 1, 4, 6, 8, 11-13, 17-19
Round-Tripping Grounds: Sachdeva Grounds alone or combined with one or more of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 (the "Round-Tripping References")	'444 patent: 1, 13, 27, 41 '879 patent: 1, 3, 4, 6-9, 11, 12, 14-17, 19, 20, 22, 23 '217 patent: 1, 3-8, 10, 11, 13-18, 20
Chishti-'929 Grounds: (a) Sachdeva Grounds alone or combined with Chishti-'929 and/or Chishti-'400 (b) Round-Tripping Grounds alone or combined with Chishti-'929 and/or Chishti-'400	'456 patent: 2, 5, 7-12, 14-16 '879 patent: 2, 10, 21 '217 patent: 2, 12
Thermoforming Grounds: Sachdeva Grounds alone or combined with Anderson, Tuncay, and/or Phan (the "Thermoforming References")	'217 patent: 8, 9, 18, 19 '879 patent: 4, 5, 12, 13, 17, 18, 23, 24 '456 patent: 6, 7, 15, 16
All-Equal Pattern Grounds: Chishti-'929 Grounds alone or combined with one or more of Tuncay, Nanda, and/or Chishti-'400 (the "All Equal References")	'444 patent: 7, 21, 35 '456 patent: 3

[redacted]

A Pattern Grounds: Chishti-'929 Grounds alone or combined with one or more of Tuncay, Giuseppe, and/or Chishti-'400 (the "A Pattern References")	'444 patent: 9, 10, 23, 24, 37, 38 '456 patent: 3
M Pattern Grounds: Chishti-'929 Grounds alone combined with one or more of Giuseppe, Tuncay, Roberts-Harry, and/or Chishti-'400 (the "M Pattern References")	'444 patent: 9, 10, 23, 24, 37, 38 '456 patent: 3
V Pattern Grounds: Chishti-'929 Grounds alone or combined with one or more of Roberts-Harry, Tuncay, and/or Chishti-'400 (the "V Pattern References")	'444 patent: 8, 22, 36 '456 patent: 3
Mid-line Shift Pattern Grounds: Chishti-'929 Grounds alone combined with one or more of Tuncay and/or Chishti-'400 (the "Mid-Line Pattern References")	'444 patent: 11, 25, 39 '456 patent: 3
Chishti-'929/Round-Tripping Grounds: Chishti-'929 Grounds alone or combined with one or more of the Round-Tripping References	'444 patent: 2-6, 14, 16-20, 28, 30-34, 42 '217 patent: 1-20 '879 patent: 1-24 '456 patent: 10, 12, 18, 19

a) Combinations With Sachdeva

The Treatment Planning Patents recite a treatment planning method of, means for, and computer readable medium with instructions for automatically adjusting the movement path of a tooth or teeth in response to determining that a collision will occur in the then-existing treatment path of the tooth or teeth. *See, e.g.*, '444 patent, claim 1 limitation 1[C] ("determining, by the host computer, an order of movement for each respective dental object such that the dental

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objects avoid colliding with or obstructing each other on their respective routes from said initial position to said desired final position"), claim 12 ("The computer-implemented method of claim 1, wherein, determining the order of movement step comprises staggering the movement of at least two dental objects"), claim 15 limitation 15 [C] ("means for determining an order of movement for each respective dental object such that the dental objects avoid colliding with each other on their respective routes from said initial position to said desired final position."), claim 26 ("wherein the means for determining the order of movement comprises means for staggering the movement of at least two dental objects"), claim 29 limitation 29[C] ("determine an order of movement for each respective dental object such that the dental objects avoid colliding with each other on their respective routes from said initial position to said desired final position"); claim 40 ("wherein the instructions to determining the order of movement, comprise instructions to stagger the movement of at least two dental objects"); '217 patent, claim 1 limitation 1[D] ("performing, by a computer processor, a first modification of the schedule of movement in response to the identifying, the first modification comprising: round-tripping the first dental object"), claim 11 limitation 11[D] ("perform a first modification of the schedule of movement in response to the identifying, the first modification comprising:"); '879 patent, claim 1 limitation 1[C] ("modifying, by one or more computer processors, the schedule of movement to avoid a collision or obstruction between two of the dental objects on their respective routes, the modifying comprising: delaying initial movement of one of the dental objects; and round-tripping one of the dental objects."), claim 9 limitation 9[C][i] ("modify the schedule of movement to avoid a collision or obstruction between two of the dental objects on their respective routes, the modifying comprising"), claim 15 limitation 15[C][i] ("modifying, by the one or more computer processors, the schedule of movement to avoid a collision or obstruction

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between two of the dental objects on their respective routes, the modifying comprising:"), claim 20 limitation 20[C][i] ("modify the schedule of movement to avoid a collision or obstruction between two of the dental objects on their respective routes, the modifying comprising:"); '456 patent, claim 1 limitation 1[D] ("performing a first modification of the schedule of movement in response to the identifying, the first modification of the schedule of movement modifying whether or not at least one of the dental objects move during at least one of the treatment stages; "), claim 4 ("wherein the determining the schedule of movement comprises analyzing, by a computer processor, the dental objects in their respective initial positions and respective final positions"), claim 6 ("further comprising producing a series of orthodontic appliances based at least on the modified schedule of movement, wherein each of the orthodontic appliances corresponds to a respective one of the treatment stage"), claim 8 limitation 8[D] ("performing a first modification of the schedule of movement in response to the identifying, wherein the first modification comprises delaying initial movement of the first of the dental objects;"), claim 11 limitation 11[D] ("performing a first modification of the schedule of movement in response to the identifying;"), claim 12 limitation 12[D] ("performing a first modification of the schedule of movement in response to the identifying"), claim 13 limitation 13[C] ("performing a first modification to the schedule of movement to avoid a collision or obstruction between a first dental object and a second dental object of the dental objects on their respective routes, the first modification of the schedule of movement modifying whether or not at least one of the dental objects move during at least one of the treatment stages"), claim 17 limitation 17[C] ("performing a first modification to the schedule of movement to avoid a collision or obstruction between a first dental object and a second dental object of the dental objects on their respective routes"), claim 18 limitation 18[C] ("performing a first modification to the schedule of

[redacted]

movement to avoid a collision or obstruction between a first dental object and a second dental object of the dental objects on their respective routes"), claim 19 limitation 19[C] ("performing a first modification to the schedule of movement to avoid a collision or obstruction between a first dental object and a second dental object of the dental objects on their respective routes").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for automatically avoiding collisions between patients' teeth as teeth are moved along their movement paths.

(i) Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia Alone

One or more of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Kuo to include these features. For example, Kuo recites "[h]aving both a beginning position and a final position for each tooth, the process next defines a tooth path for the motion of each tooth. In one embodiment, the tooth paths are optimized in the aggregate so that the teeth are moved in the quickest fashion with the least amount of round-tripping to bring the teeth from their initial positions to their desired final positions…. The tooth paths are segmented. The segments are calculated so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation. In this way, the end points of each path segment can constitute a clinically viable repositioning, and the aggregate of segment end points constitute a clinically viable sequence of tooth positions, so that moving from one point to the next in the sequence does not result in a collision of teeth." Kuo, 12:4-20. A

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POSITA reading this section, including optimizing tooth paths "in the aggregate," would at once envisage that this process could include iterating over multiple different tooth paths, where a tooth path that results in a collision is discarded and modified to avoid that collision in the next iteration. The explicit teaching of the tooth path being "discarded and modified to avoid that collision in the next iteration" further reinforces this, and would teach a POSITA that when a collision is detected, the next iteration can be modified to avoid that collision. Since Kuo teaches a computer-implemented process, a POSITA would understand that the collision avoidance step can be implemented automatically at least via the computer. Further, for example, Kuo also teaches redefining a tooth movement path, reciting "[i]f no impossible movements were required ("no" branch from step 620), the process transfers control to a path definition process (such as step 150, FIG. 2A) to redefine those parts of the treatment path having unacceptable aligners (step 630). This step can include both changing the increments of tooth motion, i.e., changing the segmentation, on the treatment path, changing the path followed by one or more teeth in the treatment path, or both." Kuo at 16:41-48. This passage would further reinforce that a tooth path can be redefined to avoid a collision, and since this process is implemented on a computer, a POSITA would understand that the collision avoidance can be implemented automatically.

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Rubbert-'568 to include these features. For example, Rubbert-'568 recites "Because the teeth are represented as complete three-dimensional virtual objects, it is possible to detect the collision between teeth or between teeth and brackets in the simulation of movement of teeth from the current to the target situation. The point cloud representing tooth objects defines a surface, when surfaces come in contact during the tooth movement a collision is simulated. This collision is detected by suitable collision detection algorithms. When the

[redacted]

collisions are detected, the user can be notified of the collision and resolve the conflict between teeth, for example by selecting one tooth as a primary tooth and moving that tooth first in an initial stage of treatment, and then moving the other tooth in a secondary stage of treatment." Rubbert-'568 at [0166]. A POSITA reading Rubbert-'568, specifically the teaching of a computer implemented method of visualizing teeth, detecting collisions, and redefining tooth movement to avoid the collision, would envisage the automatic avoidance of the collision instead of a user-implemented avoidance, given this process takes place on a computer. Further, Rubbert-'568 teaches the specific process to avoid the collision, namely "selecting one tooth as a primary tooth and moving that tooth first in an initial stage of treatment, and then moving the other tooth in a secondary stage of treatment," and therefore a POSITA would immediately understand an example of a rule to program as a computer-implemented, automatic, step to avoid a collision.

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Chishti-'511 to include these features. For example, Chishti-'511 recites "Having both a beginning position and a final position for each tooth, the process next defines a tooth path for the motion of each tooth. In one embodiment, the tooth paths are optimized in the aggregate so that the teeth are moved in the quickest fashion with the least amount of round-tripping to bring the teeth from their initial positions to their desired final positions. … The tooth paths are segmented. The segments are calculated so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation. In this way, the end points of each path segment can constitute a clinically viable repositioning, and the aggregate of segment end points constitute a clinically viable sequence of tooth positions, so that moving from one point to the next in the sequence does not result in a collision of teeth." Chishti

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’511 at 4:7-23. A POSITA reading this section, including optimizing tooth paths “in the aggregate,” would at once envisage that this process could include iterating over multiple different tooth paths, where a tooth path that results in a collision is discarded and modified to avoid that collision in the next iteration. The explicit teaching of the tooth path being “discarded and modified to avoid that collision in the next iteration” further reinforces this, and would teach a POSITA that when a collision is detected, the next iteration can be modified to avoid that collision. Since Chishti-’511 teaches a computer-implemented process, a POSITA would understand that the collision avoidance step can be implemented automatically at least via the computer. Further, for example, Chishti-’511 also teaches redefining a tooth movement path, reciting “[i]f no impossible movements were required (“no” branch from step 620), the process transfers control to a path definition process (such as step 150, FIG. 2A) to redefine those parts of the treatment path having unacceptable aligners (step 630). This step can include both changing the increments of tooth motion, i.e., changing the segmentation, on the treatment path, changing the path followed by one or more teeth in the treatment path, or both.” Chishti ’511 at 8:54-61. This passage would further reinforce that a tooth path can be redefined to avoid a collision, and since this process is implemented on a computer, a POSITA would understand that the collision avoidance can be implemented automatically.

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Treat, ClinCheck, SureSmile, and/or Insignia to include these features. Treat, ClinCheck, SureSmile, and Insignia are computer-implemented treatment planning products designed to calculate movement patterns for teeth, an objective of which is avoiding collisions of teeth during treatment. Since each of these products can detect, or enable a user to see, collisions of teeth, a POSITA would understand the basic principles to avoid a

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collision (e.g., stop one or both teeth from moving before collision or change direction before collision). A POSITA would also understand these basic principles can be implemented automatically, for example as rules in software. Since Treat, ClinCheck, SureSmile, and Insignia are software products, a POSITA would clearly understand that a feature to automatically avoid collisions is reasonable implementation.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia to incorporate these features. For example, all these references and products relate to computer-implemented methods of designing a movement path for teeth. After detecting a collision, a POSITA would immediately understand at least some options for avoiding the collision (e.g., slow movement of one or both teeth down, move one or both teeth in the mesial or labial direction, etc.). Given the references and products can be practiced as software, a POSITA would understand that additional software can be used to implement these basic collision avoidance options, and that, once implemented, the software can avoid collisions automatically. A POSITA would have been motivated to do so at least because using software can be faster and can avoid the need for human intervention.

(ii) Sachdeva

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Sachdeva with one or more of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia that

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collisions should be avoided with (2) the teachings of Sachdeva that such collisions can be avoided automatically.

Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, Insignia, and Sachdeva are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, Insignia, and Sachdeva are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need for increased automation of a tooth movement treatment planning process. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Sachdeva teaches automatically avoiding a collision that is detected in a movement path. *See, e.g.*, Sachdeva at 4:38-5:36. Sachdeva teaches a process for simulating tooth movement during treatment of an orthodontic patient, where the process can be "implemented as operational instructions, stored in memory, and executed by a processing module." *Id*. Sachdeva teaches that when a conflict (e.g., collision) is detected between two teeth, the process can resolve the conflict by selecting a priority tooth using several different criteria (e.g., whether the tooth is a foundation tooth, whether the collision is intra-arch or intra-arch, etc). *Id*. Sachdeva explains that manual planning of orthodontic treatment can result in "the quality of care var[ying] greatly from orthodontist to orthodontist," (*id*. at 1:57-59) and the need to "simulate[] tooth movement thereby enabling a scientific approach to orthodontics…and provide[] a more consistent treatment time," *id*. at 3:10-14.

[redacted]

A POSITA would have been motivated to implement Sachdeva's automatic collision avoidance in one or more of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia. Implementing Sachdeva's automatic collision avoidance would have followed the teaching, suggestion, or motivation in the prior art. For example, Sachdeva teaches that manual planning of orthodontic treatment can result in "the quality of care var[ying] greatly from orthodontist to orthodontist," (*id.* at 1:57-59) and the need to "simulate[] tooth movement thereby enabling a scientific approach to orthodontics…and provide[] a more consistent treatment time," *id.* at 3:10-14. A POSITA would understand that the methods taught in Sachdeva, including automatic collision avoidance, can enable a more robust and consistent approach to orthodontics, and therefore would have been motivated to implement this concept into the methods and processes taught in Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia.

Implementing Sachdeva's automatic collision avoidance in one or more of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia would merely have involved combining prior art elements according to known methods to yield predictable results. For example, a POSITA would know that they could combine the method of any of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia with an element from Sachdeva, automatic collision avoidance, and yield predictable results. Indeed, all of these references and products teach a computer implemented method for treatment planning, so a POSITA would understand the combination could be achieved using software. Further, Sachdeva teaches specific rules incorporated to automatically avoid a collision between teeth

[redacted]

(*see* Sachdeva at 4:38-5:36), so a POSITA would understand the types of rules to incorporate into Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia.

Implementing Sachdeva's automatic collision avoidance in one or more of Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia would also merely have involved simple substitution of one known element for another to obtain predictable results. For example, collision avoidance can be performed with alteration of a movement path using basic principles (e.g., slow movement of one or both teeth down, move one or both teeth in the mesial or labial direction, etc.). These simple rules can easily be implemented in a software algorithm, and doing so would produce predictable results based on the rules entered.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia to incorporate these features from Sachdeva. Indeed, all of these references and products teach computer implemented methods for treatment planning, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine software development practices. Further, Sachdeva teaches specific rules incorporated to automatically avoid a collision between teeth (*see* Sachdeva, 4:38-5:36), so a POSITA would understand the types of rules to incorporate into Kuo, Rubbert-'568, Chishti-'511, Chishti-'400, Chishti-'929, Tuncay, Muhammad, Treat, ClinCheck, SureSmile, and/or Insignia.

[redacted]

b) Combinations With Chishti-'929 and/or Chishti-'400

The Treatment Planning Patents recite a treatment planning method of, means for, and/or computer readable medium with instructions for, selecting a movement pattern, analyzing a movement distance, manufacturing aligners, and slowing movement. *See, e.g.*, '456 patent, claim 2 ("wherein the schedule of movement is determined by selection by a user"), claim 5 ("further comprising determining, by the host computer, an optimal number of stages for the order of movement of the dental objects"), claim 7 ("wherein the determining the order of movement, comprises, ordering the movement of the dental objects to form an all-equal pattern"), claim 8 ("wherein the determining the order of movement step comprises ordering the movement of the dental objects to form a V-shaped pattern"); claim 9 ("wherein the determining the order of movement comprises: ordering the movement of the dental objects to form an A-shaped pattern"), claim 10 ("wherein determining the order of movement step comprises ordering the movement of the dental objects to form an M-shaped pattern"), claim 11 ("wherein, determining the order of movement step comprises ordering the movement of the dental objects to form a mid-line shift pattern"); claim 12 ("wherein, determining the order of movement step comprises staggering the movement of at least two dental objects"), claim 14 ("wherein determining the schedule of movement comprises selecting a movement pattern from a plurality of predetermined movement patterns"), claim 15 ("means for determining an order of movement for each respective dental object such that the dental objects avoid colliding with each other on their respective routes from said initial position to said desired final position"), claim 16 ("wherein the means for determining the order of movement comprises: (a) means for determining a route each respective dental object will move to achieve its respective final position; (b) means for determining the distance each respective dental object will move to

[redacted]

achieve its respective final position; and (c) means for determining a rate at which each respective dental object will move along its respective route""); '879 patent, claim 2 ("wherein determining the schedule of movement comprises selecting a movement pattern from a plurality of predetermined movement patterns"), claim 10 ("wherein determining the schedule of movement comprises selecting a movement pattern from a plurality of predetermined movement patterns"), claim 21 ("wherein determining the schedule of movement comprises selecting a movement pattern from a plurality of predetermined movement patterns"); '217 patent claim 2 ("wherein the movement pattern is selected by a user"), claim 12 ("wherein the movement pattern is selected by a user").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for round-tripping one or more of a patient's teeth.

(i) Any of the Sachdeva Grounds or the Round-Tripping Grounds Alone

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to implement the Sachdeva Grounds or the Round-Tripping Grounds to include these features. For example, each of these references or products relates to planning the movement path for teeth during a course of treatment. A POSITA would understand that there are several discrete and recurring cases of malocclusion or other dental issues (e.g., underbite). Facing a recurring issue, a POSITA would understand that a predetermined pattern of tooth movement can be well suited for treating the same issue, and thus select such a predetermined pattern of movement when faced with a malocclusion (or other dental issue) that the pattern is well suited to treat. A POSITA would do so at least because selecting a predetermined pattern is more efficient than creating a movement pattern anew each time.

[redacted]

(ii) Chishti-'929 and/or Chishti-'400

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Chishti-'929 and/or Chishti-'400 with one or more of the Sachdeva Grounds or the Round-Tripping Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Sachdeva Grounds or the Round-Tripping Grounds concerning treatment planning methods, systems, and articles with (2) the teachings of Chishti-'929, and/or Chishti-'400 that a treatment path can be selected from a database of preferred treatment paths.

The Sachdeva Grounds, the Round-Tripping Grounds, Chishti-'929, and Chishti-'400 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Sachdeva Grounds, the Round-Tripping Grounds, Chishti-'929, and Chishti-'400 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need reduce the time and resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Chishti-'929 teaches that a treatment path can be selected from a database of preferred treatment paths. *See* Chishti-'929 at 33:21-34:3. Chishti-'400 also teaches systems and methods to prepare a malocclusion treatment plan "by selecting a tooth treatment pattern from a library of predetermined tooth treatment patterns; and generating the malocclusion treatment plan implementing the selected tooth treatment pattern." *See* Chishti-'400 at Abstract. These preferred treatment paths can be based on exemplary tooth arrangements, where the

[redacted]

preferred treatment paths are those that have proved "most successful with each general class of initial tooth arrangements." *See* Chishti-'929 at 33:21-34:3. A POSITA would understand that there are several recurring or "exemplary" tooth arrangements and that using previously successful treatment plans as a basis for treatment plans of the same arrangements in the future would be a potentially more efficient way to develop a treatment plan. Therefore, a POSITA would have been motivated to modify the teachings of the Sachdeva Grounds or the Round-Tripping Grounds with the teachings of Chishti-'929 and/or Chishti-'400 to select a treatment path from a database of preferred treatment paths.

Modifying the teachings of any of the Sachdeva Grounds or the Round-Tripping Grounds with the teachings of Chishti-'929 and/or Chishti-'400 as discussed above, would also merely involve combining prior art elements according to known methods to yield predictable results, and would merely involve the use of a known technique to improve similar methods in the same way.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Sachdeva Grounds or the Round-Tripping Grounds alone or in combination with Chishti-'929 and/or Chishti-'400 to incorporate these features. Indeed, all of these references and products teach computer implemented methods for treatment planning, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine software development practices. Further, a POSITA would understand that several recurring classes of initial tooth arrangements exist, and understand the generally successful treatment paths or patterns that can be sued to address these recurring arrangements. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Sachdeva Grounds or the Round-Tripping

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Grounds alone or in combination with Chishti-'929 and/or Chishti-'400 to incorporate these features.

c) Combinations with the Thermoforming References

The Treatment Planning Patents recite thermoforming an orthodontic appliance or an orthodontic aligner over a positive mold. *See, e.g.*, '217 patent at claim 8 ("further comprising producing a series of orthodontic appliances based at least on the modified schedule of movement "), claim 9 ("thermoforming a respective one of the orthodontic appliances over each of the respective positive molds"), claim 18 ("further cause at least one of the one or more processors to produce a series of orthodontic appliances based at least on the modified schedule of movement "), claim 19 ("thermoforming a respective one of the orthodontic appliances over each of the respective positive molds"); '879 patent at claim 4 ("further comprising manufacturing at least two orthodontic aligners "), claim 5 ("thermoforming an orthodontic aligner over each respective positive mold"), claim 12 ("further cause at least one of the one or more computer processors to control manufacture of at least two orthodontic aligners "), claim 13 ("thermoforming an orthodontic aligner over each of the respective positive molds"), claim 17 ("further comprising manufacturing at least two orthodontic aligner"), claim 18 ("thermoforming an orthodontic aligner over each of the respective positive molds"), claim 23 (", further cause at least one of the one or more computer processors to control manufacture of at least two orthodontic aligners"), claim 24 ("thermoforming a respective one of the orthodontic aligners over each of the respective positive molds"); '456 patent at claim 6 (", further comprising producing a series of orthodontic appliances based at least on the modified schedule of movement "), claim 7 ("thermoforming a respective one of the orthodontic appliances over each of the respective positive molds"), claim 15 ("further comprising manufacturing at least two

[redacted]

orthodontic aligners"), claim 16 ("thermoforming an orthodontic aligner over each respective positive mold").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to combine treatment planning software with a known manufacturing process, like thermoforming, for manufacturing one or more orthodontic appliances for use in the treatment planned using the treatment planning software.

(i) Any of the Sachdeva Grounds Alone

Any of the Sachdeva Grounds, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Sachdeva Grounds to include these features. For example, all of the Sachdeva Grounds teach software for planning orthodontic treatment for a patient. A POSITA would understand that in order to implement a treatment plan for a patient, one or more orthodontic appliances would need to be manufactured for use with the patient's teeth. Moreover, a POSITA would have been well aware of the benefits of thermoforming for manufacturing such orthodontic appliances. Therefore, using thermoforming when manufacturing a dental appliance would have been obvious to a POSITA.

(ii) Anderson, Tuncay, and/or Phan

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Anderson with one or more of the Sachdeva Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Sachdeva Grounds concerning treatment planning methods, systems, and articles that are used for planning orthodontic treatment, with

[redacted]

(2) the teachings of Anderson, Tuncay, and/or Phan that orthodontic aligners can be thermoformed to correspond to stages along a predetermined tooth movement path.

The Sachdeva Grounds and Anderson, Tuncay, and Phan are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths and manufacturing orthodontic aligners for teeth during the course of orthodontic or dental treatment. The Sachdeva Grounds and Anderson, Tuncay, and Phan are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need to manufacture orthodontic aligners for each stage of movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As an illustrative, non-limiting example, Anderson discloses that a thermoformed orthodontic appliance "helps to limit the discomfort of failed treatment, lower the cost to doctors and labs, and promote better treatment results." Anderson at [0032]. Anderson also discloses that its approach for thermoforming "allows improvement of as much as less than half the distortion as flat sheets experience." Anderson at [0014].

Modifying the teachings of any of the Sachdeva Grounds with the teachings of Anderson, Tuncay, and/or Phan, as discussed above, would merely involve combining prior art elements according to known methods or simple substitution of one known element for another to yield predictable results. For example, a POSITA would understand the Sachdeva Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and that orthodontic appliances are manufactured to implement the treatment plan. A POSITA would also understand Anderson, Tuncay, and/or Phan teaches that one way to

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manufacture orthodontic appliances corresponding to multiple stages of a treatment plan is to thermoform an orthodontic appliance over a positive mold. A POSITA would therefore take the general teachings of the Sachdeva Grounds, and the specific teaching of Anderson, Tuncay, and/or Phan that it was known to thermoform orthodontic appliances to correspond to treatment stages, and combine these teachings to arrive at the claimed features, at least under Plaintiff's apparent infringement theories.

Modifying the teachings of any of the Sachdeva Grounds with the teachings of Anderson, Tuncay, and/or Phan, as discussed above, would also merely be obvious to try and a POSITA would have had a reasonable expectation of success in making this combination. Indeed, all of these references and products teach methods for treatment planning where the treatment plan is used to manufacture an orthodontic appliance, so a POSITA would have understood the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Sachdeva Grounds teach that stages should be used for moving teeth and that orthodontic appliances corresponding to each stage can be manufactured, and a POSITA would have known that one common method of manufacturing was thermoforming, which could be used for thermoforming an orthodontic appliance over a positive mold, as taught in Anderson, Tuncay, and/or Phan. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Sachdeva Grounds alone or in combination with Anderson, Tuncay, and/or Phan to incorporate these features.

d) Combinations with All Equal Pattern References

The Treatment Planning Patents recite ordering the movement of teeth (or dental objects) in an all-equal pattern. *See, e.g.*, '444 patent at claim 7 ("The computer-implemented method of

[redacted]

claim 1, wherein the determining the order of movement, comprises, ordering the movement of the dental objects to form an all-equal pattern"), claim 21 ("The system of claim 15, wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects in an all-equal pattern"), claim 35 ("machine-readable medium of claim 29, wherein the instructions to determine the order of movement comprise instructions to order the movement of the dental objects to form an all-equal pattern"); '456 patent, claim 3 ("method of claim 1, wherein the schedule of movement includes one of an all-equal pattern, an A-shaped pattern, a V-shaped pattern, a mid-line shift pattern, or a M-shaped pattern."). At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for automatically avoiding collisions between patients' teeth as teeth are moved along their movement paths.

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for using movement patterns including an all-equal pattern.

(i) Any of the Chishti-'929 Grounds Alone

Any of the Chishti-'929 Grounds, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Chishti-'929 Grounds to include these features. For example, all of the Chishti-'929 Grounds teach treatment planning methods for organizing the movement of teeth. A POSITA would understand that an all-equal pattern can represent the most direct and efficient pattern for moving teeth where complex movements are not required, since the pattern

[redacted]

only entails starting and stopping movement of all teeth at the same times. Therefore, using an all-equal pattern would have been obvious to a POSITA.

(ii) Tuncay, Nanda, and/or Chishti-'400

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Tuncay, Nanda, and/or Chishti-'400 with one or more of the Chishti-'929 Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Chishti-'929 Grounds concerning treatment planning methods, systems, and articles that can include the selection of a predetermined tooth movement pattern with (2) the teachings of Tuncay, Nanda, and/or Chishti-'400 that a predetermined tooth movement pattern can include an all-equal pattern.

The Chishti-'929 Grounds and Tuncay, Nanda, and/or Chishti-'400 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Chishti-'929 Grounds and Tuncay, Nanda, and/or Chishti-'400 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need reduce the time and resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Tuncay, Nanda, and/or Chishti-'400 teaches that a predetermined tooth movement pattern can include an all-equal pattern. Tuncay teaches "[c]ases can be staged using a low-anchorage pattern or a high-anchorage pattern. This is determined based on the information contained in the doctor's prescription and diagnosis form, as well as the internal

staging protocols that the technicians follow." Tuncay at CC_ALGN_00001192. Tuncay further teaches "[a] low-anchorage staging pattern, also known as an equal staging pattern or an "X" pattern, occurs when all the teeth move concurrently throughout the sequence (Figs 12-9a and 12-9b)." *Id*. Fig 12-9b from Tuncay is reproduced here:

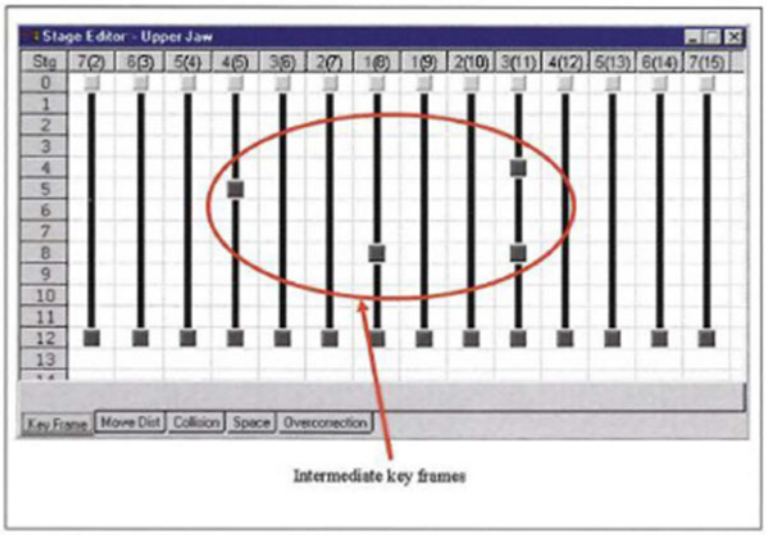


FIG 12-9b Adjusting at intermediate stages to avoid collisions.

Id. A POSITA reading Tuncay and viewing Tuncay, Fig 12-9b would understand that Tuncay teaches an all-equal pattern, as Tuncay teaches an "equal pattern" where "all the teeth move concurrently throughout the sequence. *Id*.; *see also* '444 patent at 7:40-41 ("each tooth in an 'all-equal' pattern is configured to be moved at the same time and for the same number of stages."), Fig. 3. A POSITA would understand that an all-equal pattern, as described in Tuncay, is a preferred treatment path taught to address common initial teeth arrangements such as Type 1 space closure cases. *See* Tuncay at CC_ALGN_00001192.

As another example, Nanda teaches that an orderly sequence of treatment stages is most efficient. *See* Nanda at 11. A POSITA reading Nanda would understand that one of the simplest solutions to treatment planning is to move all of the teeth at once, which would result in an all-equal pattern.

[redacted]

As another example, Chishti-'400 teaches "a computer-implemented method to prepare a malocclusion treatment plan includes selecting a tooth treatment pattern from a library of predetermined tooth treatment patterns," including an "all equal movement pattern. Chishti-'400 at [0012]-[0013]. A POSITA reading Chishti-'400 would understand that a preferred pattern for treating, for example, simple malocclusion without too many constraints may be moving all teeth in a given group at the same time, which would result in an all-equal pattern. Chishti-'400 at [0150].

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay, Nanda, and/or Chishti-'400, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Chishti-'929 Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and using a treatment path or pattern from a database of preferred treatment paths to do so. A POSITA would also understand Tuncay, Nanda, and/or Chishti-'400 teaches that one such pattern is an all-equal pattern. A POSITA would therefore take the general teachings of the Chishti-'929 Grounds, and the specific teaching of Tuncay, Nanda, and/or Chishti-'400 that one movement pattern is an all-equal pattern, and combine these teachings to arrive at the claimed features, at least under Plaintiff's apparent infringement theories.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay, Nanda, and/or Chishti-'400, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. For example, a POSITA reading Chishti-'929 would understand that one pattern for treatment is "the most linear treatment path between the initial and final positions" for all teeth. *See* Chishti-'929 at 33:21-

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34:3. If this teaching is different from teaching an all-equal pattern, a POSITA would understand that using an all-equal pattern, as taught by Tuncay, Nanda, and/or Chishti-'400, was also a known method of moving teeth from an initial to a final position. Therefore, a POSITA would understand that substituting the "most linear path" teaching of Chishti-'929 with the all-equal pattern of Tuncay, Nanda, and/or Chishti-'400, which would both be known methods, would have predictable results.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay, Nanda, and/or Chishti-'400, as discussed above, would also merely be obvious to try and have a reasonable expectation of success. For example, a POSITA faced with a basic case of malocclusion would understand that one of the most basic approaches to planning the movement of teeth would be to move them all at the same time. This would result in an all-equal pattern. Thus, a POSITA would consider the all-equal pattern obvious to try.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Tuncay, Nanda, and/or Chishti-'400 to incorporate these features. Indeed, all of these references and products teach methods for treatment planning where the teeth are moved from an initial position to a final position, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Chishti-'929 Grounds teach that a predetermined pattern can be used to plan the movement of teeth, and that the all-equal pattern is a basic pattern which is also taught directly in Tuncay, Nanda, and/or Chishti-'400. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the

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Chishti-'929 Grounds alone or in combination with Tuncay, Nanda, and/or Chishti-'400 to incorporate these features.

e) Combinations with A Pattern Reference

The Treatment Planning Patents recite ordering the movement of teeth (or dental objects) in an A pattern. *See, e.g.*, '444 patent at claim 9 ("The computer-implemented method of claim 1, wherein the determining the order of movement comprises: ordering the movement of the dental objects to form an A-shaped pattern"), claim 10 ("wherein determining the order of movement step comprises ordering the movement of the dental objects to form an M-shaped pattern"), claim 23 ("The system of claim 15, wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects in an A-shaped pattern"), claim 24 ("wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects to form an M-shaped pattern"), claim 37 ("The machine-readable medium of claim 29, wherein the instructions to determine the order of movement, comprise instructions to order the movement of the dental objects to form an A-shaped pattern"), claim 38 ("wherein the instructions to determine the order of movement comprise instructions to order the movement of the dental objects to form an M-shaped pattern"); '456 patent at claim 3 ("The method of claim 1, wherein the schedule of movement includes one of an all-equal pattern, an A-shaped pattern, a V-shaped pattern, a mid-line shift pattern, or a M-shaped pattern").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for using movement patterns including an A-shaped pattern.

[redacted]

(i) Any of the Chishti-'929 Grounds Alone

Any of the Chishti-'929 Grounds, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Chishti-'929 Grounds to include these features. For example, all of the Chishti-'929 Grounds teach treatment planning methods for organizing the movement of teeth. A POSITA would understand that an A pattern can help close the gaps between teeth and reduce the undesirable pain and the risk of anchorage loss the patient might experience caused by too many teeth moving at the same time, as it allows teeth having different positions on the arch to start moving at different stages. Therefore, using an A pattern would have been obvious to a POSITA.

(ii) Tuncay, Giuseppe, and/or Chishti-'400

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Tuncay, Giuseppe, and/or Chishti-'400 with one or more of the Chishti-'929 Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Chishti-'929 Grounds concerning treatment planning methods, systems, and articles that can include the selection of a predetermined tooth movement pattern with (2) the teachings of Giuseppe and/or Chishti-'400 that a predetermined tooth movement pattern can include an A pattern.

The Chishti-'929 Grounds and Tuncay, Giuseppe, and/or Chishti-'400 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Chishti-'929 Grounds and Tuncay, Giuseppe, and/or Chishti-'400 are

reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need reduce the time and resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Tuncay, Giuseppe, and/or Chishti-'400 disclose that a predetermined tooth movement pattern can include an A pattern. Giuseppe teaches an orthodontic treatment plan for a patient "with a diastema of over 10 mm between the upper incisors associated with widespread microdontia in both arches, especially in the upper laterals." Giuseppe, PDF page 8, book page 129. As part of the treatment plan, "a .016 x 022 SS with an elastic power chain was used on both arches to close the spaces" "[f]ollowing torque establishment." *Id*. Figs. 10-36 to 10-38 from Giuseppe are reproduced here:

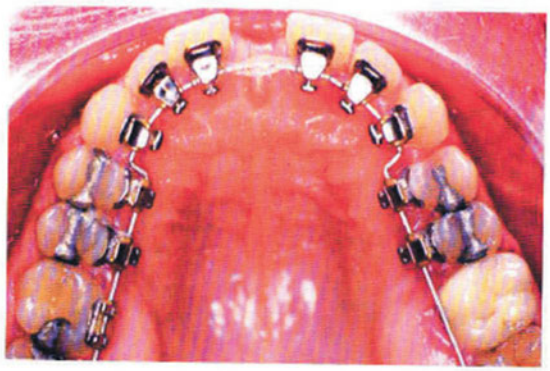


Fig 10-36 Leveling.

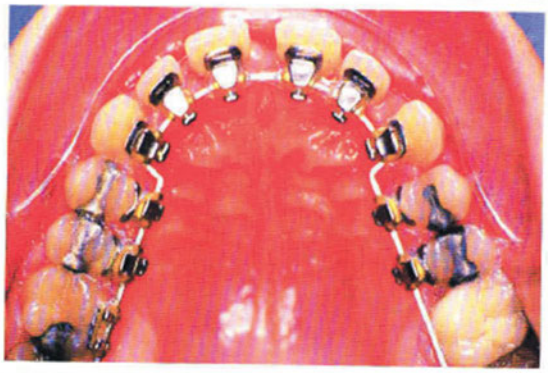


Fig 10-37 Space closing.

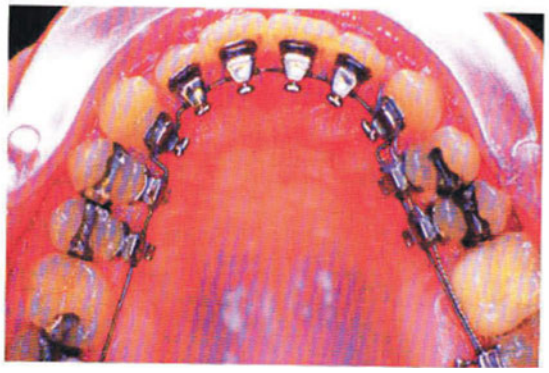


Fig 10-38 Detailing.

A POSITA would understand that Giuseppe teaches an A pattern, as Giuseppe teaches a teeth movement pattern where certain teeth have similar positions on the arch were moved beginning at the same stage and the most anterior-positioned teeth were moved first. *See* '444 patent at 7:49-61 ("In accordance with one exemplary embodiment of the invention, the A-shaped pattern provides that teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position. Moreover, the A-shaped pattern begins by moving the most anterior-positioned teeth (e.g., the incisors, or teeth in positions 1 and/or 2) then sequentially moving the next posterior-

[redacted]

positioned teeth until all of the teeth reach their final position. In accordance with an exemplary embodiment, the next posterior-positioned teeth are not scheduled to begin moving until at least approximately the half-way stage of its respective anterior-positioned teeth.”). Additionally, Chishti-’400 teaches that implementing the A-shaped movement pattern includes “sequentially moving each tooth from an incisor tooth toward a molar tooth” and that, for this pattern, “the front the front tooth is moving ahead of the next tooth.” Chishti-’400 at [0150]. A POSITA would understand that an A pattern, as described in Tuncay, Giuseppe, and/or Chishti-’400, is a preferred treatment path taught to address, for example, initial teeth arrangements with big diastema. *See* Giuseppe, PDF page 8, book page 129.

Modifying the teachings of any of the Chishti-’929 Grounds with the teachings of Tuncay, Giuseppe, and/or Chishti-’400, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Chishti-’929 Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and using a treatment path or pattern from a database of preferred treatment paths to do so. A POSITA would also understand Tuncay, Giuseppe, and/or Chishti-’400 teaches that one such pattern is an A pattern. A POSITA would therefore take the general teachings of the Chishti-’929 Grounds, and the specific teaching of Tuncay, Giuseppe, and/or Chishti-’400 that one movement pattern is an A pattern, and combine these teachings to arrive at the claimed features, at least under Plaintiff’s apparent infringement theories.

Modifying the teachings of any of the Chishti-’929 Grounds with the teachings of Tuncay, Giuseppe, and/or Chishti-’400, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. For example, a

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POSITA reading Chishti-'929 would understand that the treatment plan is limited by orthodontic constraints, such as "the minimum and maximum distances allowed between adjacent teeth at any given time, the maximum linear or rotational velocity at which a tooth should move, [and] the maximum distance over which a tooth should move between treatment steps." *See* Chishti-'929 at 32:11-14. A POSITA would understand that using an A pattern, as taught by Tuncay, Giuseppe, and/or Chishti-'400, was also a known method of moving teeth from an initial to a final position. Therefore, a POSITA would understand that substituting the "most linear path" teaching of Chishti-'929 with the A pattern of Tuncay, Giuseppe, and/or Chishti-'400, which would both be known methods, would have predictable results.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay, Giuseppe, and/or Chishti-'400, as discussed above, would also merely be obvious to try and have a reasonable expectation of success. For example, a POSITA faced with certain patient conditions, such as a case of diastema, would understand that reducing patient's pain level by prioritizing closing the gap between certain teeth and starting teeth movement in stages may be part of a preferred treatment plan. Thus, a POSITA would consider the A pattern obvious to try.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Giuseppe and/or Chishti-'400 to incorporate these features. Indeed, all of these references and products teach methods for treatment planning where the teeth are moved from an initial position to a final position, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Chishti-'929 Grounds teach that a predetermined pattern can be used to plan the movement of teeth, and that the A pattern is a basic pattern which is also taught directly in

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Tuncay, Giuseppe, and/or Chishti-'400. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Tuncay, Giuseppe, and/or Chishti-'400 to incorporate these features.

f) Combinations with the V Pattern References

The Treatment Planning Patents recite ordering the movement of teeth (or dental objects) in a V pattern. *See, e.g.*, '444 patent at claim 8 ("The computer-implemented method of claim 1, wherein the determining the order of movement step comprises ordering the movement of the dental objects to form a V-shaped pattern"), claim 22 ("The system of claim 15, wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects in a V-shaped pattern"), claim 36 ("The machine-readable medium of claim 29, wherein the instructions to determine the order of movement comprise instructions to order the movement of the dental objects to form a V-shaped pattern"); '456 patent at claim 3 ("The method of claim 1, wherein the schedule of movement includes one of an all-equal pattern, an A-shaped pattern, a V-shaped pattern, a mid-line shift pattern, or a M-shaped pattern").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for using movement patterns including a V-shaped pattern.

(i) Any of the Chishti-'929 Grounds Alone

Any of the Chishti-'929 Grounds, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

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As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Chishti-'929 Grounds to include these features. For example, all of the Chishti-'929 Grounds teach treatment planning methods for organizing the movement of teeth. A POSITA would understand that a V pattern can help reduce the undesirable pain and the risk of anchorage loss the patient might experience caused by too many teeth moving at the same time when the patient has over-crowding teeth, as it begins by moving the most posterior-positioned teeth and then sequentially moving the next anterior-positioned teeth. Therefore, using a V pattern would have been obvious to a POSITA.

(ii) Roberts-Harry, Tuncay, and/or Chishti-'400

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Roberts-Harry, Tuncay, and/or Chishti-'400 with one or more of the Chishti-'929 Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Chishti-'929 Grounds concerning treatment planning methods, systems, and articles that can include the selection of a predetermined tooth movement pattern with (2) the teachings of Roberts-Harry, Tuncay, and/or Chishti-'400 that a predetermined tooth movement pattern can include a V pattern.

The Chishti-'929 Grounds and Roberts-Harry, Tuncay, and/or Chishti-'400 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Chishti-'929 Grounds and Roberts-Harry, Tuncay, and/or Chishti-'400 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need reduce the time and

[redacted]

resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Roberts-Harry teaches that a predetermined tooth movement pattern can include a V pattern. Roberts-Harry teaches that treatment "can be accomplished by distal movement of the molars" when the upper arch is overcrowded. Roberts-Harry at 685. Fig 4 from Roberts-Harry is reproduced here:

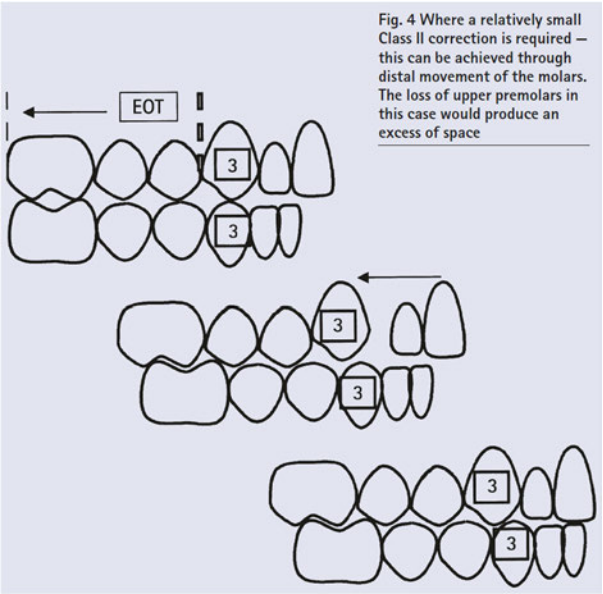


Fig. 4 Where a relatively small Class II correction is required – this can be achieved through distal movement of the molars. The loss of upper premolars in this case would produce an excess of space

Id. A POSITA reading Roberts-Harry and viewing the figure above would understand that Roberts-Harry teaches a V pattern, as Roberts-Harry teaches a pattern that moves the molars first and then anterior-positioned teeth. *Id.*; '444 patent at 9:19-23 ("the "V-shaped" pattern begins by moving the most posterior-positioned teeth (e.g., the molars, or teeth in position 7 and/or 8) then sequentially moving the next anterior-positioned teeth until all of the teeth reach their final position."). A POSITA would understand that a V pattern, as described in Roberts-Harry, is a preferred treatment path taught to address common initial teeth arrangements such as buccal occlusion cases.

[redacted]

As another example, Tuncay teaches that a "'V' pattern [] is used . . . in any case where the posterior teeth need to be distalized." Tuncay at 109-10. A POSITA reading Tuncay would understand that a V pattern is a preferred treatment path for cases where "the relief of crowding on the anterior teeth requires that the space is created by the distal movement," as taught by Tuncay.

As another example, Chishti-'400 teaches a "V-shape movement pattern" that "includes sequentially moving each tooth from a molar tooth toward an incisor tooth." Chishti-'400 at [0013]. A POSITA reading Tuncay would understand that a V pattern is a preferred treatment path for patients with over-crowding teeth.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Roberts-Harry, Tuncay, and/or Chishti-'400, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Chishti-'929 Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and using a treatment path or pattern from a database of preferred treatment paths to do so. A POSITA would also understand Roberts-Harry, Tuncay, and/or Chishti-'400 teaches that one such pattern is a V pattern. A POSITA would therefore take the general teachings of the Chishti-'929 Grounds, and the specific teaching of Roberts-Harry, Tuncay, and/or Chishti-'400 that one movement pattern is a V pattern, and combine these teachings to arrive at the claimed features, at least under Plaintiff's apparent infringement theories.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Roberts-Harry, Tuncay, and/or Chishti-'400, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. A POSITA

[redacted]

would understand that using a V pattern, as taught by Roberts-Harry, Tuncay, and/or Chishti-'400, was also a known method of moving teeth from an initial to a final position. Therefore, a POSITA would understand that substituting the "most linear path" teaching of Chishti-'929 with the V pattern of Roberts-Harry, Tuncay, and/or Chishti-'400, which would both be known methods, would have predictable results.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Roberts-Harry, Tuncay, and/or Chishti-'400, as discussed above, would also merely be obvious to try and have a reasonable expectation of success. For example, a POSITA faced with, for example, a case of buccal occlusion would understand that reducing patient's pain level by prioritizing distal movement to create space for more anterior teeth may be part of a preferred treatment plan. Thus, a POSITA would consider the V pattern obvious to try.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Roberts-Harry, Tuncay, and/or Chishti-'400 to incorporate these features. Indeed, all of these references and products teach methods for treatment planning where the teeth are moved from an initial position to a final position, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Chishti-'929 Grounds teach that a predetermined pattern can be used to plan the movement of teeth, and that the V pattern is a basic pattern which is also taught directly in Roberts-Harry, Tuncay, and/or Chishti-'400. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Roberts-Harry, Tuncay, and/or Chishti-'400 to incorporate these features.

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g) Combinations with the M Pattern References

The Treatment Planning Patents recite ordering the movement of teeth (or dental objects) in an M pattern. *See, e.g.*, '444 patent at claim 9 ("wherein the determining the order of movement comprises: ordering the movement of the dental objects to form an A-shaped pattern "), claim 10 ("The computer-implemented method of claim 1, wherein determining the order of movement step comprises ordering the movement of the dental objects to form an M-shaped pattern"), claim 23 ("wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects in an A-shaped pattern"), claim 24 ("The system of claim 15, wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects to form an M-shaped pattern"), claim 37 ("wherein the instructions to determine the order of movement, comprise instructions to order the movement of the dental objects to form an A-shaped pattern"), claim 38 ("The machine-readable medium of claim 29, wherein the instructions to determine the order of movement comprise instructions to order the movement of the dental objects to form an M-shaped pattern"); '456 patent at claim 3 ("The method of claim 1, wherein the schedule of movement includes one of an all-equal pattern, an A-shaped pattern, a V-shaped pattern, a mid-line shift pattern, or a M-shaped pattern").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for using movement patterns including an M-shaped pattern.

(i) Any of the Chishti-'929 Grounds Alone

Any of the Chishti-'929 Grounds, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

[redacted]

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Chishti-'929 Grounds to include these features. For example, all of the Chishti-'929 Grounds teach treatment planning methods for organizing the movement of teeth. A POSITA would understand that an M pattern can help reduce the undesirable pain the patient might experience caused by too many teeth moving at the same time when the patient has gaps between posterior teeth and anterior teeth, as it begins by moving the bicuspids and then sequentially moving the adjacent anterior and/or adjacent posterior teeth. Therefore, using an M pattern would have been obvious to a POSITA.

(ii) Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 with one or more of the Chishti-'929 Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Chishti-'929 Grounds concerning treatment planning methods, systems, and articles that can include the selection of a predetermined tooth movement pattern with (2) the teachings of Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 that a predetermined tooth movement pattern can include an M pattern.

The Chishti-'929 Grounds and Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Chishti-'929 Grounds and Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed

need reduce the time and resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Giuseppe, Roberts-Harry, Tuncay, and Chishti-'400 each teaches that a predetermined tooth movement pattern can include an M pattern. For example, Tuncay teaches a "reciprocal anchorage" pattern that requires mesial movement of teeth to close space between posterior teeth and anterior teeth, which would result in an M pattern. *See* Tuncay at 110, Fig 12-10b. As another example, Chishti-'400 teaches selecting treatment plan from "a library of treatment patterns," including an "M-shaped movement pattern." Chishti-'400 at [0013]. A POSITA reading Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 would understand that an M pattern is a preferred treatment path for patients having gaps between posterior teeth and anterior teeth.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Chishti-'929 Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and using a treatment path or pattern from a database of preferred treatment paths to do so. A POSITA would also understand Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 teaches that one such pattern is an M pattern. A POSITA would therefore take the general teachings of the Chishti-'929 Grounds, and the specific teaching of Roberts-Harry and/or Chishti-'400 that one movement pattern is an M pattern, and combine these teachings to arrive at the claimed features, at least under Plaintiff's apparent infringement theories.

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Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. A POSITA would understand that using an M pattern, as taught by Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400, was also a known method of moving teeth from an initial to a final position. Therefore, a POSITA would understand that substituting the "most linear path" teaching of Chishti-'929 with the M pattern of Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400, which would both be known methods, would have predictable results.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400, as discussed above, would also merely be obvious to try and have a reasonable expectation of success. For example, a POSITA faced with, for example, a case having gaps between posterior teeth and anterior teeth would understand that one potential treatment may include reducing patient's pain level by prioritizing closing the gaps and then sequentially moving the adjacent anterior and/or adjacent posterior teeth. Thus, a POSITA would consider the M pattern obvious to try.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 to incorporate these features. Indeed, all of these references and products teach methods for treatment planning where the teeth are moved from an initial position to a final position, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Chishti-'929 Grounds teach that a predetermined pattern can be used to plan the movement of teeth, and that the M pattern is a

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basic pattern which is also taught directly in Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Giuseppe, Roberts-Harry, Tuncay, and/or Chishti-'400 to incorporate these features.

h) Combinations with Mid-Line Pattern Reference

The Treatment Planning Patents recite ordering the movement of teeth (or dental objects) in a mid-line pattern. *See, e.g.*, '444 patent at claim 11 ("The computer-implemented method of claim 1, wherein, determining the order of movement step comprises ordering the movement of the dental objects to form a mid-line shift pattern"), claim 25 ("The system of claim 15, wherein the means for determining the order of movement comprises means for ordering the movement of the dental objects in a mid-line shift pattern"), claim 39 ("The machine-readable medium of claim 29, wherein the instructions to determine the order of movement comprise instructions to order the movement of the dental objects a mid-line shift pattern"); '456 patent, claim 3 ("method of claim 1, wherein the schedule of movement includes one of an all-equal pattern, an A-shaped pattern, a V-shaped pattern, a mid-line shift pattern, or a M-shaped pattern.").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for using movement patterns including a mid-line shift pattern.

(i) Any of the Chishti-'929 Grounds Alone

Any of the Chishti-'929 Grounds, alone or in combination, discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

[redacted]

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Chishti-'929 Grounds to include these features. For example, all of the Chishti-'929 Grounds teach treatment planning methods for organizing the movement of teeth. A POSITA would understand that a mid-line pattern treatment pattern can help reduce the undesirable pain the patient might experience caused by too many teeth moving at the same time when the patient's teeth are off-centered, as it begins by moving one side of the patient's arch to center then then progressively shifting the remaining teeth. Therefore, using a mid-line pattern treatment pattern would have been obvious to a POSITA.

(ii) Tuncay and/or Chishti-'400

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Tuncay and/or Chishti-'400 with one or more of the Chishti-'929 Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Chishti-'929 Grounds concerning treatment planning methods, systems, and articles that can include the selection of a predetermined tooth movement pattern with (2) the teachings of Tuncay and/or Chishti-'400 that a predetermined tooth movement pattern can include a mid-line pattern.

The Chishti-'929 Grounds and Tuncay and/or Chishti-'400 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Chishti-'929 Grounds and Tuncay and/or Chishti-'400 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need reduce the time and resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for

someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, Tuncay teaches that a predetermined tooth movement pattern may include a mid-line pattern. Tuncay teaches a "Midline Shift" pattern that requires asymmetric movement of teeth to move one side of the arch first in order to shift the mid-line. *See* Tuncay at 110, Fig 12-10b. As another example, Chishti-'400 teaches selecting treatment plan from "a library of treatment patterns," including a "symmetric staircase pattern" and an "asymmetric staircase pattern." Chishti-'400 at [0013]. A POSITA reading Tuncay and/or Chishti-'400 would understand that a mid-line pattern may be, in some cases, a preferred treatment path, such as for some patients with off centered teeth.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay and/or Chishti-'400, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Chishti-'929 Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and using a treatment path or pattern from a database of preferred treatment paths to do so. A POSITA would also understand Tuncay and/or Chishti-'400 teaches that one such pattern is a mid-line pattern. A POSITA would therefore take the general teachings of the Chishti-'929 Grounds, and the specific teaching of Tuncay and/or Chishti-'400 that one movement pattern is a mid-line pattern, and combine these teachings to arrive at the claimed features, at least under Plaintiff's apparent infringement theories.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay and/or Chishti-'400, as discussed above, would also merely involve simple substitution of one

known element for another to obtain predictable results. For example, a POSITA reading Chishti-'929 would understand that one pattern for treatment is "the most linear treatment path between the initial and final positions" for all teeth. *See* Chishti-'929 at 33:21-34:3. If this teaching is different from teaching a mid-line pattern, a POSITA would understand that using a mid-line pattern, as taught by Tuncay and/or Chishti-'400, was also a known method of moving teeth from an initial to a final position. Therefore, a POSITA would understand that substituting the "most linear path" teaching of Chishti-'929 with the mid-line pattern of Tuncay and/or Chishti-'400, which would both be known methods, would have predictable results.

Modifying the teachings of any of the Chishti-'929 Grounds with the teachings of Tuncay and/or Chishti-'400, as discussed above, would also merely be obvious to try and have a reasonable expectation of success. For example, a POSITA faced with an off-centered case would understand that one potential approach for reducing patient's pain level may include moving teeth on one side of the arc to shift centerline and then progressively shifting the remaining teeth, as part of a potential treatment plan. Thus, a POSITA would consider the mid-line pattern obvious to try.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Tuncay and/or Chishti-'400 to incorporate these features. Indeed, all of these references and products teach methods for treatment planning where the teeth are moved from an initial position to a final position, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Chishti-'929 Grounds teach that a predetermined pattern can be used to plan the movement of teeth, and that the mid-line pattern is a basic pattern which is also taught

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directly in Tuncay and/or Chishti-'400. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Chishti-'929 Grounds alone or in combination with Tuncay and/or Chishti-'400 to incorporate these features.

i) Combinations with the Round-Tripping References

The Treatment Planning Patents recite round tripping at least one dental object during the teeth movement process. *See, e.g.*, '444 patent at claim 1 limitation 1[C] ("determining, by the host computer, an order of movement for each respective dental object such that the dental objects avoid colliding with or obstructing each other on their respective routes from said initial position to said desired final position through at least one of staggering and round-tripping of at least one dental object"), claim 13 ("The computer-implemented method of claim 1, wherein determining the order of movement step comprises, round tripping at least one dental object"), claim 27 ("The system of claim 15, wherein the means for determining the order of movement comprises means for round tripping at least one dental object."), claim 41 ("The system of claim 15, wherein the means for determining the order of movement comprises means for round tripping at least one dental object"); '879 patent at claim 1 limitation 1[C] ("modifying, by one or more computer processors, the schedule of movement to avoid a collision or obstruction between two of the dental objects on their respective routes, the modifying comprising: delaying initial movement of one of the dental objects; and round-tripping one of the dental objects"), claim 3 ("further comprising recalculating at least one of the respective routes based on the modified schedule of movement"), claim 4 ("further comprising manufacturing at least two orthodontic aligners, each of the orthodontic aligners corresponding to a respective one of the treatment stages"), claim 6 ("wherein the round-tripping comprises: moving a first of the dental objects away from the respective route of a second of the dental

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objects; and moving the first dental object toward its respective final position after the second dental object has sufficiently traversed its respective route to avoid the collision"), claim 7 ("wherein the round-tripping comprises: moving a first of the dental objects away from the respective route of a second of the dental objects; and moving the first dental object toward its previous position"), claim 8 ("determining, by one or more computer processors, a respective minimum number of treatment stages for each of the dental objects; and selecting, by one or more computer processors, a largest of the respective minimum numbers of treatment stages as the total number of the treatment stages"), claim 9 ("round-tripping one of the dental objects"), claim 11 ("further cause at least one of the one or more computer processors to recalculate at least one of the respective routes based on the modified schedule of movement"), claim 12 ("further cause at least one of the one or more computer processors to control manufacture of at least two orthodontic aligners, each of the orthodontic aligners corresponding to a respective one of the treatment stages"), claim 14 ("the determining of the total number of the treatment stages comprises: determining a respective minimum number of treatment stages for each of the dental objects; and selecting a largest of the respective minimum numbers of treatment stages as the total number of the treatment stages"), claim 15 ("the schedule of movement of the first dental object by moving the first dental object out of the path of the second dental object, and once the second dental object has moved sufficiently, moving the first dental object back to the first dental object previous position before proceeding to a desired final position of the first dental object"), claim 16 ("further comprising recalculating at least one of the respective routes based on the modified schedule of movement"), claim 17 ("further comprising manufacturing at least two orthodontic aligners, each of the orthodontic aligners corresponding to a respective one of the treatment stages"), claim 19 ("the determining of the

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schedule of movement comprises determining a total number of the treatment stages; and the determining of the total number of the treatment stages comprises: determining, by one or more computer processors, a respective minimum number of treatment stages for each of the dental objects; and selecting, by one or more computer processors, a largest of the respective minimum numbers of treatment stages as the total number of the treatment stages"), claim 20 ("altering, after the determining that the altered schedule of movement still results in a collision or obstruction, the schedule of movement by round-tripping the first dental object"), claim 22 ("when executed by the one or more computer processors, further cause at least one of the one or more computer processors to recalculate at least one of the respective routes based on the modified schedule of movement"), claim 23 ("further cause at least one of the one or more computer processors to control manufacture of at least two orthodontic aligners, each of the orthodontic aligners corresponding to a respective one of the treatment stages"); '217 patent at claim 1 limitation 1[D](" performing, by a computer processor, a first modification of the schedule of movement in response to the identifying, the first modification comprising: round-tripping the first dental object), claim 3 ("wherein the selecting comprises analyzing, by a computer processor, the dental objects in their respective initial and final positions"), claim 4 ("wherein the analyzing comprises determining, by a computer processor, a respective distance needed to move each of the dental objects from its respective initial position to its respective final position"), claim 5 ("the second modification comprising slowing or stopping movement of the first dental object during one or more of the treatment stages following a previous one of the treatment stages in which the first dental object moved"), claim 6 ("the third modification comprising round-tripping the first dental object"), claim 7 ("the second modification comprising round-tripping the first dental object"), claim 8 ("comprising producing a series of

orthodontic appliances based at least on the modified schedule of movement, wherein each of the orthodontic appliances corresponds to a respective one of the treatment stages"), claim 10 ("performing, by a computer processor, a second modification of the schedule of movement in response to the identifying, the second modification comprising one or more of: delaying initial movement of the first dental object; and slowing or stopping movement of the first dental object during one or more of the treatment stages following a previous one of the treatment stages during which the first dental object moved"), claim 11 ("round-tripping the first dental object"), claim 13 ("wherein the selecting comprises analyzing the dental objects in their respective initial and final positions"), claim 14 ("herein the analyzing comprises determining a respective distance needed to move each of the dental objects from its respective initial position to its respective final position"), claim 15 ("determine that the first modification does not avoid a collision between the first and second dental objects; and perform, after the determining, a second modification of the schedule of movement, the second modification comprising slowing or stopping the movement of the first dental object during at least one of the treatment stages following a previous one of the treatment stages during which the first dental object moved"), claim 16 (", the third modification comprising round-tripping the first dental object moved"), claim 17 ("the second modification comprising round-tripping the first dental object"), claim 18 ("wherein the instructions, when executed by the one or more processors, further cause at least one of the one or more processors to produce a series of orthodontic appliances based at least on the modified schedule of movement, wherein each of the orthodontic appliances corresponds to a respective one of the treatment stages"), claim 20 ("the second modification comprising one or more of: delaying initial movement of the first dental object; and slowing or stopping movement of the first dental object during one or more of the treatment stages

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following a previous one of the treatment stages during which the first dental object moved").

At least under Plaintiff's apparent infringement theories, a POSITA would have been motivated and found it obvious to improve treatment planning software to include functionality for round-tripping one or more of a patient's teeth.

(i) Any of the Sachdeva Grounds Alone or the Chishti-'929 Grounds Alone

Any of the Sachdeva Grounds or the Chishti-'929 Grounds, alone or in combination, discloses and/or renders obvious these features. See Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Sachdeva Grounds or the Chishti-'929 Grounds to include these features, at least under Plaintiff's apparent infringement theories. For example, all of the Sachdeva Grounds and the Chishti-'929 Grounds teach treatment planning methods for organizing the movement of teeth. A POSITA would understand that treatment planning methods may, for some patients, involve round tripping, in which a first tooth is moved out of the path of a second tooth, and once the second tooth has moved sufficiently, the first tooth is moved back to its previous position before proceeding to a desired final position of that first tooth. At least under Plaintiff's apparent infringement theories, using round tripping would have been known and obvious to a POSITA.

(ii) DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in one or more of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 with one or more of the Sachdeva Grounds or the Chishti-'929 Grounds into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Sachdeva Grounds or the Chishti-'929 Grounds

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concerning treatment planning methods, systems, and articles that can include predetermining tooth movement paths, including to avoid collisions, with (2) the teachings of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 that a predetermined tooth movement path can include round tripping.

The Sachdeva Grounds, the Chishti-'929 Grounds, and DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 are from the same or an overlapping field of endeavor of the Treatment Planning Patents' alleged inventions, which encompasses the field of designing movement paths for teeth during the course of orthodontic or dental treatment. The Sachdeva Grounds, the Chishti-'929 Grounds, and DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 are reasonably pertinent to one or more supposed problems identified by the named inventors of the Treatment Planning Patents, including the supposed need reduce the time and resources needed to stage the movement of teeth during an alignment treatment. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

As noted above, DeAngelis, Begg, Becker, Kuroda, and Chishti-'027 each teaches that a predetermined tooth movement path can include round tripping. As a non-limiting example, DeAngelis teaches that root apices may be "round tripped" during a treatment plan. *See* DeAngelis at Fig. 1. Begg teaches that canine toots may be first moved away from their final positions and then "tipped back" to the get to the final desired positions. *See* Begg at 36-138, Figs. 16-19. Becker teaches that "retranspos[ing teeth] to their ideal positions" from their transposed positions "may be the preferred line of treatment" in some situations. Becker at 191. Kuroda teaches "[u]pper canine-premolar transposition" where one tooth is first moved to clear

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the path for another tooth and then transposed into its proper position. *See* Kuroda at 475-76, Fig. 3. Figure 3 from Kuroda, page 474 is reproduced here:

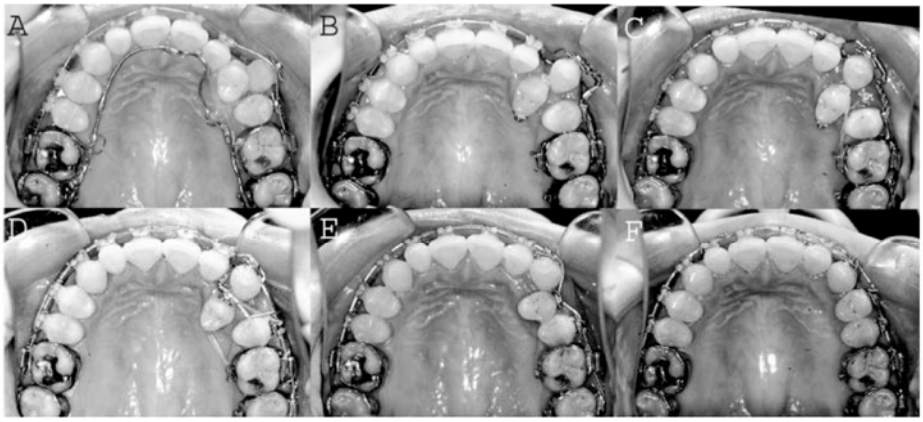


FIGURE 3. Photographs taken during the treatment progress. (A) Starting of the transposition. (B) Six months later. (C) Twelve months later. (D) Twenty-four months later. (E) Twenty-eight months later. (F) Thirty-eight months later.

Id. As another non-limiting example, Chishti-'027 teaches "specifying a sequence of tooth movements" where the stages of tooth movement are determined by, among other things, the distances between teeth. *See, e.g.*, Chishti-'027 at Figs. 8-9, [0009], [0066-0067]. A POSITA reading DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 would understand that DeAngelis, Begg, Becker, Kuroda, and Chishti-'027 each teaches round tripping. '444 patent at 12:51-55 ("'Round-tripping' is the technique of moving a first tooth out of the path of a second tooth, and once the second tooth has moved sufficiently, moving the first tooth back to its previous position before proceeding to a desired final position of that first tooth."). A POSITA would understand that round tripping, as described in DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027, can be used in treatment planning to address issues such as teeth collision.

Modifying the teachings of any of the Sachdeva Grounds or the Chishti-'929 Grounds with the teachings of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Sachdeva Grounds or the

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Chishti-'929 Grounds teach treatment planning methods for planning the movement of teeth from an initial position to a final position, and avoiding collisions between teeth to do so. A POSITA would also understand DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 teaches that one way to avoid collisions between teeth is to use round tripping. A POSITA would therefore take the general teachings of the Sachdeva Grounds or the Chishti-'929 Grounds, and the specific teaching of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 that round tripping can be used to avoid collisions between teeth, and combine these teachings to arrive at the claimed features, at least under Plaintiff's apparent infringement theories.

Modifying the teachings of any of the Sachdeva Grounds or the Chishti-'929 Grounds with the teachings of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027, as discussed above, would have been obvious to try to would have merely involve simple substitution of one known element for another to obtain predictable results. For example, a POSITA reading Chishti-'929 would understand that one way to plan a tooth's path for treatment is "the most linear treatment path between the initial and final positions" for all teeth. *See* Chishti-'929 at 33:21-34:3. But in some instances, this treatment path will result in collisions, and a POSITA would understand that using round tripping, as taught by DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027, was a known method of avoiding collisions between teeth moving from an initial to a final position. Therefore, a POSITA would understand that for at least some teeth, substituting the "most linear path" teaching of Sachdeva Grounds or the Chishti-'929 Grounds with the round tripping technique of DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027, which would both be known methods, would have predictable results.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying any of the Sachdeva Grounds or the Chishti-'929 Grounds alone or in

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combination with DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027 to incorporate these features. Indeed, all of these references and products teach methods for treatment planning where collisions are avoided as the teeth are moved from an initial position to a final position, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic practices. Further, a POSITA would understand that the Sachdeva Grounds or the Chishti-'929 Grounds teach that collisions should be avoided while moving teeth, and that round tripping is a technique for collision avoidance which is also taught directly in DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027. Therefore, a POSITA would have had a reasonable expectation of success, and would have succeeded, in modifying any of the Sachdeva Grounds or the Chishti-'929 Grounds alone or in combination with DeAngelis, Begg, Becker, Kuroda, and/or Chishti-'027.

3. The '936 Patent

Prior art references rendering the asserted claims of the '936 Patents obvious, at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions, alone or in combination with other references, are discussed below and included in Exhibits 936-01 through 936-09 and 936-11 through 936-21. *See* Section VIII [Claim Charts]. Further reasons to combine the references identified in Exhibits 936-01 to 936-09 and 936-11 to 936-21 include the nature of the problem being solved, the express, implied and inherent teachings of the prior art, the knowledge of persons of ordinary skill in the art, that such combinations would have yielded predictable results, and that such combinations would have represented known alternatives to a POSITA.

Non-limiting illustrative obviousness combinations are listed below (it should be understood that each listed combination can also include the knowledge of a POSITA).

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Invalidity Grounds	Asserted Claims of the '936 Patent
Boerjes Grounds: One or more of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D alone or combined with one or more of Geng and/or Kriveshko-'494	1, 4-6, 9-11, 12, 14-17, 19
RMC Grounds: Boerjes Grounds alone or combined with one or more of Rubbert-'217, Marshall, and/or Chishti-'850 ("RMC Grounds")	8, 10
Babayoff Grounds I: (a) Boerjes Grounds alone or combined with Babayoff-065 (b) RMC Grounds alone or combined with Babayoff-065	2-3, 7, 13, 17-20
Paley Grounds: (a) Paley alone or combined with one or more of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 (b) Any of the combinations in (a) combined with Boerjes	1, 4-6, 8-12, 14-16
Babayoff Grounds II: Paley Grounds alone or combined with Babayoff-065	2-3, 7, 13, 17-20

a) Boerjes Grounds

The '936 Patent requires selecting and removing portions from a three-dimensional model of a patient's teeth, and updating the model using second scan data. *See, e.g.*,

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- ’936 patent at claim 1 (“receive user input defining a portion of the model to be removed; remove, from the displayed model, a removed surface portion of the model to be removed according to the user input;… replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity;”);

- *Id*. at claim 4 (“wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to register the received second scan data with the model”);

- *Id*. at claim 5 (“wherein the received second scan data is registered with the model by aligning identifying data of the received second scan data with corresponding parts of the model.”);

- *Id*. at claim 6 (“wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model.”);

- *Id*. at claim 9 (“receiving user input via the displayed model demarcating a portion of the model to be retained and a surface portion of the model to be replaced; … replacing at least a portion of the surface portion of the model to be replaced according to the user input using at least a portion of the second scan data of the patient's teeth including the physically changed portion;”);

- *Id*. at claim 11 (“wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data comprises registering the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model”);

- *Id*. at claim 12 (“wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data further comprises stitching the at least the portion of the second scan data with the model”);

- *Id*. at claim 14 (“wherein the model of the patient's teeth comprises a tooth preparation having a finish line, wherein a portion of the finish line is obscured or distorted, and wherein the physical change results in the finish line not being obscured or distorted.”);

- *Id*. at claim 15 (“wherein the model of the patient's teeth comprises a tooth preparation that accurately represents a surface of a physical preparation of the patient, and wherein the method further comprises analyzing the tooth preparation of the model to determine whether the surface of the physical preparation is

suitable for a dental prosthesis; and wherein the physical change is a physical modification of the surface of the physical preparation of the patient.");

- *Id*. at claim 16 ("wherein the dental prosthesis comprises a dental crown and wherein the tooth preparation analysis comprises analysis of the model with respect to a virtual model of an opposing dentition of an opposite jaw to determine whether the tooth preparation would result in an inadequate structure for the dental crown.");

- *Id*. at claim 17 ("receive user input defining a portion of the model to be removed; after receiving the user input, remove, from the displayed model, a removed surface portion of the model to be removed according to the user input; after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner; register the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model; replace at least a portion of the removed surface portion of the model using at least a portion of the received second scan data of the patient's teeth;"); and

- *Id*. at claim 19 ("wherein the user input defining portion of the model to be removed is received by the mouse or the touch screen display"), claim 20 ("wherein the portion of the removed surface portion of the model is replaced using at least the portion of the received second scan data by registering the second scan data with the model.").

At least under Plaintiff's apparent infringement theories, a POSITA would have known and been motivated to improve a system for scanning a patient's teeth to generate a 3D model by modifying it to include functionality for selecting a portion of the 3D model, obtaining updated scan data corresponding to the selected portion, and updating the 3D model with the updated scan data.

(i) Any of Boerjes, Geng, Kriveshko-'494, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D Alone

Any of Boerjes, Geng, Kriveshko-'494, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D alone discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

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As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D to include these features. For example, all of Boerjes, Geng, Kriveshko-'494, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D teach tools and/or techniques for updating a three-dimensional model of a patient's teeth after an initial scan. A POSITA would understand that techniques for updating three-dimensional models using additional scan data would have been a beneficial tool to update a three-dimensional model of a patient's teeth to, for example, rescan an area where there were "scan deficiencies…. [or] irregularities in one or more occlusal surfaces requiring further preparation" (Boerjes at [0041]) such as "preparation requir[ing] refining or added reduction" (Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76). Therefore, techniques for updating three-dimensional models using additional scan data would have been obvious to a POSITA.

(ii) Geng and/or Kriveshko-'494

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D with one or more of Geng and/or Kriveshko-'494 into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D concerning orthodontic methods, systems, and articles that can include an intraoral scanner, with (2) the teachings of Geng and/or Kriveshko-'494 for updating a model of the patient's teeth.

Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and Kriveshko-'494 are from the same or an overlapping field of endeavor of the '936 Patent's alleged invention, which encompasses the field of scanning a patient's teeth during the course of

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orthodontic or dental treatment. Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and Kriveshko-'494 are reasonably pertinent to one or more supposed problems identified by the named inventors of the '936 Patent, including the supposed need to rescan areas of a patient's intraoral cavity where the virtual model was "partially obscured or incomplete [such as by agents or material in the patient's intraoral cavity including blood and saliva], or … [where] part of [a] physical item [such as a tooth] needs to be subsequently modified." '936 patent at 2:12-22; *see id*. at 2:1-11. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

Modifying the teachings of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D with the teachings of Geng and/or Kriveshko-'494, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand Boerjes teaches tools and/or techniques for "edit[ing] the three-dimensional representation" (Boerjes at [0077]), "for manipulating a three-dimensional representation of dentition" (Boerjes at [0208]), for "remov[ing] unwanted or unneeded areas" (Boerjes at [0208]), and for "identif[ying] … regions of a prepared tooth surface requiring additional preparation or reduction, or regions of a digital model requiring additional or supplemental scanning due to incomplete, erroneous, or potentially erroneous data" (Boerjes at [0196]). As another example, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D each teach techniques for updating three-dimensional models using additional scan data. *See, e.g.*, Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76 ("If the preparation requires refining or added reduction, then I can make needed changes and re-scan the quadrant."); Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010) (Beginning Bates No. CC_ALGN_00003676) at 325 ("At

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this point, the clinician has free reign to take any additional scans and the software will automatically add these scans to the virtual casts and re-render the image."), 326 ("At times, more scans may be required and the operator is able to add these additional scans. The operator then steps around the arch form and overlapping data is merged to create a virtual cast that will be rendered on the screen."), 327 ("As images are captured, a 3-D cast is generated on the screen in real time and the operator is able to rotate the cast in all directions to visualize the completeness of data capture. In the event a specific area of the model does not have adequate data, a varying color will appear on the monitor informing the operator to acquire more data at a given location."); Sachdeva, S*ureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001) (Beginning Bates No. CC_ALGN_00003083) at 247 ("During the initial appointment, a quick scan of the dentition can be taken to visually demonstrate the patient's needs …. A full OraScan is taken during the records appointment, integrated with conventional photographs and x-rays, and entered into an electronic patient record. OraScan Image Processing Software combines the captured images into an accurate, three-dimensional representation of the dentition, which can be viewed at the SureSmile workstation from a wide variety of perspectives.").

A POSITA would also understand that Geng and/or Kriveshko-'494 teach ways to correct scan deficiencies and update a three-dimensional model (e.g., after further preparation to a tooth). A POSITA would be motivated to combine the teachings of these references to efficiently create accurate and up-to-date models of patients' teeth.

Modifying the teachings of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D with the teachings of Geng and/or Kriveshko-'494, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable

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results. For example, a POSITA reading Boerjes would understand that Boerjes teaches tools and/or techniques for "edit[ing] the three-dimensional representation" (Boerjes at [0077]), "for manipulating a three-dimensional representation of dentition" (Boerjes at [0208]), and for "remov[ing] unwanted or unneeded areas" (Boerjes at [0208]), and for "add[ing] or supplement[ing] scanning due to incomplete, erroneous, or potentially erroneous data" (Boerjes at [0196]). As another example, a POSITA reading Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D would understand that each of the products teaches techniques for updating three-dimensional models using additional scan data. *See, e.g.*, Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76; Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010) (Beginning Bates No. CC_ALGN_00003676) at 325-27; Sachdeva, S*ureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001) (Beginning Bates No. CC_ALGN_00003083) at 247. A POSITA would understand that Geng and/or Kriveshko-'494 taught known methods of updating a three-dimensional model of a patient's teeth. A POSITA would understand supplementing the techniques taught in Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D with the teachings of Geng and/or Kriveshko-'494, which would both be known methods, would have predictable results.

Modifying the teachings of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D with the teachings of Geng and/or Kriveshko-'494, as discussed above, would also merely be obvious to try and have a reasonable expectation of success. For example, a POSITA faced with the teachings of Geng and/or Kriveshko-'494 would understand that they could be used to update a three-dimensional model of a patient's teeth since it was well known in the art that a three-dimensional model of a patient's teeth could be updated using later-acquired scan

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data. *See, e.g.*, Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76; Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010) (Beginning Bates No. CC_ALGN_00003676) at 325-27; Sachdeva, S*ureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001) (Beginning Bates No. CC_ALGN_00003083) at 247. Thus, a POSITA would consider this approach obvious to try.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, and/or E4D with Geng and/or Kriveshko-'494 to incorporate these features. Indeed, all of these references and products teach tools for updating three-dimensional models of teeth, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic and engineering practices.

b) Combinations with Rubbert-'217, Marshall, and/or Chishti-'850

The '936 Patent requires indicating a portion of a three-dimensional model of a patient's teeth that is selected for updating. *See, e.g.*,

- '936 patent at claim 8 ("wherein the computer readable medium further includes instructions that when executed by the computer system, cause the computer system to: mark, on the displayed model, the user input defined portion after receiving the user input and before removing the removed surface portion of the model.");
- *Id*. at claim 10 ("further comprising marking an area on the displayed model associated with the received user input.").

At least under Plaintiff's apparent infringement theories, a POSITA would have known and been motivated to improve a system for scanning a patient's teeth to generate a 3D model by modifying it to include functionality for indicating a selected portion of the 3D model, obtaining

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updated scan data corresponding to the selected portion, and updating the 3D model with the updated scan data.

(i) Any of the Boerjes Grounds Alone

Any of the Boerjes Grounds alone discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify any of the Boerjes Grounds to include these features. For example, all of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 teach tools for updating three-dimensional model of a patient's teeth. A POSITA would understand that such tools could be used to, for example, update a portion of the model where there were "scan deficiencies …. [or] irregularities in one or more occlusal surfaces requiring further preparation" (Boerjes at [0041]) such as "preparation requir[ing] refining or added reduction" (Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76).

(ii) Rubbert-'217, Marshall, and/or Chishti-'850

In addition, as an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in the Boerjes Grounds with one or more of Rubbert-'217, Marshall, and/or Chishti-'850 into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Boerjes Grounds concerning orthodontic methods, systems, and articles that can include an intraoral scanner, with (2) the teachings of Rubbert-'217, Marshall, and/or Chishti-'850 that describe techniques for indicating areas of a scan for updating.

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The Boerjes Grounds and Rubbert-'217, Marshall, and/or Chishti-'850 are from the same or an overlapping field of endeavor of the '936 Patent's alleged invention, which encompasses the field of scanning a patient's teeth during the course of orthodontic or dental treatment. The Boerjes Grounds and Rubbert-'217, Marshall, and/or Chishti-'850 are reasonably pertinent to one or more supposed problems identified by the named inventors of the '936 Patent, including the supposed need to delineate and remove portions of a virtual model that were "partially obscured or incomplete [such as by agents or material in the patient's intraoral cavity including blood and saliva], or … [where] part of [a] physical item [such as a tooth] needs to be subsequently modified." '936 patent at 2:12-22; *see id*. at 2:1-11. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

Modifying the teachings of the Boerjes Grounds with the teachings of Rubbert-'217, Marshall, and/or Chishti-'850, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Boerjes Grounds teach tools and/or techniques for updating, editing, and/or removing portions from three-dimensional models of patients' teeth. *See, e.g.*, Boerjes at [0041], [0077], [0189], [0196], [208]; Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76; Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010) (Beginning Bates No. CC_ALGN_00003676) at 325-27; Sachdeva, S*ureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001) (Beginning Bates No. CC_ALGN_00003083) at 247. A POSITA would also understand Rubbert-'217, Marshall, and/or Chishti-'850 teach ways to indicate what portion of a model needs updating because of scan deficiencies or irregularities. A POSITA would therefore

[redacted]

be motivated to combine the general teachings of the Boerjes Grounds, and the specific teaching of Rubbert-'217, Marshall, and/or Chishti-'850, to create a user-friendly and efficient method for creating accurate and up-to-date models of patients' teeth. *See, e.g.*, Boerjes at [0041], [0189]; Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76 ("A color map of the preparation allows you to verify proper occlusal and interproximal reduction (Figure 7) …. If the preparation requires refining or added reduction, then I can make needed changes and re-scan the quadrant."), Fig. 7 ("Color map of the preparation.").

Modifying the teachings of the Boerjes Grounds with the teachings of Rubbert-'217, Marshall, and/or Chishti-'850, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. All of these references and products teach tools for updating and/or marking three-dimensional models of teeth, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic and engineering practices. *See, e.g.*, Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76; Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010) (Beginning Bates No. CC_ALGN_00003676) at 325-27; Sachdeva, S*ureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001) (Beginning Bates No. CC_ALGN_00003083) at 247.

c) Combinations with Babayoff-065 (Babayoff Grounds I)

The '936 Patent requires discarding a remainder of second scan data used to update a three-dimensional model of a patient's teeth. *See, e.g.*,

- '936 patent at claim 3 ("wherein the system further comprises the computer system and the display; wherein the system further comprises a mouse or wherein the display comprises a touch screen display; and wherein the user input defining

portion of the model to be removed is received by the mouse or the touch screen display");

- '936 patent at claim 7 ("wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further discard a remainder of the received second scan data, the remainder including the identifying surface data, after stitching the portion of the received second scan data with the model");

- *Id*. at claim 13 ("wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using the at least the portion of the second scan data further comprises discarding a remainder of the second scan data, including the identifying surface data, after stitching the at least the portion of the second scan data with the model");

- *Id*. at claim 17 ("after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner; register the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model; replace at least a portion of the removed surface portion of the model using at least a portion of the received second scan data of the patient's teeth; discarding a remainder of the second scan data, including the identifying data, after registering the second scan data with the model");

- *Id.* at claim 19 ("wherein the system further comprises the computer system and the display; wherein the system further comprises a mouse or wherein the display comprises a touch screen display; and wherein the user input defining portion of the model to be removed is received by the mouse or the touch screen display'); and

- *Id.* at claim 20 ("wherein the portion of the removed surface portion of the model is replaced using at least the portion of the received second scan data by registering the second scan data with the model").

At least under Plaintiff's apparent infringement theories, a POSITA would have known and been motivated to improve a system for scanning a patient's teeth to generate a 3D model by modifying it to include functionality for discarding a portion of new scan data in the process of updating a 3D model using new scan data.

(i) Any of the Boerjes Grounds Alone

Any of the Boerjes Grounds alone discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

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As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Boerjes Grounds to include these features. For example, the Boerjes Grounds teach tools and/or techniques for updating, editing, and/or removing portions from a three-dimensional model of a patient's teeth after an initial scan. A POSITA would understand that "irregularities in one or more occlusal surfaces [may] requir[e] further preparation" (Boerjes at [0041]) such as "preparation requir[ing] refining or added reduction" (Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76). The need for a rescan of such areas (and the discarding of a remainder of the second scan data) have been obvious to a POSITA.

(ii) Any of the Boerjes Grounds combined with Babayoff-065

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in the Boerjes Grounds with Babayoff-065 into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Boerjes Grounds concerning orthodontic methods, systems, and articles that can include an intraoral scanner, with (2) the teachings of Babayoff-065 regarding structures of a handheld scanner and that a system for scanning a patient's teeth can allow for discarding scan aligning data.

The Boerjes Grounds and Babayoff-065 are from the same or an overlapping field of endeavor of the '936 Patent's alleged invention, which encompasses the field of scanning a patient's teeth during the course of orthodontic or dental treatment. The Boerjes Grounds and Babayoff-065 are reasonably pertinent to one or more supposed problems identified by the named inventors of the '936 Patent, including the supposed need to rescan areas of a patient's intraoral cavity where the virtual model was "partially obscured or incomplete [such as by agents

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or material in the patient's intraoral cavity including blood and saliva], or … [where] part of [a] physical item [such as a tooth] needs to be subsequently modified." '936 patent at 2:12-22; *see id*. at 2:1-11.

It would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products. Modifying the teachings of the Boerjes Grounds with the teachings of Babayoff-065, as discussed above, would make an orthodontic scanning and modeling system more efficient. For example, a POSITA would understand the Boerjes Grounds teaches a number of reasons to remove and/or rescan a portion of three-dimensional model of a patient's teeth, such as when there are "irregularities in one or more occlusal surfaces requiring further preparation." Boerjes at [0041]; *see id*. at [0189] ("[A]n automated process may locate areas of potential problems, such as occlusal high spots, occlusal clearance, occlusal irregularities, areas of poor margin preparation, areas of inadequate tooth removal, improper taper, improper draw path or removal path for a multiple unit preparation, inappropriate contour, and so forth."), [0190] ("[Q]uality control may include real time feedback during a scan, or between successive scans."), [0196] ("[A]n evaluation may conclude with an identification of regions of a prepared tooth surface requiring additional preparation or reduction, or regions of a digital model requiring additional or supplemental scanning due to incomplete, erroneous, or potentially erroneous data, which may be identified, for example, by comparison to models of 10 expected shape for dentition, surface preparations, and the like. An evaluation from a dental laboratory may request new data, or additional shaping of a prepared surface."), [0208] ("[A] second tool to remove unwanted or unneeded areas from a volume bounded by the digital surface representation."); *see also* Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76 ("If the preparation requires refining or added reduction, then I can

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make needed changes and re-scan the quadrant."); Kachalia et al., *Dentistry a la Carte: In-office CAD/CAM Technology*, CDA Journal, Vol. 38, No. 5, (May 2010) (Beginning Bates No. CC_ALGN_00003676) at 325 ("At this point, the clinician has free reign to take any additional scans and the software will automatically add these scans to the virtual casts and re-render the image."), 326 ("At times, more scans may be required and the operator is able to add these additional scans. The operator then steps around the arch form and overlapping data is merged to create a virtual cast that will be rendered on the screen."), 327 ("As images are captured, a 3-D cast is generated on the screen in real time and the operator is able to rotate the cast in all directions to visualize the completeness of data capture. In the event a specific area of the model does not have adequate data, a varying color will appear on the monitor informing the operator to acquire more data at a given location."); Sachdeva, S*ureSmile Technology in a Patient-Centered Orthodontic Practice*, JCO, Vol. 35, No. 4 (Apr. 2001) (Beginning Bates No. CC_ALGN_00003083) at 247 ("During the initial appointment, a quick scan of the dentition can be taken to visually demonstrate the patient's needs …. A full OraScan is taken during the records appointment, integrated with conventional photographs and x-rays, and entered into an electronic patient record. OraScan Image Processing Software combines the captured images into an accurate, three-dimensional representation of the dentition, which can be viewed at the SureSmile workstation from a wide variety of perspectives.").

A POSITA faced with new scan data would understand that, after new scan data is aligned with existing three-dimensional model, (i) only part of the new scan data needs to be kept such as part of the scan data corresponding to an area of the patient's dentition that underwent further preparation, and (ii) that discarding excess scan data would provide certain computing benefits, such as reducing the amount of memory needed for a computing device to

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store the three-dimensional model of a patient's teeth and reducing the processing power needed for a computing device to render and display the three-dimensional model and would merely involve combining prior art elements according to known methods to yield predictable results.

A POSITA would further have had a reasonable expectation of success, and would have succeeded, in modifying the Boerjes Grounds with Babayoff-065 to incorporate these features. Indeed, all of these references and products teach using intraoral scanners to generate three-dimensional models of patients' teeth and tools and/or techniques for updating such three-dimensional models, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic and engineering practices.

d) Combinations with the Paley (Physical Modification Reference)

The '936 Patent requires acquiring second scan data of a physically changed portion of the patient's intraoral cavity and using the second scan data to update a three-dimensional model of a patient's teeth. *See, e.g.*,

- '936 patent at claim 1 ("receive second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity; replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity;");
- *Id.* at claim 4 ("wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to register the received second scan data with the model");
- *Id.* at claim 5 ("wherein the received second scan data is registered with the model by aligning identifying data of the received second scan data with corresponding parts of the model");
- *Id.* at claim 6 ("wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data

comprise instructions to further stitch a portion of the received second scan data with the model");

- *Id.* at claim 8 ("wherein the computer readable medium further includes instructions that when executed by the computer system, cause the computer system to: mark, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model");

- *Id*. at claim 9 ("receiving second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity; replacing at least a portion of the surface portion of the model to be replaced according to the user input using at least a portion of the second scan data of the patient's teeth including the physically changed portion;");

- *Id.* at claim 10 ("further comprising marking an area on the displayed model associated with the received user input");

- *Id.* at claim 11 ("wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data comprises registering the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model");

- *Id.* at claim 12 ("wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data further comprises stitching the at least the portion of the second scan data with the model");

- *Id*. at claim 14 ("wherein the model of the patient's teeth comprises a tooth preparation having a finish line, wherein a portion of the finish line is obscured or distorted, and wherein the physical change results in the finish line not being obscured or distorted.");

- *Id*. at claim 15 ("wherein the model of the patient's teeth comprises a tooth preparation that accurately represents a surface of a physical preparation of the patient, and wherein the method further comprises analyzing the tooth preparation of the model to determine whether the surface of the physical preparation is suitable for a dental prosthesis; and wherein the physical change is a physical modification of the surface of the physical preparation of the patient."); and

- *Id*. at claim 16 ("wherein the dental prosthesis comprises a dental crown and wherein the tooth preparation analysis comprises analysis of the model with respect to a virtual model of an opposing dentition of an opposite jaw to determine whether the tooth preparation would result in an inadequate structure for the dental crown.").

[redacted]

At least under Plaintiff's apparent infringement theories, a POSITA would have known and been motivated to improve a system for scanning a patient's teeth to generate a 3D model by modifying it to include functionality for obtaining new scan data corresponding to a physically changed portion of a patient's intraoral cavity, and updating a 3D model of the patient's teeth with the new scan data.

(i) Any of Paley, Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 Alone

Any of Paley, Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 alone discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify Paley, Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 to include these features. For example, all of Paley, Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 teach tools and/or techniques for updating, editing, and/or removing portions from a three-dimensional model of a patient's teeth after an initial scan. A POSITA would understand that "irregularities in one or more occlusal surfaces [may] requir[e] further preparation" (Boerjes at [0041]) such as "preparation requir[ing] refining or added reduction" (Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76). Therefore, the need for rescan of such an area would have been obvious to a POSITA.

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(ii) Any of Paley, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 Combined with Boerjes

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to combine various teachings in Paley, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 with Boerjes into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of Paley, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 concerning orthodontic methods, systems, and articles that can include an intraoral scanner, with (2) the teachings of Boerjes, that a system for scanning a patient's teeth can allow for a physical modification to occur between a first scan and a second scan.

Boerjes, Paley, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 are from the same or an overlapping field of endeavor of the '936 Patent's alleged invention, which encompasses the field of scanning a patient's teeth during the course of orthodontic or dental treatment. Boerjes, Paley, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 are reasonably pertinent to one or more supposed problems identified by the named inventors of the '936 Patent, including the supposed need to rescan areas of a patient's intraoral cavity where the virtual model was "partially obscured or incomplete [such as by agents or material in the patient's intraoral cavity including blood and saliva], or … [where] part of [a] physical item [such as a tooth] needs to be subsequently modified." '936 patent at 2:12-22; *see id*. at 2:1-11. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

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Modifying the teachings of Paley with the teachings of Boerjes, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand that Paley, for example, teaches updating three-dimensional models of patients' teeth by rescanning surfaces and updating corresponding regions of the models. *See, e.g.*, Paley at [0055] ("[A] user can back up and rescan surfaces of the subject for which data has not been captured, or for which inadequate or defective data has been captured."), [0065] ("Where physical specifications for a particular restoration require additional removal, the regions to be removed may be depicted within the three-dimensional model using one or more visual cues for identification by the dentist."), [0066] ("A process of preparing a tooth surface, scanning the tooth surface, and analyzing the tooth Surface may be applied iteratively to refine a surface preparation. In an iterative process, a dentist may repeat steps of tooth removal and Scanning until a satisfactory surface preparation is achieved."). A POSITA would also understand that Boerjes teaches that one way to update a three-dimensional model of a patient's teeth is to use data from a second scan after making a physical modification to the patient's teeth between a first scan and the second scan. A POSITA would understand that in some instances, it is beneficial to rescan an area after a tooth has been physically modified (e.g., after the tooth has been prepared for a prosthetic or after it has undergone further preparation).

Modifying the teachings of Paley, Cadent iTero, Lava C.O.S., CEREC, OraScanner, E4D, Geng, and/or Kriveshko-'494 with the teachings of Boerjes, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. A POSITA would further have had a reasonable expectation of success. Indeed, all of

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these references and products teach using intraoral scanners to generate three-dimensional models of patients' teeth and tools and/or techniques for updating such three-dimensional models, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic and engineering practices.

e) Combinations with Babayoff-065 (Babayoff Grounds II)

As noted above, the '936 Patent requires discarding a remainder of second scan data used to update a three-dimensional model of a patient's teeth. *See, e.g.*,

- '936 patent at claims 2 ("wherein the hand-held intraoral scanner comprises a probing member with a sensing face, an illumination unit, a light focusing optics defining one or more focal planes forward the sensing face, and a translation mechanism for displacing the one or more focal planes relative to the sensing face");

- *Id.* at claim 3 ("wherein the system further comprises the computer system and the display; wherein the system further comprises a mouse or wherein the display comprises a touch screen display; and wherein the user input defining portion of the model to be removed is received by the mouse or the touch screen display");

- *Id.* at claim 7 ("wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further discard a remainder of the received second scan data, the remainder including the identifying surface data, after stitching the portion of the received second scan data with the model");

- *Id.* at claim 13 ("wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using the at least the portion of the second scan data further comprises discarding a remainder of the second scan data, including the identifying surface data, after stitching the at least the portion of the second scan data with the model");

- *Id.* at claim 17 ("after receiving the user input, remove, from the displayed model, a removed surface portion of the model to be removed according to the user input; after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner; . . . replace at least a portion of the removed surface portion of the model using at least a portion of the received second scan data of the patient's teeth; discarding a remainder of the second scan data, including the identifying data, after registering the second scan data with the model; and");

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- *Id.* at claim 18 ("wherein the hand-held intraoral scanner comprises a probing member with a sensing face, an illumination unit, a light focusing optics defining one or more focal planes forward the sensing face, and a translation mechanism for displacing the one or more focal planes relative to the sensing face");

- *Id.* at claim 19 ("wherein the system further comprises the computer system and the display; wherein the system further comprises a mouse or wherein the display comprises a touch screen display; and wherein the user input defining portion of the model to be removed is received by the mouse or the touch screen display");

- *Id.* at claim 20 ("wherein the portion of the removed surface portion of the model is replaced using at least the portion of the received second scan data by registering the second scan data with the model").

At least under Plaintiff's apparent infringement theories, a POSITA would have known and been motivated to improve a system for scanning a patient's teeth to generate a 3D model by modifying it to include functionality for discarding a portion of new scan data in the process of updating a 3D model using new scan data.

(i) Any of the Paley Grounds Alone

Any of the Paley Grounds alone discloses and/or renders obvious these features. *See* Section VIII [Claim Charts].

As an illustrative, non-limiting example, a POSITA would have been aware of and would have been motivated to modify the Paley Grounds to include these features. For example, all of the Paley Grounds teach tools and/or techniques for updating, editing, and/or removing portions from a three-dimensional model of a patient's teeth after an initial scan. A POSITA would understand that "irregularities in one or more occlusal surfaces [may] requir[e] further preparation" (Boerjes at [0041]) such as "preparation requir[ing] refining or added reduction" (Jacobson, *Taking the Headache Out of Impressions*, Dentistry Today (Sept. 2007) at 76). The need for using a rescan of such areas (and the discarding of a remainder of the second scan data) have been obvious to a POSITA.

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(ii) Babayoff-065

For many of the same reasons identified above with respect to the Babayoff Grounds I section (which is incorporated herein by reference), a POSITA would have been aware of and would have been motivated to combine various teachings in the Paley Grounds with Babayoff-065 into one method, system, or article. For example, a POSITA would have been motivated to combine (1) the teachings of the Paley Grounds concerning orthodontic methods, systems, and articles that can include an intraoral scanner, with (2) the teachings of Babayoff-065 regarding structures of a handheld scanner and that a system for scanning a patient's teeth can allow for discarding scan aligning data.

The Paley Grounds and Babayoff-065 are from the same or an overlapping field of endeavor of the '936 Patent's alleged invention, which encompasses the field of scanning a patient's teeth during the course of orthodontic or dental treatment. The Paley Grounds and Babayoff-065 are reasonably pertinent to one or more supposed problems identified by the named inventors of the '936 Patent, including the supposed need to rescan areas of a patient's intraoral cavity where the virtual model was "partially obscured or incomplete [such as by agents or material in the patient's intraoral cavity including blood and saliva], or … [where] part of [a] physical item [such as a tooth] needs to be subsequently modified." '936 patent at 2:12-22; *see id*. at 2:1-11. It therefore would have been obvious for someone of ordinary skill in the art to identify and combine elements from these references and products.

Modifying the teachings of the Paley Grounds with the teachings of Babayoff-065, as discussed above, would merely involve combining prior art elements according to known methods to yield predictable results. For example, a POSITA would understand the Paley Grounds teaches updating three-dimensional models of patients' teeth using new scan data. *See,*

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e.g., Paley at [0055] ("[A] user can back up and rescan surfaces of the subject for which data has not been captured, or for which inadequate or defective data has been captured."), [0065] ("Where physical specifications for a particular restoration require additional removal, the regions to be removed may be depicted within the three-dimensional model using one or more visual cues for identification by the dentist."), [0066] ("A process of preparing a tooth surface, scanning the tooth surface, and analyzing the tooth Surface may be applied iteratively to refine a surface preparation. In an iterative process, a dentist may repeat steps of tooth removal and Scanning until a satisfactory surface preparation is achieved."). A POSITA would also understand Babayoff-065 teaches that one way to update a virtual tooth model is to discard a portion of the virtual tooth model before replacing the removed portion or before acquiring second scan data. A POSITA faced with new scan data would understand that, after new scan data is aligned with existing three-dimensional model, (i) only part of the new scan data needs to be kept such as part of the scan data corresponding to an area of the patient's dentition that underwent further preparation, and (ii) that discarding excess scan data would provide certain computing benefits, such as reducing the amount of memory needed for a computing device to store the three-dimensional model of a patient's teeth and reducing the processing power needed for a computing device to render and display the three-dimensional model.

A POSITA would therefore take the teachings of the Paley Grounds, and combined them with the teaching of Babayoff-065 to arrive at the claimed features, at least under Plaintiff's apparent infringement theories. Modifying the teachings of the Paley Grounds with the teachings of Babayoff-065, as discussed above, would also merely involve simple substitution of one known element for another to obtain predictable results. All of these references and products teach all of these references and products teach using intraoral scanners to generate three-

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dimensional models of patients' teeth and tools and/or techniques for updating such three-dimensional models, so a POSITA would understand the combination of teachings from these references and products could be achieved using routine orthodontic and engineering practices.

VIII. CLAIM CHARTS

Individual claim charts that specify where and how in each alleged item of prior art each limitation of each Asserted Claim is found, at least under the apparent interpretation of the claims that Plaintiff applied in its Infringement Contentions, are attached to these Preliminary Invalidity Contentions as Exhibits 613-01 through 613-29 (claim charts for '613 patent); Exhibits 384-01 through 384-29 (claim charts for '384 patent); Exhibits 090-01 through 090-29 (claim charts for '090 patent); Exhibits 091-01 through 091-29 (claim charts for '091 patent); Exhibits 444-01 through 444-06, 444-08 through 444-12, 444-14 through 444-28 (claim charts for '444 patent); Exhibits 217-01 through 217-06, 217-08 through 217-12, 217-14 through 217-16, 217-18 through 217-28 (claim charts for '217 patent); Exhibits 879-01 through 879-06, 879-08 through 879-12, 879-14 through 879-16, 879-18 through 879-28 (claim charts for '879 patent); Exhibits 456-01 through 456-06, 456-08 through 456-12, 456-14 through 456-28 (claim charts for '456 patent); Exhibits 936-01 through 936-09, and 936-11 through 936-21 (claim charts for '936 patent).

IX. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

As the patentee, Plaintiff bears the initial production burden to show the existence of any secondary consideration of non-obviousness and its nexus to the claimed invention. Plaintiff has done neither here. ClearCorrect reserves the right to rebut any assertions of secondary considerations of non-obviousness raised by Plaintiff.

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Given the strength of the prior art and the strong motivation and teachings of the art discussed above, secondary considerations will not render the patent nonobvious. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483-84 (Fed. Cir. 1997). To the extent any alleged evidence of secondary considerations is relevant here, that evidence merely demonstrates the engineering, design, and marketing innovations of others besides Plaintiff, including ClearCorrect.

X. NON-STATUTORY DOUBLE PATENTING

A. THE '444 PATENT

The '444 patent is invalid under the doctrine of non-statutory double patenting. Specifically, the '444 patent was filed Aug. 30, 2007, issued Oct. 18, 2011, and has 1070 days of Patent Term Adjustment, resulting an alleged expiration date of Aug. 4, 2030. Each of the '217, '879, and '456 patents, which share a common specification with the '444 patent, has claims that are not patentably distinct over the claims of the '444 patent. Yet the '217, '879, and '456 patents, which have zero (0) days of Patent Term Adjustment, have an alleged expiration date of August 30, 2026. As a result, the '444 patent's later expiration date is impermissibly extended past the expiration date of the '217, '879, and '456 patents, and the '444 patent is invalid for non-statutory double patenting. *See In re Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023); *see also Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024).

XI. CONTENTIONS UNDER 35 U.S.C. § 101

Based on ClearCorrect's present understanding of the Asserted Claims and the apparent interpretation of the Asserted Claims that Plaintiff applied in its Infringement Contentions, the Asserted Claims of the Treatment Planning Patents and the Composite Image Patent are invalid under 35 U.S.C. § 101. In particular, the Asserted Claims relate to the implementation of

[redacted]

abstract ideas and do not claim an inventive concept as each and every limitation concerns generic, conventional processing equipment configured in a routine way, and thus, whether viewed individually or as an ordered combination, the Asserted Claims do not contain an inventive concept that amounts to substantially more than the abstract idea itself. Thus, the Asserted Claims are invalid under 35 U.S.C. § 101.

A. Legal Standard for Patent Eligibility

It is well-established that laws of nature, natural phenomena, and abstract ideas are not patentable. *E.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012). To determine whether an invention is patent eligible, a court must first consider "whether the claims at issue are directed to one of those patent-ineligible concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). If so, a court "consider[s] the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (citation omitted). The question is whether claims do "significantly more" than simply describe an abstract idea or mental process. *Mayo*, 566 U.S. at 73. Where claims recite an abstract idea or mental process and merely add steps or components that are conventional to those in the field, the claims are not patentable. *Bilski v. Kappos*, 561 U.S. 593, 610-11 (2010). Likewise, "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention." *Alice*, 573 U.S. at 223.

B. Treatment Planning Patents

All claims of the asserted Treatment Planning Patents are invalid under 35 U.S.C. § 101 because they recite ineligible subject matter.

[redacted]

Here, at *Alice* Step One, the Asserted Claims of the Treatment Planning Patents are directed to the patent-ineligible abstract idea of planning a sequence of tooth movements to straighten teeth. This process can be performed in the human mind or manually using pen and paper. The claims, as a whole and without ignoring any claim limitations, are all directed to this abstract idea, along with the instruction to 'do it on a computer.' None of the claims of the Treatment Planning Patents focus on any asserted improvement in computer capabilities. By way of example only, claim 1 of the '456 patent recites only steps that could be (and traditionally have been) performed by orthodontists and technicians, and the claim merely adds the words "a computer-implemented method" without any suggestion of a technological improvement:

> 1. A computer-implemented method comprising:
>
> determining a schedule of movement for dental objects during treatment stages of an orthodontic treatment, wherein the schedule of movement indicates whether or not each of the dental objects moves during each of the treatment stages;
>
> calculating a respective treatment path for each of the dental objects between their respective initial position and respective final position;
>
> identifying a collision between a first of the dental objects and a second of the dental objects based at least on the schedule of movement of the dental objects and the respective treatment paths;
>
> performing a first modification of the schedule of movement in response to the identifying, the first modification of the schedule of movement modifying whether or not at least one of the dental objects move during at least one of the treatment stages;
>
> determining that the first modification does not avoid a collision between the first of the dental objects and the second of the dental objects; and
>
> performing a second modification of the schedule of movement after the determining that the first modification does not avoid a collision, the second modification of the schedule

[redacted]

> of movement modifying whether or not at least one of the dental objects move during at least one of the treatment stages.

At *Alice* Step Two, none of the claims add "significantly more" to the unpatentable abstract idea. *See Mayo*, 566 U.S. at 73. Each claim limitation of the Treatment Planning Patents, individually and as an ordered combination, recites only the use of well-understood, routine, and conventional computing technology to perform functions previously known in the industry and that can be performed manually, without claiming any specific non-conventional components or methods. None of the claim limitations, alone or in combination, transforms the nature of the claims into a patent-eligible application. Further, this assertion that the claims do not add "significantly more" to the unpatentable idea is also demonstrated by the above cited references and the attached exhibits.

ClearCorrect incorporates by reference its patent-eligibility arguments presented in its Motion To Dismiss Plaintiff's Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) [Dkt. 31] and its Reply in Support of Motion To Dismiss Plaintiff's Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) [Dkt. 74].

ClearCorrect provides Exhibits 444-01 to 444-06, 444-08 to 444-12, 444-14 to 444-28, 217-01 to 217-06, 217-08 to 217-12, 217-14 to 217-16, 217-18 to 217-28, 879-01 to 879-06, 879-08 to 879-12, 879-14 to 879-16, 879-18 to 879-28, 456-01 to 456-06, 456-08 to 456-12, and 456-14 to 456-28 to show that each element of the asserted claims was well understood, routine, and/or conventional in the relevant industry. ClearCorrect also incorporates here by reference each of the prior art references disclosed in ClearCorrect's Preliminary Invalidity Contentions and charts accompanying the same. *See* Exhibits 444-01 to 444-06, 444-08 to 444-12, 444-14 to 444-28, 217-01 to 217-06, 217-08 to 217-12, 217-14 to 217-16, 217-18 to 217-28, 879-01 to

[redacted]

879-06, 879-08 to 879-12, 879-14 to 879-16, 879-18 to 879-28, 456-01 to 456-06, 456-08 to 456-12, 456-14 to 456-28.

C. Composite Image Patent

All claims of the asserted Composite Image Patent are invalid under 35 U.S.C. § 101 because they recite ineligible subject matter.

At *Alice* Step One, all claims of the Composite Image Patent are directed to the patent-ineligible abstract idea of collecting, manipulating, and displaying data, and more specifically, creating a composite image based on collecting, manipulating, and displaying data. The claims, as a whole and without ignoring any claim limitations, are all directed to this abstract idea, and none of the claims of the Composite Image Patent focus on any asserted improvement in computer capabilities. By way of example only, claim 9 of the '936 patent recites only generic data management functions involving the collection, manipulation, and display of data using generic technology—such as a "hand-held intraoral scanner" and a "display"—without any suggestion of a technological improvement:

> 9. A method for scanning a patient's teeth for a dental procedure, the method comprising:
>
> receiving first scan data of the patient's teeth from a hand-held intraoral scanner;
>
> displaying, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth;
>
> receiving user input via the displayed model demarcating a portion of the model to be retained and a surface portion of the model to be replaced;
>
> receiving second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity;

[redacted]

> replacing at least a portion of the surface portion of the model to be replaced according to the user input using at least a portion of the second scan data of the patient's teeth including the physically changed portion; and
>
> outputting, to the display, the model of the patient's teeth with the at least the portion of the surface portion replaced using the second scan data.

At *Alice* Step Two, At *Alice* Step Two, none of the claims add "significantly more" to the unpatentable abstract idea. *See Mayo*, 566 U.S. at 73. Each claim limitation of the '936 patent, individually and as an ordered combination, recites only well understood, routine, and conventional computing functions and technology previously known in the industry, without claiming any specific non-conventional components or methods. None of the claim limitations, alone or in combination, transform the nature of the claims into a patent-eligible application. Further, this assertion that the claims do not add "significantly more" to the unpatentable idea is also demonstrated by the above cited references and the attached exhibits.

ClearCorrect incorporates by reference its patent-eligibility arguments presented in its Motion To Dismiss Plaintiff's Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) [Dkt. 31] and its Reply in Support of Motion To Dismiss Plaintiff's Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) [Dkt. 74].

ClearCorrect provides Exhibits 936-01 to 936-09, and 936-11 to 936-21 to show that each element of the asserted claims was well understood, routine, and conventional in the relevant industry. ClearCorrect also incorporates here by reference each of the prior art references disclosed in ClearCorrect's Preliminary Invalidity Contentions and charts accompanying the same. *See* Exhibits 936-01 to 936-09, 936-11 to 936-21.

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XII. CONTENTIONS UNDER 35 U.S.C. § 112

In accordance with the Standing Order, ClearCorrect includes below the grounds on which it contends the Asserted Claims of the Asserted Patents are invalid under 35 U.S.C. § 112. OGP at 2. Notably, Plaintiff has not yet provided claim constructions for any claim terms, and as discussed above, its Preliminary Infringement Contentions are deficient in multiple respects and fail to provide sufficient notice of its infringement theories. ClearCorrect, therefore, cannot provide a complete list of § 112 defenses because it does not know whether Plaintiff will proffer a construction for certain terms or apply certain limitations in a way that is broader than, or inconsistent with, the construction or application that would be supportable by the disclosure set forth in the specification.

To the extent the following contentions reflect constructions of claim limitations consistent with or implicit in Plaintiff's Infringement Contentions, no inference is intended, nor should any be drawn, that ClearCorrect agrees with Plaintiff's claim constructions, and ClearCorrect expressly reserves the right to contest any such claim constructions. ClearCorrect offers these contentions in response to Plaintiff's Infringement Contentions and without prejudice to any position it may ultimately take as to any claim construction issues. ClearCorrect, therefore, reserves the right to amend or supplement these contentions under Section 112 to the extent Plaintiff proposes claim constructions, amends, or supplements its infringement allegations, and/or otherwise take positions with respect to the scope of the Asserted Claims that are broader than, or inconsistent with, the disclosure in the Asserted Patents.

A. Legal Standard for Written Description and Enablement

35 U.S.C. § 112 ¶ 1 (pre-AIA) provides:

> The specification shall contain a written description of the

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> invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112 ¶ 1.

35 U.S.C. § 112(a) (AIA) provides identical requirements:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112(a). Thus, § 112 ¶ 1 (pre-AIA) and § 112(a) prescribes two separate requirements for the specification of a valid patent: the written description requirement and the enablement requirement. *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc) ("[Section] 112, first paragraph, contains two separate description requirements: a 'written description [i] of the invention, and [ii] of the manner and process of making and using [the invention.]'").

"The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). The specification must "describe an invention understandable to [a] skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351-52. "The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity." *Enzo Biochem, Inc. v. Gen-Probe*

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Inc., 323 F.3d 956, 968-69 (Fed. Cir. 2002). This test "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art . . . [to] show that the inventor actually invented the invention claimed." *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1319 (Fed. Cir. 2017) (internal quotations and citation omitted). "The knowledge of ordinary artisans may be used to inform what is actually in the specification . . . but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification." *Id.* at 1322. "A patent owner cannot show written description support by picking and choosing claim elements from different embodiments that are never linked together in the specification." *Flash-Control, LLC v. Intel Corp.*, No. 2020-2141, 2021 WL 2944592, at *4 (Fed. Cir. July 14, 2021). Further, "[t]he written description requirement is not met when … the specification provides at best disparate disclosures that an artisan might have been able to combine in order to make the claimed invention." *Id.*

"To meet the enablement requirement, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Martek Biosciences Corp. v. Nutrinova Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (internal quotation omitted). Meeting this standard requires the specification "to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed." *In re Vaeck*, 947 F.3d 488, 496 (Fed. Cir. 1991). A court may consider the following factors when determining if a disclosure requires undue experimentation: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative

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skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010).

B. Legal Standard for Indefiniteness

35 U.S.C. § 112 ¶ 2 (pre-AIA) requires that a specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112(b) (AIA) likewise requires that a specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." A patent claim is invalid for indefiniteness if its language, when "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc*., 572 U.S. 898, 901 (2014); *see also id*. at 909 ("[A] patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." (internal quotation and citation omitted)). When claiming a measured parameter, "the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select." *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 630-31 (Fed. Cir. 2015) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341, 1344–45 (Fed.Cir.2015) (holding a claim term indefinite where a parameter "could be measured three different ways and would yield different results and the patent and prosecution history did not provide guidance as to which measure to use.").

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C. Legal Standard for Means-Plus-Function Claims

35 U.S.C. § 112 ¶ 6 provides that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." A claim element expressed in such a format "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Id*. Section 112 ¶ 6 is not limited to claim elements using the word "means"; rather, a claim element is subject to its requirements if it "fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Where Section 112 ¶ 6 applies, insufficient disclosure of structure for performing the recited function(s) renders the claim(s) reciting the claim element indefinite. *Id*. at 1352.

Means-plus-function claims directed to software require the specification to disclose an algorithm corresponding to the claimed function. *See EON Corp. IP Holdings LLC v. AT&T Mobility LLC*, 785 F.3d 616, 621 (Fed. Cir. 2015); *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008); *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1348-49 (Fed. Cir. 1999). The specification must disclose some algorithm in "understandable terms" that "provide[] sufficient structure"; it cannot merely restate the function recited in the claim. *Finisar Corp. v. DirecTV Grp.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008); *see also Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1383 (Fed. Cir. 2009) ("The ACM is essentially a black box that performs a recited function. But how it does so is left undisclosed."); *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 518 (Fed. Cir. 2012) (holding that "black box" labeled "Purchase Orders" was insufficient structure to perform the "generate purchase orders" function); *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1317 (Fed. Cir. 2012) ("[T]he

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disclosure must identify the method for performing the function, whether or not a skilled artisan might otherwise be able to glean such a method from other sources or from his own understanding.").

D. Section 112 Contentions

1. Materials Patents

The Asserted Claims of the Materials Patents are invalid under 35 U.S. C. § 112, ¶¶ 1, 2 (pre-AIA) and/or 112(a), (b) (AIA) and/or § 112, ¶ 6 and/or 112(f) for at least the reasons identified below.

The Materials Patents—the '613, '384, '090, and '091 patents—share a substantively identical specification. For many of the same reasons explained in Section III.A.1 [Priority Date] above, the Asserted Claims of the Materials Patents—at least under Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions—Materials Patents are invalid under 35 U.S.C. § 112 ¶ 1 (pre-AIA) and/or 35 U.S.C. § 112(a) (AIA) as lacking written description and lacking enablement. Specifically, according to Plaintiff's apparent interpretation of the claims as shown in its Preliminary Infringement Contentions, the Asserted Claims encompass a material comprising as few as two layers in any relative configuration comprising, *inter alia*, a co-polyester layer—under Plaintiff's apparent interpretation of the claims—having a flexural modulus of greater than [about] 150,000 psi and a polyurethane layer having a hardness of [about] 60A to [about] 85D.[26] *See* '091 patent at claims 6, 10, 18 ("a multilayer sheet"). Claims that require three or more layers encompass a third layer without any meaningful limitation on the properties of the third layer, under Plaintiff's apparent interpretation of the claims. In other words, according to the Infringement Contentions, Plaintiff

[26] The asserted claims of the '613, '384, and '090 patents encompass three or more layers. Asserted claims 6, 10, 18, 25, and 26 of the '091 patents encompass two layers.

[redacted]

interprets the Asserted Claims to encompass multi-layered structures for use in a dental aligner with ***any*** permutation of soft and hard layers, including a hard-soft-hard configuration. *See* '613 patent at claims 1, 20 ("sheet comprising three or more polymer layers"), '384 patent at claims 1, 11, 21 ("three or more polymer layers"), '090 patent at claim 1 ("a multilayer sheet" comprising "a third layer"), '091 patent at claim 1 ("a multilayer sheet" comprising "a third layer"). But, such an interpretation is not supported by the patents specification. The shared patent specification discloses only a multi-layer material for use in a dental aligner with a specific soft-hard-soft configuration.

First, the Materials Patents shared specification discloses a single specific configuration of soft-hard-soft layers in a dental appliance—in fact, it is the ***only*** embodiment disclosed. *See, e.g.*, '681 application at [0023] ("In general, structures, methods and systems of the present invention utilize a multilayer sheet for use in orthodontic appliances. The multilayer sheet can include three layers, in which a hard polymer layer is disposed between two soft polymer layers."), Abstract ("The appliance includes a hard polymer layer having a hard polymer layer elastic modulus disposed between a first soft polymer layer having a first soft polymer layer elastic modulus and a second soft polymer layer having a second soft polymer layer elastic modulus."). The original claims of the '681 application are expressly limited to a soft-hard-soft material configuration. None of the originally filed claims of the '681 application recite any other configuration.

Second, the figures included in the specifications disclose only soft-hard-soft materials. For example, Figure 2 is a diagram of the multilayer structure of the claimed invention showing "an arrangement of polymer layers in a sheet having a hard polymer layer disposed between two soft polymer layers." '681 application at [0009]. Figure 3 and Figure 4 depict processes and

[redacted]

methods for creating dental appliances from multilayer sheets in a Soft-Hard-Soft Material. *See id.* at [0031] ("The multilayer sheet 32, as depicted [in Figure 3], can include three layers: a hard polymer layer disposed between two soft polymer layers.").

Third, the prosecution history shows that a POSITA would not have understood the shared specification to demonstrate that the inventors possessed configurations other than soft-hard-soft Materials. For example, during prosecution of the '655 application (granted as the'613 patent), named inventor Chunhua Li represented to the Patent Office that her "team evaluated, in an iterative fashion, ***more than 250 distinct materials and/or material combinations*** for possible use in an improved appliance" and that "[a]fter years of development, Align produced the SmartTrack™ material (also referred to herein as "ST30"), which is a product according to the current claims comprising a multilayered material with ***a hard polymer layer between two soft polymer layers***." Sept. 16, 2019 Li Decl., ¶ 4 (ALGN00006841). Dr. Li represented that "the effectiveness of the SmartTrack material was ***unpredictable and unexpected***" and that "the SmartTrack material was developed during more ***than seven years of diligent evaluation of over 250 materials***, including numerous iterations in which materials were tested and compared, with the results used to design new materials." *Id*., ¶ 5 (ALGN00006841). Dr. Li also represented that while developing the Soft-Hard-Soft SmartTrack™ material (ST30) her team "evaluated numerous multilayer material combinations and determined that ***merely combining the materials into multiple layers was insufficient to improve performance*** relative to the [single layer, thermoplastic polyurethane] EX30 material" and "many multilayer materials tested proved inferior to the EX30 material." *Id*., ¶ 6 (ALGN00006842); *see also id.* ¶ 10 (ALGN00006843) ("the ***over 250 materials tested by my team did not provide results meeting the desired criteria***,

[redacted]

while the ***SmartTrack material as described in the current claims was found to meet Align' s criteria*** for a multilayer appliance").

Indeed, the research conducted by the inventors leading up to the '681 application corroborates that the inventors only possessed a soft-hard-soft Material. *See, e.g.*, McClellen Ltr. at 3, Sept. 13, 2024 [redacted]; ALGN00000001-ALGN00015088.

For the same reasons given above, the Materials Patents are not enabled. In addition, as named inventor Li explained, the performance of multilayer aligner materials was highly unpredictable. The SmartTrack soft-hard-soft Material was unexpectedly identified only after testing over 250 other materials (over the course of seven years) that did not meet Align's criteria for a multilayer aligner material. No specific examples disclosing the composition of an aligner are disclosed in the shared specification for the Materials Patents, even for a soft-hard-soft material, much less any other configuration. Indeed, the composition of SmartTrack is a secret. Thus, the Materials Patents fail to teach a POSITA how to make and use the full scope of the invention, including a soft-hard-soft material, a hard-soft-hard material, or other configurations encompassed by the claims as Plaintiff interprets them in its Infringement Contentions.

All of the Asserted Claims of the Materials Patents—under Plaintiff's apparent infringement theories and/or under any reasonable interpretation of the Asserted Claims—are invalid for lack of written description and enablement, *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002) ("[A] broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope"); *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 558 F. 3d 1368, 1376-79 (Fed. Cir. 2009)

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(finding the "spikeless" claims invalid for lack of written description because "the specification describes only medical valves with spikes"); *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023) ("If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."). *See* '613 patent at claims 1, 20 ("sheet comprising three or more polymer layers"), '384 patent at claims 1, 11, 21 ("three or more polymer layers"), '090 patent at claim 1 ("a multilayer sheet" comprising "a third layer"), '091 patent at claim 1 ("a multilayer sheet" comprising "a third layer"), '091 patent at claims 6, 10, 18 ("a multilayer sheet").

a) "flexural modulus greater than about 150,000 psi" ('613 patent, claims 1, 12, 20; '384 patent, claims 1, 11, 21; '090 patent claim 1; '090 patent claim 1; '091 patent claims 1, 6, 10, 18)

Asserted claims 1, 12, 20 of the '613 patent; claims 1, 11, 21 of the '384 patent; claim 1 of the '090 patent; and claims 1, 6, 10, and 18 of the '091 patent require "a hard polymer layer … having a flexural modulus greater than about 150,000 psi." Asserted claims reciting this term or asserted claims dependent from asserted claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "flexural modulus greater than 150,000 psi" means. The parameter "flexural modulus" could be "measured … different ways and would yield different results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-45). The flexural modulus of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D6272 (Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials by Four-Point Bending) [ASTM D6272 2010 Bates No. CC_ALGN_00002321], ASTM D790 (Standard Test Methods for

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Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials) [ASTM D790 2010 Bates No. CC_ALGN_00002332], and ISO 178 (Plastics — Determination of flexural properties) [ISO 178 2010 Bates No. CC_ALGN_00002356]. The specifications[27] mention "flexural modulus" four times but do not specify what test(s) could or should be used to measure flexural modulus. '613 patent at 5:57-6:1 ("For example, physical properties such . . . flexural modulus . . . can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of . . . a flexural modulus greater than about 150,000 psi"), *id*. at 6:19-30 ("For example, physical properties such as . . . flexural modulus . . . can each be specifically tailored for a particular application. In some embodiments, the soft polymer layers of the appliances can independently have a physical property of at least one of . . . a flexural modulus of greater than about 35,000 psi"). The prosecution histories also provide no guidance as to the approach to select to measure flexural modulus. Thus, the term "flexural modulus greater than 150,000 psi" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed.

[27] The specifications of each of the Materials Patents are substantially identical to the specification of the '613 patent. Accordingly, the disclosures of the '613 patent cited herein are representative of the disclosures of the other Materials Patents.

[redacted]

b) "flexural modulus greater than about 35,000 psi" ('613 patent, claim 7)

Claim 7 of the '613 patent states "the soft polymer layer comprises at least one of …. A flexural modulus of greater than about 35,000 psi…" Because the term "flexural modulus greater than 35,000 psi" is unclear, this term is indefinite and lacks sufficient written description and enablement support for the same reasons given above with respect to "flexural modulus greater than about 35,000 psi." *See* Section III.A.2.

c) "elongation at break of greater than about 200%" ('613 patent, claims 1, 12, 20; '384 patent claims 1, 11, 21; '090 patent, claim 1; '091 patent, claims 1, 6, 10, 18)

Asserted claims 1, 12, 20 of the '613 patent, claims 1, 11, 21 of the '384 patent, claim 1 of the '090 patent, and claims 1, 6, 10, and 18 of the '091 patent require "a soft polymer layer … having an elongation at break of greater than about 200%." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "elongation at break of greater than about 200%" means. The parameter "elongation at break" could be "measured . . . different ways and would yield different results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-45). The elongation at break of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D412 (Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension) [ASTM D412 2007 Bates No. CC_ALGN_00002370], ASTM D638 (Standard Test Method for Tensile Properties of Plastics) [D638 2010 2007 Bates No. CC_ALGN_00002371], ASTM D882 (Standard Test Method for Tensile Properties of Thin Plastic Sheeting) [ASTM D882 2010 Bates No. CC_ALGN_00002396], ISO 37 (Rubber, vulcanized or thermoplastic — Determination of

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tensile stress-strain properties) [ISO 37 2011 Bates No. CC_ALGN_00002428], ISO 527-1 (Plastics — Determination of tensile properties — Part 1: General Principles) [ISO 527-1 2012 Bates No. CC_ALGN_00002456], ISO 527-2 (Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics) [ISO 527-2 2012 Bates No. CC_ALGN_00002472], ISO 527-3 (Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets) [ISO 527-3 1995 Bates No. CC_ALGN_00002480, ISO527-3 2001 Bates No. CC_ALGN_00002700]. The specifications mention "elongation at break" four times but do not specify what test(s) could or should be used to measure elongation at break. '613 patent at 5:57-66 ("For example, physical properties such . . . elongation at break . . . can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of . . . an elongation at break of greater than about 70%"), *id*. at 6:19-28 ("For example, physical properties such as . . . elongation at break . . . can each be specifically tailored for a particular application. In some embodiments, the soft polymer layers of the appliances can independently have a physical property of at least one of . . . an elongation at break of greater than about 200%"). The prosecution histories also provide no guidance as to the approach to select to measure elongation at break. Thus, the term "elongation at break of greater than about 200%" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a

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skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

d) "elongation at break of greater than about 70%" ('613 patent, claim 6; '384 patent claims 7, 17; '090 patent, claim 1; '091 patent, claims 1, 6, 10, 18)

Asserted claim 6 of the '613 patent; claims 7 and 17 of the '384 patent; claim 1 of the '090 patent; and claims 1, 6, 10, and 18 of the '091 patent recite a "hard polymer comprises layer … an elongation at break of greater than about 70%." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. Because it is unclear what "elongation at break of greater than about 70%" means, this term is indefinite and lacks sufficient written description and enablement support for the same reasons given above with respect to "elongation at break of greater than about 200%." *See* Section III.A.2.

e) "elongation at yield of greater than about 4%" ('613 patent, claim 6; '090 patent, claim 1; '091 patent, claims 1, 6, 10, 18)

Asserted claim 6 of the '613 patent, claim 1 of the '090 patent, and claims 1, 6, 10, 18 of the '091 patent recite a "hard polymer layer comprises … an elongation at yield of greater than about 4%." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "elongation at yield of greater than about 4%" means. The parameter "elongation at yield" could be "measured . . . different ways and would yield different results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-1345). The elongation at yield of a material can be measured using multiple known approaches, *e.g.*, including but not limited to ASTM D412 (Standard Test Methods for Vulcanized Rubber and Thermoplastic

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Elastomers—Tension) [ASTM D412 2007 Bates No. CC_ALGN_00002357], ASTM D638 (Standard Test Method for Tensile Properties of Plastics) [D638 2010 Bates No. CC_ALGN_00002371], ASTM D882 (Standard Test Method for Tensile Properties of Thin Plastic Sheeting) [ASTM D882 2010 Bates No. CC_ALGN_00002387], ISO 37 (Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties) [ISO 37 2011 Bates No. CC_ALGN_00002397], ISO 527-1 (Plastics — Determination of tensile properties — Part 1: General Principles) [ISO 527-1 2012 Bates No. CC_ALGN_00002429], ISO 527-2 (Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics) [ISO 527-2 2012 Bates No. CC_ALGN_00002457], ISO 527-3 (Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets) [ISO 527-3 1995 Bates No. CC_ALGN_00002473, ISO527-3 2001 Bates No. CC_ALGN_00002700]. The specifications mention "elongation at yield" two times but do not specify what test(s) could or should be used to measure elongation at yield. '613 patent at 5:57-66 ("For example, physical properties such . . . elongation at yield . . . can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of . . . an elongation at yield of greater than about 4%"). The prosecution histories also provide no guidance as to the approach to select to measure elongation at yield. Thus, the term "elongation at yield of greater than about 4%" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full

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scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

f) "tensile strength at yield of between about 4000 psi and 6500 psi" ('613 patent, claim 6; '384 patent, claims 6, 16, 26; '090 patent, claim 1; '091 patent, claims 1, 6, 10, 18)

Asserted claim 6 of the '613 patent, claims 6, 16, 26 of the '384 patent, claim 1 of the '090 patent, and claims 1, 6, 10, 18 of the '091 patent recite a "hard polymer layer comprises … a tensile strength at yield of between about 4000 psi and 6500 psi." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "tensile strength at yield of between about 4000 psi and 6500 psi" means. The parameter "tensile strength at yield" could be "measured . . . different ways and would yield different results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow,* 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-1345). The tensile strength at yield of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D412 (Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension) [ASTM D412 2007 Bates No. CC_ALGN_00002357], ASTM D638 (Standard Test Method for Tensile Properties of Plastics) [D638 2010 2007 Bates No. CC_ALGN_00002371], ASTM D882 (Standard Test Method for Tensile Properties of Thin Plastic Sheeting) [ASTM D882 2010 Bates No. CC_ALGN_00002387], ISO 37 (Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties) [ISO 37 2011 Bates No. CC_ALGN_00002397], ISO 527-1 (Plastics — Determination of tensile properties — Part 1: General Principles) [ISO 527-1 2012 Bates No. CC_ALGN_00002429], ISO 527-2 (Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics) [ISO 527-2 2012 Bates No. CC_ALGN_00002457], ISO 527-3 (Plastics —

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Determination of tensile properties — Part 3: Test conditions for films and sheets) [ISO 527-3 1995 Bates No. CC_ALGN_00002473, ISO527-3 2001 Bates No. CC_ALGN_00002700]. The specifications mention "tensile strength at yield" one time but do not specify what test(s) could or should be used to measure tensile strength at yield. '613 patent at 5:62-65 ("In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of . . . a tensile strength at yield of between about 4000 pounds per square inch (psi) and 6500 psi"). The prosecution histories also provide no guidance as to the approach to select to measure tensile strength at yield. Thus, the term "tensile strength at yield of between about 4000 psi and 6500 psi" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

g) "tensile modulus of greater than about 150,000 psi" ('613 patent, claim 6; '384 patent, claims 4, 14, 24; '090 patent, claim 1; '091 patent, claims 1, 6, 10, 18)

Asserted claim 6 of the '613 patent, claims 4, 14, and 24 of the '384 patent, claim 1 of the '090 patent, and claims 1, 6, 10, and 18 of the '091 patent recite a "hard polymer layer comprises … a tensile modulus of greater than about 150,000 psi." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "tensile modulus of greater than about 150,000 psi" means. The parameter "tensile modulus" could be "measured . . . different ways and would yield different results" and the patent and prosecution history do not

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provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-1345). The tensile modulus of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D412 (Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension) [ASTM D412 2007 Bates No. CC_ALGN_00002357], ASTM D638 (Standard Test Method for Tensile Properties of Plastics) [D638 2010 2007 Bates No. CC_ALGN_00002371], ASTM D882 (Standard Test Method for Tensile Properties of Thin Plastic Sheeting) [ASTM D882 2010 Bates No. CC_ALGN_00002387], ISO 37 (Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties) [ISO 37 2011 Bates No. CC_ALGN_00002397], ISO 527-1 (Plastics — Determination of tensile properties — Part 1: General Principles) [ISO 527-1 2012 Bates No. CC_ALGN_00002429], ISO 527-2 (Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics) [ISO 527-2 2012 Bates No. CC_ALGN_00002457], ISO 527-3 (Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets) [ISO 527-3 1995 Bates No. CC_ALGN_00002473, ISO527-3 2001 Bates No. CC_ALGN_00002700]. The specifications mention "tensile modulus" three times but do not specify what test(s) could or should be used to measure tensile modulus. '613 patent at 5:57-67 ("For example, physical properties such . . . tensile modulus . . . can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of . . . a tensile modulus of greater than about 150,000 psi"), 6:19-22 ("For example, physical properties such as . . . tensile modulus . . . can each be specifically tailored for a particular application."). The prosecution histories also provide no guidance as to the approach to select to measure tensile modulus. Thus, the term "tensile modulus of greater than about 150,000 psi" is indefinite.

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Nautilus, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

h) "stress relaxation greater than about 10% at 24 hours testing in a wet environment" ('613 patent, claim 6; '090 patent, claim 10)

Asserted claim 6 of the '613 patent and claim 10 of the '090 patent recite a "hard polymer layer comprises … a stress relaxation greater than about 10% at 24 hours testing in a wet environment." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "stress relaxation greater than about 10% at 24 hours testing in a wet environment" means. The parameter "stress relaxation" could be "measured . . . different ways and would yield different results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-1345). The stress relaxation of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D6147 (Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomer-Determination of Force Decay (Stress Relaxation) in Compression) [ASTM D6147 2008 Bates No. CC_ALGN_00002481], ASTM E328 (Standard Test Methods for Stress Relaxation for Materials and Structures) [ASTM E328 2008 Bates No. CC_ALGN_00002488], ASTM D8363 (Standard Test Method for Rubber—Stress Relaxation in Tension Under Non-Isothermal Conditions) [ASTM D8363 2020 Bates No.

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CC_ALGN_00002596], ASTM D6048 (Standard Practice for Stress Relaxation Testing of Raw Rubber, Unvulcanized Rubber Compounds, and Thermoplastic Elastomers) [ASTM D6048 2012 Bates No. CC_ALGN_00002501], ISO 13145 (Rubber — Determination of viscosity and stress relaxation using a rotorless sealed shear rheometer) [ISO 13145 2012 Bates No. CC_ALGN_00002516], ISO 3384 (Rubber, vulcanized or thermoplastic — Determination of stress relaxation in compression — Part 1: Testing at constant temperature) [ISO 3384 2011 Bates No. CC_ALGN_00002538], ISO 6914 (Rubber, vulcanized or thermoplastic — Determination of ageing characteristics by measurement of stress relaxation in tension) [ISO 6914 2008 Bates No. CC_ALGN_00002558]. The specifications mention "stress relaxation" six times but do not specify what test(s) could or should be used to measure stress relaxation. '613 patent at 2:2-6 ("The multilayer dental appliances of the present invention, among many aspects, provide, for example, improved material performance, stress relaxation properties and longer working range"), *id*. at 2:43-48 ("FIG. 5 provides a stress relaxation comparison for dental appliances, in accordance with an embodiment of the present invention. FIG. 6 provides another stress relaxation comparison for dental appliances, in accordance with an embodiment of the present invention"), *id*. at 5:57-6:4 ("For example, physical properties such as . . . stress relaxation over time . . . can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of . . . a stress relaxation at 24 hours testing in a wet environment (e.g., between about 90%-100% relative humidity) is greater than 10%"), *id*. at 8:19-23 ("As shown in FIGS. 5 and 6, one example of the multilayer sheet material (Material 2) showed improved stress relaxation properties as compared to another already existing material (Material 1) at room temperature and at a 37° C./90-100% relative humidity condition"). The prosecution histories also provide no

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guidance as to the approach to select to measure stress relaxation. Thus, the term "stress relaxation greater than about 10% at 24 hours testing in a wet environment" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

i) "stress relaxation at 24 hours in a wet environment of between 90-100% humidity of greater than 10%" ('090 patent, claim 10)

Asserted claim 10 of the '090 patent recites "stress relaxation at 24 hours in a wet environment of between 90-100% humidity of greater than 10%." Because it is unclear what "stress relaxation at 24 hours in a wet environment of between 90-100% humidity of greater than 10%" means, this term is indefinite and lacks sufficient written description and enablement support for the same reasons given above with respect to "stress relaxation greater than about 10% at 24 hours testing in a wet environment." *See* Section III.A.2.

j) "compression set at about 70° C. of greater than 40% after 24 hours" ('613 patent, claim 7)

Asserted claim 7 of the '613 patent recites "the soft polymer layer comprises … a compression set at about 70° C. of greater than 40% after 24 hours." Claims incorporating this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "compression set at about 70° C. of greater than 40% after 24 hours" means. The parameter "compression set" could be "measured . . . different ways and would yield different

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results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-1345). The compression set of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D395 (Standard Test Methods for Rubber Property—Compression Set) [ASTM D395 2008 Bates No. CC_ALGN_00002574], ISO 815 (Rubber, vulcanized or thermoplastic — Determination of compression set — Part 1: At ambient or elevated temperatures) [ISO 815 2008 Bates No. CC_ALGN_00002580]. The specifications mention "compression set" two times but do not specify what test(s) could or should be used to measure compression set. '613 patent at 6:19-29 ("For example, physical properties such as . . . compression set . . . can each be specifically tailored for a particular application. In some embodiments, the soft polymer layers of the appliances can independently have a physical property of at least one of . . . a compression set at about 70° C. of greater than 40% after 24 hours"). The prosecution histories also provide no guidance as to the approach to select to measure compression set. Thus, the term "compression set at about 70° C. of greater than 40% after 24 hours" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

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k) "ultimate tensile strength of greater than about 5000 psi" ('613 patent, claim 7; '384 patent, claims 2, 12, 22; '090 patent, claim 1; '091 patent, claims 1, 6, 10, 18)

Asserted claim 7 of the '613 patent, claims 2, 12, and 22 of the '384 patent, claim 1 of the '090 patent, claims 1, 6, 10, and 18 of the '091 patent recite a "soft polymer layer comprises … an ultimate tensile strength of greater than about 5000 psi." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "ultimate tensile strength of greater than about 5000 psi" means. The parameter "ultimate tensile strength" could be "measured . . . different ways and would yield different results" and the patent and prosecution history do not provide guidance as to which measure to use. *Dow*, 803 F.3d at 630-631 (citing *Teva*, 789 F.3d at 1341, 1344-1345). The ultimate tensile strength of a material can be measured using multiple known approaches, e.g., including but not limited to ASTM D412 (Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension) [ASTM D412 2007 Bates No. CC_ALGN_00002357], ASTM D638 (Standard Test Method for Tensile Properties of Plastics) [D638 2010 2007 Bates No. CC_ALGN_00002371], ASTM D882 (Standard Test Method for Tensile Properties of Thin Plastic Sheeting) [ASTM D882 2010 Bates No. CC_ALGN_00002387], ISO 37 (Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties) [ISO 37 2011 Bates No. CC_ALGN_00002397], ISO 527-1 (Plastics — Determination of tensile properties — Part 1: General Principles) [ISO 527-1 2012 Bates No. CC_ALGN_00002429], ISO 527-2 (Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics) [ISO 527-2 2012 Bates No. CC_ALGN_00002457], ISO 527-3 (Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets) [ISO 527-3 1995 Bates No. CC_ALGN_00002473, ISO527-3 2001 Bates No. CC_ALGN_00002700]. The specifications mention "ultimate tensile

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strength" two times but do not specify what test(s) could or should be used to measure ultimate tensile strength. '613 patent at 6:19-27 ("The soft polymer layers of the appliances can have a variety of physical properties. For example, physical properties such as . . . ultimate tensile strength . . . can each be specifically tailored for a particular application. In some embodiments, the soft polymer layers of the appliances can independently have a physical property of at least one of . . . an ultimate tensile strength of greater than about 5000 psi"). The prosecution histories also provide no guidance as to the approach to select to measure ultimate tensile strength. Thus, the term "ultimate tensile strength of greater than about 5000 psi" is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

l) "soft polymer layer … having … a hardness from about 60 A to about 85 D" ('613 patent, claims 1, 4, 7, 10, 15, 20, 22; '384 patent, claims 1, 2, 8, 11, 12, 18, 21, 22, 28)

Asserted claims 1, 4, 7, 10, 15, 20 and 22 of the '613 patent and claims 1, 2, 8, 11, 12, 15, 18, 21, 22, 28 of the '384 patent recite a "soft polymer layer … having … a hardness from about 60A to about 85D." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what "soft polymer layer … having … a hardness from about 60 A to about 85 D" means. The meaning of the term "soft polymer layer … having … a hardness from about 60 A to about 85 D" is unclear because it recites a range with endpoints

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defined by two different methods (Shore A and Shore D) of measuring hardness. For example, it is unclear whether a soft polymer layer with a Shore A hardness of 60 and a Shore D hardness of 90 falls in the claimed range, or whether a soft polymer layer with a Shore D hardness of 85 and a Shore A hardness of 50 falls in the claimed range. In both cases, the soft polymer layer coincides with one endpoint of the range but falls outside the other endpoint of the range. An accused infringer would not be able to tell whether or not they infringed the claim. The term is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

m) "soft polymer layer" ('613 patent, claims 1, 4, 7, 10, 15, 20, 22; '384 patent, claims 1, 2, 8, 11, 12, 15, 18, 21, 22, 28)

Asserted claims 1, 4, 7, 10, 15, 20 and 22 of the '613 patent and claims 1, 2, 8, 11, 12, 15, 18, 21, 22, 28 of the '384 patent recite a "soft polymer layer." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what the subjective term "soft" in "soft polymer layer" means. An accused infringer would not be able to tell whether or not they infringed the claim. The term is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents

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fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

n) "hard polymer layer" ('613 patent, claims 1, 4, 7, 10, 15, 20, 22; '384 patent, claims 1, 2, 8, 11, 12, 15, 18, 21, 22, 28)

Asserted claims 1, 4, 7, 10, 15, 20 and 22 of the '613 patent and claims 1, 2, 8, 11, 12, 15, 18, 21, 22, 28 of the '384 patent recite a "hard polymer layer." Asserted claims reciting this term and asserted claims that are dependent from claims reciting this term are invalid as indefinite and for lack of enablement and lack of written description. It is unclear what the subjective term "hard" in "hard polymer layer" means. An accused infringer would not be able to tell whether or not they infringed the claim. The term is indefinite. *Nautilus*, 572 U.S. at 901 (the term "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention."). For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed. *See* Section III.A.2.

2. Treatment Planning Patents

The Asserted Claims of the Treatment Planning Patents are invalid under 35 U.S.C. § 112 for at least the reasons identified below.

a) At Least Under Align's Apparent Infringement Theories, The Asserted Claims Lack Adequate Written Description

The specification of the Treatment Planning Patents expressly describes, as prior art, an

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earlier Align U.S. patent application No. 09/169,276 by Chishti et al. (filed October 8, 1998).[28] That prior Align application discloses "human-assisted tooth positioning" in which the computer suggests target positions and treatment paths for a patient's teeth. The prior Align application also discloses using a computer to generate treatment paths along which a patient's teeth will move from initial positions as shown in an initial digital data set. The prior Align application also discloses having the computer detect collisions that will occur as the patient's teeth move along the treatment paths, and then applying an algorithm to adjust the paths to avoid a collision. *See, e.g.*, WO2000/019929 at 33 ("The routine then applies the collision detection algorithm to determine whether collisions result from the, altered paths (step 1706). If so, the routine resamples the altered paths (step 1708) and then constructs for each tooth an alternative path among the samples (step 1710). The routine continues in this manner until no collisions occur (step 1712).").

The specification of the Treatment Planning Patents also describes, as prior art, an earlier Align U.S. Patent No. 6,729,876 by Chishti et al. (filed August 29, 2001 and issued on May 4, 2004).[29] This prior Align patent discloses, among other things, "a computer-implemented method to prepare a malocclusion treatment plan" that includes "selecting a tooth treatment pattern from a library of predetermined tooth treatment patterns, and generating the malocclusion treatment plan implementing the selected tooth treatment pattern." This Align patent also specifically discloses that "The library of treatment patterns includes at least one or more of the following: all equal movement pattern, A-shaped movement pattern, V-shaped

[28] The application's disclosure is identical to WO2000/019929 (published April 13, 2000) and U.S. Patent No. 7,134,874 (filed November 30, 2003), and both the PCT application and US patent claim priority to the application.
[29] Chishti-'876's disclosure is identical to Chishti-'400 (U.S. published patent application 2004/0137400).

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movement pattern, M-shaped movement pattern, W-shaped movement pattern, Symmetric Staircase pattern, asymmetric Staircase pattern, and equal equal movement pattern." Chishti-'876 at 2:44-49.

Given this admitted Align prior art, the Treatment Planning Patents—which were filed years later—purport to disclose a different claimed invention that goes beyond the systems and methods described in the earlier Align application and patent. The Treatment Planning Patents describe, for example, the use of "round-tripping"—which the patents describe as "moving a first tooth out of the path of a second tooth, and once the second tooth has moved sufficiently, moving the first tooth back to its previous position before proceeding to a desired final position of that first tooth"—something that the prior Align patent application criticized.

To the extent, therefore, that Align contends that the claims of the Treatment Planning Patents cover systems like those described in the earlier Align application and patent, then those claims lack adequate written description because a person of skill in the art would not understand the inventors of the Treatment Planning Patents to have invented such a system. For example, the claims of the '456 patent and various other asserted claims recite methods without the purported inventive features of the Treatment Planning Patents (e.g., "round-tripping"). *See, e.g.*, '456 patent claims 1-19; '444 patent at claims 15-26, 29-40, 42. Those claims lack adequate written description because a person of ordinary skill would not have understood the inventors of the Treatment Planning Patents to have invented such a system. Similarly, to the extent that Align contends that the accused ClearCorrect products are covered by Align claims that do recite "round-tripping" (e.g., '444 patent claims 1-14, 27, 41; '217 patent claims 1-20; '879 patent claims 1-14, 20-24)—even though the ClearCorrect products are like the prior Align patents in not promoting round-tripping—then those claims would

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likewise be invalid for lack of adequate written description, because a person of skill in the art would not understand the inventors of the Treatment Planning Patents to have invented such a system. *See Cisco Sys., Inc. v. Cirrex Sys., LLC*, 856 F.3d 997, 1008 (Fed. Cir. 2017); *Cooper Cameron*, 291 F.3d at 1323 ("[A] broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope."); *ICU Medical*, 558 F.3d at 1376-79.

b) The Inventors Were Not in Possession Of and Did Not Enable "determining, by the host computer, an optimal number of stages" / "determining an optimal number of stages" / "instructions to determine an optimal number of stages" ('444 patent, claims 5, 6, 19, 20, 33, 34)

Nowhere does the common specification of the Treatment Planning Patents "demonstrate that the patentee was in possession" of a "host computer," "system," or "machine readable medium" that could determine an "optimal" number of stages. *Capon*, 418 F.3d at 1357. Nor does the specification "teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Martek*, 579 F.3d at 1378.

The "optimal" number of stages for the order of movement of the dental objects can be defined in multiple ways, reflecting considerations such as cost, patient comfort, aligner technology, etc. The specification identifies many factors that might be relevant to a determination of an optimal number of stages. *See, e.g.*, '444 patent at 14:59-15:5 ("The optimum number of stages, in one embodiment, is determined based upon the determinations of step 1130 through step 1170. Furthermore, step 1170 includes factoring any staggering, slowing down/interim key framing, and/or round-tripping needed to place the patient's teeth in their desired final position. For example, in FIGS. 3-9 the optimum number of stages needed for these respective examples factored in the type of pattern needed, the rate, the path, the distance,

staggering, slowing down/interim key framing, and/or round-tripping in determining the optimum number of stages for treating the patient's teeth. As one skilled in the art will recognize, the optimum number of stages will likely differ from patient to patient."); *id.* at 15:5-9 ("In one exemplary embodiment, determining the optimum number of stages includes determining the minimum number of stages needed for each respective tooth to be placed in its final, desired position."); *id*. at 15:9-12 ("In another exemplary embodiment, the optimum number of stages is the largest number of the minimum stages needed to place the patient's teeth in their final, desired position."). But the patent provides no guidance regarding how those or other factors should be weighed against each other to determine optimality, and the patent provides no outer bounds that define the scope of the claim and thus provides no way for a skilled artisan to know whether or not he or she is practicing these claims. The prosecution histories also provide no guidance as to how "optimal" should be defined. A skilled artisan would not have considered the inventors to have been in possession of the full scope of these claims. Nor does the specification enable a skilled artisan to practice the full scope of the claimed invention.

c) "optimal" ('444 patent, claim 5, 6, 19, 20, 33, and 34)

The claim term "optimal" is indefinite because "read in light of the specification delineating the patent, and the prosecution history, [it] fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. The claims require determination of "the optimal number of stages for order of movement of the dental object," but neither the claims nor the specification "provide objective boundaries for those of skill in the art" when making such a determination. *Intell. Ventures I LLC v. T-Mobile USA, Inc*., 902 F.3d 1372, 1381 (Fed. Cir. 2018) (citing *Nautilus, Inc. v. Biosig Instruments, Inc*., 572

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U.S. 898 (2014)). The definition of a claim term "cannot depend on an undefined standard." *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 314 F.3d 1313, 1342 (Fed. Cir. 2003).

The "optimal" number of stages for the order of movement of the dental objects can be defined in multiple ways, reflecting considerations such as cost, patient comfort, aligner technology, etc. The specification identifies many factors that might be relevant to a determination of an optimal number of stages. *See, e.g.*, '444 patent at 14:59-15:5 ("The optimum number of stages, in one embodiment, is determined based upon the determinations of step 1130 through step 1170. Furthermore, step 1170 includes factoring any staggering, slowing down/interim key framing, and/or round-tripping needed to place the patient's teeth in their desired final position. For example, in FIGS. 3-9 the optimum number of stages needed for these respective examples factored in the type of pattern needed, the rate, the path, the distance, staggering, slowing down/interim key framing, and/or round-tripping in determining the optimum number of stages for treating the patient's teeth. As one skilled in the art will recognize, the optimum number of stages will likely differ from patient to patient."); *id.* at 15:5-9 ("In one exemplary embodiment, determining the optimum number of stages includes determining the minimum number of stages needed for each respective tooth to be placed in its final, desired position."); *id*. at 15:9-12 ("In another exemplary embodiment, the optimum number of stages is the largest number of the minimum stages needed to place the patient's teeth in their final, desired position."). But the patent provides no guidance regarding how those or other factors should be weighed against each other to determine optimality, and the patent thus provides no outer bounds that define the scope of the claim and thus provides no way for a skilled artisan to know whether or not he or she is practicing these claims. The prosecution histories also provide no guidance as to how "optimal" should be defined.

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For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed.

d) "dental object" ('444 patent, claims 1-42; '217 patent, claims 1, 3-7,9-11, 13-17, 19, 20; '879 patent, claims 1, 5-9, 13-15, 18-20, 24; '456 patent, claims 1, 4, 5, 7-13, 16-19)

It is unclear what "dental object" means and, as such, this term is indefinite because "read in light of the specification delineating the patent, and the prosecution history, [it] fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. Based on the plain language of the claims, there is no definition of "dental object" that does not lead to a "nonsensical result." *Horizon Pharma, Inc. v. Dr. Reddy's Lab'ys Inc*., 839 F. App'x 500, 505 (Fed. Cir. 2021). For example, some claim terms recite a "dental object" that appears to be a physical object. *See, e.g.*, '444 patent at claim 1 ("A computer-implemented method for staging the movement of a plurality of dental objects, the method comprising: receiving, at a host computer, an electronic representation of each dental object of the plurality of dental objects in relation to one another. …"); '456 patent at claim 1 ("A computer-implemented method comprising: determining a schedule of movement for dental objects during treatment stages of an orthodontic treatment, wherein the schedule of movement indicates whether or not each of the dental objects moves during each of the treatment stages. …"). Other claim terms recite a "dental object" that appears to be an electronic object. *See, e.g.*, '217 patent at claim 1 ("A method comprising: selecting a movement pattern from a plurality of movement patterns for moving dental objects from an initial arrangement toward a final arrangement, the dental objects being based on output of a scanning device, …."); '879 patent at claim 1 ("A computer-implemented method comprising: determining, by one or more computer

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processors, a schedule of movement for dental objects during treatment stages, the dental objects being based from output of a scanning device, wherein the schedule of movement indicates whether each of the dental objects moves during each of the treatment stages. …"). Indeed, in the claims cited immediately above, "dental objects" are recited with both apparent meanings.

The result is that the asserted claims are indefinite. *Horizon Pharma*, 839 F. App'x at 505 (similarly finding claim indefinite where "both clauses are incomprehensible. … Reading the claim literally, a dose form, which is an inanimate object, cannot set a goal.").

For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed.

e) "desired" ('444 patent, claims 1, 15, 29; '879 patent, claims 9, 15)

In the context of the asserted patents, it is unclear what "desired" means, and as such, this term is indefinite because "read in light of the specification delineating the patent, and the prosecution history, [it] fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. The definition of a claim term "cannot depend on an undefined standard." *Amgen*, 314 F.3d at 1342 (finding indefinite claim requiring comparison to moving target since the patent failed to direct those of ordinary skill in the art to a standard by which the appropriate comparison could be made).

The specification repeatedly refers to the final "desired" position of a patient's teeth. The specification, however, describes the "desired" position as follows: "A mold of the patient's bite is initially taken and ***desired*** ending positions for the patient's teeth (***i.e., a functionally and aesthetically optimum position***) are determined, based on a prescription provided by an

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orthodontist or dentist." '444 patent at 1:39-43. Thus, according to the specification, the term "desired" has both functional and aesthetic components. But the specification fails to inform what a "functionally … optimum position" is or what an "aesthetically optimum position" is, and thus the claims are invalid as being indefinite. Indeed, there could be multiple "functionally optimum position[s]" as well as multiple "aesthetically optimum position[s]." The patent does not provide a skilled artisan with sufficient guidance to determine whether he or she is practicing this limitation, and the claims using the term "desired" are therefore invalid as indefinite.

For the same reasons, the claims are invalid for lack of enablement and lack of written description: the patents fail to teach those skilled in the art how to make and use the full scope of the claimed feature and fail to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed.

f) Means-Plus-Function Terms (§ 112, ¶ 6)

The limitation(s) of the '444 patent listed below, which all use the word "means", are governed by Section 112, ¶ 6. Each of the claims in which these limitations appear is indefinite because the specification fails to disclose the corresponding structure (specifically, the required algorithm) for each limitation. *See Aristocrat Tech. Australia*, 521 F.3d at 1333-34 ("In cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, this court has consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor. … Thus, in a means-plus-function claim 'in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.'").

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In addition, because the specification does not provide sufficient structure, the claims are also invalid for inadequate written description and lack of enablement.

- "means for receiving an electronic representation of each dental object of the plurality of dental objects in relation to one another" ('444 patent, claim 15)
- "means for receiving an electronic representation of a desired final position for each respective dental object" ('444 patent, claim 15)
- "means for determining an order of movement for each respective dental object such that the dental objects avoid colliding with each other on their respective routes from said initial position to said desired final position" ('444 patent, claim 15)
- "means for determining a route each respective dental object will move to achieve its respective final position" ('444 patent, claim 16)
- "means for determining the distance each respective dental object will move to achieve its respective final position" ('444 patent, claim 16)
- "means for determining a rate at which each respective dental object will move along its respective route" ('444 patent, claim 16)
- "means for determining (a), (b), and (c) in relation to each of the other dental objects" ('444 patent, claims 17 and 18)
- "means for adjusting at least one of the route and the rate of at least one dental object to avoid collision with at least one other dental object" ('44 patent, claim 18)
- "means for determining an optimal number of stages for the order of movement of the dental objects" ('444 patent, claims 19)
- "means for determining the optimal number of stages" ('444 patent, claims 20)
- "means for determining a total distance each respective dental object will move" ('444 patent, claim 20)
- "means for dividing the total distance for each dental object by its respective maximum speed to determine a number of movement stages for each dental object" ('444 patent, claim 20)
- "means for determining a number of non-movement stages for each respective dental object" ('444 patent, claim 20)
- "means for adding the number of movement stages to the number of non-

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movement stages for each dental object to determine a minimum number of stages for each respective dental object" ('444 patent, claim 20)

- "means for selecting the largest of the minimum number of stages" ('444 patent, claim 20)
- "means for determining the order of movement" ('444 patent, claims 21, 22, 23, 24, 25, 26, 27, 28
- "means for ordering the movement of the dental objects in an all-equal pattern" ('444 patent, claim 21)
- "means for ordering the movement of the dental objects in a V-shaped pattern" ('444 patent, claim 22)
- "means for ordering the movement of the dental objects in an A-shaped pattern" ('444 patent, claim 23)
- "means for ordering the movement of the dental objects to form an M-shaped pattern" ('444 patent, claim 24)
- "means for ordering the movement of the dental objects in a mid-line shift pattern" ('444 patent, claim 25)
- "means for staggering the movement of at least two dental objects" ('444 patent, claim 26)
- "means for round tripping at least one dental object" ('444 patent, claim 27)
- "means for slowing the movement of at least one dental object" ('444 patent, claim 28)

3. '936 Patent

The Asserted Claims are invalid under 35 U.S.C. § 112 for at least the reasons identified below.

a) "further stitch" ('936 patent, claim 6)

Claim 6 of the '936 patent requires that certain instructions recited in claim 1 "comprise instructions to further stitch a portion of the received second scan data with the model." The claim is indefinite because it is unclear how there can be "further stitch[ing]" when there is no

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previous mention of stitching in the claim. Claim 6 depends from claims 1, 4, and 5, and none of these claims mentions stitching a portion of the of the second scan data with the model.

For the same reasons, the claim is invalid for lack of enablement and lack of written description: the patent fails to teach those skilled in the art how to make and use the full scope of the claimed feature and fails to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed.

b) "further discard" ('936 patent, claim 7)

Claim 7 of the '936 patent requires that certain instructions recited in claim 1 "comprise instructions to further discard a remainder of the received second scan data." The claim is indefinite because it is unclear how there can be "further discard[ing]" when there is no previous mention of discarding in the claim. Claim 7 depends from claims 1, 4, 5, and 6, and none of these claims mentions discarding a remainder of the second scan data.

For the same reasons, the claim is invalid for lack of enablement and lack of written description: the patent fails to teach those skilled in the art how to make and use the full scope of the claimed feature and fails to disclose an invention understandable to a skilled artisan or show that the inventor actual invented the alleged invention claimed.

c) "translation mechanism for displacing the one or more focal planes relative to the sensing face" ('936 patent, claims 2, 18)

A claim term is subject to § 112, ¶ 6 if the claim term fails to recite sufficiently definite structure. *Media Rights Techs., Inc. v. Capital One Fin Corp.*, 800 F.3d 1366, 1371-37 (Fed. Cir. 2015). The claim language "translation mechanism for displacing the one or more focal planes relative to the sensing face" ('936 patent, claims 2, 18) does not recite sufficiently definite structure and instead recites only function for the claimed "translation mechanism."

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The specification fails to disclose a corresponding structure for this claim term, beyond the mere recitation of "a translation mechanism for displacing said focal plane relative to the structure along an axis defined by the propagation of the incident light beams." '936 patent at 18:58-60. Thus, the patent fails to disclose sufficient structure for the "translation mechanism" term, and the term is therefore indefinite. *See, e.g.*, *Media Rights*, 800 F.3d at 1374-75 (finding "compliance mechanism" to be means-plus-function term and that specification failed to adequately disclose structure to perform functions). Because the specification does not provide sufficient structure, the claims are also invalid for inadequate written description and lack of enablement.

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Respectfully submitted,

/s/ Marissa A. Lalli _____

Melissa R. Smith
Texas Bar No. 24001351
GILLAM AND SMITH, LLP
303 South Washington Avenue
Marshall, TX 75670
Tel: (903)934-8450
Fax: (903)934-9257
melissa@gillamsmithlaw.com

James Travis Underwood
Texas Bar No. 24102587
GILLAM AND SMITH, LLP
102 N. College, Suite 800
Tyler, TX 75702
Tel: (903) 934-8450
Fax: (903)934-9257
travis@gillamsmithlaw.com

Joseph J. Mueller
Vinita Ferrera
Mark A. Ford
Marissa A. Lalli
Harry D. Hanson
Holly A. Ovington
Tyler L. Shearer
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6000
Fax: (617) 526-5000
joseph.mueller@wilmerhale.com
vinita.ferrera@wilmerhale.com
mark.ford@wilmerhale.com
marissa.lalli@wilmerhale.com
harry.hanson@wilmerhale.com
holly.ovington@wilmerhale.com
tyler.shearer@wilmerhale.com

Omar A. Khan
WILMER CUTLER PICKERING HALE AND DORR LLP
250 Greenwich Street
New York, NY 10007
Tel: (212) 230-8800
Fax: (212) 230-8888
omar.khan@wilmerhale.com

R. Gregory Israelsen
Gerard A. Salvatore
Robert B. Stiller
WILMER CUTLER PICKERING HALE AND DORR LLP
2100 Pennsylvania Avenue, NW
Washington, DC 20037
Tel: (202) 663-6000
Fax: (202) 663-6363
greg.israelsen@wilmerhale.com
jerry.salvatore@wilmerhale.com
robert.stiller@wilmerhale.com

Hannah Santasawatkul
Texas State Bar No. 24107617
WILMER CUTLER PICKERING HALE AND DORR LLP
1225 17th Street, Suite 2600
Denver, Colorado 80202
Tel. (720) 274-3135
Fax: (720) 274-3133
hannah.santasawatkul@wilmerhale.com

Attorneys for Defendants and Counterclaim-Plaintiffs ClearCorrect Operating, LLC ClearCorrect Holdings, Inc.

Attorneys for Defendant Institut Straumann AG

Attorneys for Counterclaim Plaintiff Straumann USA LLC

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document, along with the referenced charts, has been served via electronic mail on September 26, 2024, to all counsel of record.

/s/ Marissa A. Lalli
Marissa A. Lalli