

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Patent Owner.

Case No. IPR2025-00821
U.S. Patent No. 11,648,091

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,648,091**

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<u>Exhibit</u>	<u>Description</u>
EX1117	L. Gao and A. Wichelhaus, <i>Forces and Moments Delivered by the PET-G Aligner to a Maxillary Central Incisor for Palatal Tipping and Intrusion</i> , 87 Angle Orthodontist 534 (2017)
EX1118	Internet Archive, <i>Eastman Product Data Sheets Tritan Copolyester MX710, EX401, MX711, TX1000, TX1001, TX1500HF, TX1501HF, TX2000, TX2001</i> (archived Aug. 17, 2009, Nov. 21, 2008, Nov. 19, 2008, Nov. 22, 2008, Nov. 23, 2008) (last visited Apr. 12, 2025),

CLAIM INDEX

<u>Claim No.</u>	<u>'091 Patent Claim Language</u>
1[pre]	A multilayer sheet comprising:
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, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and
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 ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and
1[c]	a third layer;
1[d]	wherein the first layer has an elastic modulus greater than the second layer; and
1[e]	wherein the multilayer sheet is incorporated into an orthodontic appliance.
2	The multilayer sheet of claim 1, wherein the third layer contains a single polymer, and wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer; and wherein the first layer is disposed between the second layer and the third layer.
3	The multilayer sheet of claim 1, comprising a fourth layer containing a single polymer, wherein the single polymer of the fourth layer is a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer; and wherein the first layer and the third layer are disposed between the fourth layer and the second layer.

<u>Claim No.</u>	<u>'091 Patent Claim Language</u>
4	The multilayer sheet of claim 1, wherein the first layer has a light transmission between 400 nm and 800 nm of greater than about 75%.
5	The multilayer sheet of claim 1, wherein the first layer is coextruded with or laminated to the third layer.
6[pre]	A multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:
6[a]	a multilayer sheet comprising:
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, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and
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; and
6[d]	wherein the multilayer sheet forms a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement.
7	The multilayer dental aligner of claim 6, wherein the multilayer sheet further comprises a third layer containing a single polymer, and wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer or a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer.
8	The multilayer dental aligner of claim 6,

<u>Claim No.</u>	<u>'091 Patent Claim Language</u>
	wherein the multilayer sheet further comprises a third layer containing a single polymer, wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer; wherein the multilayer sheet further comprises a fourth layer containing a single polymer, wherein the single polymer of the fourth layer is a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer, and wherein the third layer and the first layer are disposed between the second layer and the fourth layer.
9	The multilayer dental aligner of claim 6, wherein the first layer has an elastic modulus greater than the second layer.
10[pre]	A multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:
10[a]	a multilayer sheet comprising:
10[b]	a first layer consisting of a co-polyester, the co-polyester having a flexural modulus of greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%;
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;
10[d]	a third layer; and
10[e]	wherein the multilayer sheet forms a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement.

<u>Claim No.</u>	<u>'091 Patent Claim Language</u>
11	The multilayer dental aligner of claim 10, wherein the third layer consists of a same or different co-polyester or a same or different thermoplastic polyurethane elastomer.
12	The multilayer dental aligner of claim 11, wherein the first layer is disposed adjacent to the third layer.
13	The multilayer dental aligner of claim 11, wherein the first layer is co-extruded with or laminated to the third layer.
14	The multilayer dental aligner of claim 10, wherein the multilayer sheet further comprises a fourth layer and wherein the first layer and the third layer are disposed between the second layer and the fourth layer.
15	The multilayer dental aligner of claim 14, wherein the fourth layer consists of a same or different thermoplastic polyurethane elastomer.
16	The multilayer dental aligner of claim 10, wherein the first layer is disposed between the second layer and the third layer.
17	The multilayer dental aligner of claim 10, wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer.
18[pre]	A multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:
18[a]	a multilayer sheet comprising:
18[b]	a first layer consisting of a co-polyester, the co-polyester having an elongation at break of greater than 70%, a flexural modulus of greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, and a tensile strength at yield of 4000-6500 psi; and

<u>Claim No.</u>	<u>'091 Patent Claim Language</u>
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; and
18[d]	wherein the multilayer sheet forms a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement.
19	The multilayer dental aligner of claim 18, wherein the multilayer sheet further comprises a third layer.
20	The multilayer dental aligner of claim 19, wherein the third layer consists of a same or different thermoplastic polyurethane elastomer.
21	The multilayer dental aligner of claim 19, wherein third layer consists of a same or different co-polyester, and wherein the third layer is co-extruded with or laminated to the first layer.
22	The multilayer dental aligner of claim 19, wherein the third layer is disposed adjacent the first layer.
23	The multilayer dental aligner of claim 18, wherein the thermoplastic polyurethane elastomer of the second layer has a compression set of greater than 40% after 24 hours at 70° C.
25	The multilayer dental aligner of claim 18, wherein the first layer has a light transmission between 400 nm and 800 nm of greater than about 75%.
26	The multilayer dental aligner of claim 18, wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer.

I. PRELIMINARY STATEMENT

U.S. Patent 11,648,091 discloses and claims methods of making multilayer polymer sheets and dental appliances for positioning a patient's teeth, which have a "first" copolyester layer and "second" TPU layer. Some claims recite a third or fourth layer. (EX1001, claims 1, 6, 10, 18.)

The '091 patent specification discloses only one layer configuration: a hard middle layer disposed between two soft external layers ("soft-hard-soft"). (*E.g.*, EX1001, 2:5-7) The specification neither discloses nor enables any other layer configuration. Patent Owner nonetheless asserts the '091 patent in co-pending litigation against a layer configuration not disclosed in the specification—*hard-soft-hard*. (*See* EX1014, 47-48.) Patent Owner's infringement arguments incorrectly assume that a person of ordinary skill in the art ("POSITA") would have known how to modify the disclosed soft-hard-soft configuration to create a dental aligner with the opposite configuration ("hard-soft-hard"), ignoring layer configuration's impact on an aligner's properties and efficacy.

While Patent Owner's assumptions are wrong and the claims are invalid under 35 U.S.C. §112, those issues do not affect the obviousness analysis here. This petition establishes that every challenged claim would have been obvious over prior art disclosing soft-hard-soft layer configurations and polymers with the claimed mechanical properties. The claims were allowed only after Patent Owner limited two

recited layers to each have a “single polymer”—and one in particular to a co-polyester with certain properties—while distinguishing certain claims from prior-art layers comprising polycarbonate. A prior-art reference not of record during prosecution, however, provided compelling reasons to replace polycarbonate with a specific co-polyester (Tritan) that meets all the recited properties. Every ground herein includes that reference (*Porter*).

The cited prior art disclosing multilayer dental aligners renders the claims obvious, including as Patent Owner asserts them in district court. *Kalili*, for example, discloses a two-layer appliance using TEXIN 990R thermoplastic polyurethane (“TPU”) elastomer as the soft layer and polycarbonate as the hard layer. Meanwhile, *Porter* provides a motivation and expectation of success to replace the polycarbonate in *Kalili* with Tritan copolyester, which lacks of the harmful bisphenol-A (“BPA”) chemicals present in polycarbonate and has “superior chemical resistance” and “reduce[d] [] risk of product failure from environmental stress cracking.” (EX1006, 60-63, 76.) *Porter* discloses that Tritan meets all claimed properties for the ’091 patent claims’ copolyester layer and *Texin 990R* discloses all claimed limitations for the TPU. This combination alone thus renders obvious the ’091 patent claims requiring only two layers.

Further, *Wen* discloses advantages of dividing polymer layers into thinner sublayers, which “more easily conform[] to the physical tooth models than a single

thick layer” and “allow more intimate contact between sheets and therefore help bond the films to one another,” especially for “polymers of disparate properties,” which are more likely to delaminate. (EX1008, [00212]-[00213].) Based on *Wen*, a POSITA would have found it obvious to modify *Kalili*’s soft-hard configuration to use thinner hard layers, resulting in a soft-hard-hard appliance meeting claims of the ’091 patent requiring a “third” layer. (EX1008, [00212]-[00213].)

All challenged claims are invalid as obvious over combinations based on *Tadros*, which discloses a “soft-hard-soft” dental appliance with a rigid inner layer and soft, elastomeric outer layers. A POSITA would have been motivated to combine *Tadros* with *Kalili* and *Texin 990R* (disclosing TEXIN 990R) and *Porter* (disclosing Tritan copolyester) to obtain the claimed invention with a reasonable expectation of success. Both *Tadros* and *Kalili* disclose multilayer dental appliances for positioning teeth and *Kalili* discloses that TEXIN 990R’s “outstanding” properties make it particularly well-suited for dental applications (like *Tadros*). Moreover, both *Tadros* and *Porter* disclose using copolyester in the rigid layer to improve on polycarbonate. (EX1003, [0097], [0100]; EX1006, 62-63.)

II. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner requests review and cancellation of claims 1-23 and 25-26 of the ’091 patent based on the following prior art and grounds. This Petition, supported

by the Declaration of Dr. Tim A. Osswald, demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim. (EX1007, ¶¶2, 11-12, 16-26, 346-50.) Dr. Osswald is a respected expert in the field of polymers and material science. (EX1007, ¶¶1-10; EX1015.)

<u>Exhibit</u>	<u>Reference</u>	<u>Prior-Art Status¹</u>	<u>Use in Prosecution</u>
EX1005	<i>Kalili</i>	§102(b)	Considered.
EX1006	<i>Porter</i>	§102(b)	Not of record.
EX1009	<i>Texin 990R</i>	§102(b)	Considered.
EX1008	<i>Wen</i>	§102(b)	Not substantively considered.
EX1003	<i>Tadros</i>	§102(b)	Considered.

<u>Ground</u>	<u>Claims Challenged</u>	<u>35 U.S.C.</u>	<u>Reference(s)</u>
1	6, 9, 18, 23, 25-26	§103	<i>Kalili, Texin 990R, Porter</i>

¹ Prior-art status has been assessed under pre-AIA 35 U.S.C. §102. The '091 patent claims priority to a May 14, 2012 provisional application. (EX1001, p.2, (60).) While Petitioner disputes entitlement to this priority date, all asserted references qualify as prior art as of that date.

<u>Ground</u>	<u>Claims Challenged</u>	<u>35 U.S.C.</u>	<u>Reference(s)</u>
2	1-2, 4-7, 9-14, 16-23, 25-26	§ 103	<i>Kalili, Texin 990R, Porter, Wen</i>
3	1, 4-7, 9-13, 16-20, 22-23, 25-26	§ 103	<i>Tadros, Porter, Kalili, Texin 990R</i>
4	1-23, 25-26	§ 103	<i>Tadros, Porter, Kalili, Texin 990R, Wen</i>

III. TECHNICAL BACKGROUND AND ASSERTED PRIOR ART

A. Thermoforming Multilayer Polymer Sheets with Soft and Hard Layers Was Well Known

Thermoforming is a manufacturing process where a heated thermoplastic sheet is stretched and formed into a desired shape using a mold, then cooled and trimmed to create a finished product. (EX1007, ¶¶27-29; EX1036-EX1039.) Thermoforming has been refined and expanded over time to produce a wide range of commercial products. (EX1007, ¶28.) At least 15 years before the '091 patent's earliest priority date, thermoforming was used to produce plastic dental appliances for straightening teeth. (EX1020 (describing a “thermoformed plastic dental retainer”); EX1007, ¶¶28, 50.)

Multilayer sheets can be created by various methods. (EX1007, ¶¶31-45; EX1040-EX1047.) By the 1970s, the advantages of thermoforming multilayer polymer sheets incorporating both hard and soft materials were well known.

(EX1007, ¶30.) It was understood that a “polymer layer in a multilayer sheet or film can exhibit different mechanical behavior from a free film of the same material,” and that “[p]articularly striking effects can be observed in laminar composites containing a ‘hard’ component and a ‘soft’ component.” (EX1019, 154; EX1007, ¶¶30, 49.) For example, “a laminar composite containing a layer of high-modulus, low elongation polymer sandwiched (with good adhesion) between layers of a high-elongation material” “may act to prevent transverse crack propagation in the hard layer” “[w]hen the composite is tested to failure in tension.” (EX1019, 154-55; EX1007, ¶49.)

Obtaining these desirable properties requires good adhesion between layers, which depends on the specific hard and soft polymers used. (EX1019, 155, 148; EX1007, ¶¶51, 54.) One strategy to improve adhesion between layers of disparate polymers is to “introduc[e] a thin layer of a third polymer that shows good adhesion to both of the materials” (i.e., a “tie layer”). (EX1019, 150; EX1007, ¶¶40-41.) Such adhesive lamination improves bonding without altering bulk properties. (EX1007, ¶¶ 39-41.) Another strategy was using thinner layers, which decreases “the degree of adhesion required in order for one layer to influence the response of its neighbor.” (EX1019, 150; EX1007, ¶¶51-56.)

Accordingly, by the 1970s, “multilayer sheet[s] containing as many as five or six layers [were] being produced for applications requiring good thermoformability,

heat sealability, stress crack resistance, barrier to gases and water vapor, and low taste and odor transfer.” (EX1019, 160-162; EX1007, ¶30.)

B. Multilayer Dental Aligners with Soft and Hard Polymer Layers Having the Claimed Mechanical Properties Were Well Known

By the earliest priority date, multilayer dental aligners comprising hard and soft polymer layers were well known. (See EX1007, ¶¶46-50; EX1010, EX1019; EX1048-EX1052.) For example, *Kalili*, published in January 2011 and claiming priority to 2006, discloses a two-layer dental aligner, with a rigid polycarbonate layer adhered to a soft TPU layer that contacts the teeth. (EX1005, [0069], claim 3.) *Tadros*, published in 2005, describes a three-layer dental aligner with “softer” elastomeric material surrounding a hard central layer on both sides (i.e., “soft-hard-soft” layer configuration). (EX1003, Abstract, [0073].)

Polymers with the '091 patent's claimed properties were also well known. For example:

- *Porter* discloses commercially available Tritan copolyester with properties within the ranges claimed for the '091 patent's hard layer. (EX1006, 60, 63, 76.)
- *Kalili* discloses using TEXIN 990R TPU elastomer, which has the properties claimed for the '091 patent's soft layer. (EX1005, [0069]; EX1009, 3.)

C. The Asserted Prior Art

As shown below, each reference is analogous art to the '091 patent and to each other. *Kalili*, *Wen*, and *Tadros* are directed to the field of polymeric dental aligners, while *Porter* and *Texin 990R* are pertinent to the problem of improved aligner materials as they describe polymers explicitly identified by the other references or within a class of polymers identified as suitable for dental aligners. (EX1001, 1:54-57; EX1007, ¶¶98-128, 145-176.)

1. *Kalili*

Kalili discloses an “invisible” (i.e., clear), removable, two-layer dental appliance for repositioning teeth and methods of manufacturing the same. (EX1005, p.1 (57), [0002], [0012], [0063], claims 1, 12; EX1007, ¶115.)

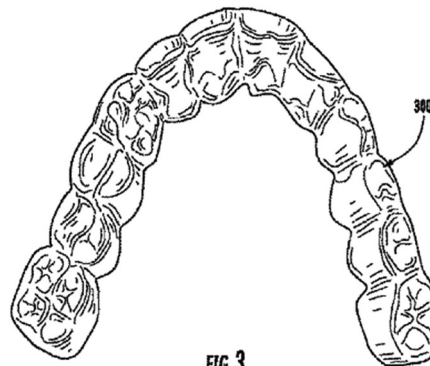


FIG. 3
(EX1005, Fig. 3.)

A “single sheet of material ... may be formed from a variety of materials” such as “polycarbonate with a lower modulus inner [i.e., tooth-contacting] lining.” (EX1005, [0053].) *Kalili* specifically identifies TEXIN 990R as an “outstanding”

soft layer, stating that the liner may be a TPU “such as TEXIN® 990R resin with a shore hardness of approximately 90A.” (EX1005, [0069]; claim 3; EX1007, ¶¶116-20.) The “lower elastic modulus on the inner [i.e., tooth-contacting] layer may allow for greater patient comfort, [and] less tooth, bone and root damage.” (EX1005, [0009].)

Kalili also discloses fabricating dental appliances by “heat[ing]” and “vacuum[ing]” laminate sheets over printed teeth models. (EX1005, [0015].) *Kalili* discloses that a series of such appliances can be created from “incrementally modif[ied]” tooth models and used sequentially to incrementally reposition a patient’s teeth. (EX1005, Abstract, [0011], [0055]; EX1007, ¶115.)

Kalili is a U.S. patent application published on Jan. 27, 2011, more than one year before the ’091 patent’s earliest possible priority date of May 14, 2012. (EX1005, (43).) *Kalili* therefore is prior art under pre-AIA 35 U.S.C. §102(b).

2. *Porter*

Porter discloses a specific class of polymers—Tritan copolyesters—with reported mechanical properties withing the ranges recited for the hard layer in the ’091 patent claims.² (EX1006, 63, 76; EX1007, ¶125.) *Porter* discloses several

² The Tritan copolyesters available as of the ’091 patent’s earliest possible priority date had similar mechanical properties. (EX1007, ¶¶104-105; EX1118.)

benefits of replacing polycarbonate with Tritan copolyesters, including to avoid ingesting BPAs, simplify manufacturing, and improve product durability in harsh environments. (EX1006, 60-63, 76; EX1007, ¶¶126-27, 88-108.) *Porter* would have been particularly relevant to selecting materials for dental aligners, which must be durable and non-toxic. (EX1007, ¶125.)

Porter, a December 2007 article printed in *Plastics Technology* magazine, is a prior-art printed publication. As detailed in the declaration of librarian Lauren Gluckman, “*Porter* was received by the Penn State Libraries DEC 11 2007 as set forth in the date stamp on the cover page” and “would have been available to the public within a few days of being checked-in and cataloged on DEC 11 2007.” (EX1012, ¶¶1-14, 20-28, 34-35; EX1013; EX1025.)

Therefore, *Porter* was publicly available more than four years before the ’091 patent’s earliest possible priority date of May 14, 2012, and is a prior-art printed publication under pre-AIA 35 U.S.C. §102(b).

3. *Texin 990R*

Texin 990R is a manufacturer’s product information sheet for the TEXIN 990R TPU polymer disclosed in *Kalili*. (EX1007, ¶128.) *Texin 990R*, published in 2002, discloses the mechanical properties of that material, including ultimate elongation (i.e., elongation at break) of 450%, Shore hardness of 90A, tensile

strength (i.e., ultimate tensile strength) of 5,000 psi, and compression set of 75% after 22 hours at 70 °C.³ (EX1009, 3; EX1007, ¶128.)

³ *Texin 990R*, like *Porter*, discloses properties of the polymer before any later processing to form a multilayer sheet or aligner. Patent Owner's district court Preliminary Infringement Contentions incorrectly assume such processing has no effect on the polymer's disclosed properties. (E.g., EX1014, 47-60.) Petitioner disagrees. A POSITA would have understood that certain manufacturing techniques (e.g., coextrusion, extrusion lamination) would alter the polymer's properties. A POSITA also would have understood, however, that other techniques such as adhesive lamination would preserve the polymer's properties as disclosed in the manufacturer's datasheet. (EX1007, ¶¶31-41, 104 n.2, 170.)

Because the asserted prior art discloses a technique that would **preserve** these properties when forming a multilayer sheet (adhesive lamination), and given Patent Owner's district-court assertions, Petitioner relies herein on *Texin 990R* and *Porter* to establish properties of a layer within a multilayer sheet. Patent Owner cannot dispute this approach—its infringement assertions rely on manufacturer datasheets to allegedly prove certain properties after a polymer has been processed into a multilayer sheet, **regardless** of manufacturing technique. (E.g., EX1014, 47-60.)

Texin 990R is a prior-art printed publication because it was publicly accessible nearly a decade before the '091 patent's May 14, 2012 priority date, as shown by the "current as of" date of "November 2002." (EX1009, 4.) A reference's own notice of its availability date is probative of its public accessibility. *See Int'l Bus. Machs. Corp. v. Intellectual Ventures II LLC*, IPR2014-00681, Paper 11 at 13-14, 16 (PTAB Oct. 30, 2014) (determining software user's guide "was published and accessible to users of the corresponding product" based on the year identified in the guide's copyright notice); *Ford Motor Co. v. Cruise Control Techs. LLC*, Case IPR2014-00291, Paper 44 at 7-8 (PTAB June 29, 2015) (holding reference was a printed publication based on copyright notice date in combination with declaration testimony).

Texin 990R's public accessibility is further shown by its being a public "bulletin" produced by the manufacturer, Bayer MaterialScience, to provide product information and directing the public to "contact Bayer MaterialScience" for further information. (EX1009, 4.) Publication by a well-known source like Bayer in the ordinary course of business further evidences public availability. *See Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, 2019 WL 7000067, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential) (publication of book by established publisher supported public accessibility, leading to institution); *see also CIM Maint. Inc. v. P&RO Sols. Grp., Inc.*, IPR2017-00516, Paper 8 at 18-20 (PTAB June 22, 2017).

Other evidence further confirms public availability. For example, *Texin 990R* was submitted to the Office in a January 6, 2011 Information Disclosure Statement (“IDS”) during prosecution of *Kalili*, which was published on January 27, 2011. (EX1024, IDS, Jan. 6, 2011, at 3). *See LG Electronics, Inc. v. Advanced Micro Devices, Inc.*, IPR2015-00329, Paper 13 at 10-13 (PTAB July 10, 2015) (holding reference’s dated copyright notice together with listing in IDS was sufficient at institution stage to show reasonable likelihood that reference was a printed publication). Patent Owner also amended the ’091 patent claims in response to a rejection citing *Texin 990R*. (EX1018, 109, 132-33.)

Archives of Bayer’s webpages further support public availability. Identical values of TEXIN 990R’s mechanical properties as those disclosed in *Texin 990R* had already been publicly disclosed by at least May 26, 2001, on the website “Bayer Polymers Product Guide – Properties,” as shown by the Internet Archive. (EX1026; EX1012, ¶¶1-5, 15-19, 29-35; EX1027-EX1035); *see Vidstream LLC v. Twitter, Inc.*, 981 F.3d 1060, 1066 (Fed. Cir. 2020) (affirming public accessibility of book based in part on Internet Archive page showing the book was offered for sale on Amazon.com). That webpage shows TEXIN 990R’s mechanical properties from a 1996 Bayer datasheet. Because this publicly accessible datasheet matches the properties disclosed in *Texin 990R*, it further confirms *Texin 990R*’s public accessibility. Further, *Texin 990R* provides contact information to Bayer

MaterialScience, including the public website
“www.BayerMaterialScienceNAFTA.com.” (EX1009, 4.)

For all these reasons, *Texin 990R* is a printed publication and prior art under at least pre-AIA 35 U.S.C. §102(b).

4. *Wen*

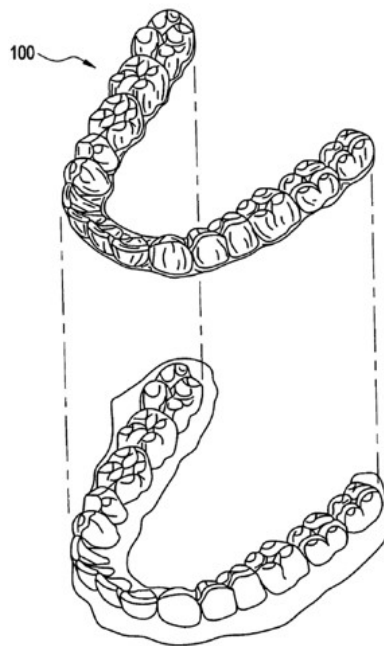
Wen discloses multilayer dental aligners for repositioning a patient’s teeth and methods of making such aligners. (EX1008, [00189]-[00231]; EX1007, ¶¶121-23.) *Wen* discloses several benefits achieved by using multiple uniform polymer sublayers rather than a single, thicker layer of the same polymer. These thinner layers improve thermoforming of multilayer dental aligners because they (1) “more easily conform[] to the physical tooth models than a single thick layer” and (2) “allow more intimate contact between sheets and therefore help bond the films to one another.” (EX1008, [00212]-[00213]; EX1007, ¶124; *see also* EX1019, 150 (“[T]he thinner the layers, the lower will be the degree of adhesion required in order for one layer to influence the response of its neighbor.”).)

Wen is an international patent application published on Sept. 14, 2006, more than five years before the ’091 patent’s earliest possible priority date of May 14, 2012. (EX1019, (43).) *Wen* therefore is prior art under pre-AIA 35 U.S.C. §102(b).

5. *Tadros*

Tadros discloses a dental appliance for repositioning teeth comprising a hard “polymeric mixture” disposed between two soft layers. (*See, e.g.*, EX1003, Abstract, [0073], [0090], claim 1; EX1007, ¶¶109, 113.) *Tadros* sought to achieve a dental appliance that could be “advantageously used for repositioning teeth” that “displays properties of optical clarity, stain resistance, and transparency, which makes the appliance invisible when used in the oral cavity.” (EX1003, [0015]; EX1007, ¶¶109-10.) Further, *Tadros* sought to create appliances that are “easy to install” and “more comfortable to wear than braces” and “displays properties of toughness and creep resistance.” (EX1003, [0015]; EX1007, ¶¶109-10.)

FIG. 3



(EX1003, Fig. 3.)

Tadros's discloses that the hard layer should "have a tensile strength and modulus effective to reposition teeth." (EX1003, [0015], [0068]; EX1007, ¶110.) *Tadros* uses a sheet of pure polycarbonate as an example of a hard layer with ideal repositioning properties. (EX1003, [0097], Tables 2, 4, & 5; EX1007, ¶110-11.) *Tadros* seeks to maintain pure polycarbonate's desirable properties while also having improved thermoforming and molding properties. Specifically, *Tadros* aims to create hard layers with lower glass transition temperature and thermoforming temperature than polycarbonate. (EX1003, [0100], [0113].) *Tadros* explains that "a lower glass transition temperature and a lower thermoforming temperature generally facilitate an easier deformation of the sheet over dental mold material" by "reduc[ing] fitting corrections due the difference in the coefficient of thermal expansion of the material of the appliance and the mold material." (EX1003, [0113].) *Tadros* notes that these improved molding characteristics ultimately "improve[] dimensional stability and insure[] a good and easy fit to patient's teeth" in the final dental appliance. (EX1003, [0100].)

For the soft outer layers, *Tadros* discloses using elastomers, including polyurethanes, "to alleviate pain, discomfort and bleeding gums." (EX1003, [0073]; EX1007, ¶¶111-12.) *Tadros* further discloses fabricating the appliances by "vacuum forming" over "positive tooth models." (EX1003, [0085]-[0090]; EX1007, ¶114.)

Tadros is a U.S. patent application published on May 12, 2005, seven years before the '091 patent's earliest possible priority date of May 14, 2012. (EX1003, (43).) *Tadros* therefore is prior art under pre-AIA 35 U.S.C. §102(b).

IV. THE '091 PATENT

A. Level of Ordinary Skill

A POSITA would have had at least a four-year undergraduate degree in materials science, mechanical engineering, chemical engineering, or a related field and at least two years of experience in the field of polymer science, combined with at least two years of experience in the field of design, manufacture, and processing of thermoformable polymer sheets for use in various applications, such as in orthodontic and dental appliances. Additional education could substitute for professional experience and vice versa. (EX1007, ¶¶13-15.)

B. The '091 Patent Specification

The specification of the '091 patent discloses “multilayer polymer sheets” and “related methods, systems, and appliances.” (EX1001, Abstract; EX1007, ¶¶129-30.) Specifically, the '091 patent discloses “multilayer dental positioning appliances.” (EX1001, 1:19-21.)

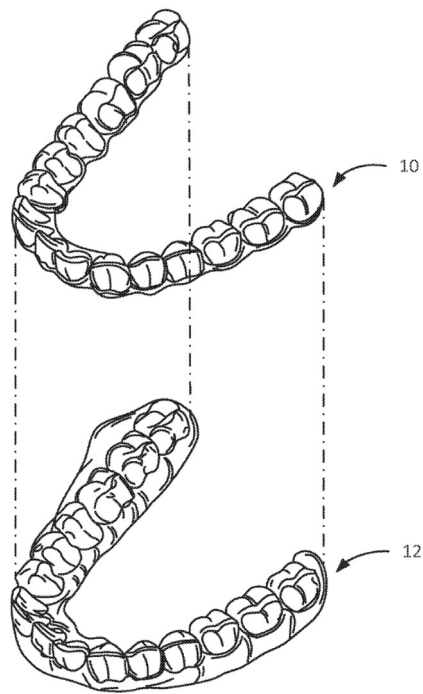


FIG. 1
(EX1001, Fig. 1.)

The '091 patent acknowledges that repositioning appliances were in use before the priority date, noting that “systems including a series of preformed appliances/aligners have become commercially available from Align Technology, Inc. ... under the trade name Invisalign®.” (EX1001, 1:30-40 (citing U.S. Patent Nos. 6,450,807 and 5,975,893, and invisalign.com); EX1007, ¶139.)

The '091 patent purports to have invented new “*multilayer* dental appliances” that “include[] a hard polymer layer disposed between two soft polymer layers.” (EX1001, 2:5-10; EX1007, ¶¶130-34.) The specification refers repeatedly *and exclusively* to appliances with this soft-hard-soft configuration. (See EX1001, 2:5-7 (“The multilayer appliances can include a hard polymer layer disposed between two

soft polymer layers.”); *see also* EX1001, 2:23-25, 2:38-41, 5:14-16, 5:26-28, 5:37-41, 6:37-39, 7:18-20, 7:53-55, 8:22-24.) The '091 patent specification does not describe or enable any other layer configuration. (EX1007, ¶133.)

The '091 patent discloses that the hard polymer layer and each soft polymer layer may be made up of multiple layers of polymer material. (EX1001, 5:56-59, 6:59-61; EX1007, ¶135.) The patent does not allege these sublayers are novel. (EX1007, ¶136.) Figure 2, annotated below, exemplifies this arrangement. Multilayer sheet 20 includes a **hard polymer layer 24** disposed between a **first soft polymer layer 22** and a **second soft polymer layer 26**, each comprising several polymer layers. (EX1001, 2:38-41, 5:23-26.)

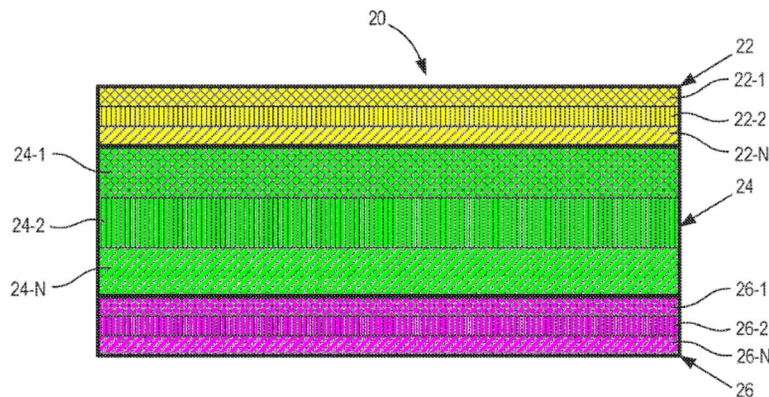


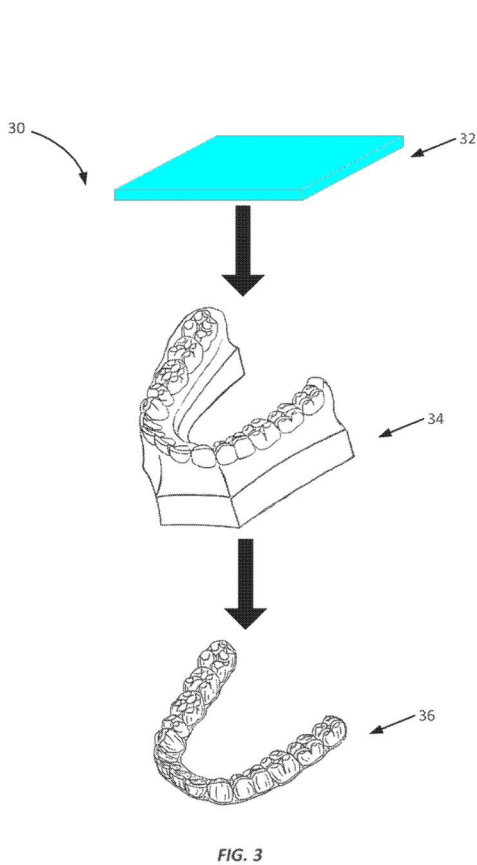
FIG. 2
(EX1001, Fig. 2.)

Even embodiments including these optional sublayers do not deviate from the configuration where the outermost layers are soft polymers.

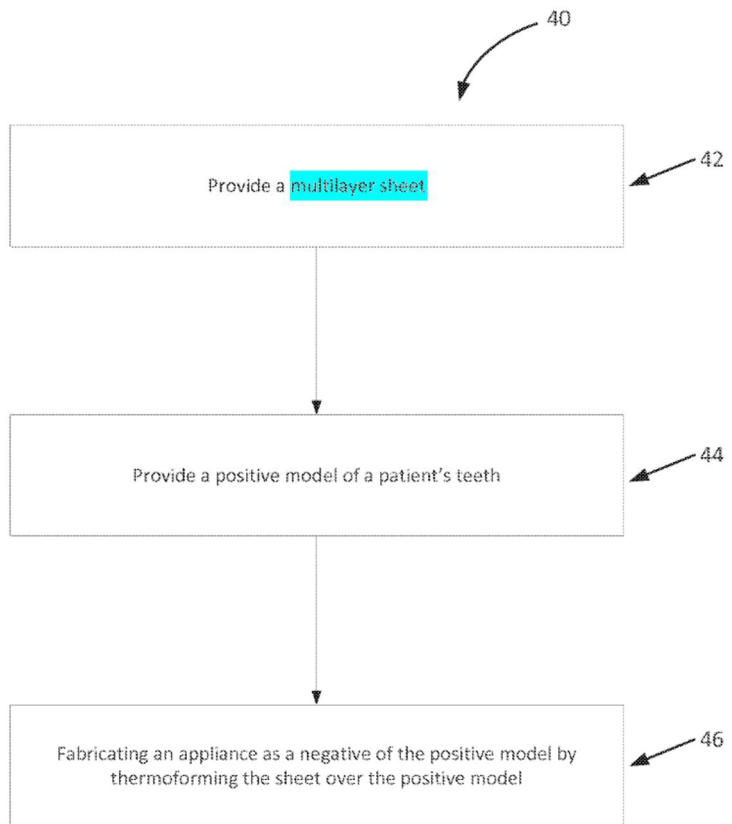
The specification further identifies potential materials and certain physical and mechanical properties of the **hard polymer layer** and the **first** and **second soft**

polymer layers. (EX1007, ¶137; *See e.g.*, EX1001, 5:28-31 (relative thickness), 5:31-34 (thickness of hard layer), 5:34-37 (thickness of soft layers), 5:37-41 (thickness of the multilayer sheet), 5:44-56 (material used for hard layer), 5:67-6:10 (tensile strength, elongation, tensile modulus, flexural modulus, stress relaxation, and light transmission of hard layer), 6:11-19 (material(s) used for soft layers), 6:28-36 (hardness, tensile strength, elongation, compression set, flexural modulus, and light transmission of soft layers).) None of these characteristics or properties are purported to be novel. (EX1007, ¶¶57-87; EX1053-EX1067.)

The specification describes the manufacturing technique of thermoforming, which, as discussed above, was well known. (EX1007, ¶¶138-40; *see Supra* III.A.) The only allegedly novel feature of the manufacturing process is the use of a multilayer sheet 32 that “can include three layers: a hard polymer layer disposed between two soft polymer layers.” (EX1001, 7:18-20.) Figures 3 and 4, annotated below, exemplify this process.



(EX1001, Fig. 3.)



(EX1001, Fig. 4.)

C. The '091 Patent Claims

The '091 patent's independent claims recite “a multilayer sheet” comprising a first layer comprised of a copolyester, a second layer comprised of a TPU, and, in some claims, a third layer, wherein the multilayer sheet is incorporated into an

orthodontic appliance. (EX1001, claims 1, 6, 10, 18.)⁴ The claims further specify numerical ranges for certain mechanical properties of either the hard or soft polymer

⁴ As explained below in Section IV.D and in Petitioner's invalidity contentions in the co-pending litigation, the '091 patent's specification shows that Patent Owner developed a single soft-hard-soft material that later became the company's SmartTrack material. (EX1022, 268-288.) Patent Owner nonetheless asserts in the litigation that the claims cover configurations beyond soft-hard-soft. (EX1014, 47-48.) Indeed, Patent Owner asserts the claims against Petitioner's hard-soft-hard multilayer polymer sheet, which has the exact opposite configuration from the soft-hard-soft configuration Patent Owner purportedly invented. (EX1023, ¶¶84-90.) The efficacy of repositioning teeth using dental aligners that either alter the relative placement of the hard and soft layers, or replace layers with other polymers without guidance to do so, is unpredictable, and the '091 patent specification does not provide any guidance as to how to implement such alternatives. (EX1007, ¶133.) Accordingly, the claims lack written description and enablement under §112, issues reserved for the co-pending litigation.

These §112 disputes do not affect the obviousness analysis here. (EX1007, ¶133.) Under any claim interpretation, every challenged claim is unpatentable as

layer(s) used in making the appliance (e.g., flexural modulus, elongation at break, and hardness). (EX1001, claims 1, 6, 10, 18; EX1007, ¶¶141-43.).

D. The '091 Patent Prosecution History

The '091 patent claims priority to Application No. 13/470,681 (the “Parent application”), filed on May 14, 2012 (now U.S. Patent No. 9,655,691). (EX1001-EX1002.) The application that issued as the '091 patent (No. 17/902,445) was the fourth application in a series of continuations from Application No. 15/476,655, which issued as U.S. Patent No. 10,973,613. All these applications share substantively similar specifications that disclose only soft-hard-soft layer configurations. (*See, e.g.*, EX1010, 3-5, 29-32 (claims 1, 13, 20); *see generally* EX1011, EX1018.)

1. Prosecution of the Parent Application

During prosecution of the Parent application, Patent Owner repeatedly relied on the soft-hard-soft layer configuration to overcome rejections, and this is the only configuration the specification discloses or enables. For example, when the Examiner objected to the abstract for “not convey[ing] ... applicant’s invention”

obvious based on the prior-art soft-hard-soft configurations in Grounds 3-4. Additionally, claims 1-7, 9-23, and 25-26 are also invalid as unpatentable based on the configuration in Grounds 1-2.

(EX1010, 934), Patent Owner amended the abstract to refer to the patent's soft-hard-soft layer configuration (EX1010, 1004, 1007).

The Examiner allowed the claims based on a Declaration from Dr. Chunhua Li, the first-named inventor, discussing purportedly unexpected results shown by the “SmartTrack material (ST30),” “a product according to the instant claims **comprising a layered material with a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer.**” (EX1010, 1237, 1239.)⁵ Dr. Li alleged that the claimed appliances “exhibit unexpectedly positive results” as “evidenced by clinical studies” comparing the soft-hard-soft SmartTrack (ST30) material to a uniform polyurethane appliance. (EX1010, 1236, 1239-41, 1243.) The Parent application's claims were allowed only “based upon evidence of unobvious or unexpected advantageous properties of a layered material of a **hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer,**” (EX1010, 1376.)

2. Prosecution of the '655 Application

Like the Parent Application, every as-filed claim in the '655 Application required a three-layer, soft-hard-soft appliance. (EX1011, 42-44, 96.) In response to rejections, Patent Owner amended the claims to eliminate the express requirement

⁵ Emphasis added throughout the Petition unless otherwise noted.

for a soft-hard-soft configuration and broaden the claims to cover two-layer, soft-hard appliances, despite the lack of written description or enablement support for this amendment. (EX1011, 625-28. (*compare* amended claim 20, *with* new claims 34 and 37).)

Patent Owner relied on a new declaration from inventor Dr. Li, which **added** statements alleging, for the first time, that the newly-claimed two-layer aligner would “exhibit the[] beneficial functions” as a three-layer, soft-hard-soft configuration, and **removed** statements limiting the description of the invention to Patent Owner’s SmartTrack material. (EX1011, 600, 603-04.) The Examiner, however, maintained the previous rejections, rejecting the declaration’s arguments and noting the alleged unexpected results were limited to the soft-hard-soft configuration of SmartTrack and failed to support the broadened two-layer claims. (EX1011, 631, 633, 708-710.)

Applicants subsequently alleged certain deficiencies in the prior art, arguing that the specific TPU used cited by the Examiner was too hard and the PVC layer in a secondary reference was not durable enough. (EX1011, 684-85, 766-69.) The Examiner thereafter allowed the claims, pointing to the failure of one reference (not asserted herein) to teach hard and soft layers with the recited properties and finding Dr. Li’s “unexpectedly positive results” argument “persuasive.” (EX1011, 846-47.) All issued claims of the ’613 patent require three layers.

3. Prosecution of the '445 Application

Despite previous rejections in the related '655 application that Patent Owner failed to support claims covering two-layer appliances, as-filed claims 6 and 20 of the '445 application required only a “first layer” and “a second layer.” (EX1018, 25, 27.) Patent Owner never reconciled these two-layer claims with the specification’s narrow disclosure of soft-hard-soft configurations.

Patent Owner was forced to limit the '091 patent claims to layers “consisting of” a single polymer—thus excluding layers containing mixtures of polymers. The as-filed claims of '445 application had encompassed layers with polymeric mixtures. (EX1018, 25-28.) The Examiner found, however, that the Parent application only provided support for properties of the “layers as a whole,” whereas the as-filed claims recited properties of individual polymers (i.e. properties of “a copolyester” or “a [TPU]”). (EX1018, 89-90.) The Examiner noted that “said layer does not inherently have the same physical properties as the layer as a whole,” and thus lacked written-description support. (EX1018, 89-90.)

The Examiner also rejected the claims as obvious, noting that it would have been obvious to replace the layers in *Tadros*’s soft-hard-soft appliance with “known,

commercially available” polymers disclosing the claimed properties.⁶ (EX1018, 108-112.) The Examiner relied on *Kalili*’s disclosure of TEXIN 990R and a separate reference’s disclosure of copolyester mixtures, which had the properties of the claimed TPU and copolyester layers, respectively. (EX1018, 108-112.)

In response, Patent Owner narrowed the claims to layers “consisting of” a single polymer, thus requiring layers of pure copolyesters or TPUs. (EX1018, 126-29.) The Examiner allowed the claims, stating that the record prior art failed to disclose a multilayer sheet comprising (i) a layer “consisting of” a copolyester with the recited properties, (ii) a layer “consisting of” a TPU with the recited properties and (iii) a third layer. (EX1018, 158-61.) The Examiner did not apply any prior art disclosing pure copolyester layers, such as *Porter* (which was not of record).

V. CLAIM CONSTRUCTION

The Board construes claims in accordance with 37 C.F.R. §42.200(b) and *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Claims need only be construed to the extent necessary to resolve a controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

⁶ This prior-art combination relied upon by the Examiner differs substantively from Grounds 3-4, which additionally rely on *Porter* (not cited during prosecution of any patents in the ’091 patent family).

No terms require construction and the claims are invalid over the asserted art under any possible construction consistent with *Phillips*. (EX1007, ¶144.) In co-pending litigation, neither party offered terms for construction. (EX1021.) Here, Petitioner applies the prior art consistent with Patent Owner’s assertions in its Infringement Contentions (EX1014, 47-60), which are Patent Owner’s statements before a federal court on the scope of a patent claim, and the Office thus may consider them to determine the proper meaning of the claims. 35 U.S.C. §301(a)(2), (d); *Peloton Interactive, Inc. v. NEC Corporation*, IPR2023-01239 (Paper 16), 16-17 (PTAB Mar. 4, 2024) (instituting review where Petitioner “appl[ied] the prior art consistent with what appears to be [Patent Owner]’s interpretation of the claims as indicated in the Infringement Contentions”); *Donnelly Distribution LLC v. Russo Trading Co., Inc.*, IPR2019-00761, Paper 8, 17-18 (PTAB Sept. 6, 2019 (instituting review where Petitioner demonstrated the prior art met the claims “in view of Patent Owner infringement contentions” accusing a structure similar to the prior art)).

VI. CLAIMS 1-23 AND 25-26 ARE UNPATENTABLE OVER THE PRIOR ART

A. Ground 1: Claims 6, 9, 18, 23, and 25-26 Would Have Been Obvious Over *Kalili* in View of *Porter* and *Texin 990R*.

As explained below, a POSITA would have been motivated to combine *Kalili*, *Porter*, and *Texin 990R* to arrive at the claims challenged in Ground 1 with a reasonable expectation of success. (EX1007, ¶¶145, 147-158.)

1. Independent Claim 6

Claim 6[pre]-6[a]

“A multilayer dental aligner for repositioning a patient’s teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:”

“a multilayer sheet comprising:”

Kalili’s appliance is made from “[a] polymer sheet” and has a “higher modulus outer [i.e., non-tooth contacting] layer and a lower modulus inner [i.e., tooth-contacting] layer.” (EX1005, [0069], [0015], Abstract.) This “single sheet of material ... may be formed from a variety of materials” such as “polycarbonate with a lower modulus inner [i.e., tooth-contacting] lining.” (EX1005, [0053].)

Kalili discloses incorporating the multilayer sheet into “[a]n invisible, removable orthodontic repositioning appliance ... for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement.” (EX1005, Abstract, [0015].) *Kalili*’s appliance “position[s] a patient’s teeth.” (EX1005, p.1 (57), claim 12.)⁷ *Kalili* also discloses methods of making the disclosed appliance. (EX1005, [0015].) *Kalili* thus meets the limitations of claim 6[pre]-6[a]. (EX1007, ¶¶177-79.)

⁷ *Kalili*’s disclosures (like *Tadros*’s, Grounds 3-4) contain at least as much detail as the ’091 patent that its method provides a tooth-positioning appliance.

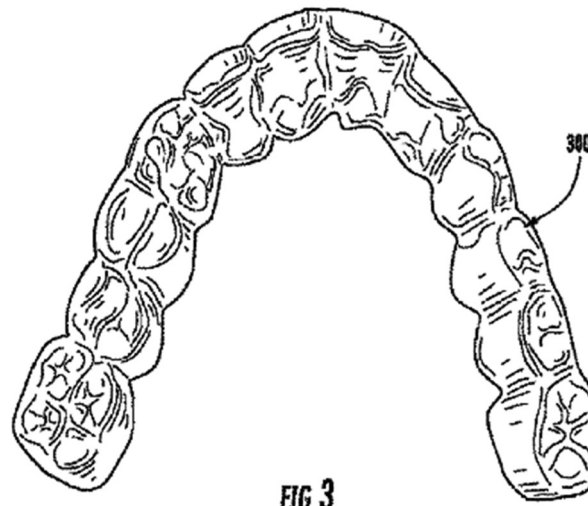


FIG. 3
(EX1005, Fig. 3.)

Claim 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, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength

(EX1007, ¶178; *see, e.g.*, EX1001, 3:60-62.) To the extent a POSITA would have understood the '091 patent as enabling a tooth-positioning appliance, a POSITA also would have been able to practice *Kalili's* and *Tadros's* methods of repositioning teeth. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020); *In re Publicover*, 813 F. App'x 527, 532 (Fed. Cir. 2020).

at yield of 4000-6500 psi, and an elongation at break of
greater than 70%; and”

Kalili discloses using polycarbonate as the higher-modulus layer material. (EX1005, [0053].) *Porter*, however, discloses replacing polycarbonate with “Tritan copolyester[s],” developed and marketed as a BPA-free alternative to polycarbonate with similar modulus properties, “increased heat resistance and toughness,” “superior chemical resistance,” and “reduce[d] [] risk of product failure from environmental stress cracking.” (EX1006, 60-61, 63, 76; EX1007, ¶180.)

Porter discloses that Tritan copolyester meets every property recited for “a first layer” in claim 6[b]: flexural modulus of 225,000 psi (“greater than 150,000 psi”); elongation at yield of 6% (“greater than 4%”); tensile modulus of 225,000 psi (“greater than 150,000 psi”); tensile strength at yield of 6,200 psi (between “4000-6500 psi”); and elongation at break of 210% (“greater than 70%”). *Porter* thus discloses “a first layer” as recited in claim 6[b]. (EX1006, 63; EX1007, ¶181.)

A POSITA would have been motivated and found it obvious to use a single-polymer layer of Tritan to avoid the harmful BPAs released from polycarbonate aligners, while also improving performance characteristics. (EX1007, ¶¶88-108, 148-158, 182; EX1006, 60-61, 63; EX1068-EX1113, EX1114-EX1117, EX1118.) *See, e.g., Hologic, Inc. v. Minerva Surgical, Inc.*, 764 F. App’x 873, 880-81 (Fed. Cir. 2019) (holding claims to medical device obvious by relying on general

“motivation to make a device safer”); *In re Kross*, 825 F. App’x 758, 760-62 (Fed. Cir. 2020) (finding motivation and expectation of success in substituting “similar” polymer that addressed known prior-art cracking and splitting problems); *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 631 F. Supp. 2d 1010, 1036-37 (N.D. Ill. 2009), *aff’d*, 683 F.3d 1356, 1364-65 (Fed. Cir. 2012) (obvious to substitute materials where both materials exhibited similar properties that would be useful in the field of the invention).

Further, a POSITA would have had a reasonable expectation of success of replacing *Kalili*’s polycarbonate layer with Tritan copolyester given Tritan’s proven use in thermoforming processes and extruded-sheet applications, its durability in the “harsh” environments of “heat, hydrolytic and chemical attack, and applied stress” required for dental applications, and past industry success replacing polycarbonate with Tritan. (EX1006, 60-63, 76; EX1003, [0069]; EX1007, ¶¶148-158, 183); *Kross*, 825 F. App’x at 760-62. Further, the prior art specifically instructed a POSITA to use Tritan. (EX1104.)

A POSITA would have understood that adhesive lamination would preserve Tritan’s properties within the layer, without cross-linking or mixing of layers. (*See* EX1007, ¶184.) Accordingly, the first layer would “contain[] a single polymer” of pure Tritan copolyester, as claimed. (EX1007, ¶¶180-84.)

Claim 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; and”

Kalili discloses a specific TPU elastomer that meets these claim limitations. (EX1007, ¶¶185-89.) The lower-modulus inner layer in *Kalili*’s exemplary appliance is “a polyurethane,” and *Kalili* specifically identifies “TEXIN® 990R resin with a shore hardness of approximately 90A.” (EX1005, [0069], [0074].) A POSITA would have been motivated and found it obvious to use a single-polymer layer of TEXIN 990R, TPU elastomer, based on *Kalili*’s disclosure of its desirable qualities for use in a layered dental aligner, including “outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility” and “good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics.” (EX1005, [0069].)

Texin 990R discloses that TEXIN 990R meets the claimed properties of the “second layer” in claim 6, including ultimate tensile strength of 5,000 psi (“greater than 5000 psi”), elongation at break of 450% (“greater than 200%”), and hardness

of 90A (from “60A to 85D”).⁸ (EX1009, 3; *supra* Section III.C.3; EX1007, ¶¶68-77, 186-188 (explaining that a POSITA would interpret *Texin 990R* as disclosing an ultimate tensile strength of greater than about 5,000 psi and even if the “tensile strength” reported in *Texin 990R* were interpreted as tensile strength at yield, TEXIN 990R’s ultimate tensile strength would necessarily exceed or equal to the reported tensile strength at yield).)

Although it was known that the mechanical properties of a polymer (or free film) can change when combined into a multilayer sheet (e.g., during coextrusion or extrusion lamination) (*see supra* Section III.A), a POSITA also would have known of manufacturing processes (i.e., adhesive lamination) that preserve the desirable mechanical properties reported for TEXIN 990R even after such combination. (EX1007, ¶189.) For example, a POSITA would have expected that using tie layers (*see supra* Section III.A; EX1007, ¶¶31, 39-41) to bond TEXIN 990R to the other layers would preserve TEXIN® 990R’s reported mechanical properties during processing, and thus the resulting soft layer would have the properties disclosed in *Texin 990R*.

A POSITA also would have understood that in adhesive lamination there would not be cross-linking or mixing between layers. (*See* EX1007, ¶31.)

⁸ *See supra* n.3.

Accordingly, the second layer would “contain[] a single polymer” of pure TEXIN 990R TPU as required by the claim.

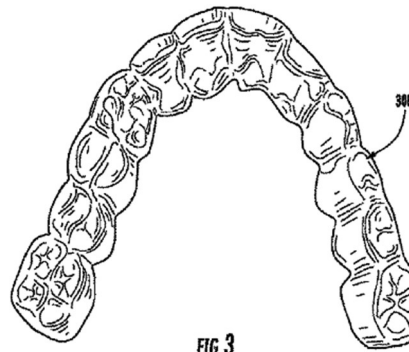
A POSITA would have understood that the reported tensile strength of 5,000 psi discloses the claimed range of “greater than 5000 psi.” (EX1007, ¶188.) “[A] *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties.” *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985)). On similar facts, the Federal Circuit held that claimed range of “less than 6 pounds per cubic feet” *prima facie* obvious over a prior-art range of “between 6lbs/ft³ and 25lbs/ft³.” *In re Brandt*, 886 F.3d 1171, 1177 (Fed. Cir. 2018).

Claim 6[d]

“wherein the multilayer sheet forms a plurality of tooth-receiving cavities configured to receive and reposition the patient’s teeth from the first arrangement toward the second arrangement.”

Kalili discloses that the multilayer sheet is incorporated into “[a]n invisible, removable orthodontic repositioning appliance ... for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement.” (EX1005, Abstract, [0015].) *Kalili* further discloses that its appliance is for “positioning a patient’s

teeth” and is manufactured by forming the multilayer sheet over a positive model to create numerous “indentations” configured to receive and reposition teeth. (EX1005, p.1 (57), [0015], [0053], [0088], claims 1, 12; EX1007, ¶190.)⁹ *Kalili* thus renders this limitation obvious. (EX1007, ¶¶190-91.)



(EX1005, Fig. 3.)

2. Claim 9

“The multilayer dental aligner of claim 6, wherein the first layer has an elastic modulus greater than the second layer.”

As described above, combining *Kalili* with *Porter* and *Texin 990R* results in a soft-hard dental aligner wherein the “first layer” (Tritan, disclosed in *Porter*) has an elastic modulus (225,000 psi) greater than the flexural modulus of the “second layer” (6,000 psi for TEXIN 990R, disclosed in *Kalili* and *Texin 990R*), rendering claim 9 obvious. (See claim 6; EX1007, ¶¶60-67, 192-93 (explaining that a

⁹ See *supra* n.7.

polymer's tensile modulus (or elastic modulus) is essentially identical to its flexural modulus under typical use conditions).)

3. Independent Claim 18

Claim 18 is substantively identical to claim 6. Claims 18[pre], 18[a], 18[b], 18[c], and 18[d] are met for the same reasons detailed above for claims 6[pre], 6[a], 6[b], 6[c], and 6[d], respectively. Claim 18 thus would have been obvious for the same reasons detailed above. (EX1007, ¶194.) A comparison of the claims is shown in EX1007, ¶142.

4. Claim 23

“The multilayer dental aligner of claim 18, wherein the thermoplastic polyurethane elastomer of the second layer has a compression set of greater than 40% after 24 hours at 70° C.”

TEXIN 990R, the TPU of the second layer, has compression set of 75% at 70°C after 22 hours. (EX1009, 3.) As Dr. Osswald explains, compression set after 24 hours would exceed or equal to compression set after 22 hours. The cited art thus discloses this element, rendering claim 23 obvious. (EX1007, ¶¶77, 195-96.)

5. Claim 25

“The multilayer dental aligner of claim 18, wherein the first layer has a light transmission between 400 nm and 800 nm of greater than about 75%.”

Porter discloses that Tritan (the “first layer”) has a total light transmittance of 90%, which as Dr. Osswald explains, meets the claim limitation requiring light transmission between 400 nm and 800 nm of greater than about 75%. (EX1006, 63; EX1007, ¶¶87, 197-98.) The asserted combination thus renders claim 25 obvious.

6. Claim 26

“The multilayer dental aligner of claim 18, wherein the copolyester has an elastic modulus greater than the thermoplastic polyurethane elastomer.”

Tritan copolyester, disclosed in *Porter*, has an elastic modulus (225,000 psi) greater than the flexural modulus of the TEXIN 990R TPU (6,000 psi) in *Kalili*, rendering claim 26 obvious. (See EX1006, 63; EX1009, 3; EX1007, ¶¶60-67, 199-200 (explaining tensile modulus (or elastic modulus) of a polymeric material is practically identical to its flexural modulus under typical use conditions).)

B. Ground 2: Claims 1-7, 9-23 and 25-26 Would Have Been Obvious Over *Kalili* in View of *Porter* and *Texin 990R* as in Ground 1 and Further in View of *Wen*

As explained below, a POSITA would have been motivated to combine *Kalili*, *Porter*, *Texin 990R*, and *Wen* to arrive at the claims challenged in Ground 2 with a reasonable expectation of success. (EX1007, ¶¶145, 147-58, 171-76.)

1. Independent Claim 1

Claim 1[pre]

“A multilayer sheet comprising:”

Kalili meets this limitation. (EX1007, ¶201.) Its appliance includes a “higher modulus outer [i.e., non-tooth contacting] layer and a lower modulus inner [i.e., tooth-contacting] layer.” (EX1005, [0069], Abstract.) *Kalili*’s appliance is made from “[a] polymer sheet.” (EX1005, [0015].) This “single sheet of material ... may be formed from a variety of materials” such as “polycarbonate with a lower modulus inner [i.e., tooth-contacting] lining.” (EX1005, [0053].)

Claim 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, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and”

As detailed above for claim 6[b] in Ground 1, a POSITA would have been motivated to replace *Kalili*’s polycarbonate layer with a single-polymer layer of Tritan co-polyester (disclosed in *Porter*) to eliminate BPAs, improve longevity, and

benefit from Tritan’s proven and desirable mechanical properties that are similar to polycarbonate. (*See* Ground 1, claim 6[b].)

Porter discloses that Tritan copolyester meets every property recited for “a first layer” in claim 1[a]: flexural modulus of 225,000 psi (“greater than 150,000 psi”); elongation at yield of 6% (“greater than 4%”); tensile modulus of 225,000 psi (“greater than 150,000 psi”); tensile strength at yield of 6,200 psi (between “4000-6500 psi”); and elongation at break of 210% (“greater than 70%”). (EX1006, 63; EX1007, ¶¶202-04.)

Claim 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 ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and”

As detailed above for claim 6[c] in Ground 1, *Kalili* discloses TEXIN 990R’s desirable properties as the soft layer in a multilayer dental aligner. (*See* Section III.C.1) *Texin 990R* discloses that TEXIN 990R, a TPU elastomer, meets the properties of the “second layer containing a single polymer” in claim 1[b], including ultimate tensile strength of 5,000 psi (“greater than 5000 psi”), elongation at break of 450% (“greater than 200%”), and hardness of 90A (from “60A to 85D”).

(EX1009, 3; EX1007, ¶¶68-71, 205-07 (explaining that even if the “tensile strength” reported in *Texin 990R* were interpreted as tensile strength at yield, TEXIN 990R’s ultimate tensile strength would necessarily exceed or equal to the reported tensile strength at yield).) As described above, a POSITA would have understood the tensile strength of *Texin 990R* to be “greater than 5,000 psi.” (EX1007, ¶206; *see* Ground 1, claim 6[c].)

Claim 1[c]

“a third layer;”

The layers in *Kalili*’s multilayer sheet are adhered to each other by lamination. (EX1005, claim 20 (“outer layer **laminated** to the inner layer”), [0063], [0082].) As noted above, a POSITA would have known that the first (hard) layer and second (soft) layer could be laminated by using a tie layer with good adhesion to both materials. (EX1019, 150; EX1007, ¶¶208, 39-41; *see supra* Sections III.B, III.C.3.)

Wen, similar to *Kalili*, discloses that “[t]he combination of different dental aligner layers of different properties” can avoid “discomfort to the patient.” (EX1008, [00199].) *Wen* also similarly discloses that “two or more polymer sheets may be laminated to one another to form a single sheet that is heated and vacuum-formed ... to provide multi-layer dental aligners.” (EX1008, [00210].)

To improve fabrication of such a multilayer dental aligner, *Wen* adds that, “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 the aligner-making material using vacuum forming.” (EX1008, [00212].) *Wen* explains that “thinner layers can be more easily conformed to the physical tooth models than a single thick layer” and that “[t]hinner films allow more intimate contact between sheets and therefore help bond the films to one another,” especially where “polymers of disparate properties” are used, which are more likely to “delaminate from one another.” (EX1008, [00212]-[00213].)

Based on these disclosures, a POSITA would have been motivated to modify the single, higher-modulus hard layer in *Kalili* to use two or more thinner layers of the same material (totaling the same overall thickness as the single layer). A POSITA would have understood that doing so would improve tooth conformity and inter-layer bonding—especially between the layers with disparate properties—as taught in *Wen* (e.g., resulting in a soft-hard-hard layer configuration). (EX1007, ¶¶171-76, 208-12.)



A POSITA also would have understood that sufficient adhesion between layers of disparate properties was necessary to achieve the desired interlayer

interactions and that thinner layers would lower the degree of adhesion required. (EX1019, 150.)

A POSITA would have had a reasonable expectation of success in producing and thermoforming a polymer sheet with three polymer layers based on *Wen*'s explicit teachings and industry practice of thermoforming polymer sheets with up to seven layers. (EX1019, 160-162; EX1007, ¶213.) Further, both *Kalili* and *Wen* teach the use of multilayer polymer sheets comprising layers of different hardness, thermoformed into dental aligners over a positive model of a patient's teeth. (*Wen* [00189], [00197]-[00198], [00207], [00210].)

Thus, the additional hard layer in the resulting soft-hard-**hard** configuration resulting from combining *Kalili* with *Wen* is a "third" layer as in claim 1[c].¹⁰ (EX1007, ¶214.)

Claim 1[d]

"wherein the first layer has an elastic modulus greater than the second layer; and"

¹⁰ While subdividing **existing** layers in a particular configuration was well known, changing layer properties or the relative order of hard and soft layers has unpredictable effects on an aligner's properties and efficacy. (EX1007, ¶55.)

The “first layer” (Tritan, disclosed in *Porter*) has an elastic modulus (225,000 psi) greater than the flexural modulus of the “second layer” (6,000 psi for TEXIN 990R, disclosed in *Kalili* and *Texin 990R*). (See claim 1[pre]-1[c]; EX1007, ¶¶60-67, 215 (explaining a polymer’s tensile modulus (or elastic modulus) is practically identical to its flexural modulus under typical use conditions).) A POSITA would have a reasonable expectation of success adhering Tritan and TEXIN® 990R layers through lamination to form a multilayer sheet would preserve the properties of the polymers used in the layers, and thus that the cited art discloses a “first layer [that] has an elastic modulus greater than the second layer.” (EX1007, ¶¶39-41, 215.)

Claim 1[e]

“wherein the multilayer sheet is incorporated into an orthodontic appliance.”

Kalili discloses that the multilayer sheet is incorporated into “[a]n invisible, removable orthodontic repositioning appliance....” (EX1005, Abstract, [0015].) *Kalili* further discloses that its appliance is for “positioning a patient’s teeth.” (EX1005, p.1 (57), claim 12.)



FIG. 3
(EX1005, Fig. 3.)

Kalili also discloses methods of making the disclosed appliance. (EX1005, [0015].) First, “a model of the digital file [of the patient’s teeth] is printed using rapid prototype 3D printers.” (EX1005, [0015].) Then, “[a] polymer sheet is heated and vacuumed over the printed model.” (EX1005, [0015]; EX1007, ¶¶216-17.)

2. Claim 2

“The multilayer sheet of claim 1, wherein the third layer contains a single polymer, and wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer; and wherein the first layer is disposed between the second layer and the third layer.”

As detailed for claim 1[c], a POSITA would have been motivated with a reasonable expectation of success to combine the cited prior art to make a soft-hard-hard multilayer sheet. In that sheet, depicted above, the “first” and “third” layers are both single-polymer layers of Tritan copolyester, with the central hard “first” layer disposed between the second and third layer. The asserted prior-art combination thus

renders claim 2 obvious. (EX1007, ¶¶218-20; *see also* claim 6[b]-6[c] (explaining each layer is a single polymer.)

3. Claim 4

“The multilayer sheet of claim 1, wherein the first layer has a light transmission between 400 nm and 800 nm of greater than about 75%.”

Porter discloses that Tritan (the “first layer”) has 90% total light transmittance, which as Dr. Osswald explains, discloses a material with light transmission between 400 nm and 800 nm of greater than about 75%, as claimed. (EX1006, 63; EX1007, ¶¶87, 221-22.) The asserted combination thus renders claim 4 obvious.

4. Claim 5

“The multilayer sheet of claim 1, wherein the first layer is coextruded with or laminated to the third layer.”

Kalili discloses that its multilayer sheet is laminated and *Wen* provides further disclosures on lamination. (*See* claim 1[c].) Accordingly, a POSITA would have been motivated to adhere the layers in a multilayer sheet using lamination, including the hard layers of Tritan (i.e., the “first” and “third” layers). The asserted combination thus renders claim 5 obvious. (EX1007, ¶¶223-24.)

5. Claim 7

“The multilayer dental aligner of claim 6, wherein the multilayer sheet further comprises a third layer containing a single polymer, and wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer or a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer.”

As detailed above for claim 6, a POSITA would have been motivated to modify *Kalili* based on *Wen* to use thinner sublayers of Tritan copolyester, giving a soft-hard-hard configuration, wherein the “first” and “third” layer are the same co-polyester (Tritan). (See claim 6, 1[c]; EX1007, ¶¶171-76, 225-27.) The asserted prior-art combination thus renders claim 7 obvious.

6. Independent Claim 10

Claim 10 contains substantively identical limitations to claim 1. Claims 10[pre], 10[a], 10[b], 10[c], 10[d], and 10[e] are met for the same reasons detailed above for claims 1[pre]/1[e], 1[pre], 1[a], 1[b], 1[c], and 1[e], respectively. Claim 10 thus would have been obvious for the same reasons. (EX1007, ¶¶228, 201-17; see *supra* claim 1.) A comparison of the claims is shown in EX1007, ¶142.

7. Claim 11

“The multilayer dental aligner of claim 10, wherein the third layer consists of a same or different co-polyester or a same or different thermoplastic polyurethane elastomer.”

As detailed for claim 1[c], the third layer in the multilayer sheet or dental aligner is Tritan, the same copolyester as the first layer, rendering claim 11 obvious. (EX1007, ¶¶229-31; *see* claim 1[c].)

8. Claim 12

“The multilayer dental aligner of claim 11, wherein the first layer is disposed adjacent to the third layer.”

As detailed for claim 2, the “first layer” is “disposed adjacent” to the “third layer,” rendering claim 12 obvious. (EX1007, ¶¶232-33; *see* claim 2.)

9. Claim 13

The multilayer dental aligner of claim 11, wherein the first layer is co-extruded with or laminated to the third layer.

As detailed for claim 5, the “first layer” of Tritan can be laminated to the “third layer” of Tritan. (EX1007, ¶¶234-35; *see* claim 5.) The asserted combination thus renders claim 13 obvious.

10. Claim 14

“The multilayer dental aligner of claim 10, wherein the multilayer sheet further comprises a fourth layer and

wherein the first layer and the third layer are disposed
between the second layer and the fourth layer.”

As detailed above, *Wen* discloses several advantages of using a “plurality of thinner layers of the aligner-making material” instead of “a thick layer of the same aligner-making material.” (*See supra* claim 1; EX1008, [00212]-[00213].) *Wen*’s teaching relates to arrangements of “two **or more** polymer sheets.” (EX1008, [00210]. Accordingly, a POSITA would have been motivated and found it obvious to modify *Kalili*’s appliance by replacing the single, higher-modulus layer with **two or more** thinner layers of the same material (collectively having the same total thickness as the single layer) to improve tooth conformity and inter-layer bonding—especially between the layers with disparate properties—as taught in *Wen* (e.g., resulting in a soft-hard-hard-**hard** layer configuration). (*See supra* claim 1[c]; EX1007, ¶¶171-76, 236.)



A POSITA would have had a reasonable expectation of success in producing and thermoforming a polymer sheet with these four polymer layers based on *Wen*’s

explicit disclosures and long-standing industry practice of thermoforming polymer sheets with many (e.g., seven) layers. (EX1019, 160-162; EX1007, ¶¶30, 237.) Further, both *Kalili* and *Wen* teach use of multilayer polymer sheets comprising layers of different hardness, thermoformed into dental aligners. (*See supra* claim 1[c]; *Wen* [00189], [00197]-[00198], [00207], [00210].) In the resulting *soft-hard-hard-hard* layer configuration, the outer hard layer is a “fourth” layer. Thus, the innermost “first” and “third” layers of Tritan copolyester are disposed between “the second layer and the fourth layer” as claimed. (EX1007, ¶¶236-38, *see supra* Section III.C.4.)

11. Claim 16

“The multilayer dental aligner of claim 10, wherein the first layer is disposed between the second layer and the third layer.”

In the obvious soft-hard-hard configuration of claim 10, the “first” central hard layer is disposed between a soft “second” layer and hard “third” layer, as detailed and depicted for claim 1[c], rendering claim 16 obvious. (EX1007; ¶¶239-40.)

12. Claim 17

“The multilayer dental aligner of claim 10, wherein the copolyester has an elastic modulus greater than the thermoplastic polyurethane elastomer.”

As detailed for claim 1[d], Tritan co-polyester's elastic modulus exceeds that of TEXIN 990R TPU, rendering claim 17 obvious. (EX1007, ¶¶241-42; *see* claim 1[d].)

13. Claim 19

“The multilayer dental aligner of claim 18, wherein the multilayer sheet further comprises a third layer.”

As detailed above, a POSITA would have been motivated to modify *Kalili* based on *Wen* to use thinner sublayers of Tritan copolyester, resulting in a soft-hard-hard configuration, wherein the “first” and “third” layer are both Tritan. (EX1007, ¶¶243-44; *see* claims 18, 1[c].) The asserted combination thus renders claim 19 obvious.

14. Claim 20

“The multilayer dental aligner of claim 19, wherein the third layer consists of a same or different thermoplastic polyurethane elastomer.”

A POSITA would have been equally motivated to modify *Kalili* based on *Wen* to use thinner sublayers of TEXIN 990R, resulting in a soft-**soft**-hard configuration, wherein the “second” and “third” layer are both TEXIN 990R TPU. (EX1007, ¶¶245-47; *see* claim 1[c], 1[d].) The asserted combination thus renders claim 20 obvious.



15. Claim 21

“The multilayer dental aligner of claim 19, wherein third layer consists of a same or different co-polyester, and wherein the third layer is co-extruded with or laminated to the first layer.”

Kalili’s multilayer sheet is laminated and *Wen* provides further disclosures on lamination. (*See* claim 1[c].) Accordingly, a POSITA would have been motivated to laminate all layers, including the hard layers of Tritan (i.e., the “first” and “third” layers) to one another, rendering claim 21 obvious. (EX1007, ¶¶248-50.)

16. Claim 22

“The multilayer dental aligner of claim 19, wherein the third layer is disposed adjacent the first layer.”

In the obvious soft-hard-hard aligner, the “first” and “third” layers are both Tritan copolyester, with the “first layer” adjacent to the “third layer,” Rendering claim 22 obvious. (EX1007, ¶¶251-52; *see* claim 1[c].)

17. Claims 6, 9, 18, 23, and 25-26

These claims, which as detailed above would have been obvious under the prior-art combination in Ground 1, are equally obvious here, where Ground 2 merely adds the state of knowledge from an additional prior-art source, *Wen*. (EX1007, ¶253.)

C. Ground 3: Claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26 Would Have Been Obvious Over *Tadros* in View of *Porter*, *Kalili* and *Texin 990R*

As explained below, a POSITA would have been motivated to combine *Tadros*, *Porter*, *Kalili*, and *Texin 990R* to arrive at the claims challenged in Ground 3 with a reasonable expectation of success. (EX1007, ¶¶146-48, 159-70.)

1. Independent Claim 1

Claim 1[pre]

“A multilayer sheet comprising:”

Tadros discloses “formable sheets” used to manufacture dental appliances, which can consist of at least three layers—a central hard layer disposed between two soft layers. (EX1003, [0001], [0067], [0073].) *Tadros*’s soft-hard-soft sheet is analogous to the soft-hard-soft sheet disclosed in the ’091 patent. (EX1007, ¶¶254-55.)

Claim 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, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and”

Tadros’s central hard layer provides a tough, creep-resistant material with “a tensile strength and modulus effective to reposition teeth” that can also be easily thermoformed into a clear dental appliance. (EX1003, [0015], [0068], [0089], [0100].) *Tadros* highlights pure polycarbonate as having ideal modulus properties but insufficient thermoforming capabilities, noting that “[i]t is generally desirable for the glass transition temperature of the [hard layer] to be less than that of polycarbonate” because “lower glass transition temperature and a lower thermoforming temperature generally facilitate an easier deformation of the sheet over the dental mold material.” (EX1003, [0097], [0113].) Further, *Tadros* highlights comparative copolyesters (specifically, PCCD variations) as having better thermoforming capabilities than polycarbonate but insufficient modulus properties. (EX1003, [0097], [0113].)

Tadros sought to create a material that combined the best features of pure polycarbonate and pure copolyester. (EX1007, ¶257.) *Tadros* discloses that, to effectively reposition teeth comparable to pure polycarbonate, the hard layer should have a tensile modulus of about 1,500-2,500 N/mm². (EX1003, [0068], Table 2.) To improve thermoforming compared to pure polycarbonate, the hard layer should have a glass transition temperature of about 120°C or less, which is “at least about 25°C less” than a comparative pure polycarbonate sample. (EX1003, Table 3, [0113]; *see also* EX1003 [0054].) *Tadros* also discloses the ideal thermoforming temperature as about 180°C or less, which is 23°C lower than that of polycarbonate. (EX1003, [0100].)

To create a hard layer combining polycarbonate’s modulus properties and copolyester’s thermoforming properties, *Tadros* used polycarbonate-copolyester mixtures. (EX1003, [0022]-[0023].) A POSITA would have known, however, that polycarbonate-based dental aligners, including those disclosed in *Tadros*, would release harmful BPAs. (EX1006, 61-63.) A POSITA thus would have been motivated to replace *Tadros*’s hard mixture with a BPA-free alternative that achieved *Tadros*’s goals of sufficient tensile modulus and improved thermoforming. (EX1003, [0015], [0068], [0089], [0100]; EX1007, ¶¶258-59.)

Porter discloses Tritan copolyesters as a BPA-free product with similar modulus properties to polycarbonate that could “be thermoformed faster and at

lower temperatures than polycarbonate sheet[s].” (EX1006, 62-63.) Tritan meets the goals for *Tadros*’s hard layer. (EX1003, [0015], [0068], [0089], [0100].) *Porter* also discloses specific properties of Tritan that satisfy *Tadros*’s benchmarks for the hard layer: tensile modulus of 1,551 N/mm² (about 1,500 N/mm² to about 2,500 N/mm²); glass transition temperature of 108°C (about 120°C or less); and would have understood the thermoforming temperature to be slightly above 108°C (about 180°C or less). (EX1006, 62-63.)

A POSITA therefore would have been motivated and found it obvious to substitute a single-polymer layer of Tritan copolyester, as disclosed in *Porter*, for the polycarbonate-containing hard layer in *Tadros*’s soft-hard-soft aligner to improve product safety and performance. (EX1007, ¶¶159-65, 256, 260.) A POSITA would have understood that manufacturing techniques such as adhesive lamination would result in a first layer “containing a single polymer” of pure Tritan copolyester. (*See* EX1007, ¶263.)

A POSITA would have had a reasonable expectation of success in doing so based on Tritan’s proven use in thermoforming processes and extruded-sheet applications, its durability in the “harsh” environments of “heat, hydrolytic and chemical attack, and applied stress” required for dental aligners, and past industry success in replacing polycarbonate with Tritan copolyester. (EX1006, 60-63; EX1007, ¶261); *Kross*, 825 F. App’x at 760-62.

Porter discloses that Tritan copolyester meets every property recited for “a first layer” in claim 1[a]: flexural modulus of 225,000 psi (“greater than 150,000 psi”); elongation at yield of 6% (“greater than 4%”); tensile modulus of 225,000 psi (“greater than 150,000 psi”); tensile strength at yield of 6,200 psi (between “4000-6500 psi”); and elongation at break of 210% (“greater than 70%”).¹¹ (EX1006, 63; EX1007, ¶262.)

Claim 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 ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and”

Tadros discloses using soft layers—preferably “elastomers” such as “polyurethanes—surrounding the hard layer to “alleviate pain, discomfort and bleeding gums.” (EX1003, [0073].) A POSITA would have been motivated to use a single-polymer layer of the specific thermoplastic polyurethane elastomer disclosed in *Kalili* (TEXIN 990R) in *Tadros*’s soft-hard-soft aligner with a reasonable expectation of success for several reasons. (EX1007, ¶¶166-70, 264-67.) Both

¹¹ See *supra* n.3.

references address identical subject matter—removable dental aligners for repositioning teeth. (EX1003, [0015]; EX1005, Abstract, [0015].) Further, both references disclose multilayer polymer sheets and aligners, and preferred configurations of hard and soft layers. (EX1003, [0067], [0073]; EX1005, [0069].) And both *Tadros* and *Kalili* identify benefits of using a soft tooth-contacting layer, including greater patient comfort and less tooth, bone and root damage. (EX1003, [0073]; EX1005, [0009].)

A POSITA would have been further motivated to make this combination based on *Kalili*'s disclosure of numerous advantages of using TEXIN 990R TPU as the soft layer in a dental aligner, including “outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility” and “good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics.” (EX1005, [0069].) A POSITA would have understood that TEXIN 990R's advantages would be equally desirable for *Tadros*'s soft layers.

As explained above, a POSITA would have known that certain manufacturing processes (e.g., during coextrusion or extrusion lamination) can change a polymer's mechanical properties, but that others (i.e., adhesive lamination) preserve the properties. (*See supra* Sections III.B, III.C.3; EX1007, ¶268.) Laminating TEXIN® 990R to the other layers using tie layers (*see supra* Section III.B, III.C.3; EX1007,

¶¶39-41) would preserve TEXIN® 990R’s reported mechanical properties during processing, and a POSITA therefore would have expected the resulting soft layer to have the same properties disclosed in *Texin 990R*. (See EX1007, ¶31.)

Thus, based on *Kalili*’s disclosures regarding TEXIN 990R’s “outstanding” properties in dental applications, a POSITA would have been motivated to use TEXIN 990R as the soft layers in *Tadros*’s multilayer aligner, as shown below.



A POSITA would have had a reasonable expectation of success in doing so. **First**, *Kalili* discloses using TEXIN 990R for the same application and purpose as the lining layers of *Tadros*. (EX1007, ¶¶269-70; EX1003, [0073]); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). **Second**, according to Patent Owner’s assertions in its Preliminary Infringement Contentions, properties of the soft polymer recited in a manufacturer’s datasheet are evidence of its properties **after** being combined with other polymers in a multilayer sheet. (EX1014, 48-49.) **Third**, a POSITA would have known that adhesive lamination, in contrast to coextrusion, would preserve the

polymer's properties when formed into a multilayer sheet. *See* Section III.B; EX1007, ¶¶272, 39-41.) A POSITA would have understood that manufacturing techniques such as adhesive lamination would result in a second layer “containing a single polymer” of pure Texin 990R. (*See* EX1007, ¶272.)

Texin 990R discloses that Texin 990R meets the claimed properties of the “second layer” recited in claim 1, including ultimate tensile strength of 5,000 psi (“greater than 5000 psi”), elongation at break of 450% (“greater than 200%”), and hardness of 90A (from “60A to 85D”). (EX1009, 3.; EX1007, ¶¶68-71, 271 (explaining that even if the “tensile strength” reported in *Texin 990R* were interpreted as tensile strength at yield, Texin 990R’s ultimate tensile strength would necessarily exceed or equal to the reported tensile strength at yield).) As detailed above in Ground 1 for claim 6[c], a POSITA would have understood that the reported tensile strength of 5,000 psi discloses the claimed range of “greater than 5000 psi.” *In re Brandt*, 886 F.3d at 1177. (*See* claim 6[c] (Ground 1), Section III.C.3; EX1007, ¶¶187-88, 271.)

Claim 1[c]

“a third layer;”

As detailed for claim 1[pre]-[c], the additional “soft” layer in *Tadros*’s soft-hard-**soft** configuration is “a third layer.” (*See* claim 1[pre]; EX1003, [0073]; EX1007, ¶273.)

Claim 1[d]

“wherein the first layer has an elastic modulus greater than the second layer; and”

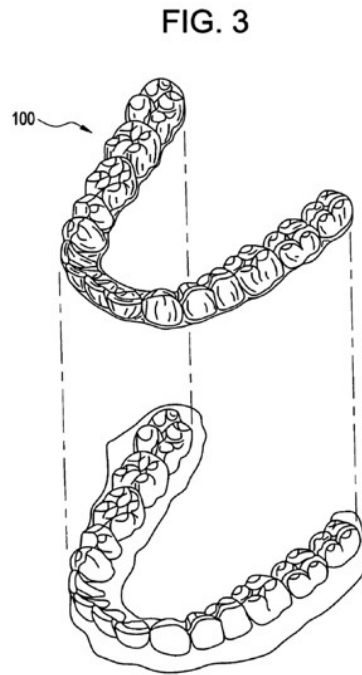
As detailed above, *Tadros* in combination with *Porter*, *Kalili*, and *Texin 990R* results in a soft-hard-soft sheet wherein the “first layer” (Tritan, disclosed in *Porter*) has an elastic modulus (225,000 psi) greater than the flexural modulus of the “second layer” (6,000 psi for TEXIN 990R, disclosed in *Kalili* and *Texin 990R*). (See claim 1[pre]-1[c]; EX1007, ¶¶60-67, 274 (explaining a polymer’s tensile modulus (or elastic modulus) is practically identical to its flexural modulus under typical use conditions).) A POSITA would have known that certain manufacturing processes (e.g., adhesive lamination) preserve the desirable mechanical properties reported for Tritan and TEXIN® 990R even after such combination, such that the layer modulus is equivalent to the polymer’s modulus. (EX1007, ¶¶274, 39-41.)

Claim 1[e]

“wherein the multilayer sheet is incorporated into an orthodontic appliance.”

Tadros discloses that its multilayer sheet can be formed into an orthodontic appliance for “incremental repositioning of teeth.” (EX1003, [0015]; *see also*

claim 19 (“method for maintaining or repositioning teeth in the oral cavity”);
EX1003, [0006]-[0007], [0021].)¹²



(EX1003, Fig. 3.)

Tadros also discloses manufacturing the appliance by “thermoforming the sheet over a replica of a patient’s teeth” (EX1003, claim 21; *see also* EX1003, [0069].) As to forming a sheet, a POSITA would have known of suitable techniques for adhering multiple polymer layers together, such as by adhesive lamination using a tie layer. (EX1019, 150; *see* Section III.B; EX1007, ¶¶275-78.) *Tadros*’s formed aligner has “cavities designed to receive teeth.” (EX1003, Abstract, [0006]-[0008].)

¹² *See supra* n.7.

2. Claim 4

“The multilayer sheet of claim 1, wherein the first layer has a light transmission between 400 nm and 800 nm of greater than about 75%.”

Porter discloses that Tritan (the “first layer”) has 90% total light transmittance, which as Dr. Osswald explains, discloses a material with light transmission between 400 nm and 800 nm of greater than about 75%, rendering claim 4 obvious. (EX1006, 63; EX1007, ¶¶87, 279.)

3. Claim 5

“The multilayer sheet of claim 1, wherein the first layer is coextruded with or laminated to the third layer.”

As described above, a POSITA would have known of manufacturing processes (e.g., adhesive lamination) that preserve the desirable properties reported for Tritan and TEXIN 990R. (EX1007, ¶¶39-41.) A POSITA therefore would have been motivated to and had a reasonable expectation of success in creating a laminated dental appliance, wherein the hard layer of Tritan (“first layer”) is laminated to an outer soft layer of TEXIN 990R (“third layer”), rendering claim 5 obvious. (EX1007, ¶¶280-82.)

4. Independent Claim 6

Claim 6[pre]-6[a]

“A multilayer dental aligner for repositioning a patient’s teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:”

“a multilayer sheet comprising:”

As detailed for claim 1[e] (Ground 3) and 6[pre] (Ground 1), *Tadros* discloses forming the soft-hard-soft multilayer sheet into a dental aligner that reposition teeth from a first arrangement to a second arrangement. (*See, e.g.*, EX1003, [0015]; *see also* EX1005, [0009], [0015], [0053], [0069].)¹³ *Tadros* thus renders 6[pre]-6[a] obvious. (EX1007, ¶¶283-85.)

Claim 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, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and”

¹³ *See supra* n.7.

As discussed above, a POSITA would have been motivated and found it obvious to use a single-polymer layer of Tritan copolyester, disclosed in *Porter*, as the central hard layer in the *Tadros*'s multilayer sheet. (See claim 1[pre]-1[a].) A POSITA would have understood that manufacturing techniques such as adhesive lamination would result in a first layer "containing a single polymer" of pure Tritan copolyester. (See EX1007, ¶¶286-88.)

As disclosed in *Porter*, Tritan copolyesters meet every property recited for "a first layer" in claim 6: flexural modulus of 225,000 psi ("greater than 150,000 psi"); elongation at yield of 6% ("greater than 4%"); tensile modulus of 225,000 psi ("greater than 150,000 psi"); tensile strength at yield of 6,200 psi (between "4000-6500 psi"); and elongation at break of 210% ("greater than 70%"). (EX1006, 63; EX1007, ¶287.)

Claim 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; and"

As detailed above, a POSITA would have been motivated to use a single-polymer layer of TEXIN 990R TPU, disclosed in *Kalili*, as the outer soft layers in

Tadros's multilayer aligner. (See claim 1[b].) A POSITA would have understood that manufacturing techniques such as adhesive lamination would result in a second layer "containing a single polymer" of pure Texin 990R. (See EX1007, ¶¶289-91.)

Texin 990R discloses that TEXIN 990R meets the claimed properties of the "second layer" in claim 6, including ultimate tensile strength of 5,000 psi ("greater than 5000 psi" (see claim 1[b])), elongation at break of 450% ("greater than 200%"), and hardness of 90A (from "60A to 85D").¹⁴ (EX1009, 3.; EX1007, ¶¶68-71, 290 (explaining that, even if the "tensile strength" reported in *Texin 990R* were interpreted as tensile strength at yield, TEXIN 990R's ultimate tensile strength would necessarily be greater than or equal to the reported tensile strength at yield).)

Claim 6[d]

"wherein the multilayer sheet forms a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement."

As detailed for claim 1[e], *Tadros* discloses forming a multilayer sheet into an orthodontic appliance for repositioning teeth that has "cavities designed to receive teeth." (EX1003, Abstract, [0006]-[0008], [0015]; EX1007, ¶¶109-14, 275-78, 292-93.)

¹⁴ See *supra* n.3.

5. Claim 7

“The multilayer dental aligner of claim 6, wherein the multilayer sheet further comprises a third layer containing a single polymer, and wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer or a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer.”

As detailed above, the additional soft layer in Tadros’s soft-hard-**soft** configuration is a “third layer.” (*See* claim 1[pre]; EX1003, [0073].) It would have been obvious for a POSITA to use TEXIN 990R for both soft layers, such that the “third layer...is a same of different thermoplastic polyurethane elastomer as the single polymer of the second layer.”].) A POSITA would have understood that manufacturing techniques such as adhesive lamination would result in a third layer “containing a single polymer” of pure Texin 990R. (EX1007, ¶¶294-96.)

6. Claim 9

“The multilayer dental aligner of claim 6, wherein the first layer has an elastic modulus greater than the second layer.”

As detailed above, Tritan co-polyester’s elastic modulus exceeds that of TEXIN 990R TPU, rendering claim 9 obvious. (*See* claim 1[d]; EX1007, ¶¶297-98.)

7. Independent Claim 10

Claim 10 contains substantively identical limitations to claim 1. Claims 10[pre], 10[a], 10[b], 10[c], 10[d], and 10[e] are met for the same reasons detailed above for claims 1[pre]/1[e], 1[pre], 1[a], 1[b], 1[c], and 1[e], respectively. Claim 10 thus would have been obvious for the same reasons detailed above. (EX1007, ¶299.) A comparison of the claims is shown in EX1007, ¶142.

8. Claim 11

“The multilayer dental aligner of claim 10, wherein the third layer consists of a same or different co-polyester or a same or different thermoplastic polyurethane elastomer.”

As detailed above, the third layer consists of the same TEXIN 990R TPU as the second layer, rendering claim 11 obvious. (EX1007, ¶¶300-02; *see* claim 7.)

9. Claim 12

“The multilayer dental aligner of claim 11, wherein the first layer is disposed adjacent to the third layer.”

As discussed above the “first” hard layer is disposed adjacent to the additional “third” soft layer, rendering claim 12 obvious. (EX1007, ¶¶303-04; *see* claim 1[c].)

10. Claim 13

“The multilayer dental aligner of claim 11, wherein the first layer is co-extruded with or laminated to the third layer.”

As detailed above, the layers of the soft-hard-soft configuration can be joined by adhesive lamination, rendering claim 13 obvious. (EX1007, ¶¶305-06; *see* claim 5.)

11. Claim 16

“The multilayer dental aligner of claim 10, wherein the first layer is disposed between the second layer and the third layer.”

As detailed above, the “first” hard layer is disposed between the “second” soft layer and additional “third” soft layer, rendering claim 16 obvious. (EX1007, ¶¶307-08; *see* claim 1[c].)

12. Claim 17

“The multilayer dental aligner of claim 10, wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer.”

As detailed above, Tritan co-polyester’s elastic modulus exceeds that of TEXIN 990R TPU, rendering claim 17 obvious. (EX1007, ¶¶309-10; *see* claim 1[d].)

13. Independent Claim 18

Claim 18 is substantively identical to claim 6. Claims 18[pre], 18[a], 18[b], 18[c], and 18[d] are met for the same reasons detailed above for claims 6[pre], 6[a], 6[b], 6[c], and 6[d], respectively. Claim 18 thus would have been obvious for the

same reasons detailed above. (EX1007, ¶311.) A comparison of the claims is shown in EX1007, ¶142.

14. Claim 19

“The multilayer dental aligner of claim 18, wherein the multilayer sheet further comprises a third layer.”

As described above, *Tadros* discloses a soft-hard-**soft** configuration, wherein the additional soft layer is “a third layer,” rendering claim 19 obvious. (EX1007, ¶¶312-13; *see* claim 1[pre]; EX1003, [0073].)

15. Claim 20

“The multilayer dental aligner of claim 19, wherein the third layer consists of a same or different thermoplastic polyurethane elastomer.”

As detailed above, the third layer is TEXIN 990R, the same TPU as the second layer, rendering claim 20 obvious. (EX1007, ¶¶314-16; *see* claim 7.)

16. Claim 22

“The multilayer dental aligner of claim 19, wherein the third layer is disposed adjacent the first layer.”

As detailed above, the “first” hard layer is disposed adjacent to the additional “third” soft layer, rendering claim 22 obvious. (EX1007, ¶¶317-18; *see* claims 1[c], 12.)

17. Claim 23

“The multilayer dental aligner of claim 18, wherein the thermoplastic polyurethane elastomer of the second layer has a compression set of greater than 40% after 24 hours at 70° C.”

Texin 990R, the TPU of the second layer, has compression set of 75% at 70°C after 22 hours. (EX1009, 3.) As Dr. Osswald explain, compression set after 24 hours would be greater than or equal to compression set after 22 hours, and thus the cited art discloses this element. (EX1007, ¶¶77, 319-20.) The asserted combination thus renders claim 23 obvious.

18. Claim 25

“The multilayer dental aligner of claim 18, wherein the first layer has a light transmission between 400 nm and 800 nm of greater than about 75%.”

Porter discloses that Tritan, the “first layer”, has 90% total light transmittance, which as Dr. Osswald explains, discloses a material with light transmission between 400 nm and 800 nm of greater than about 75%, as claimed. (EX1007, ¶¶87, 321-22.) The asserted combination thus renders claim 25 obvious.

19. Claim 26

“The multilayer dental aligner of claim 18, wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer.”

As detailed for claim 1[d], Tritan co-polyester’s elastic modulus exceeds that of TEXIN 990R TPU, rendering claim 26 obvious. (EX1007, ¶¶323-24.)

D. Ground 4: Claims 1-23 and 25-26 Would Have Been Obvious Over *Tadros* in View of *Porter*, *Kalili* and *Texin 990R* as in Ground 3 and Further in View of *Wen*.

As explained below, a POSITA would have been motivated to combine *Tadros*, *Porter*, *Kalili*, *Texin 990R*, and *Wen* to arrive at the claims challenged in Ground 4 with a reasonable expectation of success. (EX1007, ¶¶146-48, 159-76.)

1. Claim 2

“The multilayer sheet of claim 1, wherein the third layer contains a single polymer, and wherein the single polymer of the third layer is a same or different co-polyester as the single polymer of the first layer; and wherein the first layer is disposed between the second layer and the third layer.”

As detailed above, *Tadros* discloses a soft-hard-soft configuration and, based on *Porter* and *Kalili*, a POSITA would have been motivated to use Tritan as the hard inner layer and Texin 990R as soft outer layers. (EX1007, ¶325.) The asserted combination thus renders claim 2 obvious.

As disclosed in *Wen*, it was known as of the priority date that replacing a single polymer layer with multiple thinner layers of the same polymer (collectively having the same overall thickness) offers several advantages. (EX1008, [00210], [00212] (discussing “plurality of thinner layers”).) *Wen* explains that thinner layers “more easily conform[] to the physical tooth models” and “help bond the films to one another,” especially for “polymers of disparate properties,” which more easily “delaminate from one another.” (EX1008, [00212]-[00213].) A POSITA would have known that sufficient interlayer adhesion was necessary, and that thinner layers decrease the degree of adhesion required. (EX1019, 150; EX1007, ¶326.)

Accordingly, a POSITA would have been motivated and found it obvious to use two or more thinner, single-polymer layers of Tritan to achieve the advantages in *Wen*—improved tooth conformity and inter-layer bonding, especially between layers with disparate properties. (EX1007, ¶¶171-76, 327.) A POSITA also would have been motivated to combine *Wen* with *Tadros* because both disclose multilayer dental aligners for positioning teeth, including layer composition and configuration, and thermoforming multilayer polymer sheets comprising layers of different hardness. (*See supra* claim 1; EX1008 [00189], [00197]-[00198], [00207], [00210]; EX1007, ¶¶327, 330 (explaining adhesive lamination results in single-polymer layers).)

A POSITA would have had a reasonable expectation of success in combining the asserted references. A POSITA would have understood that the hard layer in *Tadros*'s soft-hard-soft configuration could be subdivided into two thinner layers of the same material based on *Wen*'s disclosures and industry practice of thermoforming polymer sheets with many layers. (EX1019, 160-162; EX1007, ¶328.) Further, a POSITA would have understood that *Wen*'s teaching applies to hard layers of "polyesters," such as Tritan copolyester. (EX1008, [00201].)

The resulting configuration (depicted below) is a soft-hard-hard-soft aligner, wherein the first and third layer are the same Tritan copolyesters (*Porter*) disposed between second and fourth layers of TEXIN 990R (*Kalili* and *Texin 990R*). In this configuration, the first copolyester layer is disposed between the second and third layers, rendering the claim obvious. (EX1007, ¶¶329-31.)



2. Claim 3

"The multilayer sheet of claim 1, comprising a fourth layer containing a single polymer, wherein the single polymer

of the fourth layer is a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer; and wherein the first layer and the third layer are disposed between the fourth layer and the second layer.”

As detailed above, it would have been obvious for a POSITA to combine *Tadros*, *Kalili*, and *Porter* in view of *Wen* to make a soft-hard-hard-soft aligner, wherein the first and third layer are Tritan copolyesters disposed between second and fourth layers of Texin 990R. In this configuration, the fourth layer is the same Texin 990R TPU as the second layer. (EX1007, ¶¶332-34.) The asserted combination thus renders claim 3 obvious.

3. Claim 8

“The multilayer dental aligner of claim 6,

wherein the multilayer sheet further comprises a third layer containing a single polymer, wherein the single polymer of the third layer is a same or different copolyester as the single polymer of the first layer;

wherein the multilayer sheet further comprises a fourth layer containing a single polymer, wherein the single polymer of the fourth layer is a same or different thermoplastic polyurethane elastomer as the single polymer of the second layer, and

wherein the third layer and the first layer are disposed between the second layer and the fourth layer.”

As detailed above, it would have been obvious for a POSITA to combine *Tadros, Kalili, Porter, and Wen*, to make a multilayer dental aligner from a **soft-hard-hard-soft** sheet. (Section III.B; claims 1[e], 6[pre], 3; EX1007, ¶¶145-76, 335-38.) In that sheet, the **first** and **third** layers are the same, single-polymer Tritan copolyester; the **second** and **fourth** layers are the same, single-polymer TPU (Texin 990R); and the **first** and **third** layer are disposed between the **second** and **fourth** layer. The asserted combination thus renders claim 8 obvious.

4. Claims 14-15, 21

14. “The multilayer dental aligner of claim 10, wherein the multilayer sheet further comprises a fourth layer and wherein the first layer and the third layer are disposed between the second layer and the fourth layer.”

15. “The multilayer dental aligner of claim 14, wherein the fourth layer consists of a same or different thermoplastic polyurethane elastomer.”

21. “The multilayer dental aligner of claim 19, wherein third layer consists of a same or different co-polyester, and wherein the third layer is co-extruded with or laminated to the first layer.”

For the reasons detailed above for claims 2, 3, and 8[a]-8[c], the prior-art combination also discloses and renders obvious claims 14-15 and 21. (EX1007, ¶¶339-45.)

5. Claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26

These claims, which as detailed above would have been obvious under the Ground 3 prior-art combination, are equally obvious under Ground 4, which merely adds *Wen*'s disclosures regarding using multiple thinner layers. (EX1007, ¶346.)

VII. THE BOARD SHOULD NOT EXERCISE DISCRETION TO DENY INSTITUTION

Petitioner stipulates that, if IPR is instituted for the '091 patent, it will not pursue in the parallel district court case for the '091 patent any ground raised or that could have been reasonably raised in this Petition, and all defendants to the litigation have agreed to be bound by this stipulation. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 19 (Dec. 1, 2020). Petitioner reserves its rights to oppose any discretionary denial arguments Patent Owner may make pursuant to the procedures detailed in the Office's March 26, 2025 Memorandum ("Interim Processes for PTAB Workload Management").

VIII. MANDATORY NOTICES

A. Real Party-in-Interest Under 37 C.F.R. §42.8(b)(1)

The real parties-in-interest are ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc., Institut Straumann AG, and Straumann USA, LLC.

B. Related Matters Under 37 C.F.R. §42.8(b)(2)

To the best of Petitioner's knowledge, the '091 patent is, or has been, involved in the following district court litigations and Board proceedings.

<u>Name</u>	<u>Number</u>	<u>Court</u>	<u>Filed</u>
<i>Align Technology, Inc. v. ClearCorrect Operating, LLC, et al.</i>	6:24-cv-00187	WDTX	April 11, 2024

C. Lead and Back-Up Counsel Under 37 C.F.R. §42.8(b)(3)

<u>Lead Counsel</u>	<u>Back-Up Counsel</u>
Charles T. Collins-Chase Reg. No. 78,019	Luke J. McCammon Reg. No. 70,691
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP 901 New York Ave NW Washington, DC 20001 Tel: 202-408-4108 Fax: 202-408-4400	Melanie M. Magdun Reg. No. 79,768
	Kyle W. Howarth Reg. No. 82,053
	Finnegan, Henderson, Farabow, Garrett & Dunner, LLP 901 New York Ave NW Washington, DC 20001 Tel: 202-408-4000 Fax: 202-408-4400

D. Service Information Under 37 C.F.R. §42.8(b)(4)

Please address all correspondence to counsel at the addresses above. Petitioner consents to service by email.

IX. GROUND FOR STANDING

The '091 patent is available for *inter partes* review. Petitioner is not barred or estopped from requesting such review.

X. CONCLUSION

For the reasons above, Petitioner requests that the Board institute *inter partes* review and cancel each challenged claim.

Respectfully submitted,

Dated: April 14, 2025

By: /Charles T. Collins-Chase/
Charles T. Collins-Chase,
Reg. No. 78,019

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the foregoing Petition contains 13,958 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Respectfully submitted,

Dated: April 14, 2025

By: /Charles T. Collins-Chase/
Charles T. Collins-Chase,
Reg. No. 78,019

CERTIFICATE OF SERVICE

The undersigned certifies that, in accordance with 37 C.F.R. §§ 42.6(e) and 42.105(a), the **Petition for *Inter Partes* Review of U.S. Patent No. 11,648,091, the associated Power of Attorney, and Exhibits 1001-1003, 1005-1015, 1018-1118** were served via FedEx Priority Overnight delivery on April 14, 2025, on the correspondence address of record below indicated in the U.S. Patent Office's Patent Center for U.S. Patent No. 11,648,091:

Douglas J. Clark
Align, Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

A courtesy copy has been concurrently served by the same means on Patent Owner's litigation counsel at:

Brian C. Nash
MORRISON & FOERSTER LLP
300 Colorado Street, Suite 1800
Austin, TX 78701

Dated: April 14, 2025

Respectfully submitted,

/Daniel E. Doku/

Daniel E. Doku
Senior Litigation Legal Assistant
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP