

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC.,
Petitioner,

v.

ALIGN TECH., INC.,
Patent Owner,

Case No. IPR2025-00818

U.S. Patent No. 10,973,613

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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I. Introduction

It is undisputed that *Tadros*'s hard layer, *Kalili*'s Texin 990R, and *Porter*'s Tritan satisfy every claimed layer property. Techniques for combining hard and soft layers into a sheet and thermoforming the sheet to produce a dental aligner were also known and conventional. The claimed methods were therefore obvious.

Unable to contest these points, Align addresses only selected portions of the prior art, ignoring other disclosures cited in the Petition. Align's arguments thus cannot rebut obviousness. *Recor Med., Inc. v. Medtronic Ireland Mfg. Unlimited Co.*, 2025 WL 944511, at *2-4 (Fed. Cir. Mar. 27, 2025) (prior art "must be considered for everything it teaches") (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1076 (Fed. Cir. 2015)).

For Grounds 1-2, Align wholly ignores the Petition's reliance on *Tadros*'s disclosure of PETG copolyester in a hard layer and never addresses *Kalili*'s recommendation to use Texin 990R for its "outstanding" soft-layer properties. For Grounds 2-3, Align ignores *Wen*'s disclosures of beneficially combining multiple layers using adhesive lamination *before* thermoforming.

Align also fails to meaningfully dispute that using "basic" adhesive lamination techniques was obvious or that adhesive lamination offered advantages over coextrusion. Indeed, Align's expert, Dr. Kimmel, admitted that coextrusion was "extremely complex" and refused to compare it to adhesive lamination. [REDACTED]

Align’s secondary-considerations evidence cannot rescue patentability—it suffers from many fatal flaws and lacks nexus, as detailed below. All claims should therefore be held unpatentable as obvious.

II. Align Fails to Rebut the Petition’s Obviousness Grounds

A. *Tadros* Discloses Using a Copolyester in the Hard Layer (Grounds 1-2)

Align does not dispute that *Tadros* discloses a central “polymeric mixture” layer having the claimed flexural or tensile modulus greater than 150,000 psi. Pet., 30-31 (citing EX1003, [0068], [0023]); EX1007, ¶¶169-70; POR, 13-17. Instead, Align asserts that (1) the Petition relied “exclusively” on PC-PCCD mixtures and (2) PCCD is not a copolyester. POR, 13-14. Both assertions are incorrect.

1. Align Fails to Address the Petition’s Reliance on *Tadros*’s PC-PETG Layer

The Petition relies on *Tadros*’s disclosure that “[p]referred polymeric mixtures’... include polycarbonate mixed with a copolyester such as ‘[PCCD,’ [and] ‘[PETG.]’” Pet., 30 (emphasis added); EX1003, [0023]. PETG is a copolyester, as Dr. Kimmel confirmed. EX1149, 62:11-13 (Q. “Is PETG a copolyester?” A. “Yes.”); EX1148, ¶¶5-8; EX1158. All claims therefore would have been obvious based on *Tadros*’s disclosures of a PC-PETG polymeric-mixture layer

and that its polymeric-mixture layers should have a flexural or tensile modulus of greater than 150,000 psi. Pet., 30; EX1003, [0023], [0068]. Align's arguments, which never address PETG, fail for this reason alone. *Recor*, 2025 WL 944511, at *2-4 (prior art "must be considered for everything it teaches").

2. *Tadros* Discloses that PCCD Is a Copolyester

PCCD is a copolyester, contrary to Align's arguments. Align argues that because *Tadros* calls PCCD a "cycloaliphatic polyester" it cannot also be a copolyester. POR, 14. Both parties' witnesses, however, testified that "polyesters" are a category that includes "copolyesters." EX1148, ¶¶9-12; EX1150, 153:5-154:4. Indeed, *Tadros* also refers to PETG copolyester as a "polyester." EX1003, [0023]. A POSITA would have understood that, like PETG, *Tadros*'s PCCD is a *copolyester*. EX1148, ¶¶9-40; EX1151, [0001], [0462] (PCCD "copolyester"); EX1163.

a. Align's "Monomer" Theory Is Wrong

Align incorrectly asserts that *Tadros*'s PCCD diagram (Formula VIII) shows a *monomer*. POR, 15-17; EX2014, ¶¶49-50. As Dr. Osswald explained, Formula VIII depicts a *polymer*. EX2017, 25:1-4. *Tadros*'s recurring unit requires *polymerizing* a CHDM diol monomer with a diacid monomer (CHDA or DMCD), forming a *copolymer*. EX1148, ¶¶13-22; EX1160-EX1161; EX1149, 41:16-21, 47:12-48:2, 48:11-49:3 (Dr. Kimmel conceding that polymerizing two or more

different monomers creates a copolymer, “[f]ull stop”). Align’s “monomer” theory—i.e., that *Tadros*’s recurring unit is allegedly “a single *monomer*, meaning that PCCD is not a copolymer, and accordingly not a copolyester”—is therefore wrong. *See* POR, 16 (emphasis added).

Indeed, Align’s theory, if credited, would eliminate the entire class of alternating copolymers (e.g., A-B-A-B-A-B) by mischaracterizing the A-B repeat unit as a single monomer. EX1148, ¶¶21-22. Dr. Kimmel appeared to recognize this problem with his “monomer” theory during cross-examination, refusing to answer questions about alternating copolymers. EX1149, 46:10-15 (“I don’t specifically deal with that issue....”), 47:1-3 (“Whether I know or not isn’t the issue....”).

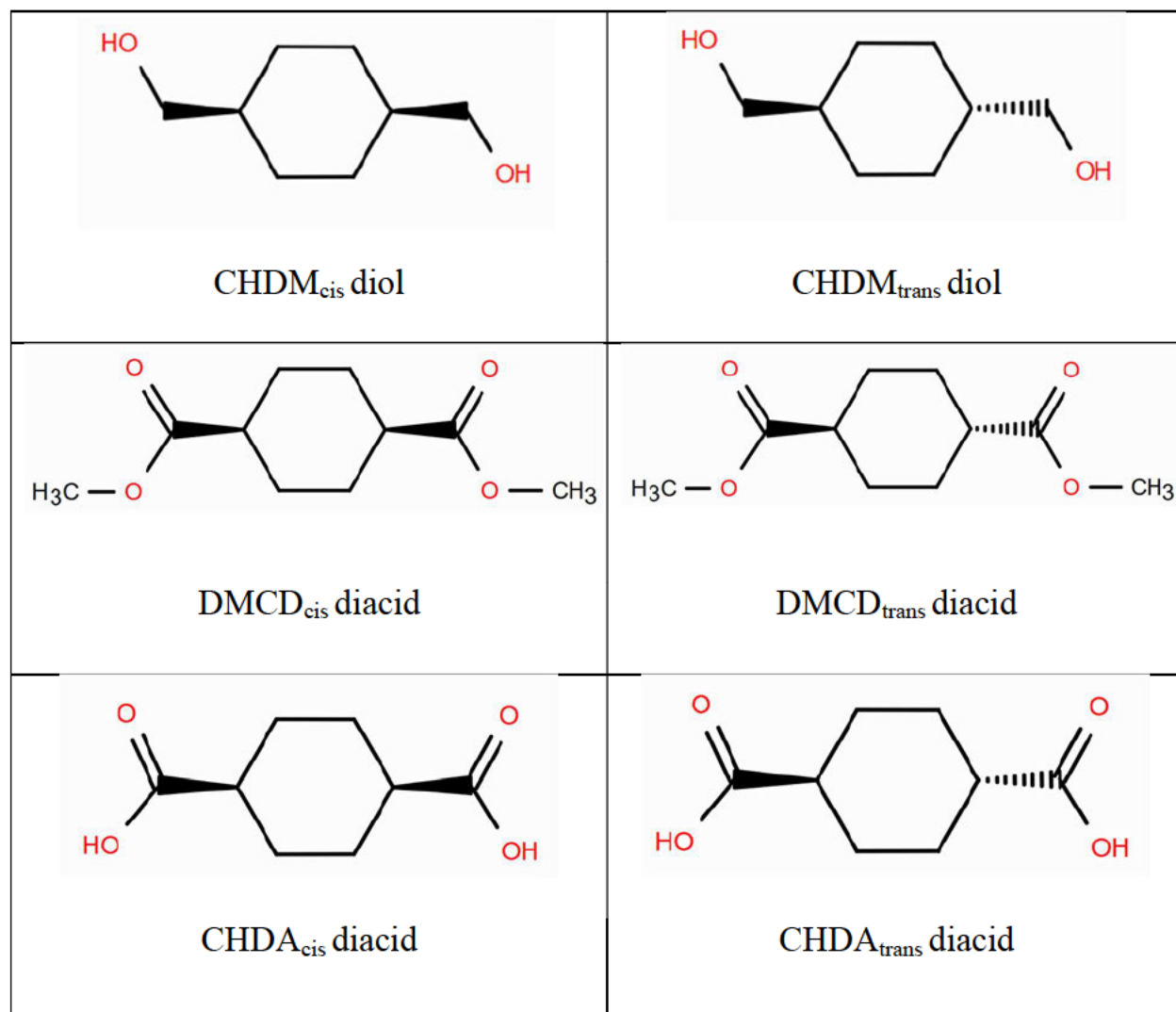
b. *Tadros* Discloses Preferably Using Additional Monomers

Align argues that “even PCCD formed from different isomers... would be considered a homopolymer.” POR, 17. This argument cannot be squared with both parties’ expert testimony that (1) *cis* monomers and *trans* monomers have different chemical structures and (2) using two different monomers as the diacid or diol produces a copolyester. EX1148, ¶¶23-40; EX1149, 50:21-51:2, 65:20-66:20, 67:2-13.

Align disregards *Tadros*’s disclosure that, “[w]hen a mixture of isomers... is used” the result is “a *copolyester*.” EX1003, [0045]. Indeed, *Tadros* discloses that PCCD is formed from “the *cis*- or *trans*-isomer or a *mixture of cis- and trans-isomers*

thereof,” which are depicted below. EX1003, [0042], [0045], [0050]-[0051];

Pet., 30.



EX1148, ¶¶26-29.

Align misreads *Tadros*'s paragraph [0045] as preferring “all-trans” PCCD. POR, 17. *Tadros* discloses preferably using “a ratio of cis- to trans-isomers of about 1:3.” EX1003, [0042], [0045] (75% trans, 25% cis), [0047], [0050]-[0051]; EX1148, ¶26 n.1; *Recor*, 2025 WL 944511, *2-4.

Align’s arguments also appear based on an inaccurate “homopolymer” comment in *Brunelle*. POR, 17; EX2019, 4101; EX1148, ¶¶30-34. In substance, however, *Brunelle* discloses making PCCD from isomeric mixtures of monomers, which both experts testified produces PCCD copolyester. EX1149, 41:16-21, 48:11-49:3; EX1148, ¶¶30-32. *Brunelle* also nowhere contradicts *Tadros*’s express disclosures, which correctly refer to isomeric mixtures in PCCD as forming a “copolyester.” EX1003, [0045]; EX1148, ¶¶29-32.

Tadros (and *Brunelle*) further disclose incorporating additional diol monomers beyond CHDM (e.g., ethylene glycol and butanediol) into the PCCD chain, again yielding a copolyester. EX1003, [0042]; EX2019, 4103; EX1148, ¶¶35-39; EX1149, 50:21-51:2.

Accordingly, Align’s arguments fail to disturb the obviousness of using a PCCD copolyester with polycarbonate in *Tadros*’s central polymeric-mixture layer. Pet., 30-31.

B. Align Fails to Rebut the Motivation to Use Texin 990R from *Kalili* as the Soft Layer in *Tadros*’s Multilayer Material (Grounds 1-2)

The Petition details *Tadros*’s disclosure of elastomers as preferred soft outer layers “to alleviate pain, discomfort[,] and bleeding gums” and TPUs as “[s]uitable” elastomers. Pet., 10 (citing EX1003, [0073]); POR, 24 (acknowledging *Tadros* discloses TPUs as suitable). The POR addresses *Tadros* in isolation, never acknowledging or rebutting *Kalili*’s specific guidance to use Texin 990R TPU for

this same purpose based on its “outstanding” properties. Pet., 31-33 (citing EX1003, [0073]; EX1005 [0009]); EX1005, [0069]; POR, 21-27. *Tadros* and *Kalili* thus provide ample guidance for the proposed combination. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (when patent “simply rearranges old elements with each performing the same function it had been known to perform... the combination is obvious”). Nonobviousness “cannot be established by attacking references individually,” as Align attempts here, when the challenge is “based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Align also implausibly argues that a POSITA lacked motivation to use *Tadros*’s PC-copolyester hard layer because BPA-free Tritan copolyesters later became available. POR, 22-23. This argument is legally irrelevant—polycarbonate mixtures and Tritan were both obvious options by 2012. Indeed, Align *itself* marketed prior-art polycarbonate aligners (PC30) for years. EX2016, ¶7. Obviousness does not require using “the *best* option, only... a *suitable* option.” *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197-98 (Fed. Cir. 2014). *Tadros* and *Kalili* confirm that polycarbonate and polycarbonate-copolyester mixtures were known, suitable options. EX1003, [0022]-[0023]; EX1005, [0069].

C. A POSITA Would Have Been Motivated to Use Tritan (from Porter) as the Hard Layer in *Kalili*'s Aligner (Ground 3)

1. *Porter* Is Analogous Art

Align does not dispute that *Porter* announced Tritan's arrival as a drop-in replacement for polycarbonate with desirable properties (e.g., flexural modulus, stress-crack resistance, BPA-free). Pet., 8-9, 57-58; EX2017, 76:18-77:6. Nor does Align dispute that Tritan satisfies the claimed hard-layer limitations. Align instead largely repeats its unfounded POPR arguments, seeking to cabin *Porter* to "durable consumer goods, and housewares" while disregarding the industry-wide recognition of Tritan. POR, 38-49; POPR, 21-29; *see also* DI 21-22. These arguments fail for several reasons.

First, as Dr. Osswald explained in his declaration and deposition, "the polymer technology industry [] was hungry for a replacement of polycarbonate because of the BPA issues" and "Eastman brought that solution in the form of Tritan." EX2017, 53:3-54:2, 68:24-69:7; EX1007, §IV.D. Indeed, Tritan's launch brought "a sigh of relief [for] anybody making anything that would come into contact with the mouth." EX2017, 61:17-22, 71:11-25. *Porter* made a "splash" by benchmarking Tritan's performance against a polymer's "worst enem[y]"—the dishwasher. EX2017, 56:3-6, 57:23-58:18 ("if something will resist a dishwasher, it can resist any environmental stress cracking condition"), 62:8-63:20, 64:22-66:7, 67:9-19. *Porter* also describes Tritan's desirability in "sheet[s]" with

“thermoforming.” EX1006, 62-63; Pet., 58. Unsurprisingly, the dental and orthodontics field quickly adopted Tritan. EX2017, 55:24-55:2, 74:4-11, 82:17-83:1, 96:15-23; EX1104, 5:55-61 (disclosing desirable use of BPA-free Tritan in mouthguard); *see also* EX1150, 159:14-161:6 ([REDACTED] [REDACTED]).

Second, as Dr. Osswald testified, material scientists like himself received *Plastics Technology* publications like *Porter* and other plastics-engineering journals touting BPA-free Tritan. EX2017, 52:17-54:2, 58:3-9 (“even just a [non-POSITA] picking up newspapers at the time, they knew BPA was in polycarbonate”). Thus, contrary to Align’s representations, *Porter* was not “plucked” out of a “sea of prior art” (POR, 39)—a POSITA would have been aware of polycarbonate’s shortcomings (e.g., BPA, high thermoforming temperature) and welcomed *Porter*’s disclosure of the Tritan “solution” for myriad polycarbonate applications, including dental appliances. EX2017, 53:17-56:8.

Third, Align’s very reliance on Dr. Kimmel’s experience contradicts its attempt to distinguish consumer-food appliances from dental appliances. Dr. Kimmel has no dental experience. He nonetheless characterized his consumer-food appliance experience (e.g., water bottles) as “representative of the skills and experience that one would have working with polymers that would be used for dental appliances.” EX1149, 13:16-21, 32:3-19, 39:20-40:19; EX2015. He testified that

“the same sorts of skills” in consumer-goods plastics “applies to making other plastic articles.... It’s the [] same basic technology.” EX1149, 19:15-20:6, 40:21-41:8. Thus, even if a POSITA understood *Porter* as addressing only food appliances, *Porter* would have commended itself to a POSITA’s attention by announcing Tritan as an improved material in applications—including dental aligners—that previously used polycarbonate. EX1148, ¶¶48-53.

2. A POSITA Would Have Recognized Tritan Was Desirable for Use in Dental Aligners

Align incorrectly argues that a POSITA would have looked to other non-BPA-containing polymers in *Kalili* instead of Tritan. POR, 42-49. This does not rebut Tritan’s suitability. *PAR Pharm.*, 773 F.3d at 1197-98. Further, Align nowhere addresses the other polymers’ properties or compares them to Tritan, which Dr. Osswald explained was unique and groundbreaking because it was BPA-free *while improving* on other polycarbonate properties. EX1007, §IV.D.2, ¶¶161-66; EX2017, 57:8-16, 61:3-7; EX1148, ¶¶54-61; EX1166.

[REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *UCB, Inc. v. Actavis Labs UT, Inc.*, 65 F.4th 679, 695 (Fed. Cir. 2023) (considering whether a POSITA would have done exactly what the patentee did does not violate §103). Align *itself* uses Tritan as SmartTrack’s rigid inner layer, surrounded by two TPU elastomer outer layers. [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]. [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] *KSR*, 550 U.S. at 419 (refusing to grant “patent protection to advances that would occur in the ordinary course without real innovation”).

3. Align Incorrectly Seeks to Impose an Unclaimed “Medical Grade” Requirement

Align incorrectly contends that a POSITA would only have used medical-grade polymers. POR, 8-9, 40-41, 47; EX1148, ¶¶62-63. *Tadros* and *Kalili* disclose dental aligners without any medical-grade requirement. *E.g.*, EX1003, [0023]; EX1005, [0069]. [REDACTED]

[REDACTED]

[REDACTED]

contain no medical-grade limitations.

D. Align Fails to Address *Wen*'s Complete Disclosure (Grounds 2-3)

Align incorrectly characterizes *Wen* as only disclosing sequentially thermoforming individual polymer layers one-by-one over a tooth model. POR, 33-38. Align never addresses *Wen*'s disclosures—cited in Dr. Osswald's declaration and the Petition—of beneficially combining multiple thin layers into a multilayer sheet before thermoforming:

- “[T]he first and second layer may be combined prior to forming over the tooth model....”
- “[T]wo or more polymer sheets may be laminated to one another to form a single sheet that is heated and vacuum-formed over the arch models to provide multi-layer dental aligners.”
- “The different layers (e.g., first and second layers) may be attached to each other directly, or an adhesive may be used to connect the different layers.”

EX1008, [0207]-[0208], [0210]; EX1007, ¶¶41, 123, 155, 164, 211, 239; Pet., 46-52.

Align thus improperly cherry-picks selected embodiments and fails to consider *Wen* for all that it teaches, including its disclosure of combining thinner layers before thermoforming. *Recor*, 2025 WL 944511, at *2-4. *Wen* discloses several benefits of using multiple thinner layers in a multilayer sheet, including

conformation to tooth models and improved layer bonding, and does not limit the applicability of those benefits to any method of making the multilayer sheet. EX2017, 30:23-32:15, 35:4-21, 39:25-40:21; EX1148, ¶¶41-47.

Dr. Kimmel speculates that multiple thinner layers could risk “slippage” or “delamination” during unclaimed, downstream uses. EX2014, ¶83; 37 C.F.R. §42.65(a). But *Wen* describes no such concerns, and the prior art encouraged “good adhesion” (not bad) between layers. EX1019, 154-155. Regardless, Dr. Kimmel does not dispute that laminating multiple thin layers and thermoforming the resulting sheet over a tooth model, as *Wen* describes, was within a POSITA’s skill. EX1148, ¶¶41-47; EX1164-EX1165.

E. Align’s Adhesive-Lamination Arguments Fail (All Grounds)

In the co-pending litigation, Align’s position is that even techniques that use high heat and cause mixing or cross-linking between layers (e.g., coextrusion) predictably maintain the properties of the polymers used for each layer. Pet., 14 n.3. EX1014, 13-14. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Petitioner explained that adhesive lamination was suitable and preferred (e.g., compared to coextrusion) because it preserves the “outstanding” properties of the disclosed layer materials (e.g., Texin 990R) due to the absence of

cross-linking between layers. Pet., 33; EX1005, [0069]. Either way, the challenged independent claims were obvious, as they do not require any particular fabrication method for the claimed multilayer “sheet.” *Apple, Inc. v. Uniloc Luxembourg, S.A.*, 2019 WL 2518360, at *5 (PTAB June 18, 2019) (“we are not aware of any requirement... that a challenge must show all of the unclaimed implementation and design details for an asserted combination”).

1. Align and Dr. Kimmel Fail to Rebut Motivation to Use Adhesive Lamination

Align does not dispute that *Tadros*, *Kalili*, and *Wen* all disclose lamination as a suitable method to produce dental appliances, including using adhesives. EX1005, [0056], [0063], [0074]-[0076], [0088], claim 20; EX1008, [0208]; EX1003, [0080], [0088]-[0090]. A POSITA would have known that “lamination” in these references includes adhesive lamination. EX1007, ¶¶120, 123, 155 (“Wen discloses that the layers may optionally be attached to one another by ‘an adhesive’”).

The Petition and Dr. Osswald also explained *why* a POSITA would have chosen adhesive lamination—it is a “basic” process that avoids cross-linking between layers (e.g., as occurs during coextrusion), preserving the “outstanding” layer properties disclosed in the prior art. *E.g.*, Pet., 14 n.3, 33, 51, 69; EX1007, ¶¶40-41; EX1148, ¶¶64, 75. Thus, contrary to Align’s assertions (POR, 25), the Petition explains why a POSITA *would have been motivated* to use adhesive lamination, not merely that a POSITA *could have* done so.

Align’s argument against motivation for adhesive lamination fails for several additional reasons. *First*, Align’s speculation that adhesive lamination might change layer properties contradicts Align’s consistent position that properties *do not change regardless of manufacturing method*. *Supra* §II.E.

Second, Dr. Kimmel conceded that he never compared adhesive lamination to coextrusion (or any other technique). Even the basic question of whether coextrusion was preferable to adhesive lamination was “not a question that [he had] considered....” EX1149, 94:20-95:8. He refused to answer other questions about whether his concerns were unique to lamination (e.g., whether delamination also occurs with coextrusion) as “beyond the scope” of his opinions. EX1149, 95:10-20 (“I just don’t discuss that”), 77:12-17, 92:16-94:5 (refusing to testify about “what actually happens in a co-extrusion process that makes it different” than adhesive lamination). Dr. Kimmel admitted he refused to answer questions about coextrusion because it is “an extremely complex process” that you “could write a book about.” EX1149, 78:5-80:1; EX1150, 105:6-107:1 (Align outsources SmartTrack coextrusion). That complexity provides further motivation to use a “basic” process like adhesive lamination that preserves desirable layer properties, as Dr. Osswald testified. EX1148, ¶¶65-75.

Third, Align’s selective reading of *Ebnesajjad* (POR, 19-21) ignores *Wen*’s disclosure of using adhesive lamination to make dental aligners. EX1007, ¶123;

EX1008, [0208]. Align and Dr. Kimmel cherry-pick excerpts from *Ebnesajjad*, ignoring its disclosures of numerous advantages of adhesive lamination and techniques that would not cause any of the issues (e.g., cross-linking) Align posits. POR, 19-20; EX2014, ¶114. For example, *Ebnesajjad* discusses improving adhesion by cleaning or roughing the layer surface before applying adhesive, neither of which would cause cross-linking or alter polymer properties. EX1042, 16-17, 154, 171-72; EX1148, ¶¶76-81; *Belden*, 805 F.3d at 1076. Align also cites *Ebnesajjad*'s discussion of "[n]atural or vegetable-origin adhesives" to argue some adhesives might lead to bacteria and mold (POR, 25), ignoring *Ebnesajjad*'s disclosure of "physiologically harmless" adhesives with "very good adhesion." EX1148, ¶72 (citing EX1042, 5, 144-45, 177). A POSITA would know to use nontoxic and "basic" adhesive lamination processes. EX1148, ¶¶72, 77-81.

Fourth, Align contradicts the patent specification, which describes lamination for suitably combining layers without special instructions or any mention of Dr. Kimmel's unsupported concerns. *See* EX1001, 6:32-64. If anything beyond ordinary skill was required to laminate such layers together and thermoform the resulting sheet, it was incumbent on Align to disclose it. *In re Publicover*, 813 F. App'x 527, 532 (Fed. Cir. 2020) (affirming obviousness).

Accordingly, Dr. Osswald's testimony stands un rebutted that adhesive lamination compared favorably to other techniques (e.g., coextrusion) and would have been obvious to use. EX1148, ¶¶64-81.

2. Align's Attempt at Reclassifying Adhesives as Structural "Polymer Layers" is Incorrect and Unsupported (Ground 1 Only)

Align incorrectly asserts that an adhesive in a laminated multilayer sheet should count in the total number of "polymer layers" of the claims. POR, 28-30. As the Petition states, however, adhesives are not structural layers and the Ground 1 combination satisfies the layer and sheet characteristics recited in claims 12-15. Pet., 7, 42-43.

First, as Dr. Osswald explains, a POSITA would have known that adhesive lamination may use solvents that evaporate (rather than polymer glue), leaving no remaining "layer." EX1148, ¶¶79, 82-83; EX1042, 412 ("Adhesion is attained by means of evaporation of the solvent...").

Second, Align's argument contradicts the patent specification, which never refers to the interfaces of laminated or coextruded sheets as "layers" in the claims or figures. EX1148, ¶¶84-88; EX1154-1155. Indeed, Align's declarants consistently describe SmartTrack as a three-layer product, even though the three layers have an interfacial boundary "layer" where soft and hard layers adhere. EX2016, ¶15; EX2014, ¶126; EX1148, ¶¶84-88. The '613 patent's CPC subclass is consistent with

this, explaining that a film formed on a layer by spreading a substance thereon is not considered to constitute a layer itself if it serves only as an adhesive. EX1001, (B32B subclass).

Third, a “tie-layer” is not a structural layer because, as Dr. Osswald explains, a POSITA would not consider the miniscule amount of glue a “layer” since it does not affect the bulk mechanical properties of the multilayer sheet. EX1148, ¶¶89-91.

III. Alleged Secondary-Considerations Do Not Support Nonobviousness

A. Align Fails to Establish Nexus

Align does not contend any presumption of nexus applies and fails to meet its burden of establishing actual nexus. POR, 53-56. Its alleged secondary-considerations evidence is therefore insufficient to avoid obviousness.

1. SmartTrack Is Not Commensurate with the Claims

Align fails to establish that the claims are commensurate with SmartTrack or that other aligners within the claims would “behave in the same manner,” as required. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); EX2016, ¶¶15-17; EX1150, 112:12-119:12; EX1140; EX1141. The claims require only one soft layer comprising *any* TPU and one hard layer comprising *any* copolyester, with a third layer (or more layers) that Dr. Kimmel testified can be “any polymer that exists.” EX1149, 109:5-111:12 (Q. “[T]here are many types of co-polyester, right?” A. “Yes, yes, yes there are”... Q. “There are many types of TPUs, right?” A. “Yes, there are”).

Despite the admittedly copious materials and layer configurations that Align never made, clinically tested, or commercialized, Align’s secondary-considerations arguments concern only the *soft-hard-soft* SmartTrack product. EX1150, 133:19-135:1; EX1149, 112:2-21, 113:17-123:19. SmartTrack thus cannot be commensurate with the claims (as Align asserts them). Indeed, named inventor Ms. Li previously told the Office that multi-layer materials *other than* SmartTrack (*soft-hard-soft*) were “inferior.” EX1010, 1237-38(¶¶4-7).

SmartTrack’s layer properties are also not commensurate with the claims. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

Property	Range in Claims 1, 6 or 7	[REDACTED]	SmartTrack Layer Value
Tensile modulus	>150,000	[REDACTED]	[REDACTED]
Elongation at yield	>4%	[REDACTED]	[REDACTED]
Elongation at break	>70%	[REDACTED]	[REDACTED]
Tensile strength	>5,000	[REDACTED]	[REDACTED]
Flexural modulus	>150,000	[REDACTED]	[REDACTED]

Align also nowhere alleges that making aligners with hard or soft layers having less desirable properties than SmartTrack’s “will behave in the same manner.” *Kao*, 639 F.3d at 1068. Align therefore fails to demonstrate that alleged secondary-

¹ EX1007, §IV.C.2 (tensile and flexural moduli are equivalent for isometric materials).

considerations based on SmartTrack “direct[ly] result” from the claimed limitations, as required. *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

Align’s argument that SmartTrack “embodies” (i.e., falls within) certain claims is legally insufficient to prove nexus. POR, 54-56; *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 97 F.4th 915, 935 n.11 (Fed. Cir. 2024) (“To the extent the court's nexus analysis consists of the mere observation that... [a product] embodies the claims,” that was “insufficient.”); *FMC Techs., Inc. v. OneSubsea IP UK Ltd.*, IPR2019-00935, Paper 45 at 85 (PTAB Oct. 14, 2020) (such a “ cursory explanation” for nexus is “insufficient”); *Fox Factory v. SRAM, LLC*, 944 F.3d 1366, 1377 (Fed. Cir. 2019). Dr. Kimmel also admitted that SmartTrack does not embody dependent claims 3, 11, and 19. EX1149, 113:7-116:3. SmartTrack thus is not coextensive with—and lacks nexus to—all independent claims for this additional reason. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) (independent claims are “at least as broad as the claims that depend from them”).

2. Align Already Attributed Its Secondary-Considerations Evidence to a Different Patent

Nexus is also lacking because Align previously submitted an inventor declaration by Ms. Li attributing the same SmartTrack secondary-considerations evidence to a critical feature (i.e., *soft-hard-soft* configuration) expressly claimed in the earlier ’691 patent, which Align has not asserted against ClearCorrect. Pet., 24-26; EX1002, claim 1 (requiring a “hard inner polymer layer” and two “soft outer

polymer layer[s]”); EX1010, 1234-42. Ms. Li cited the same clinical trial, representing that SmartTrack was “a product according to the instant claims comprising a... hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer.” *Id.* (¶¶11, 4, 7). She also represented that “*only the materials of the instant claims*” satisfied Align’s development criteria. *Id.* (¶¶5-6) (emphasis added).

SmartTrack thus cannot be coextensive with the ’613 patent claims because it includes a critical feature—a *soft-hard-soft* configuration—“claimed by a different patent and that materially impacts the product’s functionality.” *Fox Factory*, 944 F.3d at 1375; *Yita LLC v. MacNeil IP LLC*, IPR2023-00172, Paper 70 at 106-08 (PTAB June 6, 2024) (separate patenting is “problematic” for nexus-in-fact). Dr. Kimmel never considered whether the narrower ’691 patent also covered SmartTrack. EX1149, 139:3-21.

[REDACTED]

[REDACTED]

[REDACTED]

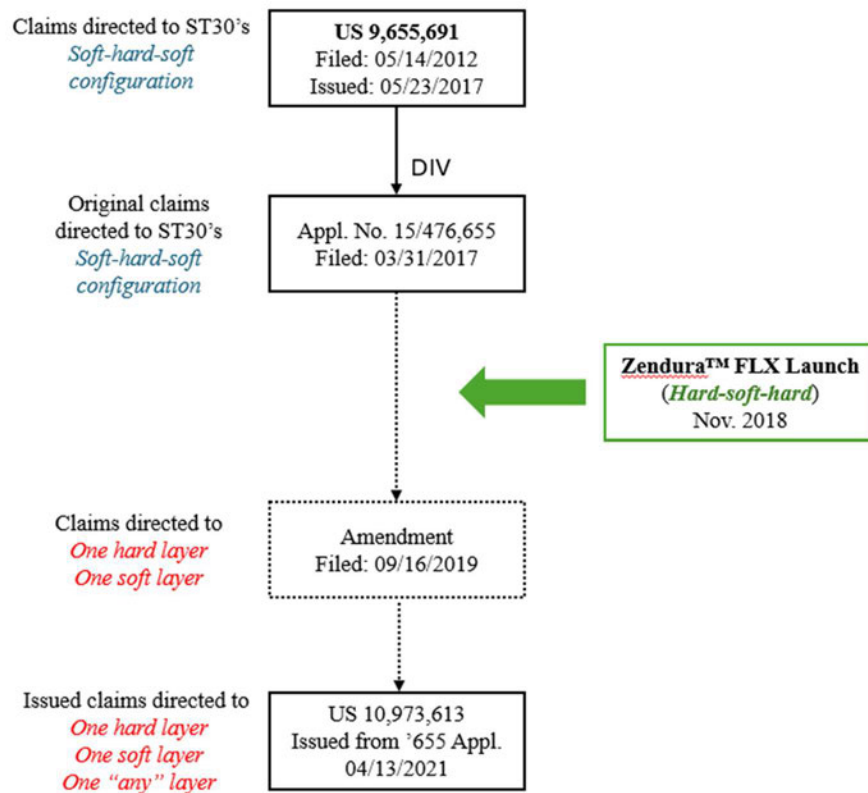
[REDACTED]

[REDACTED]

[REDACTED]

3. Align Intentionally Distanced Its Claims from SmartTrack

During prosecution of the '613 patent, the original claims required a *soft-hard-soft* configuration. EX1011, 16, 42. But in 2019, after Zendura™ FLX launched with an opposite *hard-soft-hard* configuration, Align amended its claims, seeking to eliminate any *soft-hard-soft* limitation, destroying any nexus. EX1011, 615-28, 498, 750-59, 841-48; EX1167-EX1168.



Ms. Li then submitted a second declaration (EX1011, 598-606), contradicting her previous representations to the Office regarding the '691 patent (EX1010, 1234-42):

Inventor Declaration, '691 Prosecution (<i>soft-hard-soft</i> claims)	Inventor Declaration, '613 Prosecution (<i>hard layer; soft layer; one other layer</i>)
"[O]nly the materials of the instant claims met Align's development criteria." (§5)	"[O]nly the materials according to the current claims met Align's development criteria." (§5)
"[M]erely combining the materials into multiple layers was insufficient to improve performance relative to the EX30 material." (§6)	"I would expect that the presence of only two such layers (i.e., a hard polymer layer and a soft polymer layer according to the current claims) would also provide beneficial and surprisingly superior properties of elongation, time stress-relaxation, durability, and thermoform ability." (§4)

The Board should reject Align's shifting secondary-considerations positions as "the result of litigation bias" and "lack[ing] credibility," and thus "entitled to little or no weight." *Yita*, IPR2023-00172, Paper 70 at 108.

B. Align Fails to Establish Unexpected Results

No SmartTrack-related results were unexpected. The SmartTrack clinical-trial results of 26% improvement in "on-track" and 34% decrease in "off-track" patients demonstrates, at best, a difference in degree. POR, 58; EX2016, ¶¶26-30; *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005) (32-43% improvement does "not represent a 'difference in kind'" as "required to show unexpected results"); *cf. In re*

Albrecht, 514 F.2d 1389, 1395-96 (CCPA 1975) (crediting unexpected dual activity as difference-in-kind where prior-art compounds exhibited single activity).

Moreover, Align failed to provide testimony from a *clinical* declarant providing appropriate context for the alleged *clinical* results (let alone prove a difference-in-kind) from the trial or retrospective analysis. *See* POR, 57-59. Align's declarants admittedly have no experience measuring tooth movement. EX1149, 13:16-14:20; EX1150, 133:19-135:1 ("I'm just a material person").

Align also never compared SmartTrack to the closest prior art, which the Examiner identified as Align's own two-layer aligners in DeSimone (EX1156), not EX30. EX1011, 881-82. DeSimone reports similar multilayer aligner properties as in the '613 patent, but Align never addresses this closer prior art, instead comparing SmartTrack to the single-layer EX30. EX1156, 1:50-60, 2:42-67, 5:34-50, fig.4, claim 1. *Millennium Pharmaceuticals, Inc. v. Sandoz Inc.* does not apply here, as DeSimone reports *Align's own* multilayer aligners. 862 F.3d 1356, 1369 (Fed. Cir. 2017) (not requiring reproduction of *another party's* technology); EX1011, 599(¶3).

C. Align Fails to Establish Copying or Commercial Success

Align's copying allegations fail. The *hard-soft-hard* Zendura FLX aligner material launched in 2018, when Align was only claiming *soft-hard-soft* configurations. *Supra* §III.B. If anything, Align's changed claiming strategy sought to copy aspects of using Zendura FLX—not the other way around.

Align also fails to link any commercial success of “Invisalign® Clear Aligners” specifically to the claimed features. EX2018, ¶2. Align admits its “competitive advantage” resulted from a “multivariable equation” involving market power, brand strength, and its “ecosystem” of products and services (e.g., treatment plans, dental molds, scanners, and software). EX1144, 6; EX1145, 8, 12; EX1157, 51:11-18, 77:11-22, 79:5-80:3, 90:17-91:1, 92:6-14, 95:6-16, 105:7-8; 122:17-123:7; 138:10-21; 161:9-162:20. Indeed, Align represents Invisalign® as “*so much more than just a clear aligner, it’s an entire ecosystem*” of technologies. EX1146, 1 (emphasis added); EX1167; *Microsoft Corp. v. Interdigital Patent Holdings, Inc.*, IPR2024-00305, Paper 42 at 39-45 (PTAB June 23, 2025) (Airdrop feature within Apple’s “ecosystem” lacked nexus).

In contrast, Align’s commercial-success declarant admitted he did not consider *any* of the ’613 patent’s claimed features or the relative contributions of 300+ other patents covering Invisalign®. EX1147; EX1167; EX1157, 42:13-20; 126:14-127:1; 164:19-22; 165:18-166:3; 166:13-169:5; *Geneoscopy, Inc. v. Exact Scis. Corp.*, IPR2024-00459, Paper 39 at 25-34 (PTAB July 9, 2025) (no commercial success for product marked by “dozens” of other patents).

Further, because Align already “dominated” the market before SmartTrack’s launch, it leveraged its incumbent status and market power to switch existing EX30 customers to SmartTrack and expand into nascent international markets. POR, 3;

EX2031, 9-11, 5 (listing “record fiscal year” before SmartTrack launch); EX1157, 60:4-13 (EX30 customers had “no choice” in switching to SmartTrack), 101:15-102:3, 33:17-34:1, 70:4-18, 134:7-21. The Federal Circuit has rejected commercial success where a patentee was already the market leader and all sales “transferred” to a new product. *Purdue Pharma L.P. v. Accord Healthcare, Inc.*, 2024 WL 5244764, at *9-10 (Fed. Cir. Dec. 30, 2024).

Accordingly, Align’s secondary-considerations evidence fails. The totality of evidence relating to obviousness thus establishes that the challenged claims are unpatentable.

IV. The Board Should Reject Align’s Unsupported Arguments that Bay Materials, Smartee, or AlliedStar Are RPIs

Align sought to avoid institution by representing to the Director that “each real party-in-interest” was already a defendant in the parallel litigation. Paper 7, 18. Bay Materials (“Bay”), AlliedStar, and Smartee have never been defendants there and are not RPIs here. After institution, Align flip-flopped, asserting for the first time in a (now-denied) Director Review request that Bay was an unnamed RPI. Papers 19, 22, 29. The POR raises nothing new, and thus Align’s threadbare RPI challenge fails to shift any burden to ClearCorrect and should be rejected.

The POR never alleges that Bay controls ClearCorrect or funds this proceeding—indeed, Bay does not. Paper 18, 10 (any arguments not raised in the POR may be waived). The record correctly demonstrates that Bay does not own

ClearCorrect (or vice versa). POR, 66; EX2014, ¶154. Rather, ClearCorrect and Bay are separate entities within the Straumann Group. *See* EX2008, 5 (¶4), 85 (¶¶25-27); Pet., 74. The record further demonstrates, as Align admits, that Bay is a plastics *supplier* to ClearCorrect and other customers, selling the Zendura FLX product that Bay independently developed before Straumann acquired Bay. EX1023, ¶18; EX2008, 5(¶4), 26(¶80), 30(¶100); EX2014, ¶154. A customer/supplier relationship between entities within a “corporate family tree” is insufficient. *Toshiba Memory Corp. v. Anza Tech., Inc.*, IPR2018-01597, Paper 56 at 15 (PTAB Mar. 12, 2020).

The record further demonstrates that Bay, unlike ClearCorrect, has no infringement risk in the parallel litigation, as Bay does not make dental aligners. EX1023, 1; 2019 Consolidated TPG, 14 (“the ‘real party-in-interest’ is the party that desires review of the patent”).

The above facts easily distinguish this case from Align’s reliance on *AIT*, where joint-defense entity RPX filed a petition to benefit a time-barred defendant in parallel litigation. *Applications in Internet Time, LLC, v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018). Here, ClearCorrect filed this IPR at its own behest, not at the behest of a raw-material supplier and sister company that has no infringement risk. *Nuseed Ams. Inc. BASF Plant Sci. GmbH*, IPR2017-02176, Paper 16 at 6-11 (PTAB Apr. 11, 2018) (sister company was not an RPI, including because it was not at risk of infringing).

Align’s RPI arguments concerning Smartee and AlliedStar are likewise meritless. No national-security concerns are present, as neither company is on the Department of Commerce’s “entity list.” *See* October 28, 2025 Memorandum. Neither company has any involvement in this proceeding or the parallel litigation, and Align does not contend otherwise. *Corning Optical Commc’ns. v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 14-15 (PTAB Aug. 18, 2015) (“A party does not become a RPI merely through association... in an endeavor unrelated to the IPR”).

Contrary to Align’s arguments, there is also no inconsistency with upholding a different patent in the different Bay IPR proceeding involving different parties and a different commercial product. POR, 66.

V. Conclusion

ClearCorrect respectfully requests cancellation of all challenged claims.

Respectfully submitted,

Dated: May 29, 2026

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(c)(1), the undersigned hereby certifies that the foregoing **Petitioner's Reply to Patent Owner's Response** contains 5,518 words, excluding the parts exempted under 37 C.F.R. § 42.24(c) as measured by the word-processing system used to prepare this paper.

Dated: May 29, 2026

By: / Charles T. Collins-Chase /

Charles T. Collins-Chase,

Reg. No. 78,019

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Petitioner's Reply to Patent Owner's Response** was served on May 29, 2026, via e-mail directed to counsel of record for the Patent Owner at the following:

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