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. IPR2025-00817
U.S. Patent No. 10,791,936

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST[1]

[1] This Response was authorized by e-mail dated November 19, 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 13, "Referral Decision") or in the Institution Decision (Paper 16, "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.

Patent Owner also conflates the Board's merits analysis in the Institution Decision with the Acting Director's separate discretionary assessment. For the third time, Patent Owner attempts to mislead the Board by arguing that the challenged claims differ materially from the '192 patent claims addressed in IPR2019-00134. DR Req. 8-9. As Petitioner explained and the Acting Director recognized, however, several unpatentable claims of the '192 patent are similar to the challenged claims. Paper 1 ("Pet."), 6-8, 15; Paper 8 ("DD Req. Opp."), 16-17, 20. The Acting Director correctly found that the Examiner erred by failing to explain any patentable distinction despite this similarity and correctly considered such material error as part of a holistic assessment when referring the Petition to the Board. Referral Decision 2-4. Patent Owner identifies no error in that assessment.

Patent Owner has no basis for speculating that the Board took the Acting Director's referral as a signal that institution was required. The Board's Institution Decision did not cite or rely on the '192 patent, the IPR on that patent, or the references at issue in that IPR; its merits findings focused on the prior art and combinations presented in the Petition. DI 22-24. Patent Owner itself acknowledges this. DR Req. 9. 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.

Finally, Patent Owner's challenge to the Board's obviousness analysis under Ground 2 merely rehashes the limitation 1[h] arguments the Board already rejected. DI 22-24. The Board thoroughly analyzed the combined teachings of Boerjes and Geng and the motivations to combine them. *Id.* at 20-24. Patent Owner identifies no misunderstanding of the prior art or misapplication of obviousness law; it simply disagrees with the Board's conclusion. That is not a basis for Director Review.

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 New RPI Theory Is Improper and Unsupported

Patent Owner's Request improperly raises a new, unfounded RPI argument, and fails to present evidence to support that argument. DR Req. 11-14.

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.

On the merits, Petitioner properly identified all RPIs and Patent Owner fails to show any defect in that identification. *See* Pet. 84 (identifying ClearCorrect Holdings, Inc.; Straumann USA, LLC; and Institut Straumann AG as RPIs).

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. 12-14. 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. 12-13. The '936 patent claims are directed to an intraoral scanner, not aligners. Bay Materials' business has nothing to do with intraoral scanners. 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-1038, ¶ 4; Ex-1039, ¶¶ 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, nor does it make or sell any intraoral scanner. 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. 13-14; *Corning*, IPR2014-00440, Paper 68, 14-15. In fact, there was none.

Likewise, AlliedStar has no involvement in this proceeding. While AlliedStar designed the hardware of the accused SIRIOS intraoral scanner sold by ClearCorrect, Patent Owner did not accuse the SIRIOS intraoral scanner as an accused product until Patent Owner's Supplemental Preliminary Infringement Contention filed June 16, 2025, two months after the Petition was filed. Patent Owner does not allege that AlliedStar has ever been involved in this proceeding, much less how or why AlliedStar would have had any control or direction over the Petition *before* the SIRIOS scanner was even accused of infringement. In fact, it has had no involvement.

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 '936 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 § 11.E.1). Patent Owner's RPI allegations should be rejected.

B. Patent Owner Identifies No Error in the Acting Director's Holistic Discretionary Assessment

The Acting Director determined that "discretionary denial of institution is not appropriate in these proceedings" in view of "all relevant considerations" and "based on the totality of the evidence and arguments the parties have presented." Referral Decision 2. Patent Owner's attempt to re-argue *Fintiv* factor 2 based on improper new evidence fails to show any error in that holistic assessment, which included both *Fintiv* and § 325(d) considerations.

1. Improper New Trial Date Evidence 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-1029, 3; DD Req. Opp. 25. 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. 5-6 (citation omitted). Rather, it shows that the trial date has now been postponed twice (Ex-1035, 4; Ex-1043, 3; DR Req. 5-6) and does not change the fact that Judge Albright's docket remains very full (Ex-1033; Ex-1034) 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. 24-29. 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-1044, 16. And Patent Owner does not even address the 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. Referral Decision 2. Petitioner has consistently been ready to follow the scheduling order and meet the scheduled trial date, whether in February 2026 (Ex-1043, 3), May 2026 (Ex-1035, 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 11 ("DD Req. Reply"), 1-3; Referral Decision 2-4.

2. Patent Owner Identifies No Error in the Acting Director's § 325(d) Analysis

The Acting Director also found that the Office's material error during prosecution counsels against discretionary denial. Referral Decision 3. She found that the Examiner was aware of the related '192 patent IPR (IPR2019-00134) but did not discuss why the challenged claims were patentably distinct from those the Board found unpatentable in that IPR, despite their strong similarity. *Id.* Patent Owner fails to show any error in these findings.

Patent Owner attempts to mislead by reasserting that the claims in the '192 patent IPR are materially different because those claims do not require rescanning after "an intervening physical change." DR Req. 9; Paper 15 ("PO Sur-reply"), 2; DD Req. Reply 3 ("claims lacked the physical modification limitation at issue here"). But as Petitioner explained, and the Acting Director correctly found, similar to the challenged claims, several unpatentable claims of the '192 patent involved rescanning a patient's intraoral cavity after it was physically changed. Pet. 1, 6-8 (discussing claims 13, 15-18); DD Req. Opp. 16-19; *see, e.g.*, Ex-1025, 31:63-32:3 (Claim 18) ("said second physical portion of said second physical part corresponds to said first physical portion of said first physical part wherein *said at least a part of said surface of interest has been physically altered*" (emphasis added)).

Despite the challenged claims being similar to those unpatentable claims of the '192 patent, and despite the Examiner being aware of the '192 patent and its IPR, the Examiner inexplicably found that the challenged claims were distinguishable over the prior art by updating scans "*where the intra-oral cavity (e.g.[,] dentition) is modified in between the scans*," which is clearly *inconsistent* with the Board's findings in the '192 patent IPR. Pet. 6-8 (alteration in original) (quoting Ex-1002, 238-39); DD Req. Opp. 16-17, 20; DR Req. 9.

The Acting Director correctly found a clear examination deficiency and referred the Petition to the Board to ensure that patents are not insulated from review

where examination was deficient. *See Microsoft Corp. v. Partec Cluster Competence Ctr. GmbH*, IPR2025-00318, Paper 9, 3 (Director June 12, 2025) (referring petition "because of Petitioner's showing of material error during patent examination" and "it is an appropriate use of Office resources to review the potential error"); *Anthony Inc. v. ControlTec, LLC*, IPR2025-00559, Paper 12, 2 (Director July 16, 2025) (referring petition because the examiner materially erred by overlooking prior art teachings), Paper 19, 2 (Director Nov. 3, 2025) (denying Director Review Request).

Further, the Board's evaluations and conclusions in the Institution Decision confirm that the Examiner materially erred by not considering Boerjes and its combination with Geng. DD Req. Opp. 14-18; DI 20-24; *Tesla, Inc. v. Charge Fusion Techs., LLC*, IPR2025-00152, Paper 11, 2-3(Director June 12, 2025); *Embody, Inc. v. LifeNet Health*, IPR2025-00248, Paper 13, 2 (Director June 26, 2025); *Anthony*, IPR2025-00559, Paper 12, 2. Patent Owner does not dispute that neither Boerjes nor Geng was considered by the Examiner during prosecution. *See generally* DD Req. Nor does it dispute that it was aware of Boerjes long before the '936 patent was granted but never submitted Boerjes to the Examiner. DD Req. Opp. 4-5. The Examiner allowed the claims because the prior art cited did not disclose that "*the intra-oral cavity (e.g.[,] dentition) is modified in between the scan*s." Ex-1002, 238-39 (emphasis added); Pet. 6; DD Req. Opp. 4-5. But Boerjes discloses precisely what the Examiner said was missing here. The Board found, and Patent

Owner does not dispute, that Boerjes discloses receiving "*the second scan data including surface data of a physically changed portion of the patient's intraoral cavity*" of limitation 1[g]. DI 13-14, 22 (emphasis added); *see generally* Paper 10 ("Prelim. Resp.").

In sum, the Acting Director correctly referred the Petition to the Board to correct two material examination deficiencies: (1) allowing the claims of the '936 patent without distinguishing the Board's unpatentability findings on similar claims, and (2) not considering Boerjes and its combination with Geng.

C. There Is No Error in the Board's Institution Decision

The Board instituted this proceeding based on the combination of Boerjes and Geng under Ground 2. DI 20-24. The Board found that Boerjes teaches all elements of claim 1 except 1[e], 1[f], and 1[h]. *Id.* at 22. For example, the Board found that Boerjes teaches element 1[g] reciting "second scan data including surface data of a physically changed portion of the patient's intraoral cavity." *Id.* at 13-14, 22. The Board then found that "Geng teaches a system that allows for multiple scans of the dentition to occur and data from a subsequent scan is used to supplement the first scan, based on indications from a user of where such supplementation should occur," and that "Geng's disclosure matches the language of limitations 1(e), 1(f) and 1(h)." *Id.* at 23-24; Pet. 47-51. Finally, the Board found motivation to combine: "Geng's editing function would improve the efficiency and accuracy of Boerjes's system, and

the incorporation of that editing function would have involved merely applying known techniques to improve a known and similar system in the same way." DI 23.

Patent Owner does not dispute that these factual findings are well supported by the evidence. Rather, Patent Owner argues that the Board allegedly erred because Geng does not disclose "stitching together *before-and-after models that have undergone an intervening physical change*," and "the panel did not find[ ]that Geng taught limitation 1(h), whether alone or in combination with Boerjes." DR Req. 8. But this argument attacks the references individually and fails to address the combination. The Board evaluated—and rejected—this argument, noting that "the Petition addressing limitation 1(h) addresses the disclosures of both Boerjes and Geng." DI 24 (citing Pet. 47-51); *see In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (one cannot show nonobviousness by attacking references in a combination individually). Nothing in the Institution Decision reflects any misunderstanding of the references or any improper obviousness analysis.

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: November 26, 2025

By: / Kathleen A. Daley /
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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST** was served on November 26, 2025, via email directed to counsel of record for Patent Owner at the following:

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