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
Patent No. 11,648,091

PATENT OWNER'S SUR-REPLY

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I. INTRODUCTION

Petitioner's obviousness challenges rest on irreconcilably inconsistent positions, contradicting both arguments in district court as well as evidence and argument in the petition itself. If the petition challenges are not undermined on this basis alone (and they should be), the challenge is further deficient because Petitioner's expert, Dr. Osswald, confirmed he completely ignored all objective evidence of nonobviousness.[1] Petitioner cannot meet its burden to show obviousness of any challenged claim.

Highlighting the Petition's deficiencies, the Reply relies on several new arguments which should be given no weight. Regarding Tadros, the petition failed to justify replacing its polymer mixtures and botched its rationale for turning to copolyester, and the new Reply argument fails to remedy this. Regarding Kalili, the petition theory was incurably based on a mischaracterization of Tadros as "prefer[ing]" TPUs, and the Reply never grapples with Petitioner's district court argument that a POSITA would be essentially paralyzed by unpredictability even when considering known TPU elastomers. Regarding Wen, the petition ignored

[1] The related Bay Materials IPR, where Dr. Osswald opined regarding evidence of nonobviousness that is pertinent here when it served his client's interests, further confirms this oversight is not harmless error. *See, e.g.*, POR, 64-66.

that Wen's teachings about sub-divided layers did not apply to multilayer sheets, so the Reply improperly shifts to newly proposed combinations.

Accordingly, the patentability of each challenged claim should be upheld.

II. PETITIONER IS IN NO POSITION TO DEFEND ITS OBVIOUSNESS CHALLENGES (ALL GROUNDS)

Each petition ground cherry-picked materials from voluminous categories, proposed various substitutions/modifications, introduced "tie layers," and called the results *predictable*. *See, e.g.*, Pet., 32, 43, 53, 59, 74 ("predictable results" and "expectation of success"); Paper 17, 16-17 (Institution Decision premised on claim of sufficient predictability). As the POR explained (17-18, 24-27, 30, 39, 52), however, the *predictability* upon which all grounds are based could never withstand the scrutiny of the petition's own conflicting evidence and admissions.

Trial has now concluded in the co-pending district court litigation, making Petitioner's irreconcilable positions even worse. At district court, Petitioner argued repeatedly, and without qualification, that multi-layer aligner material interactions are *unpredictable*—and that the field in general is *unpredictable*—convincing the jury to find the claims (while described and infringed) were not enabled. Paper 49. For example, Petitioner insistently argued to the court that the field is not predictable:

[redacted]

13 And I'll make one note here, Your Honor,
14 which we'll pick up as we go through this. This is not
15 a so-called predictable art in terms of developing
16 these clear aligners. The particular research and
17 development process required to develop an efficacious
18 clear aligner is very complicated and frankly very
19 unpredictable. And it takes a lot of experimentation
20 to develop an efficacious clear aligner that will
21 function for its purpose of straightening teeth that
22 will be safe, that will be sufficiently comfortable,
23 sufficiently stain resistant. This takes an enormous
24 amount of work to develop these types of aligners.

EX2036, 93:1-11, 221(56:13-24); *see also id.*, 280-81(115:4-116:8) ("this is an unpredictable science" and "the amount of work required to arrive at an efficacious aligner is immense"). Petitioner also elicited expert testimony that multi-layer aligner technology is *unpredictable*.

2 Q. And if you -- if you need a lot of trial and
3 error, does that make a -- an art -- a field
4 predictable or unpredictable?
5 A. No. A lot of trial and error means it's
6 unpredictable.
7 Q. Now, is making a multi-layer material for use
8 in a dental aligner, is that predictable or
9 unpredictable?
10 A. It is unpredictable.

EX2036, 107:18-108:11, 388(771:2-13) (Dr. Spiegelberg's testimony). Petitioner argued the category of TPUs alone was so voluminous that unpredictability in the art would essentially prevent a POSITA from knowing where to start even when presented with known options. *Compare* EX2036, 320-21(703:25-704:21) (thousands of types of TPUs), *with* Grounds 1-4 (cherry-picking Texin 990R).

When confronted with Petitioner's district court arguments (which he had not seen before), Dr. Osswald had no valid explanation. Rather, he tried to justify Petitioner's district court position by concocting a different skill level applicable to those arguments, one in which the POSITA is ignorant of the state of the art. Dr. Osswald testified that "things are unpredictable" when you "start from zero" but "unpredictability is taken away by using the references, by having the prior art." EX2036, 98:20-21, 100:16-20. Of course, this bizarre distinction is legally erroneous; a POSITA is presumed knowledgeable, both in an IPR and at district

court. *See, e.g.*, *Storer v. Clark*, 860 F.3d 1340, 1350 (Fed. Cir. 2017) ("*Knowledge of the prior art is presumed*, as well as skill in the field of the invention."); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) ("The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art.").

There is no valid explanation for Petitioner's inconsistent positions on unpredictability and the Reply provides none. Predictability was central to both Petitioner's obviousness argument in this IPR and the Board's institution decision. Given its arguments at district court, Petitioner is in no position here to argue that combining the prior art materials would have yielded *predictable* results. *Cf. New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) ("Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position," especially against the same party. (quoting *Davis v. Wakelee*, 156 U.S. 680, 689 (1895)). The petition challenges fail for at least this reason. Petitioner's conflicting argument both here and at district court underscores the failure to meet its burden of proof in demonstrating obviousness as alleged.

III. THE REPLY FAILS TO REMEDY THE PETITION'S DEFICIENCIES REGARDING DEVIATING FROM TADROS'S TEACHINGS (GROUNDS 3-4)

The petition did not show that a POSITA would replace Tadros's polymer mixture with Porter's copolyester. The Reply's new attempts to shore up the

petition's deficient showing fail.

A. The Reply Fails to Remedy the Petition's Deficient Rationale for Substituting Copolyester for Tadros's Hard Layer

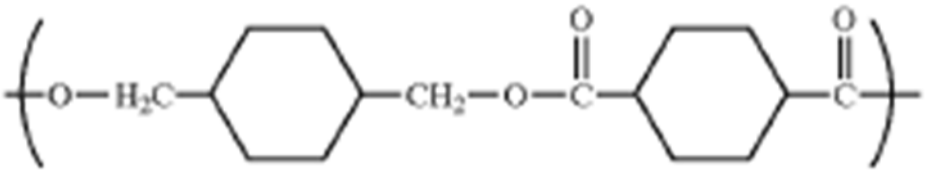
The petition argued that a POSITA would have been led to Porter's copolyester because Tadros taught "polycarbonate-copolyester mixtures," namely "PCCD variations," as a hard layer. Pet., 54-55. As the POR explained, this argument fails at least because Tadros's PCCD is not a copolyester, and the petition did not even attempt to show that it was. POR, 40-44. Petitioner tries to backpedal from its petition theory by now arguing it is "irrelevant" whether PCCD is a copolyester because the focus should be on avoidance of polycarbonate alone (Reply, 7-8), but the petition is built around an assertion that "[a] POSITA would thus have sought to replace Tadros's hard *mixture* with a BPA-free alternative," citing "copolyester's thermoforming properties" as a basis for turning to Porter. Pet., 55 (emphasis added); *see also id.* ("Tadros sought to create a material that combined the best features of the pure polycarbonate and pure copolyester."). Petitioner thus cannot avoid its misplaced reliance on PCCD as a copolyester.

In response, the Reply (6-8) turns to a different polymer—PETG mixtures. PETG appears not once in the petition—the only Tadros polymers discussed were PCCD and polycarbonate. The Reply's new PETG-based rationale is an impermissible departure from the petition theory and should be disregarded as such. *Intelligent Bio-Systems v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369

(Fed. Cir. 2016) (proper to disregard reply containing new theory or arguments). The Reply's new prosecution-history argument for non-PCCD copolyesters (7 n.1) is likewise new and improper.

The Reply's argument that PCCD is a copolyester (7-8) also fails. As Dr. Kimmel explained, a polymer formed by a single type of recurring polyester unit is a homopolyester, whereas a copolyester requires reacting *multiple different* diacids or diols to form *different* types of polyester units. EX2014, ¶49; POR, 15. Tadros expressly describes its PCCD as having the *same* recurring polyester units. Formula VIII (below) shows Tadros's PCCD has only *one type of repeat polyester unit* and is thus *not* a copolyester.

(VIII)



EX1003, [0050].

Attacking a strawman ("Align's 'Monomer' theory"), the Reply (7-8) pivots to the irrelevant discussion of whether the single polyester unit of Tadros could be imagined as a combination of two sub-components and relabeled a "copolymer" (not a copolyester). EX1148, ¶18.

This is a pure diversionary tactic. The salient and unrebutted fact is Tadros

describes its PCCD as having a single recurring polyester unit—not a combination of different polyester units. It is ultimately irrelevant whether Tadros's single polyester unit might be reimagined by its (non-polyester) subcomponents and whether those subcomponents may or may not be called "monomers." To the extent there is any conflicting "monomer theory," it is owned by Dr. Osswald from his earlier testimony. *See* EX2017, 25:8-9 ("Does formula VIII show multiple monomers? A No."). It remains undisputed that (1) Tadros Formula VIII includes only one polyester unit, which repeats, and (2) neither newly identified subcomponent is a polyester unit. EX2036, 11:24-13:19. There is no PCCD "copolyester" formed from different polyester units and Tadros does not teach otherwise.

The Reply's (7) citation to new EX1151 is both untimely and irrelevant to Tadros' *different* composition. Dr. Osswald agrees, EX1151 does not describe the same PCCD composition consisting of the same repeating polyester units as in Tadros. EX2036, 28:3-18 (Eastman's "PCCD" and Tadros's Formula VIII are "different formulations"); *see* EX1151, [0003] (polyester "comprising units" of PCCD), [0194], claim 1(B)(ii)(a)-(b) (further comprising "additional glycol or polymeric glycol residues"); EX2036, 17:12-19:22, 22:9-18, 24:6-28:12. Tadros's PCCD does not contain the "additional" residues in Eastman's composition "comprising" PCCD units. EX1003, [0050].

The Reply (7-8) also incorrectly contends a PCCD isomer mixture teaches a copolyester (it doesn't). Importantly, cis and trans isomers have the same chemical formula, differing only in their stereochemistry. Because of this, Dr. Kimmel explains, with corroborating evidence, a POSITA would not consider a mixed-isomer form of Tadros's PCCD a copolyester. EX2014, ¶¶51-52 (citing EX2019, 4101, table 6); EX2020, 173. The Reply (6 (citing EX1149, 41:16-21, 47:12-48:2, 48:11-49:3)) mischaracterizes Dr. Kimmel's deposition; the cited testimony addresses the meaning of homopolymers and copolymers generally, never mentions isomer mixes, and confirms copolyesters require multiple polyester units. The Reply (7) also mischaracterizes Tadros's [0045]; Tadros never teaches that forming a polyester of a mixture of isomers produces a copolyester. *See* EX2036, 21:16-21, 22:5-8, 28:20-22, 33:18-25, 38:9-17, 39:17-20. The Reply's fabrications (7-8) regarding Tadros's "express disclosures" fail as no such disclosures exist.

Ultimately, Petitioner seeks to replace objective evidence, which is unanimously against them, with uncorroborated say-so. The Reply wholly ignores Brunelle's description of PCCD with a cis/trans mixture as a "homopolymer." EX2019, 4101. Additional literature confirms PCCD (including cis/trans mixes) is a homopolyester, not a copolyester. EX2036, 29:15-32:11, 36:24-37:21, 42:8-13, 49:17-50:4, 54:5-11, 62:12-22; *id.* 138-41(2:55-58, 5:3-20), 142-54(2:10-18), 160. Dr. Osswald attempts to sidestep the objective evidence by arguing Tadros defines

"copolyester" differently than the scientific literature. EX2036, 21:16-21, 32:24-25, 33:24-25, 37:19-38:3, 62:18-22. Again, Tadros never calls its PCCD a "copolyester." In any event, it is Petitioner's burden to show the claimed copolyester under the plain meaning to a POSITA, not some imagined idiosyncratic definition never even used by Tadros.

B. Petitioner Does Not Justify Ignoring Tadros's Teachings to Use a Polymer Mixture

As explained in the POR, Tadros exclusively teaches using polymeric mixtures as hard layers. POR, 44-47. The Reply does not dispute this. Nor does Petitioner dispute Dr. Kimmel's explanation that Tadros discloses 2,775 different mixtures of material types for hard layers, including 2,701 different non-polycarbonate mixtures. EX2014, ¶60. The petition ignored this fundamental aspect of Tadros in arguing a POSITA would have veered from these teachings in favor of a single-polymer hard layer.

The Reply argues (8-10) that Tadros had goals beyond producing polymer mixtures, but it cannot avoid the fact that Tadros taught that the means to achieve these goals was using polymer mixtures, not pure polymers. EX2014, ¶¶65-66. Nor would a general desire to vary material properties like glass transition temperatures suffice to point a POSITA to Porter in particular. EX2014, ¶¶67-68; POR, 44-47. Indeed, in cross-examination, Dr. Osswald repeatedly asserted that a POSITA would be motivated based on Tadros to use a *polymer mixture*, not a pure polymer.

EX2036, 53:3-8, 62:25-63:3 (POSITA would be "satisfied with Tadros" and "replace the hard layer of polycarbonate" with "mixtures"), 84:12-20 (POSITA would say "I am going to use Tadros's mixtures.").

IV. PETITIONER'S HINDSIGHT ARGUMENTS FAIL TO JUSTIFY ITS RELIANCE ON PORTER (ALL GROUNDS)

Petitioner's unpredictability arguments undermine its obviousness combinations and corroborate improper hindsight. Petitioner's unsubstantiated cherry-picking of Porter's dishwasher plastic for the petition's dental-aligner copolyester only makes matters worse.

The Reply (8-10) does not dispute Porter never mentions dental aligners. As the POR explains (18-21), Rafih's injection-molded mouthguards provide no tooth-moving forces and thus have little relevance, if any, to thermoformed dental aligners. Moreover, Petitioner's argument that Tritan was BPA-free is contradicted by its arguments in IPR2025-00818 and IPR2025-00819 that a POSITA would be motivated to use Tadros' polycarbonate mixture. POR, 16-17. Petitioner cannot have it both ways and the Reply never grapples with this self-defeating argument. Similarly, the Reply's (10) assertion of suitability is both legally insufficient and cuts against Petitioner. Petitioner itself presents both Kalili and Tadros as providing many "suitable" options with no justification for abandoning them. Conversely, Petitioner never established in the first place that Porter's dishwasher plastic was suitable for dental positioning aligners. And the Reply does not rebut

testing data showing that Tritan and other copolyesters actually showed *poor* durability. EX2016, ¶24; EX2027; EX2014, ¶¶143-44.

Attacking a strawman, the Reply mischaracterizes the POR as imposing a requirement that the aligner material be "medical-grade." Reply, 6. The salient question goes to Petitioner's burden. As the POR explained (14-16), the petition gave no good reason (and the Reply still does not) why a POSITA would have looked past many "suitable" BPA-free materials identified for orthodontic or other medical uses. Petitioner's argument that substituting materials into layers of a dental aligner was unpredictable only highlights this deficiency. *See* POR, 26; Pet., 22 n.4; *supra* §II.

The Reply's arguments (5-6) relying on Align's own path to invention are unquestionably improper hindsight and only confirm the tainted nature of Petitioner's obviousness theory. Petitioner's reliance on *UCB, Inc. v. Actavis Labs UT, Inc.* is inapposite. That case involved the question of unexpected results, not *prima facie* obviousness, and the court acknowledged it *was* error to consider the inventor's path but found the error harmless in view of additional evidence and concessions by patent owner's expert, which are not present here. 65 F.4th 679, 694-95 (Fed. Cir. 2023).

Lastly, the Reply's attempt (5) to disguise its improper hindsight is incomplete and misleading. Petitioner fails to inform the Board that, long in

advance of these IPRs, its sister company, Bay Materials, obtained SmartTrack material and its data sheet, tested the product, and produced SmartTrack simulates. EX2036, 420-22(803:17-805:9). It then launched Zendura FLX (Petitioner's aligner material) using Tritan as a hard layer. EX2010, Table 3 (hard layer material of sample 2 is "Polyester B," which is "Tritan"); EX2026, ¶182 (Zendura FLX properties: table 3, sample 2).

V. PETITIONER UNDERMINES MOTIVATION AND EXPECTED SUCCESS IN COMBINING TADROS AND KALILI (GROUNDS 3-4)

In addition to the problems with replacing Tadros's polymer mixtures with Porter's Tritan, the POR also explained the petition's failure to establish a reasoned basis for turning from Tadros's elastomer teachings to a polyurethane found in Kalili. POR, 48-52. Petitioner's arguments alleging motivation to do so along with expected success are incompatible with their assertions of wild unpredictability. *See supra* §II; *see also* Reply, 11 (citing *KSR* for predictable combinations). Indeed, in addition to self-defeating argument advanced at district court, the petition undermined its own challenge when stating that "replac[ing] layers with other polymers," like substituting Kalili's polyurethane elastomer into Tadros's layers, "is unpredictable." Pet., 22 n.4. Yet, the asserted obviousness grounds rely on an irreconcilable assumption of predictability. *See also* Reply, 6 (again citing

KSR for *predictable* combinations). The Reply doubles down on the irreconcilable conflicts in its own arguments and positions rather than resolving them.

The petition's motivation was based on mischaracterizing Tadros as identifying polyurethanes (TPU) as preferred "elastomers." POR, 49-50. Tadros says no such thing and the Reply offers no dispute. Nor does the Reply grapple with Petitioner's irreconcilable district court assertions that a POSITA would have been stymied by unpredictability when considering the large number of known TPU elastomers. EX2036, 321(704:9-13).

As noted above, the Reply also never resolves the inconsistencies between the Grounds here and in IPR2025-00818 and IPR2025-00819, claiming here that Tadros' polycarbonate is unsuitable and harmful to patients, yet arguing in the parallel IPRs that that polycarbonate as in Tadros would be perfectly "suitable" for aligner material. POR, 16-17. For example, the Reply's argument in IPR2025-00818 and IPR2025-00819 that polycarbonate was suitable undermines the arguments here, where Petitioner inconsistently asserts the industry was "hungry" to replace polycarbonate due to its unsuitability as a BPA-containing material. It is Petitioner's burden to resolve its own irreconcilable assertions (not PO's burden), and the Reply offers only head-spinning contradictions—each ground fails as a result.

VI. THE PETITION MISAPPREHENDED WEN'S INCOMPATIBLE SEQUENTIAL THERMOFORMING TECHNIQUE (GROUNDS 2 AND 4)

As the POR explained, Grounds 2 and 4 were based on a misapprehension, asserting Wen discloses sub-dividing layers in a sheet for subsequent thermoforming. POR, 32-36; EX2014, ¶¶80-83, 87-89. Dr. Osswald agreed that no such embodiment is found in Wen. The Reply (11-13) concedes as much.

Improperly pivoting to new argument, the Reply now proposes mixing-and-matching different embodiments. The Reply does not dispute that none of Wen's cited passages discuss subdividing a layer in the context of forming a multilayer sheet. Reply, 12. Nor does Petitioner dispute that the additional art the petition cited failed to support the proposed combination. *See* POR, 36-38; EX2014, ¶¶77-79, 84-86. There is simply no prior art support for Petitioner's new proposal and the Reply cites none.

Abandoning prior art support (there is none), the Reply (12-13) resorts to improperly asking Align to prove a negative in asserting Wen "does not limit the applicability of those benefits to any method." Such assertions cannot satisfy Petitioner's burden. The assertion (13) the combination "was within a POSITA's skill" improperly seeks to replace prior art teachings with say-so about knowledge in the art. *See* Coke Morgan Stewart, Enforcement and Non-Waiver of 37 C.F.R. §42.104(b)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews, https://www.uspto.gov/sites/default/files/documents/

aapa_memo_final__signed.pdf (Jul. 31, 2025) (general knowledge may not supply missing claim limitation). The Reply's (13) "good adhesion" argument lacks corroboration and makes no sense; Petitioner offers no basis to conclude that two half-layers glued together (i.e., now three layers) would adhere better than a single, solid layer. The Reply's new exhibit (EX1164) is untimely and provides no help: it does not involve adjacent, identical layers, and its discussion of slippage requires specially localized heating absent from Petitioner's proposed combination. EX1164, 4:39-55. The Reply offers no rebuttal to Dr. Kimmel's testimony regarding inapplicability and detrimental effects, added cost/complexity, etc. EX2014, ¶¶82-83, 88-89. Whether a POSITA could split layers says nothing about whether there was a reason to do so. *E.g.*, *InTouch Techs., Inc. v. VGO Commc'ns*, 751 F.3d 1327, 1352 (Fed. Cir. 2014).

At bottom, no prior art discloses splitting a thick layer into multiple thin ones for a subsequently thermoformed multilayer sheet or any benefit in doing so.

VII. PETITIONER HAS NOT MET ITS BURDEN TO SHOW MOTIVATION TO USE ADHESIVE LAMINATION (ALL GROUNDS)

At district court, Petitioner's broadside attack on the state of the art as highly unpredictable was not limited to a type of lamination. It is not in a position to credibly argue otherwise here. And although the Reply (14-15) attempts to dismiss as "speculation" the notion that adhesive lamination causes the same "cross-linking" and "molecular diffusion" the petition blamed for unpredictably altering

mechanical properties, the POR cited Petitioner's own evidence for that point. POR, 25-26 (citing EX1042). The Reply (15-16) provides no valid response to its own conflicting *Ebnesajjad* reference and offers only a scattershot of new argument. The Reply (15-16) newly proposes "roughing" the surface to minimize (not eliminate) cross-linking and asks to selectively ignore adhesives that present mold and bacteria problems. None of this is found in the petition materials. The Reply (16) generically asserts a "POSITA would know" of a nontoxic adhesive but does not claim the glue from the petition would be known as nontoxic. Petitioner's concocted IPR narrative was never substantiated and still is not.

Even if adhesive lamination is considered, as the POR explains, the petition gave no meaningful justification for pivoting to adhesive lamination specifically or addressed known drawbacks. POR, 24-27, 50-52. The Reply (14, 16) mischaracterizes the art and the '091 patent; none of Tadros, Kalili, or the '091 patent mention "adhesive lamination." *See also* EX2036, 79:9-15. Critically, Dr. Kimmel's testimony and evidence regarding disadvantages and problems with adhesive lamination are unrebutted entirely. Instead, the Reply (15) criticizes Align for not proving coextrusion's superiority. This bizarre assertion is irrelevant to Petitioner's burden to show motivation for adhesive lamination as proposed. Align has no burden to address an approach Petitioner expressly disavowed.

VIII. PETITIONER FAILS TO REBUT THE POR'S SHOWING OF OBJECTIVE INDICIA OF NONOBVIOUSNESS

As an initial matter, Petitioner's expert Dr. Osswald performed his analysis without any consideration of objective indicia of nonobviousness, confirming during his second deposition that he did not consider the evidence raised in the patent owner response and never substantively addressed objective indicia in either of his declarations. EX2036, 112:23-115:22. This failure to consider critically important evidence leaves Petitioner with no expert testimony assessing the ultimate question of obviousness from the perspective of a POSITA in view of the fully developed record and all four *Graham* factors. *See Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 1983) (evidence relating to secondary indicia "must always be considered" (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)); *InTouch Techs., Inc. v. VGo Communs., Inc.*, 751 F.3d 1327, 1352 n.8 (Fed. Cir. 2014) (to testify to obviousness, expert "must consider all factors relevant to that ultimate question," including evidence of objective indicia).

Petitioner does not fill the vacuum caused by this lack of evidence (*see* Reply, 17-25), as explained below.

A. Petitioner Fails To Rebut Align's Showing Of Nexus To SmartTrack

The POR showed that SmartTrack aligners demonstrated unexpectedly superior performance and commercial success attributable to the specific

combination of materials recited in the challenged claims. POR, 53-61; EX2014, ¶151; EX2018, ¶6.The Reply fails to rebut Align's nexus showing.

First, the Reply (17) mischaracterizes the independent claims, asserting they encompass "*any* TPU" and "*any* copolyester," instead of only those with the recited properties. The Reply (17) also mischaracterizes the first-named inventor's (Dr. Li's) declaration testimony. The only materials she described as "inferior" were outside the scope of the claims. EX1010, 1238 (PVC materials inferior); EX1001 (no PVC in specification or claims). Nor do the claims encompass EX30, which is neither a copolyester nor a TPU, let alone a multilayer material comprising both. EX2016, ¶8; Reply, 18.

Petitioner also asserts (18) SmartTrack's superiority is not commensurate with the scope of the claims because Align does not allege aligners having "layers having less desirable properties" than SmartTrack will behave similarly. That misses the point entirely: aligners lacking the recited properties would be outside the scope of the independent claims. EX2016, ¶151.

The Reply (18-19) does not dispute SmartTrack embodies each independent claim (*see also* EX2036, 396(779:23-25)), and its cited cases regarding coextensiveness are inapposite. For example, *Janssen* and *Fox Factory* discussed whether a presumption of nexus applied where a patented product included critical unclaimed features or inventions. *Janssen Pharms., Inc. v. Teva Pharms. USA,*

Inc., 97 F.4th 915, 935 n.11 (Fed. Cir. 2024); *Fox Factory v. SRAM, LLC*, 944 F.3d 1366, 1377 (Fed. Cir. 2019); *see FMC Techs., Inc. v. OneSubsea IP UK Ltd.*, IPR2019-00935, Paper 45, 85-87 (Oct. 14, 2020). Here, Dr. Kimmel testified a POSITA would have attributed SmartTrack's superior performance to the specific combination of recited materials and properties. EX2014, ¶151; *cf.* EX2014, ¶¶143-44 (aligners with only one of the two recited materials showed poor performance). *Fox Factory* confirms there is a nexus because Align's evidence of secondary considerations is attributable to the claimed invention, as opposed to prior art features in isolation. 944 F.3d at 1377-78.

The Reply (19) asserts SmartTrack lacks nexus to the claims because some dependent claims include features absent from SmartTrack, indicating the independent claims are not limited to SmartTrack. If that were the law, no patent owner could show nexus for any open-ended claim. At best, the Reply suggests that there is no *presumption* of nexus for dependent claims 2, 3, 8, 14, 15, and 21, which says nothing about whether nexus exists for them, let alone the other claims.

Petitioner's nexus arguments are particularly egregious in view of positions that Dr. Osswald and unnamed RPI Bay Materials took in an earlier IPR. In IPR2025-01214, they both argued Zendura FLX had unexpected results. EX2025, 54-62; EX2026, ¶¶177-182. Zendura FLX, like SmartTrack, falls within the scope of the independent claims. That alone should end the inquiry. Moreover, in the

prior IPR, Dr. Osswald and Bay Materials argued Zendura FLX both embodied and was coextensive with even broader claims than those challenged here (e.g., requiring only one hard *polyester or copolyester* layer and one elastomeric layer of any material with hardness from A80 to D75). EX2014, ¶¶156-57 (citing EX2025, 51-54; EX2026, ¶¶171-76); EX2036, 115:23-129:10. Petitioner's argument that unexpected results lack nexus should not be credited here, where their own expert and sister company argued there was nexus between even broader claims and Zendura FLX in the prior IPR.

The Reply's argument (19-20) that SmartTrack lacks nexus because it falls within the scope of other patents similarly fails. *Fox Factory* confirms that secondary indicia can be attributed to multiple patents so long as they each "generally cover the same invention." 944 F.3d at 1377. Here, a POSITA would attribute SmartTrack's unexpectedly superior properties to the combination of the two recited materials (TPU elastomer and copolyester with the respective material properties) in a multilayer configuration. EX2014, ¶151. Dr. Li's declaration (Reply, 21) only reinforces the point—the claims at issue here and in the other patent to which Petitioner points recite layers of the same two materials: TPU elastomer and copolyester. Petitioner's attempt to turn the soft-hard-soft configuration into a "critical feature" is unsupported attorney argument. Reply, 19-20. No expert testified that *soft-hard-soft* was critical to SmartTrack's

performance.

See In re Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (embodiment showing unexpected result with reason to expect similar behavior for other embodiments establishes commensurate scope).

Petitioner's arguments regarding Patent Owner's prosecution process similarly fail. Petitioner again relies on unsupported attorney argument that *soft-hard-soft* was an essential element. Reply, 20-22. Dr. Li did not state that *soft-hard-soft* was essential. Rather, she explained that combining the recited materials (copolyester and TPU) met Align's development criteria, while merely combining other tested materials into layers did not produce the same improved performance. EX1010, 1237-38; *see also* EX2036, 264(90:17-22), 290(125:11-13) (finding written description for full scope of claims).

B. The Reply Does Not Rebut The POR's Evidence of Unexpected Results

The POR provided evidence of SmartTrack's unexpected results, including two clinical trials and a retrospective analysis. POR, 58-60. Petitioner does not dispute these results, which Dr. Kimmel confirmed a POSITA would have viewed as demonstrating surprising, unexpected improvements. Notably, Align immediately switched its aligner material from EX30 to SmartTrack, which remains the market-leader today. EX2014, ¶148; EX2016, ¶30; EX1010, 1240-41.

Petitioner claims the TREX Study's results were not unexpected, arguing that even a 32-43% improvement is insufficient based on a case involving unrelated technology. Reply, 22-23 (citing *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005)). Petitioner presents no expert testimony to support its difference-in-degree argument. *Kao Corp. v. Unilever United States, Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) ("no hard-and-fast rule" regarding threshold for unexpected results). Even if its bare numerical-range argument were valid (and it is not), Petitioner ignores the retrospective study's showing of a *75% improvement*. *See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 149 F.3d 1309, 1321 (Fed. Cir. 1998); *In re Hoch*, 428 F.2d 1341, 1344 n.5 (C.C.P.A. 1970) (significant difference in degree shows unexpected result). Indeed, Petitioner itself argued unpredictability here (Pet., 22 n.4); it cannot now claim, without any evidence, that the improvements shown for aligners made according to the instant claims would

have been expected.

The Reply's complaint that Align did not provide testimony from a clinical declarant (23) is also meritless; Petitioner's own POSITA definition does not require clinical skill, clinicians performed the reported tooth measurements, Petitioner's expert has no clinical experience, and Petitioner made no showing that the inventors and an expert like Dr. Kimmel lack the capacity to judge the relevant aligner properties. EX2016, ¶30; EX2027.

Lastly, the Reply's argument that a DeSimone embodiment should have been tested (23) is unsupported and contrary to the evidentiary record. Dr. Li's declaration in prosecution explained why a POSITA would have expected DeSimone's aligners to exhibit inferior performance to EX30, and Petitioner offers no rebuttal here. EX1011, 600-01. Accordingly, EX30, not DeSimone, is the closest prior art comparator. Indeed, aligners made according to the instant claims far exceed competitors' results and have consequently led the market for over a decade, replacing EX30 as the prior market leader. *See* EX2016, ¶30; EX2018, ¶6; EX1157, 172:18-173:13 (doctor surveys confirm increased confidence due to SmartTrack material, and it was universally agreed at Align that SmartTrack helped "change the trajectory for this company"); EX2030, 12; EX2031, 13.

C. The Reply Uses The Wrong Copying Test and Barely Attempts to Rebut Commercial Success

The Reply's sole argument against copying (24) is that Align's previously

issued claims did not expressly encompass Zendura FLX aligners. These aligners have now been found to infringe challenged claims. Regardless, Petitioner misapprehends the copying analysis—Petitioner and Bay Materials copied Align's SmartTrack material composition, not the already-issued claims.

Regarding commercial success, the Reply (24-25) does not dispute Invisalign's marked commercial success. Instead, the Reply speculates that other factors may also have influenced that success. Petitioner does not dispute that nearly all Invisalign aligners since 2013 have consisted of SmartTrack material, that the number of patients treated with these aligners have been tenfold higher than in the prior 13-year period, or that Align's revenue from aligner sales has seen a correspondingly astronomical increase. *See* EX2018, ¶¶4-6. Nor does Petitioner provide any evidence rebutting Mr. Kusima's testimony that this growth was critically tied to SmartTrack. EX2018, ¶6; EX1157, 172:18-173:13; EX2030, 12 (survey results confirming this); EX2031, 13.

Petitioner's arguments regarding other patents are merely an unsupported attack on nexus or speculation that Align's market position may have influenced its success via "transferred" sales. Reply, 24-25. But as explained above, the POR

demonstrated nexus between the instant claims and SmartTrack. Moreover, Petitioner provides no evidence supporting its speculation about market position, nor does its unsupported transference hypothesis account for Align's tenfold increase in patients treated over a comparable timespan. Accordingly, Petitioner fails to rebut Align's showing of commercial success.

IX. PETITIONER HAS FAILED TO DISCLOSE ALL RPIS

A party is an RPI if it is "a clear beneficiary that has a preexisting, established relationship with the petitioner." *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018). The POR (65-67) showed that Bay Materials satisfies this test, and the Reply does not meet its burden to refute this. *See Tianma Microelectronics Co. v. LG Display Co.*, IPR2025-01579, Paper 12, 9 (Mar. 18, 2026) (precedential) (petitioner bears RPI burden). The evidence that Bay Materials is an RPI is thus undisputed at this juncture.

The Reply (25-26) claims Bay Materials has no infringement risk, yet this unsupported assertion cannot meet Petitioners' burden, particularly in light of evidence showing Bay Materials acted in concert with Petitioner and encouraged its infringing manufacture of aligners. *E.g.*, EX2024; EX2008, 8-9 ¶18. Indeed, at district court, ClearCorrect described Bay Materials' Zendura FLX as the product at issue and argued Align amended its claims to cover Zendura FLX. EX2036, 238(73:15-16), 276(111:14-17), 331(714:9-12).

Rather than dispute Bay Materials' close connection and ability to benefit, Petitioner tries to distract from this issue by pretending that the RPI issue was waived (25-26). However, Align's pre-institution briefing was plainly discussing the *named* RPIs, whereas the RPI record has been further developed post-institution, confirming Bay Materials' RPI status. POR, 66-67. In addition, Petitioner has never even attempted to meet its burden to show that Bay Materials lacks the ability to control this IPR. *Sun Pharms. Indus., Inc. v. Biofrontera Inc.*, PGR2026-00021, Paper 12, 2 (May 26, 2026).

Moreover, Petitioner seeks to use its relationship with Bay Materials as a sword and shield in the instant proceedings, preventing discovery of (1) inconsistent arguments by Dr. Osswald—the same expert both here and in Bay Materials IPR2022-01214; and (2) Bay Materials's undisputed analysis and testing of SmartTrack. *Supra* §IV. Similarly, Petitioner advances grounds here premised on predictability, in contradiction to Dr. Osswald and Bay Materials's arguments that aligner materials affected properties in unpredictable ways. Pet., 59; EX2025, 44, 46-47. Petitioner likewise seeks to sidestep Dr. Osswald's and Bay Materials's secondary indicia arguments for Zendura FLX and SmartTrack in IPR2022-01214, such as concessions of SmartTrack's commercial success, by inexcusably turning a blind eye to that evidence now. EX2025, 51-62; Reply, 17-25. Petitioner's gamesmanship in this regard underscores the importance of its failure to name all

RPIs here.

X. CONCLUSION

Accordingly, the Board should uphold the challenged claims' patentability.

Respectfully submitted,

Date: July 15, 2026

/ Michael T. Rosato /
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XI. APPENDIX – EXHIBIT LIST

EXHIBIT NO.	DESCRIPTION
2001	Claim Construction Order, *Align Technology Inc. v. ClearCorrect Operating LLC*, et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 5, 2025)
2002	Scheduling Order, *Align Technology Inc. v. ClearCorrect Operating LLC*, et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Aug. 5, 2024)
2003	Fourth Scheduling Order, *Align Technology Inc. v. ClearCorrect Operating LLC*, et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 12, 2025)
2004	DocketNavigator Median Time-to-Trial Statistics for Judge Alan D. Albright and for W.D. Tex. Overall, July 1, 2020 – July 1, 2025
2005	Judge Albright Patent FAQ, https://www.txwd.uscourts.gov/for-attorneys/judge-albright-courtroom-faq/ (accessed July 3, 2025)
2006	Joint Request to Amend the Claim Schedule, *Align Technology Inc. v. ClearCorrect Operating LLC*, et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 6, 2025) (ECF No. 187)
2007	Preliminary Claim Constructions, *Align Technology Inc. v. ClearCorrect Operating LLC*, et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jan. 21, 2025)
2008	Defendants' Answer, Affirmative Defenses, and Counterclaims (Public Version), *Align Technology, Inc. v. ClearCorrect Operating LLC*, Case No. 6:24-CV-00187 (W.D. Tex. Jul. 16, 2024) (ECF No. 56)
2009	International Application Publication No. WO 2018/222864 to Stewart et al.
2010	U.S. Patent No. 10,946,630 to Stewart et al.
2011	U.S. Patent No. 7,641,828 to DeSimone et al.
2012	U.S. Patent No. 2006/0078841 to DeSimone et al.
2013	ClearCorrect Prior Art Narrowing Disclosure, *Align Technology, Inc. v. ClearCorrect Operating, LLC*, Civil Action No. 6:24-cv00187-ADA-DTG

2014	Declaration of Dr. Robert Kimmel
2015	Curriculum Vitae of Dr. Robert Kimmel
2016	Declaration of Yan Chen - – Board and Parties Only
2017	Osswald Deposition Transcript
2018	Declaration of Naga Kusima
2019	Daniel J. Brunelle et al., "Optimization of poly(1,4-cyclohexylidene cyclohexane-1,4-dicarboxylate (PCCD) preparation for increased crystallinity," 47(11) *Polymer* 4094 (2006)
2020	James L. Throne, Understanding Thermoforming, Ch. 11 (2008)
2021	U.S. Patent No. 8,178,647 (Hawkins)
2022	ClearCorrect Support – Aligner FAQs, https://support.clearcorrect.com/hc/en-us/articles/204800937-Aligner-Material-FAQs
2023	ClearCorrect – The Premier Aligner Clinical Evidence Summary, https://www.straumann.com/content/dam/sites/clearcorrect/xy/landing/aao-2025/113896_ClearCorrect_PremierAligner_SummaryClinicalEvidence_Superside_V3.pdf
2024	Zendura Dental – Why Zendura, https://www.zenduradental.com/pages/why-choose-zendura
2025	*3M Co. v. Bay Materials LLC*, IPR2022-01214, Paper 21 (Patent Owner's Response) (Apr. 12, 2023)
2026	*3M Co. v. Bay Materials LLC*, IPR2022-01214, Exhibit 2006 (Osswald Declaration, Public Version) (Excerpt) (Apr. 12, 2023)
2027	Align Technology, "SmartTrack: Technology that's made to move" (2018)
2028	Timothy Wheeler et al., "Effect of aligner material on orthodontic tooth movement," 1(1) Journal of Aligner Orthodontics 21 (2017)
2029	Zendura Dental – The Zendura Story, https://www.zenduradental.com/pages/the-zendura-story
2030	Align Technology 2013 Q1 Financial Slides

2031	Align Technology 2012 Q4 Financial Slides
2032	Align Technology 2025 Q5 Financial Slides
2033	*3M Co. v. Bay Materials LLC*, IPR2022-01214, Paper 77 (Final Written Decision) (Jan. 16, 2024)
2034	Supplemental Declaration of Dr. Robert Kimmel [Served, not filed]
2035	Email to Board regarding request for authorization for motion for discovery (Mar. 27, 2026)
2036	Osswald Reply Deposition Transcript

CERTIFICATE OF COMPLIANCE

Pursuant to § 42.24(d), the undersigned certifies that this paper contains no more than 5,600 words, not including the portions of the paper exempted by § 42.24(b). According to the word-processing system used to prepare this paper, the paper contains 5,560 words.

Respectfully submitted,

Date: July 15, 2026

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CERTIFICATE OF SERVICE

I certify that the foregoing Patent Owner's Sur-Reply was served on this 15th day of July, 2026, on Petitioner at the following electronic service addresses:

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