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. IPR2025-00818
Patent No. 10,973,613

PATENT OWNER'S SUR-REPLY

[redacted]

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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. For example, the Reply abandons the petition's expressly proposed "tie layers" (*e.g.*, Pet., 33, 35, 54) in favor of newly imagined evaporating layers. Regarding Tadros, the petition botched identification of any 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 paralyzed by unpredictability even when

[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 64-65.

[redacted]

considering known TPU elastomers. Regarding Wen, the petition ignored 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., 34, 46, 49, 50, 56 ("predictable results" and "expectation of success"); Paper 22, 13 ("*predictable* results"); Paper 17, 15-16 (Institution Decision applying *KSR's* "finite number of identified, *predictable* solutions" rationale). As the POR explained (17-21, 22-23, 26-27, 51-52), 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]

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

[redacted]

Q. And if you -- if you need a lot of trial and error, does that make a -- an art -- a field predictable or unpredictable?

A. No. A lot of trial and error means it's unpredictable.

Q. Now, is making a multi-layer material for use in a dental aligner, is that predictable or unpredictable?

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 1-3 (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 defended Petitioner's district court position as applying a different skill level 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).

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.

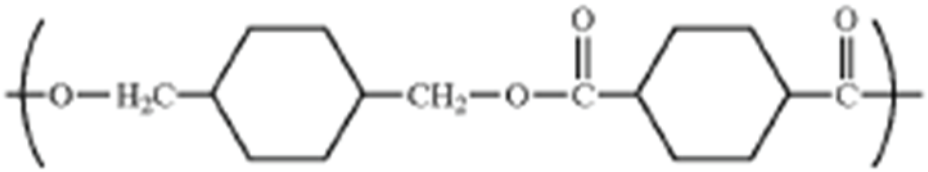
III. THE REPLY FAILS TO REMEDY THE PETITION'S DEFICIENCIES REGARDING A HARD COPOLYESTER LAYER (GROUNDS 1-2)

A. Petitioner Has Not Shown PCCD is a Copolyester (Because It is Not)

The petition relied solely on PCCD described in "Samples 4 and 5" of Tadros—which the reference never identifies as a copolyester. POR, 13-17. 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 (3-4) 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

[redacted]

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 (annotated as red/blue in the Reply) 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 (3) 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"); 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 (4-5) 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,

[redacted]

4101, table 6); EX2020, 173. The Reply (6 (citing EX1149, 41:16-21, 48:11-49:3)) mischaracterizes Dr. Kimmel's deposition; the cited testimony addresses the meaning of homopolymers and copolymers generally and never mentions isomer mixes or copolyesters. The Reply (4) 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 (6) 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 (6) does not dispute Brunelle's description of PCCD with a cis/trans mixture as a "homopolymer"—it just complains Brunelle is "inaccurate." Additional literature, however, 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

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by Tadros.

Finally, the Reply's new argument (6) that Tadros disclosed incorporating "additional diol monomers…into the PCCD chain" should be disregarded as untimely. Even if considered, the argument fails because Tadros' [0042] never discusses forming PCCD from the different diols listed.

B. The Reply's Pivot to PETG is Untimely and Insufficient

The petition relied solely on PCCD described in "Samples 4 and 5" as the alleged copolyester satisfying the independent claims' mechanical properties. Pet., 30-31 (POSITA would use "exemplary hard polymeric mixtures" of Samples 4 and 5). Recognizing Tadros' PCCD is not a copolyester, the Reply (2-3) improperly pivots to a *different* material—a PETG mixture.

But the petition did not rely on PETG as the claimed copolyester or for the claimed mechanical properties. Rather, the petition's single PETG mention is incidental in reference to the PCCD mixture. Pet., 30. The Reply's new PETG argument is therefore improper and should be disregarded. *Intelligent Bio-Systems v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016).

Even if considered, Petitioner's new reliance on PETG would not cure the petition's deficiencies because the petition never even alleged PC-PETG has the recited flexural modulus. *See* EX1007, ¶170 (addressing only Samples 4 and 5, which are PCCD); Pet., 30-31. Petitioner cannot meet its burden by mixing-and-

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matching a stray reference to PETG with specific mechanical properties of PCCD samples.

IV. PETITIONER UNDERMINES MOTIVATION AND EXPECTED SUCCESS IN COMBINING TADROS AND KALILI (GROUNDS 1-2)

In addition to the deficiencies of Tadros discussed above, 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 21-27. Petitioner's arguments alleging motivation to do so along with expected success are incompatible with their assertions of wild unpredictability. *Supra* §II; *see also* Reply, 7 (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, 7 (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, 23-24. 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

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been stymied by unpredictability when considering the large number of known TPU elastomers. EX2036, 321(704:9-13).

The Reply also never resolves its self-defeating assertions in IPR2025-00820 and Ground 3 here that Tadros' polycarbonate is unsuitable and harmful to patients (undermining Grounds 1-2) or its assertion in Ground 1 that polycarbonate as in Tadros would be perfectly "suitable" for aligner material (undermining Ground 3). POR, 22-23. The Reply (7) only further undermines Ground 3 by again asserting the suitability of polycarbonate (rather than motivation to replace it). Likewise, Reply (8) undermines Grounds 1-2 in inconsistently asserting an industry "hungry" to replace polycarbonate. 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.

V. PETITIONER HAS FAILED TO SHOW THE TIE LAYERS ADDED IN ITS COMBINATIONS MEET CLAIMS 12-15'S LIMITATIONS (GROUND 1)

Ground 1 expressly proposed introducing additional "tie layers," which defeat the challenges to claims 12-15. *See, e.g.*, Pet., 7, 33, 35; POR, 28-30 (Osswald confirming reliance on a polymer glue layer). The Reply fails in its attempt to run away from its own argument.

First, the Reply (17) newly proposes using "solvents that evaporate" so no residual polymer ("tie layer") is left between layers. But the petition (7, 33) expressly proposed using a "tie layer" of a "third polymer" between each of the

[redacted]

blind eye to that evidence now. EX2025, 51-62; Reply, 18-26. Petitioner's gamesmanship in this regard underscores the importance of its failure to name all RPIs here.

XI. CONCLUSION

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

Respectfully submitted,

Date: July 15, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

XII. 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	ClearCorrect Prior Art Narrowing Disclosure, *Align Technology, Inc. v. ClearCorrect Operating, LLC*, Civil Action No. 6:24-cv-00187-ADA-DTG
2013	[Reserved]

[redacted]

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

[redacted]

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

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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 5,582 words.

Respectfully submitted,

Date: July 15, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

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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:

Charles Collins-Chase
Luke McCammon
Melanie Magdun
Kyle Howarth
Jason Stach
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
Charles.Collins-Chase@finnegan.com
Luke.McCammon@finnegan.com
Melanie.Magdun@finnegan.com
Kyle.Howarth@finnegan.com
jason.stach@finnegan.com

Respectfully submitted,

Date: July 15, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182