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

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST[1]

[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 § 325(d) arguments ignore the fact that *Porter*, which was not of record during prosecution, discloses a motivation to replace polycarbonate with Tritan copolyester. Specifically, *Porter* addresses an industry-wide shift away from polycarbonate following the discovery that it leaches BPAs that have adverse effects on human health, providing an express motivation to use Tritan and disclosing properties for Tritan that match those recited in the challenged claims. That motivation was not disclosed in any art considered during prosecution, and the Examiner's failure to consider this motivation was a material error under § 325(d). Patent Owner has not shown any error in the Acting Director's analysis or the Board's finding that this motivation in *Porter* supports institution.

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." *Wi-Fi 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. 10-14. 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 '090 patent directed to dental aligners, and AlliedStar does not make or sell dental aligners accused of infringing the '090 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 '090 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.") 18. 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. 18-22. 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.") 8-24; DD Req. Opp. 16-36; Paper 12, ("DD Req. Reply") 1-2; Referral Decision 2-4.

C. Patent Owner Identifies No Error in the Acting Director's Analysis and the Board's Institution Decision

All three grounds of the Petition include an important new piece of prior art (*Porter*) that supplies precisely the elements that the Examiner believed were missing—a specific type of copolyester having the exact properties recited in the claim. The *Porter* reference also provides a compelling motivation to use this specific copolyester in place of BPA-containing polycarbonate polymers in certain prior-art applications.

Acknowledging that *Porter* was not before the Examiner, Patent Owner nonetheless argues that the grounds "rel[y] primarily" on other prior art and dismisses *Porter* as "uncompelling and irrelevant." DR Req. 7-8. These arguments are no more persuasive now than they were when Patent Owner raised them in its Request for Discretionary Denial and its Preliminary Response. DD Req. 28, 32 (attempting to dismiss *Porter* as non-analogous art without a motivation to combine); Paper 9, ("Prelim. Resp.") 8-9, 17-20 (same). The Acting Director and the Board appropriately rejected these arguments. *See* Referral Decision 4; DI 11-15. The failure of the Examiner to consider the new and compelling *Porter* reference is thus a material error under § 325(d), and Patent Owner has not shown any error in the Acting Director's and Board's decisions.

Porter discloses not only a specific copolyester with desirable properties, but also a compelling motivation to use that copolyester to replace polycarbonate in certain applications. *Porter* discloses that polycarbonate had been discovered to leach harmful BPAs, which were known to be an endocrine disruptor and cause certain cancers. *See, e.g.*, Paper 1, ("Pet.") 2, 7, 13, 35, 47, 58, 59, 69; Ex. 1007, ¶¶ 88-97; DD Req. Opp. 4-10. *Porter* addresses this concern with polycarbonate and recommends a specific polymer as a replacement—an innovative copolyester called "Tritan"—which improved on polycarbonate's desirable properties while also being BPA-free. Ex. 1006, 60, 63 (explaining "Tritan was the answer" to health concerns from BPA-containing polycarbonate, by providing a BPA-free polymer with "significantly increased heat resistance and toughness" as compared with polycarbonate). *Porter* discloses Tritan's properties, which match those recited in the challenged claims. *See* Pet. 14 n.3.

Porter is analogous prior art relevant to dental aligners. *Porter* provides a compelling motivation to replace polycarbonate with Tritan copolyester in applications where the polymer will be exposed to moisture, elevated temperatures, and hydrolytic attack, which Patent Owner does not dispute would include dental aligners. Ex. 1006, 61, 63. *Porter* expressly discusses Tritan's applicability in "countless applications for clear plastics" in the consumer goods industry, including in "extruded sheet applications" prior to thermoforming into a mold—the same

known manufacturing process Patent Owner uses for fabricating its claimed dental appliance. Ex. 1006, 60, 62-63 (discussing "benefits for molders"); Ex. 1001, claim 1 ("providing a multilayer sheet" including the first (co-polyester) layer and "thermoforming the multilayer sheet" to create the 3D appliance).

Especially when viewed in the context of the prominent multi-industry shift away from using polycarbonates to avoid BPAs (Ex. 1007, ¶¶ 88-97), *Porter*'s teachings are highly relevant to dental aligners. *See, e.g.*, Ex. 1007, ¶¶ 98-99 (discussing shift in the dental industry away from polycarbonate, and prior art, such as *Rafih* (Ex. 1104), using Tritan in dental appliances to avoid BPA leaching); Pet., 7-8 (citing Exs. 1068–1116). *Porter* nonetheless was not of record during prosecution, nor was any reference addressing the industry shift away from polycarbonates in applications where a human could ingest BPAs, such as food containers (or dental aligners).

Patent Owner cannot dispute *Porter*'s disclosure of this motivation to replace the polycarbonate with Tritan in prior-art dental aligners (e.g., in *Tadros* or *Kalili*), nor can Patent Owner dispute that *Porter* discloses that Tritan has properties falling squarely within the challenged claims. Instead, Patent Owner misleadingly argues that BPA-free polymers were already disclosed in references considered by the Examiner. Yet Patent Owner's argument that *Porter* "adds nothing" and is "uncompelling" ignores the fact that the other references the Examiner considered

did not address the same motivation to replace polycarbonate with BPA-free Tritan that *Porter* expressly discloses. This was a material error, and Patent Owner's arguments to the contrary simply cannot be squared with the facts.

The Acting Director previously considered this evidence as part of her thorough, "holistic assessment" of "all" discretionary denial arguments and concluded that referral was appropriate. *See, e.g.*, DD Req. Opp. 4-10 (describing material error related to *Porter*); Referral Decision 4. The Acting Director thus expressly considered and rejected Patent Owner's arguments about *Porter*.

Patent Owner argues that, because the Acting Director highlighted material errors from other proceedings in her Referral Decision, the only "logical conclusion" is the *absence* of material error related to *Porter*. DR Req. 8. This argument ignores the Acting Director's statements that "the proceedings discussed [in the Decision] are exemplary" and "there is evidence in the record indicating that the Office erred in a manner material to patentability for the remaining proceedings." Referral Decision 4. The Acting Director considered the same arguments raised here regarding *Porter* as part of her holistic assessment and determined that referral was appropriate. Patent Owner fails to show any error in that analysis.

The Board's institution decision further details why Patent Owner's arguments fail. The Board found that Petitioner showed "reasonable pertinence of Porter's disclosure to the problem faced by inventor of the '090 patent" and

presented "persuasive evidence" that a POSITA would have been motivated to modify Tadros's aligner to have a hard layer of Tritan" based on the teachings of *Porter*. DI 12-13; *see also* DI 11-15. As the Board recognized, "Petitioner and Dr. Osswald provide persuasive evidence that an ordinarily skilled artisan would have recognized the desirability of replacing Tadros's BPA-laden polycarbonate with a BPA-free material like Tritan." *Id.* The Board thus correctly rejected Patent Owner's argument that the motivation in *Porter* was not compelling.

The Board also agreed with Petitioner that *Porter* was analogous art. DI 11-12. According to the Board, "Petitioner and Dr. Osswald provide significant evidence and reasoning tending to show that Porter's discussion of Tritan logically would have commended itself to the attention of an inventor facing the problem of selecting an aligner hard layer." *Id.* As an example, the Board discussed other prior art, such as *Rafih* (Ex. 1104), which specifically used BPA-free Tritan in an oral appliance, as well expert testimony that this would have informed a POSITA that "*Porter*'s guidance regarding replacing polycarbonate with Tritan applies to dental appliances." *Id.* at 12. The Board thus correctly rejected Patent Owner's attempt to cabin *Porter* as nonanalogous art.

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. 9. 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. Patent Owner has not persuasively explained how the Acting Director and Board's decisions, both independently rejecting Patent Owner's arguments here, were in error.

IV. Conclusion

For these reasons and those in the Petition and pre-institution briefings, 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 TO DIRECTOR REVIEW REQUEST** was served on December 1, 2025, via email directed to counsel of record for Patent Owner at the following:

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