

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. IPR2025-00820
U.S. Patent No. 11,648,090

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

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As authorized on September 10, 2025, this Reply¹ responds to Patent Owner's discussion of (1) purported unexpected results and (2) adhesive lamination.

I. THE PETITIONS EXPLAIN HOW THE ALLEGED UNEXPECTED RESULTS CONFLICT WITH HOW PATENT OWNER HAS ASSERTED THE CHALLENGED CLAIMS

The Petitions do not “fail[] to rebut the objective indicia that were established during prosecution.” IPR2025-00820, Paper 9 ('090 POPR) at 6-7. Instead, they detail the prosecution histories, including two declarations allegedly showing unexpected results—one submitted in prosecution of a parent patent (not at issue here) and a second in the '613 patent prosecution. IPR2025-00820, Paper 1 ('090 Pet.) at 23-29. The Petitions address alleged unexpected results in the declarations, including clinical data showing that “ST30,” a three-layer aligner with “a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer,” outperformed a single-layer aligner (“EX30”). '090 Pet. 24-26.

Further, the Petitions expressly note the inconsistency between the characteristics of the *soft-hard-soft* ST30 aligner referred to in the Declarations and how Patent Owner now asserts the challenged claims in parallel litigation against Petitioner's *hard-soft-hard* aligner product (the exact opposite layer configuration).

¹ The text of this Reply is identical in IPR2025-00818, -00819, -00820, and -00821, but record citations have been updated for each proceeding.

The Petitions note that, whereas Patent Owner “developed a single soft-hard-soft material that later became the company’s SmartTrack material,” Patent Owner “nonetheless asserts in the litigation that the claims cover configurations beyond soft-hard-soft” even though the specifications fail to describe or enable such materials. *E.g.*, ’090 Pet. 22-23, 22 n.4. The Petitions thus address the inconsistency between the ST30 material referred to in the declarations and Patent Owner’s litigation arguments asserting the claims as broadly covering other layer configurations. Contrary to the POPR’s assertions, the Petitions present arguments addressing objective indicia and there is no basis to deny institution on these facts.

This distinguishes Patent Owner’s cited cases. In *Gilead Sciences, Inc. v. United States*, the petitioner made only “vague assertions about the results being attributable to the prior art and a lack of nexus.” IPR2019-01456, Paper 17 at 53 (PTAB Feb. 5, 2020). In *Coalition for Affordable Drugs V LLC, v. Hoffman La-Roche Inc.*, the petitioner failed *both* to establish that a POSITA would have combined the asserted prior art to arrive at the claimed invention *and* to substantively address unexpected results. IPR2015-01792, Paper 14 at 15-18 (PTAB Mar. 11, 2016). In *Apple Inc. v. Samsung Electronics Co.*, the patent challenger “did not dispute” objective indicia or related jury fact findings. 839 F.3d 1034, 1062 (Fed. Cir. 2016) (en banc).

Where, as here, the Petitions explain the inconsistency between purported

objective evidence and Patent Owner’s own interpretation and assertion of its claims, the Board should institute “to allow further evidence regarding any alleged unexpected results or other secondary considerations to be developed during trial.” *Mylan Pharms., Inc. v. Allergan, Inc.*, IPR2016-01129, Paper 8 at 21-22 (PTAB Dec. 8, 2016); *see also Phigenix, Inc. v. Immunogen, Inc.*, IPR2014-00676, Paper 11 at 16-22 (PTAB Oct. 29, 2014) (instituting and rejecting argument that petition failed to address unexpected results); *Apotex Inc. v. Cellgene Corp.*, IPR2023-00512, Paper 7 at 51-52 (PTAB July 20, 2023) (instituting where Office was “led astray by . . . erroneous arguments regarding purported unexpected results.”). That is particularly true given the strong prima facie case presented in the Petitions.

Patent Owner’s arguments are additionally deficient as to the ’384, ’090, and ’091 patents, where no unexpected results declaration was submitted in prosecution. Patent Owner cites no authority for its position that secondary considerations never addressed during prosecution must be addressed in an IPR petition.

II. THE PETITIONS ESTABLISH MOTIVATION TO USE ADHESIVE LAMINATION

Patent Owner does not dispute that the Petitions put forward prior-art materials having the claimed properties of each layer in the claimed multilayer sheet. *See, e.g.*, ’090 POPR 23. Nor does Patent Owner dispute that at least two “normal” manufacturing techniques were well known in the art for forming multilayer plastics—adhesive lamination and coextrusion—and that a POSITA would have

understood that adhesive lamination retains the properties of the subsidiary materials whereas coextrusion alters those properties. '090 POPR 23-25. Instead, Patent Owner argues that prior-art materials with the claimed properties can only be combined to achieve the multilayer aligners recited in the claims if the subsidiary materials are combined using adhesive lamination.²

Even if the Board accepted Patent Owner's argument, it should still institute review because the Petitions *do explain* why a POSITA would have been motivated to use adhesive lamination to combine prior-art polymer materials to achieve the claimed invention. Every ground relies on art expressly disclosing *laminated* multilayer aligners (e.g., *Kalili*, *Wen*), and the Petitions detail *exactly* why and how a POSITA would have been motivated to combine this art to successfully achieve the claimed aligners, including the claimed layer configurations and properties. *See, e.g.*, '090 Pet. 6, 11-12, 39, 40, 55-56. Petitioner's expert declarations further detail this motivation, including a POSITA's knowledge of how to make laminated multilayer aligners and known advantages of using adhesive lamination to bond

² This argument conflicts with Patent Owner's litigation position that subsidiary materials combined using manufacturing techniques that would alter the polymer's properties (e.g., coextrusion) allegedly infringe based on polymer properties reported in a manufacturer's datasheet. *See, e.g.*, '090 Pet., 14-15 n.3.

layers. *E.g.*, IPR2025-00820, EX1007 ¶¶31, 39-42, 45, 51, 116, 120 (citing *Kalili*, EX1005 at [0056], [0063], [0074]-[0076], [0088]), 122-123 (citing *Wen*, EX1008 at [00208], [00210]), 140, 155, 172-174, 188 n.5, 231, 247.

While many manufacturing methods were well known in the art (none of the challenged claims require use of adhesive lamination specifically), the Petitions and expert declarations nonetheless further explain why lamination (*e.g.*, with tie layers) would be appropriate and desirable to create the claimed aligners. *E.g.*, '090 Pet. 6, 39, 40, 55-56; EX1007 ¶¶41, 51. They note, for example, that this method would effectively bond layers of disparate polymers and would not be expected to alter their pre-existing properties. *Id.* The Petitions thus establish both a motivation to combine the asserted art to achieve the claimed invention *and* a motivation and reasonable expectation of success in doing so using adhesive lamination.

Unlike the cases Patent Owner cites (*e.g.*, '090 POPR 25), the Petitions are not limited to what a POSITA “would have been able to do.” They establish motivation and reasonable expectation of success for combining the cited art to achieve the claimed aligners.

III. CONCLUSION

For these reasons and those detailed in the Petitions, Petitioner requests that the Board institute review.

Respectfully submitted,

Dated: September 17, 2025

By: / Charles T. Collins-Chase /
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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Petitioner's Reply to Patent Owner's Preliminary Response** was served on September 17, 2025, via email directed to counsel of record for the Patent Owner at the following:

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