

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. IPR2025-00819
U.S. Patent No. 11,154,384

**AUTHORIZED RESPONSE TO DIRECTOR REVIEW
REQUEST¹**

¹ This Response was authorized by e-mail dated November 21, 2025
(Ex. 3102).

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I. Introduction

Patent Owner's Director Review Request (Paper 19, "DR Req.") improperly raises new arguments and evidence and identifies no errors in the Decision Referring the Petition to the Board (Paper 14, "Referral Decision") or in the Institution Decision (Paper 17, "DI").

First, Patent Owner's new RPI argument is untimely, improper, and has no merit. Petitioner disclosed all RPI entities as required by 35 U.S.C. § 312(a)(2). None of the entities Patent Owner alleges as RPIs funded, directed, or controlled preparation of the Petition or this proceeding. Patent Owner's speculative argument makes no allegations to the contrary. Further, Patent Owner never challenged Petitioner's RPI identification in its pre-institution briefing. Raising such a highly fact-dependent RPI issue now unfairly prejudices Petitioner.

Second, Patent Owner identifies no error in the Acting Director's holistic assessment of the discretionary denial arguments and evidence. Rather, it collapses that analysis to a single *Fintiv* factor and re-argues *Fintiv* factor 2 based on the now-later projected trial date. But Patent Owner's improper new evidence does not help Patent Owner as the projected trial date was extended further due to Patent Owner's ongoing discovery delays. Having obtained that extension in district court, Patent Owner now asks the Director to undo the Acting Director's reasoned discretionary denial assessment. Patent Owner should not get a second bite at the apple.

Further, Patent Owner's assertions regarding adhesive lamination simply rehash arguments the Board already considered and rejected, and they also misconstrue the arguments in the Petition and reasoning in the Board's Institution Decision. The Petition identifies both a motivation and reasonable expectation of success in using manufacturing techniques that would not alter polymer properties, such as adhesive lamination. *E.g.*, Paper 1, ("Pet.") 34-36. The Board thus found that the Petition adequately supports its arguments that a POSITA would have been motivated to use adhesive lamination to achieve the proposed combination. *See* DI 15-16. Patent Owner's assertions to the contrary simply cannot be squared with the facts.

Finally, Patent Owner has no basis for speculating that the Board took the Acting Director's referral as a signal that institution was required. Patent Owner's suggestions that the Board treated the referral as requiring institution is a red herring and disregards the Board's thorough and independent obviousness analysis

Director Review is reserved for correcting errors or addressing important policy issues—not for advancing new evidence or arguments, or rehashing arguments that have already been thoroughly considered and rejected, as Patent Owner's Request does here. The Request should therefore be denied.

II. Legal Standard

Director Review provides a mechanism to correct errors at the institution stage. USPTO, Director Review Process § 2.B (last visited Nov. 20, 2025). Director Review is limited to the record that was before the Board; the Director does not consider new arguments or evidence. *Id.* § 3.E; 37 C.F.R. § 42.75(c)(3) (“Absent Director authorization, a request for Director Review may not introduce new evidence.”). No errors are present here. Both the Institution Decision and the Referral Decision are well supported and should not be disturbed.

III. Argument

A. Patent Owner’s Unsupported New RPI Theory Is Improper for Director Review

Patent Owner’s Request improperly raises a new, unfounded RPI argument, and fails to present evidence to support that argument. DR Req. 10-14.

New evidence and arguments should not be presented in the Director Review Process. The USPTO’s Director Review guidance states that the Director will “not consider new evidence or new arguments not part of the official record” (Director Review Process § 3.E; 37 C.F.R. § 42.75(c)(3)) and therefore need not reach the merits of Patent Owner’s new RPI argument. Patent Owner never disputed Petitioner’s RPI identification before institution. As a consequence, Petitioner has not had a full and fair opportunity to respond to Patent Owner’s allegations (Ex. 3102), and the Board has never considered this “highly fact-dependent

question.” PTAB Consolidated Trial Practice Guide (Nov. 2019) (“TPG”) at 13. Refusing to consider Patent Owner’s new evidence and argument would prevent parties from sandbagging Petitioners after institution decisions issue.

The Director’s October 28, 2025, Memorandum and precedential designation of *Corning Optical Communications RF, LLC v. PPC Broadband Inc.*, IPR2014-00440, Paper 68 (PTAB Aug. 18, 2015) (precedential except § II.E.I), do not excuse Patent Owner’s failure to raise any RPI arguments pre-institution. That new guidance is for the Board to enforce pre-*SharkNinja* RPI requirements. No law or policy restrained Patent Owner from raising the RPI issue before Institution.

The RPI analysis asks “at whose *behest* the petition has been filed.” *WiFi One, LLC v. Broadcom Corp.*, 887 F.3d 1329, 1336 (Fed. Cir. 2018) (emphasis added) (citation omitted); TPG 14. While there is no bright-line test, courts and the Board typically consider non-exhaustive factors, such as whether a party exercises control over, funds, or directs the petition or proceeding. *Uniloc 2017 LLC v. Facebook Inc.*, 989 F.3d 1018, 1027-28 (Fed. Cir. 2021) (citing *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1342-43 (Fed. Cir. 2018)); *see also Wi-Fi One*, 887 F.3d at 1336; *Corning*, IPR2014-00440, Paper 68, 14-15; TPG 15-18.

Patent Owner asserts that Bay Materials, AlliedStar, and Smartee should have been named as RPIs because they are affiliated with the Straumann Group (the relevant entities of which are identified as RPIs) or have business relationships with

Petitioner ClearCorrect. DR Req. 11-14. The mere fact of some relationship and benefits, however, does not establish RPI to this proceeding. *See RPX Corp. v. Applications in Internet Time, LLC*, IPR2015-01750, Paper 128, 30-31 (PTAB Oct. 2, 2020) (precedential) (mere facts of a pre-existing relationship and benefits to the alleged RPI alone are insufficient to require a finding that the party is an RPI). None of the entities identified by Patent Owner has participated in the preparation or filing of the Petition, or exercised control, directed, or funded this proceeding. Patent Owner does not even allege any such involvement, let alone point to any evidence.

Contrary to Patent Owner's allegation, Bay Materials has no involvement in this proceeding and is *not* "the manufacturer of the aligners accused in the district court litigation." DR Req. 11. Moreover, Bay Materials sells clear aligner materials to ClearCorrect and other aligner manufacturers; it does not make or sell aligners that are also at issue in the parallel district court litigation, and is not accused of infringing any of the patents asserted in that litigation. Ex. 1023, ¶ 4; Ex. 1129, ¶¶ 4, 18; *Corning*, IPR2014-00440, Paper 68, 14-15 ("A party does not become a[n] RPI merely through association with another party in an endeavor unrelated to the IPR proceeding.").

Similarly, Smartee has no involvement in this proceeding and does not make or sell any product accused in the parallel district court litigation. Patent Owner does not allege otherwise. Patent Owner's improper submission of new evidence

regarding a future strategic partnership between Straumann and Smartee does not indicate any participation, direction, or control of the Petition by Smartee. DR Req. 12-14; *Corning*, IPR2014-00440, Paper 68, 14-15. In fact, there was none.

Likewise, AlliedStar has no involvement in this proceeding. This IPR challenges claims of the '384 patent directed to dental aligners, and AlliedStar does not make or sell dental aligners accused of infringing the '384 patent. *Corning*, IPR2014-00440, Paper 68, 14 (“A party does not become a RPI merely through association with another party in an endeavor unrelated to the IPR proceeding.”).

Nor does this proceeding implicate any of the concerns raised in the Director’s Memorandum about “opaque” arrangements that may allow improper influence by malign foreign actors. DR Req. 3-4. Straumann Group partially owns AlliedStar and Smartee—not the other way around—and those investments were all publicly disclosed. Neither AlliedStar nor Smartee is on the Department of Commerce’s “entity list.” No national security concerns are implicated here.

Patent Owner’s speculative RPI arguments do not come close to showing any RPI defect in the Petition challenging the '384 patent. *Corning*, IPR2014-00440, Paper 68, 13 (“A patent owner challenging a petitioner’s RPI disclosure must provide sufficient evidence to show the disclosure is inadequate.”) (non-precedential § II.E.1). Patent Owner’s RPI allegations should be rejected.

B. Patent Owner’s Improper New Evidence Regarding Trial Date Shows No Error in the Acting Director’s *Fintiv* Analysis

The Director need not reach the merits of Patent Owner’s argument on *Fintiv* factor 2 because it is entirely premised on unauthorized new evidence (*see* 37 C.F.R. § 42.75(c)(3); Director Review Process § 3.E). It is nonsensical to allege error in the Referral Decision that was expressly “based on the totality of the evidence and arguments the parties have presented” (Referral Decision 2-3) by citing evidence that was not presented.

Nonetheless, even if the Director considered Patent Owner’s new assertions on *Fintiv* factor 2, they fail to show any error. The Acting Director evaluated the record and reasonably assessed *Fintiv* factor 2 as neutral. She acknowledged that (1) the district court proceeding involves a number of challenged patents, (2) at the time had a projected trial date that had been extended to May 2026 (now further extended to June 2026 due to Patent Owner’s delay), and (3) the median time-to-trial statistics indicate that trial was unlikely to occur before November 2027. *Id.* at 2. She properly considered the median time-to-trial statistics for Judge Albright, which show time to trial consistently increasing since 2021—from 22.5 months to 42.6 months by January 2025. Ex. 1120, 3; Paper 10, (“DD Req. Opp.”) 22. On that record, she concluded that “it is unclear whether a final written decision in this proceeding will issue after the district court trial occurs.” Referral Decision 2. Patent Owner identifies no reason why this conclusion was unreasonable.

Patent Owner points to a newly submitted partial transcript as evidence of a “hard” trial date in June 2026, but this does not change the facts the Acting Director already considered. DR Req. 5-7 (citation omitted). Rather, it shows that the trial date has now been postponed twice (Ex. 1126, 4; Ex. 1133, 3; DR Req. 5-6) and does not change the fact that Judge Albright’s docket remains very full (Ex. 1124; Ex. 1125) and that the court routinely adjusts trial dates in light of new filings and case developments, as it has done here. The Acting Director thus did not err in relying on the median time-to-trial statistics, which suggest an expected trial date well after the expected final written decision. DD Req. Opp. 21-26. Indeed, the new evidence Patent Owner submits confirms that the Acting Director was right to think that the trial date could slip—it has since slipped further from May 2026 to June 22, 2026. DR Req. 5-6; Ex. 1134, 16. And Patent Owner does not even address that Judge Albright has two *other* trials scheduled to begin the same week as the parallel litigation in this case—*Redstone Logics v. Qualcomm*, No. 7:24-cv-00231, with jury selection and trial set for June 22, 2026, and *Intellectual Ventures v. Tesla*, No. 1:24-cv-00884, with jury selection set for June 25, 2026, and trial set for June 29, 2026.

Patent Owner’s selective quotes also omit the fact that it was Patent Owner’s own discovery delays that pushed the projected trial date back to June 22, 2026. DR Req. 5-6. Patent Owner points to Petitioner’s litigation counsel stating to the district court that the case was “on track” for the June 22, 2026, trial date that “Align has

proposed.” *Id.* (citation omitted). But those statements merely reflect counsel’s good-faith understanding of the then-current schedule. Petitioner has consistently been ready to follow the scheduling order and meet the scheduled trial date, whether in February 2026 (Ex. 1133, 3), May 2026 (Ex. 1126, 4), or June 2026.

Patent Owner’s new assertions—showing a second extension of the projected trial date—only reinforce the soundness of the Acting Director’s assessment of *Fintiv* factor 2 as neutral. *See Volkswagen Grp. of Am., Inc. v. Longhorn Auto. Grp. LLC*, IPR2025-01064, Paper 9, 2 (Director Oct. 10, 2025) (*Fintiv* factor 2 neutral where district court’s scheduled trial date is four months before, but the time-to-trial statistics suggest trial will begin one month after, projected final written decision due date); *Straumann USA, LLC v. Smart Denture Conversions, LLC*, PGR2025-00054, Paper 11, 2 (Director Oct. 17, 2025) (*Fintiv* factor 2 neutral where final written decision due date is December 26, 2026; the district court’s scheduled trial date is October 19, 2026; but the time-to-trial statistics suggest trial would not begin until July 2027).

And Patent Owner does not show any error in the Acting Director’s considerations of other factors or weighing of the *Fintiv* factors as a whole, which also considered the likelihood of a stay, overlap of issues, the relative stage of the district court case, and other circumstances, including settled expectations and the

merits. *See* Paper 7, (“DD Req.”) 8-25; DD Req. Opp. 20-39; Paper 12, (“DD Req. Reply”) 1-2; Referral Decision 2-4.

C. The Board Did Not Err in Granting Institution Decision

The Board instituted review of the ’384 patent based on a thorough analysis of the parties’ evidence and arguments. Patent Owner does not dispute that the Petition relies on prior art disclosing every element of the claimed dental aligners. Nor does Patent Owner dispute that review of the ’384 patent is appropriate to correct the Examiner’s material error in failing to apply a reference during prosecution (*Tadros*) that Patent Owner was later forced to distinguish via amendment in continuation applications. Instead, Patent Owner’s request to vacate the Institution Decision largely rehashes the same arguments regarding adhesive lamination that the Board already considered and rejected in instituting review.

In an attempt to achieve a different outcome this time, Patent Owner mischaracterizes the Petition and Institution Decision but still fails to show any error. DR Req. 7-9; Paper 9, (“Prelim. Resp.”) 14-20; DI 14-16. Most notably, Patent Owner’s arguments ignore the Petition’s explanation of the advantages of adhesive lamination that would have motivated a skilled artisan to use that technique to achieve the proposed prior-art combination. Patent Owner likewise ignores the Board’s statements pointing specifically to those portions of the Petition in rejecting Patent Owner’s adhesive lamination arguments as a basis for non-institution. Patent

Owner's Request should be denied because the Board's well-reasoned decision is supported by the record, and Patent Owner fails to show any error.

Patent Owner's arguments misstate the facts—the Petition and corresponding expert declaration specifically explain why lamination (*e.g.*, with tie layers) would be appropriate and desirable to create the claimed aligners. *E.g.*, Pet. 7-8, 12, 15 n.3, 36, 37 n.7, 37-38, 41 n.8, 54-55, 60; Ex. 1007 ¶¶31, 39-42, 45, 51, 104 n.2, 116, 120. They note, for example, that adhesive lamination would effectively bond layers of disparate polymers and would not be expected to alter the polymers' preexisting properties. *Id.* The Petition thus establishes 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 techniques that would not alter the polymer's properties, such as adhesive lamination. Patent Owner cites some of these same portions of the Petition, but ignores the express motivation discussed therein. *See, e.g.*, DR Req. 8 (citing Pet. 29, 36, 37-38, 54, 60).

In the Board's thorough review of the parties' arguments and evidence, it pointed to those same portions of the Petition in rejecting Patent Owner's argument that Petitioner had not "shown that a POSITA would have been motivated to use adhesive lamination." DI 14-16 (citing Pet. 34-36); *see also* Prelim. Resp. 9, 17-20, 32. The Board recognized that the Petition *does explain* why a POSITA would have

been motivated to use adhesive lamination to combine prior-art polymer materials to achieve the claimed invention:

We also disagree with Patent Owner’s arguments about “adhesive lamination” using “tie layers” at this point in the proceeding. Prelim. Resp. 14–18. On this record, *we are persuaded that Petitioner has adequately supported its arguments that one of ordinary skill in the art would have been motivated to use adhesive lamination to achieve the proposed combination.*

DI 14-16 (citing Pet. 34–36; Ex. 1007 ¶¶ 31, 39–42, 147–154, 174–176) (emphasis added); *see also* DI 20, 22. The Board further considered this argument with regard to the *Kalili* and *Tadros* references, concluding that, “[t]o create the laminated multilayer aligner proposed, *Petitioner’s suggested use of a particular type of well-known lamination, i.e. adhesive lamination, is sufficiently developed and supported in the Petition.*” DI 14-16 (citing Pet. 34-36) (emphasis added).

The Board thus expressly considered Patent Owner’s arguments and found them unpersuasive. Patent Owner’s mere dissatisfaction with the Board’s decision does not warrant vacating institution, nor does repeating the same factually inaccurate assertions regarding the contents of the Petition.

Patent Owner’s argument regarding unpredictability likewise contradicts the facts. The Petition *never* “argued that the types of modifications it proposed were

unpredictable.” DR Req. 9. On the contrary, Petitioner argued that a POSITA would have been motivated to use adhesive lamination precisely because it provides desirable and *predictable* results, including by “preserv[ing] the polymer’s properties as disclosed in the manufacturer’s datasheet.” Pet. 15 n.3. And while the Petition recognizes that “alter[ing] the relative placement of the hard and soft layers, or replac[ing] layers with other polymers without guidance to do so, is unpredictable,” (Pet. 23), neither of the grounds involves any such alteration or replacement. Instead, both grounds rely on express disclosures regarding appropriate layer configurations and polymers for the hard and soft layers. Patent Owner cannot point to anything in the Petition suggesting that the proposed use of adhesive lamination is unpredictable.²

Faced with the Board’s well-supported reasoning regarding motivation to use adhesive lamination, Patent Owner now argues that the Institution Decision adopted a new “obvious-to-try rationale.” As an initial matter, this argument is irrelevant given the Board’s finding that the Petition identifies sufficient motivation to use adhesive lamination, separate and apart from whether it would have been obvious to

² Tellingly, Patent Owner’s citation to the Institution Decision “acknowledging this issue” only cites to the DI’s summary of Patent Owner’s own arguments, which the Board rejected.

try this well-known manufacturing method. The Board thus did not “substitut[e]” its own “alternative rationale.” DR Req. 9. Any reasoning regarding whether it may also have been obvious to try adhesive lamination would not alter the Board’s finding that the Petition identifies a motivation to use adhesive lamination specifically. Indeed, the Board’s analysis for ground 2 addresses only the motivation to use adhesive lamination and does not mention “obvious to try,” further refuting Patent Owner’s suggestion that an “obvious to try” analysis was key to institution. DI 20-22.

Instead, the Board’s discussion of known techniques for forming multilayer polymer sheets—including adhesive lamination, coextrusion, and extrusion lamination—correctly recognizes that a POSITA would have known the possible approaches for combining the cited art and the advantages and disadvantages of each approach. DI 14-16. Again, Patent Owner is wrong in asserting that the Petition suggests that anything about the proposed use of adhesive lamination was “unpredictable.” DR Req. 9. As the Petition states, a POSITA would have understood which manufacturing techniques would alter the polymer’s properties and which techniques would not. *E.g.*, Pet. 15 n.3. In this context, the Petition establishes that a POSITA would have been motivated, based on *Kalili*’s disclosure of using “lamination” to create a multilayer aligner and the “outstanding” properties

of TEXIN 990R, to use a manufacturing technique that would “**preserve**” those properties. *Id.*

Patent Owner’s arguments regarding unpredictability also conflict with the arguments it has made in the parallel district court litigation. There, Patent Owner’s infringement assertions rely on the assumption that a polymer’s properties do not change when processed into a multilayer sheet, *regardless* of what manufacturing technique is used. *Id.* Patent Owner’s arguments in the district court therefore are based on the assumption that the available manufacturing techniques achieve entirely *predictable* results, counter to its arguments here.

Finally, Patent Owner has no basis for speculating that the Board took the Acting Director’s referral as a signal that institution was required. DR Req. 7. Patent Owner cites nothing to support this unfounded assertion, which ignores the Board’s thorough and independent analysis of the Petition, the Preliminary Response, and the cited prior art.

IV. Conclusion

For these reasons and those in the Petition and pre-institution briefing, Petitioner requests that the Director deny Patent Owner’s Director Review Request.

Respectfully submitted,

Dated: December 1, 2025

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

The undersigned certifies that the foregoing **AUTHORIZED RESPONSE
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