

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. IPR2025-00821
Patent No. 11,648,091

**PATENT OWNER'S BRIEF IN SUPPORT OF
DISCRETIONARY DENIAL**

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I. INTRODUCTION

Patent Owner Align Technology, Inc. (“PO” or Align) requests the Director to exercise discretion to deny institution of *inter partes* review of U.S. Patent No. 11,648,091 (“the ’091 patent”), pursuant to Memorandum, *Interim Processes for PTAB Workload Management* (USPTO Dir. Mar. 26, 2025) (“Workload Memo”).

The present case, like all the related IPR petitions (IPR2025-00814 – IPR2025-00821), is a textbook instance that warrants exercising discretion to deny the challenge. Due to Petitioner’s delay, the Board’s final written decision wouldn’t be expected until 6 months after trial in the Western District of Texas. Petitioner’s lack of diligence is inexcusable and the resulting waste of judicial resources self-inflicted. Despite challenging patents issued years ago, litigation between the parties since 2011, and dozens of failed patent challenges initiated more than a decade ago, Petitioner went dormant for years and waited until the last day of the statutory period to file IPRs. Worse yet, Petitioner’s delayed challenge merely asks the Board to revisit the same prior art references that were already expressly considered by the Office. The “new” reference is strung together in a series of overlapping four- and five-reference combinations and addresses “Dishwasher Safe” plastic, not a dental appliance for positioning a patient’s teeth as claimed. Even if considered analogous art, it is cited for a copolyester

cumulative to art the examiner already considered. The Board's limited time and resources are better allocated elsewhere. 35 U.S.C. §316(b); Workload Memo.

First, the *Fintiv* framework favors discretionary denial, as Petitioner is currently pursuing the same invalidity arguments raised in the petition in a parallel district court proceeding. Petitioner has long known of this patent and the patents in the '091 patent's family but waited to file this IPR until the last day before the statutory bar date.¹ As a result, the district court case is now at an advanced stage and Petitioner's arguments will be addressed by the district court months before a final written decision in this proceeding. Petitioner's promise of a *Sotera* stipulation subsequent to institution does not mitigate the waste of judicial resources arising from overlapping issues, given the late stage of the case by the time of an expected institution decision, and given Petitioner's failure to challenge

¹ Petitioner has now belatedly filed IPR challenges against four related multilayer dental appliance patents (IPR2025-00818, -00819, -00820, & -00821), three related dental treatment planning patents (IPR2025-00814, -00815, & -00816), and a dental model imaging patent (IPR2025-00817). All eight challenged patents (plus another related patent unchallenged in IPR) are asserted in the same copending district court litigation.

(or direct its stipulation to) all of the patents asserted in the parallel litigation. And Petitioner's lengthy acquiescence to the validity of Align's patents further supports denial of institution based on the parties' settled expectations.

Second, the petition offers nothing new but instead recycles art and arguments the Office previously considered, making denial appropriate under §325(d). The petition relies primarily on previously considered art (i.e., 4 of the 5 grounds references). The sole "new" reference is a secondary reference used in 3-, 4-, or 5-reference combinations, is non-analogous "Dishwasher" art, and is at best cumulative to art already considered during prosecution.

Moreover, during prosecution of a parent application of the '091 patent, the Office considered and was persuaded by evidence of objective indicia of nonobviousness. 35 U.S.C. §131. Yet despite acknowledging these findings, Petitioner leaves them unaddressed while advancing three- and four-reference obviousness grounds in an art even Petitioner admits is unpredictable. Known objective evidence of nonobviousness must be considered in a *Graham* inquiry for a petitioner to meet its unshifting burden of proof and failure to do so leaves the petition's obviousness inquiry incurably deficient. The Office's previous consideration of the art and arguments advanced in the petition, and Petitioner's failure to provide evidence countering the objective indicia of nonobviousness

provides a strong basis to deny the petition using the Director's authority under §325(d).

Accordingly, the present petition is a poor use of the Board's limited time and resources. Align respectfully requests the Director exercise discretion and *deny institution*.

II. BACKGROUND

Align Technology, Inc. designs, develops, manufactures and markets high-technology, custom-manufactured orthodontic devices, as well as providing related products and services including dental scanning and treatment planning.

Petitioner ClearCorrect, a competing dental-aligner manufacturer, has been aware of Align's patent portfolio since at least 2011, when Align first sued Petitioner for patent infringement in *Align Technology, Inc. v. ClearCorrect Inc.*, No. 4:11-cv-00695 (S.D. Tex. Feb. 28, 2011). Align also filed two ITC actions against Petitioner in 2012: *In the Matter of Certain Incremental Dental Position Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562; and *In the Matter of Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same*, Inv. No. 337-TA-833.

Beginning in 2015, Petitioner launched a multi-year campaign challenging Align's patent portfolio. From 2015 to 2017, Petitioner filed a total of 26 reexamination requests challenging Align's patents: Reexamination Control Nos.

90/013,581;

90/013,947;

90/013,457;

90/013,904;

90/013,905;

90/013,917;

90/013,606;

90/013,946;

90/013,775;

90/020,116;

90/013,506;

90/013,788;

90/014,090;

90/013,491;

90/013,911;

90/013,912;

90/013,918;

90/013,607;
90/013,777;
90/014,049;
90/013,579;
90/013,981;
90/013,505;
90/013,928;
90/013,929; and
90/013,931.

These challenges failed almost entirely: only one patent claim was canceled (*see* Reexamination Control No. 90/013,788) and only a single patent claim was amended (*see* Reexamination Control No. 90/013,607), while all other challenged claims were upheld as patentable.

Petitioner also filed two IPRs challenging Align's patents, neither of which resulted in any canceled claims. *ClearCorrect Operating LLC v. Align Technology, Inc.*, IPR2016-00270, Paper 55 (Apr. 9, 2019) (terminating case after remand from Federal Circuit); *ClearCorrect Operating LLC v. Align Technology, Inc.*, IPR2017-01829, Paper 10 (Feb. 5, 2018) (denying institution). The second of these cases challenged U.S. Patent No. 8,038,444 (the '444 patent), which had never been asserted against Petitioner, but which is now asserted in the parallel litigation.

After its unsuccessful challenges to Align’s patent portfolio and its proven infringement in both the ITC and in district court, Petitioner settled with Align. EX1023, ¶2. Petitioner gave up on its strategy of challenging Align’s patent portfolio before the Office, and as of 2017, ceased filing new challenges against Align’s patents. Petitioner maintained this state of acquiescence until the filing of these IPR petitions in April of 2025.

In 2024, Align filed a new lawsuit (the “parallel litigation”) to remedy Petitioner’s continuing infringement of nine of Align’s patents. EX1023. These patents include the ’091 patent and three other patents infringed by aligners made using materials manufactured by Bay Materials, LLC, which like ClearCorrect is a member of the Straumann Group. *Id.*, ¶42. The asserted patents also include the ’444 patent and three related patents, as well as U.S. Patent No. 10,791,936. *Id.* The parallel litigation is currently pending in the Western District of Texas before Judge Albright, with jury trial scheduled on May 11, 2026.

Petitioner waited a year after being served with the complaint alleging infringement of these patents; then, with just ten months remaining before the court had scheduled trial, Petitioner filed IPR petitions challenging eight of the nine asserted patents, including the instant petition challenging the ’091 patent. *See* EX2002 (setting Feb. 16, 2026, trial date); EX2003 (updating trial date to May 11, 2026). The ninth is the ’444 patent that Petitioner previously challenged

unsuccessfully in IPR2017-01829. Petitioner is now time barred on the '444 patent, making it impossible for Petitioner's IPR petitions to resolve the parallel litigation. As explained below, the Director should exercise discretion to deny institution of the instant petition.

III. THE DIRECTOR SHOULD EXERCISE DISCRETION TO DENY THE PETITION

The Director should exercise discretion to deny institution for multiple reasons. First, the *Fintiv* framework under §314(a) weighs strongly in favor of discretionary denial due to overlap with the parallel litigation in the Western District of Texas, which will come to trial before a final written decision is due in this proceeding. Denying institution would avoid wasting judicial resources, as well as uphold the settled expectations demonstrated by Petitioner's longstanding acquiescence to the validity of Align's patents. Second, the *Advanced Bionics* framework under §325(d) weighs in favor of discretionary denial because the petition advances art and arguments previously considered by the Office and fails to show material error.

Accordingly, for the reasons detailed below, the Director should exercise discretion to deny institution of the petition.

A. *Fintiv* Weighs in Favor of Discretionary Denial under §314(a)

The Director should exercise discretion under 35 U.S.C. §314(a) to not institute this proceeding. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11

(March 20, 2020) (precedential). As Petitioner admits, a parallel District Court litigation is ongoing between the parties before Judge Albright in the Western District of Texas. *See* Pet., 78; *supra*, §II. This parallel litigation is already in its late stages and will finish long before a final written decision would issue in these proceedings. There is significant overlap of issues between this proceeding and the parallel litigation, and additional factors including settled expectations of the parties and the proven weakness of the recycled petition grounds further favor discretionary denial.

1. Factor 1: The District Court Litigation Has Not Been Stayed And Is Unlikely To Be Stayed Even If This Petition Were Instituted

This factor weighs against institution because a stay of the parallel litigation is highly unlikely. Petitioner has not sought a stay, and the Board's institution decision is expected by November 8, 2025. Because the parallel litigation will be in its late stages by the expected time of the institution decision, it is unlikely that Judge Albright would grant a stay even if the petition were instituted. *E.g., Sonrai Memory Ltd. v. Micron Tech., Inc.*, No. 1:23-CV-01407-ADA, 2024 U.S. Dist. LEXIS 231280, at *2, *7 (W.D. Tex. May 29, 2024) (Albright, J.) (denying stay when *Markman* hearing was held and fact discovery opened two weeks before institution).

In particular, by mid-November—just six months before the trial is to begin—infringement and invalidity contentions will be finalized, document production will be complete, fact discovery will be closed, and expert reports will be imminently due. *See* EX2003. The *Markman* hearing was completed in the parallel litigation three months before the instant petition was even filed, and a final claim construction order has already issued. *Supra* §II. Given the advanced stage of the parallel litigation, the district court will have “expended significant resources” by the time of an institution decision and would be unlikely to grant a stay. *See Sonrai*, 2024 U.S. Dist. LEXIS 231280, at *2, *7.

Furthermore, although Align asserted nine patents against Petitioner in the parallel litigation, Petitioner only filed IPR challenges against eight of these patents. In 2017, Petitioner filed an IPR challenge against the remaining patent, U.S. Patent No. 8,038,444, but institution was denied on the merits. *See ClearCorrect Operating LLC v. Align Technology, Inc.*, IPR2017-01829, Paper 10 at 17 (Feb. 5, 2018). Petitioner is time barred from challenging the ’444 patent in an *inter partes* review, so even granting all pending IPR petitions would not eliminate all patents from the parallel litigation. These circumstances further diminish any chance of a stay. *See, e.g., Smart Mobile Techs. LLC v. Apple Inc.*, No. 6:21-cv-00603-ADA, 2023 U.S. Dist. LEXIS 137593, at *18-19 (W.D. Tex.

Aug. 8, 2023) (Albright, J.) (denying stay where institution was granted for some but not all asserted patents).

Accordingly, Factor 1 favors denying institution.

2. Factor 2: A Final Written Decision Would Likely Issue Six Months After Trial

This factor weighs against institution because trial is scheduled to begin six months before the projected final written decision is due. “If the court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution....” *Fintiv*, Paper 11 at 9.

Over a year into the litigation, the parties in the parallel litigation jointly requested trial in May 2026, and the court has issued a revised scheduling order setting trial for May 11, 2026. EX2003; EX2006.² Were the Director to not

² While the parties and the Court have all agreed on a May 2026 trial date, Petitioner (ClearCorrect) advocated for an even more accelerated pre-trial calendar. For example, Petitioner requested earlier pre-trial dates for the service of final infringement and invalidity contentions and the close of fact and expert discovery than was ordered by the Court. See EX2006; EX2003. Thus, while Petitioner was

discretionarily deny institution, the Board’s institution decision would be expected by November 8, 2025. Accordingly, the projected statutory deadline for a final written decision would be November 8, 2026, six months after the trial date of May 11, 2026. Judge Albright is unlikely to grant any further adjustment to the trial date, as he has a practice of “not mov[ing] the trial date except in extreme situations.” EX2005. The scheduling of the district court’s trial date six months before the expected date of final written decision weighs strongly in favor of denying institution. *See, e.g., Samsung Elecs. Co. v. TrueSight Commc’ns LLC*, IPR2025-00123, Paper 12 at 7, 10-11 (Apr. 22, 2025) (instituting trial over *Sotera* stipulation where district court trial had been scheduled “at least six months before the projected statutory deadline for a final written decision,” finding this factor “favors discretionary denial”); *Nokia of Am. Corp. v. Cellco P’ship*, IPR2025-00037, Paper 14 at 10, 15-16 (Apr. 25, 2025) (same).

While the court’s recent adoption of a trial date agreed to by both parties gives confidence that it is no mere preliminary estimate, even if median time-to-trial statistics were used instead of the scheduled trial date, the conclusion would

exercising a lack of diligence in bringing its IPR challenges, it was advocating for an accelerated pre-trial calendar.

still be that the trial would precede the expected final written decision. The median time-to-trial for the Western District of Texas as a whole is 25 months, with Judge Albright having the same median time-to-trial. EX2004. As the complaint was filed and served in the parallel litigation in April 2024, a 25-month time-to-trial would predict a trial date of May 2026, six months before a predicted final written decision date in this case. The median time-to-trial statistics thus dictate the same conclusion as the scheduled trial date: that trial will occur long before a final written decision would be expected.

Accordingly, Factor 2 strongly favors denying institution.

3. Factor 3: The Court And Parties Have Invested Heavily In The Parallel Litigation

This factor weighs against institution because the parties and the court have already invested and will continue to invest significant resources in the parallel litigation. The Board weighs “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.” *Fintiv*, Paper 11 at 9. The Board has also explained that if, at the time of an institution decision, the district court will have issued substantive orders related to the challenged patent, such as a claim construction order, this fact weighs in favor of denial. *See Fintiv*, Paper 11 at 9-10. Here, the *Markman* hearing took place before the petition was even filed and the district court has already issued its

final claim construction order. Accordingly, the parties and the court have invested heavily, given the advanced stage of the litigation.

Moreover, the Board has explained it considers the Petitioner's diligence in filing the petition in weighing this factor. *Id.*, 11 (considering whether "the petitioner filed the petition expeditiously, such as promptly after becoming aware of the claims being asserted..."). The Petitioner here has been anything but diligent.

The complaint in this case was served on April 15, 2024, and Petitioner waited until the last day before its statutory bar date to file the instant petition. Consequently, the parties and the district court had already completed a substantial amount of work before the petition was even filed. Fact discovery began and preliminary infringement contentions were served in July 2024, and invalidity contentions were served in September 2024, seven months before the instant petition was filed. *See* EX2002. The district court held a *Markman* hearing and issued preliminary constructions in January 2025, three months before the petition was filed. *See* EX2002; EX2007. The district court subsequently issued a final claim construction order adopting substantially identical constructions. *See* EX2001.

On or about the time the Board decides whether to institute this IPR in November 2025, still more resources will have been expended. Document

production will have long been substantially completed (July 18, 2025); final infringement and invalidity contentions will be served (August 22, 2025); fact discovery, including all depositions of fact witnesses, will have closed (October 17, 2025); and expert discovery will be well underway with expert reports due contemporaneously (Nov. 14, 2025). EX2003. In sum, the parallel district court litigation will be in its late stages with a substantial amount of work already completed.

As the Director has noted, “factor 3 strongly favors discretionary denial” when around the time of institution, “the parties had served extensive infringement and invalidity contentions, served opening and rebuttal expert reports, filed claim construction briefs, and conducted several depositions” and the court “also had held a claim construction hearing and construed the disputed claim terms.”

Motorola Sols., Inc. v. Stellar, LLC, IPR2024-01205, Paper 19 at 3 (Mar. 18, 2025) (Order Granting Director Review, Vacating the Decision Granting Institution, and Denying Institution of *Inter Partes* Review). Here, the similarly late posture and degree of expended resources confirm that factor 3 strongly favors denying institution.

4. Factor 4: There Is Significant Overlap Between Issues Raised In The Petition And In The Parallel Litigation

This factor weighs against institution given the significant overlap between the petition and the parallel litigation. The parallel litigation involves the '091 patent challenged in the instant proceeding as well as eight other patents, seven of which are subject to IPR challenges by Petitioner.

In its invalidity contentions, Petitioner has identified the same art advanced in the instant petition, along with other art it reasonably could have raised earlier. *See* EX1022, 34-37 (identifying references including Tadros, Kalili, Wen, Texin 990, and Porter,³ matching art asserted in instant IPR). Furthermore, Petitioner has identified other alleged prior art, including system and device art, as available in obviousness combinations with the same art relied on in the petition grounds. EX1022, 31-34 (alleging public use and sale), 38-44 (identifying references as teaching knowledge in art), 137-38 (identifying various combinations including references cited in instant IPR).

³ The petition identifies the article “Dishwasher Safe,” by David S. Porter and Randy S. Beavers, as Porter (EX1006); the infringement contentions identify this same article as “Beavers et al.”

While Petitioner has offered a *Sotera* stipulation not to pursue for this patent “any ground raised or that could have been reasonably raised in this petition” (Pet., 71),⁴ the Director has confirmed that such a stipulation does not eliminate the overlap of issues considered in factor 4, as such a stipulation is not sufficient to ensure that IPR proceedings are a “true alternative” to district court proceedings. *Motorola*, Paper 19 at 3-4; *see also* Chief Admin. Pat. J., *Guidance on USPTO’s Recission of “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation”* 2-3 (March 24, 2025) (*Sotera* stipulation not dispositive of *Fintiv* analysis). The stipulation offered here does little to mitigate overlap of issues and waste judicial resources for several reasons.

First, Petitioner at district court has entangled the same prior art references asserted here together with non-IPR eligible art and arguments in a way that minimizes the impact of its stipulation. Here, as in *Motorola*, Petitioner’s district court invalidity contentions “include combinations of the prior art asserted in these

⁴ Petitioner states that all defendants in the parallel litigation have agreed to be bound by the stipulation. To avoid confusion or misleading argument from Petitioner, the defendants named in the parallel litigation are member entities of the same Straumann Group.

proceedings with unpublished system prior art,” which Petitioner’s stipulation does not moot. *Motorola*, Paper 19 at 4; *cf. Ingenico Inc. v. IOENGINE, LLC*, 136 F.4th 1354, slip op. at 15-16 (Fed. Cir. May 7, 2025) (any ground including art “known or used by others, on sale, or in public use” is a ground that “could not have been raised during the IPR”).

Second, the belated filing of the petition and advance stage of the litigation ensures that significant amounts of overlapping efforts will be completed that are not undone by stipulation. Specifically, the late timing of the institution decision, scheduled after all fact discovery is complete and at about the same time expert reports are due, means that most of the overlapping efforts in the district court proceeding will already have occurred before Petitioner’s stipulation could go into effect.

Third, Petitioner has offered no stipulation regarding the ’444 patent, which is not subject to an IPR challenge, so the district court will still be required to consider a full panoply of art combinations during trial for at least that patent. This further diminishes any potential effect Petitioner’s stipulation might otherwise have had regarding judicial efficiency.

Accordingly, Petitioner’s *Sotera* stipulation at best mitigates only some concerns of duplication, and this factor still favors denial.

5. Factor 5: The Parties Are The Same In Both Proceedings

Petitioner is a defendant in the parallel litigation, as is each real party-in-interest, so “this factor weighs in favor of discretionary denial.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 15 (May 13, 2020) (informative).

6. Factor 6: Other Circumstances Weigh Against Institution

Consistent with the Director’s memorandum providing for interim processes for PTAB workload management, additional factors favor discretionary denial. *See* Workload Memo, 2 (“all relevant considerations” to be evaluated in determining whether to exercise discretionary denial).

To begin with, the merits of the petition are weakly based on recycled references and an obviousness analysis that is incurably deficient for not properly addressing known evidence of nonobviousness. As confirmed in the petition, all but one of the grounds references were considered during prosecution, and the examiner further credited evidence of nonobviousness in allowing the claims of a parent application. *See* Pet., 4, 25-27. That application—Application No. 15/476,655 (the ’655 application) issued as U.S. Patent No. 10,973,613 (the ’613 patent)—has claims substantively similar to those the ’091 patent’s claims; indeed, the ’091 patent’s claims include limitations requiring layers respectively “consisting of,” rather than “comprising” co-polyester and thermoplastic polyurethane elastomer with specific sets of properties. *Compare, e.g.*, EX1004,

claim 1 (method of making dental appliance with three layers including hard copolyester layer and soft thermoplastic polyurethane elastomer layer), *with, e.g.*, EX1001, claim 1 (multilayer sheet with parallel, narrower limitations regarding materials and properties, incorporated into dental appliance). Yet, despite findings during prosecution of the '655 application by the examiner of unexpected results deriving from the claimed invention, the petition advances obviousness challenges that ignore the examiner's findings while cobbling together numerous references, including a "Dishwasher Safe" plastic reference (Porter) completely unrelated to dental aligners. *See also* Pet., 25-29 (conceding, during discussion of prosecution history of '091 patent and family members, that the examiner credited objective indicia for the corresponding claims of the '655 application). Where an examiner relied on evidence of objective indicia in allowing claims, such evidence must be factored into an obviousness analysis *in the petition* in order to show a reasonable likelihood to prevail. Conversely, failure to address and rebut that evidence in the petition means that the Petitioner did meet its burden at the petition stage. *See, e.g., Gilead Sciences, Inc. v. United States*, IPR2019-01456, Paper 17 at 52-53 (Feb. 5, 2020) ("Petitioner's failure to persuasively address the [unexpected] results in its petition means Petitioner falls short of its burden to establish a reasonable likelihood of success in prevailing on its challenge."); *see also Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) ("Objective indicia of

nonobviousness must be considered in every case where present.”); *Coalition for Affordable Drugs V LLC, v. Hoffman La-Roche Inc.*, IPR2015-01792, Paper 14 at 17-18 (Mar. 11, 2016) (denying institution due to petitioner not addressing the objective indicia of nonobviousness relied upon in part by the examiner). Here, Petitioner concedes but disregards the evidence of objective indicia, including unexpected results and unpredictability, found in the prosecution history of the ’091 patent’s family, while presenting a hindsight-infused challenge that uses the disclosure of the ’091 patent to breeze over the inventive process and reconstruct the claimed invention. The weakness of the petition’s case is further underscored by its reliance on art already considered by the Office, as discussed in further detail in §III.B.

The Office’s prior expenditure of resources in response to challenges raised by ClearCorrect against Align patents, and the resulting settled expectations of the parties, further favor discretionary denial. Stewart Memorandum, 2. For example, the Director has held that a petitioner’s awareness of a patent owner’s applications related to a challenged patent “and failure to seek early review of the patents favors denial,” outweighing even multiple *Fintiv* factors that may otherwise weigh against denial. *E.g., iRhythm Techs. Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10 at 3 (Jun. 6, 2025) (petitioner’s knowledge of one of patent owner’s applications and decision to leave it unchallenged for years after it issued strongly favored

discretionary denial for the same and related patents). As discussed above in Section II, Petitioner raised multiple challenges against Align's patent portfolio dating back a decade. These failed challenges have already resulted in the expenditure of substantial Office resources to no significant effect. For example, between 2015 and 2017, Petitioner filed 26 reexamination requests challenging patents assigned to Align, resulting in only one canceled claim and one amended claim. *Supra* §II.

Petitioner has also raised unsuccessful IPR challenges against Align's patents in the past, including a petition against a patent that had not been asserted in district court at the time, and which is in the same family as three other patents challenged in its current IPRs. *See ClearCorrect Operating LLC v. Align Technology, Inc.*, IPR2017-01829, Paper 10 at 2 (Feb. 5, 2018) (challenging U.S. Patent No. 8,038,444, of which the patents challenged in IPR2025-00814, IPR2025-00815, and IPR2025-00816 are continuations). The Board denied institution, finding no reasonable likelihood that any claim was unpatentable. *Id.*, 17. Despite knowing of this patent family since 2017, Petitioner then sat on its hands for years. Petitioner has raised no further challenge to any family member, or any other Align patent, until 2025.

In total, Petitioner has now advanced 26 reexamination requests and 10 IPR petitions against Align's patents, with essentially no success to date. *See supra* §II.

These unsuccessful challenges against Align’s patent portfolio stretching back a full decade not only show a waste of Office resources, but also show that Petitioner abandoned its challenges against Align’s patent portfolio and maintained this abandonment for many years. This longstanding acquiescence to the validity of Align’s patents, including patents related to those currently challenged by Petitioner, confirms the parties’ settled expectations of validity for Align’s patents, including the patent subject to the instant petition.

Nor is this acquiescence limited to the particular patents already challenged—Petitioner’s raising of challenges to patents not asserted in district court shows that Petitioner was aware of Align’s patent portfolio more broadly, yet abandoned any challenges for many years. More particularly, Petitioner and its real parties in interest have shown their longstanding awareness of other patent families of Align, including the patent family of the ’091 patent. As noted in the petition (pp. 23-24), the ’091 patent is in the same family as U.S. Patent No. 9,655,691 (the ’691 patent, EX1002), which issued in 2017. The ’691 patent was discussed in the specification of International Patent Application No. PCT/US2018/035384, filed on May 31, 2018, by Bay Materials, LLC. EX2009, [0107]. Petitioner has admitted that Bay Materials is a “related company” to ClearCorrect; that Bay Materials, like ClearCorrect, is “a member of the Straumann Group”; that the Straumann Group acquired ClearCorrect in 2017 and Bay Materials in 2019; and

that Bay Materials produces the plastic used in the ClearCorrect aligners accused in the parallel litigation. EX2008, ¶¶4, 18, 139, 141. Bay Materials is thus related to both Petitioner and real-parties-in-interest Institut Straumann AG and Straumann USA, LLC, confirming the longstanding knowledge of the '691 patent family by Petitioner and related parties since 2018.

Moreover, Petitioner and its affiliate entity Bay Materials, in the petition and elsewhere, have argued that the relevant field is unpredictable. In IPR2022-01214 of U.S. Patent No. 10,946,630,⁵ Bay Materials, an entity co-owned with and represented by the same counsel as Petitioner here, advanced arguments that undermine the positions Petitioner takes in the present IPR. *3M Co. v. Bay Materials, LLC*, IPR2022-01214, Paper 21 (Apr. 12, 2023). In that IPR, Bay Materials argued that variations of physical properties of layered, multi-material aligners behaved unpredictably so as to support non-obviousness. *See id.*, 44, 46-47 (arguing that various properties, including layer thickness and other material properties, affected multilayer aligners' properties including modulus and rigidity

⁵ U.S. Patent No. 10,946,630's earliest claimed priority date is May 31, 2017; years after the effective filing date of the '613 patent. EX2010; *see* Pet., 11, 13, 15 (identifying '613 patent as having a "May 14, 2012, priority date").

“in unpredictable ways”). Stuck with its prior arguments to the Office, Petitioner here attempts unconvincingly to cabin this unpredictability to selections of particular polymers “without guidance to do so.” Pet., 22 n.4; *see also id.*, 14 n.3 (further asserting that manufacturing methods have unpredictable effects on multi-layered material compositions). Yet it now inconsistently proposes combinations in which it selects materials to meet the claims without any specific “guidance” to select the particular combination of materials recited. *See id.*, 27-73 (advancing multi-reference combinations to select various configurations of materials and layers). Petitioner’s failure to square its obviousness arguments with its statements regarding the art’s unpredictability further undermines the petition’s case.

Thus, in view of the settled expectation of the parties, Petitioner’s waste of Office resources, and the overall weakness of the petition, the factor 6 considerations weigh in favor of discretionary denial.

Accordingly, given the totality of the circumstances present in this case, discretionary denial is justified.

B. Advanced Bionics Weighs in Favor of Discretionary Denial under §325(d)

The Director should exercise discretion to not institute this challenge under 35 U.S.C. §325(d) because (1) the same or substantially the same art or arguments were previously presented to the Office; and (2) Petitioner fails to demonstrate that

the Office erred in a material manner. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GMBH*, IPR2019-01469, Paper 6 at 8-9 (Feb. 13, 2020) (precedential). As detailed more below, the petition relies on art and arguments explicitly considered by the Office, and Petitioner fails to show that the Office erred in a material manner in its prior evaluations. As the petition's obviousness challenges merely rehash issues already resolved by the Office, the petition should be denied under §325(d).

1. Advanced Bionics Step 1

The petition advances grounds based on art and arguments identical to or substantially similar to those already considered by the Office and overcome during prosecution. *See Advanced Bionics*, Paper 6 at 9-10 & n.10 (listing *Becton, Dickenson* factors).

The petition asserts four grounds against the '091 patent claims, each applying a combination of three, four, or five references. *See Pet.*, 6. Ground 1 alleges obviousness over Kalili, Texin 990R, and Porter; ground 2 adds Wen; and ground 3 alleges obviousness over Tadros, Kalili, Porter, and Texin 990R; and ground 4 maps a combination of all five references (Tadros, Kalili, Porter, Texin 990R, and Wen) to all challenged claims. *Id.* As Petitioner acknowledges, each of Tadros, Kalili, Wen, and Texin 990R was disclosed to the Office and considered by the examiner during prosecution of the '091 patent. *See Pet.*, 4; *Ecto World*,

LLC v. Rai Strategic Holdings, Inc., IPR2024-01280, Paper 13 at 3-5 (May 19, 2025) (precedential §A) (disclosure on IDS satisfies *Advanced Bionics* step 1). In the parent '655 application, each of these references were each disclosed in information disclosure statements respectively containing only small numbers of references. See EX1011, 661-63 (examiner-signed IDS disclosing Wen (foreign patent document no. 6) along with only 17 other documents), 728-29 (examiner-signed IDS disclosing Kalili (U.S. patent document no. 7) and Texin 990R (non-patent literature document no. 1) together along with just 10 other documents), 858-59 (examiner-signed IDS disclosing Tadros (U.S. patent document no. 7) along with just 13 other documents); cf. *Ecto World*, Paper 13 at 7 & n.3 (noting 25 references or fewer as a size typical for an IDS). And during prosecution of the application leading to the '091 patent, the examiner applied Tadros, Kalili, and Texin 990R, in combination with other references, in an office action. EX1018, 108-12. The examiner also discussed Tadros and Kalili, as well as numerous other references, in detail in the notice of allowance, concluding that the prior art failed to anticipate or render obvious the recited limitations. EX1017, 159-60. The examiner thus conducted a thorough, searching evaluation of the prior art during prosecution.

Not only does Petitioner concede that the examiner substantively considered the primary references applied in the current IPR, but they were also considered for

parallel claims in the parent '655 application and allowed upon a showing of secondary indicia that was found persuasive by the examiner. EX1011, 882; *see also id.*, EX1011, 661-63, 728-29, 858-59; *cf. Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1347 (Fed. Cir. 2001) (examiner presumed follow rules prescribed by MPEP); MPEP §609 (“Once the minimum requirements of [regulations governing IDS submissions] are met, the examiner has an obligation to consider the information.”).

Petitioner identifies only one reference—Porter (“Dishwasher Safe” plastic)—that was not expressly evaluated during previous Office proceedings. But this reference is at best cumulative to the art already considered by the Office. The petition relies on Porter only for a teaching of a copolyester with certain properties, yet the examiner in both the '091 patent and its parent, the '613 patent, expressly considered prior art with disclosures to which Porter adds no meaningful new teachings. *See* EX1011, 717 (applying U.S. Patent No. 7,641,828 to DeSimone in office action); EX1018, 273 (“The closest prior art of record is considered to be DeSimone et al. (U.S. 7,641,828)....”); EX2011, 5:66-67 (copolyesters), 4:25-35 (material properties); EX1018, 108-02, 159-60 (applying and allowing claims over “DESIMONE ET AL (US 2006/0078841)”); EX2012, [0017] (copolyesters), [0006] (material properties). Accordingly, Petitioner’s only basis to distinguish its

grounds from the art applied during prosecution—Porter’s teachings—are merely cumulative to the art already considered and overcome during examination.

The petition’s obviousness grounds also acknowledge, but leave unaddressed, arguments considered by the Office. As noted above, during prosecution of the parent ’655 application, the examiner considered a declaration by Dr. Chunhua Li indicating the presence of objective indicia of nonobviousness associated with multilayer aligners including the materials and properties also recited in the claims of the ’091 patent, including unexpectedly positive results relative to the closest prior art. *See* EX1011, 598-606. *Compare* EX1001, claims; *with* EX1004, claims (reciting parallel limitations). This evidence included, for example, findings of unpredictability in the combinations of materials used in multi-layer aligners and clinical trial results showing unexpectedly superior performance for aligners made with a mix of hard and soft layers of the type recited in the claims of the ’091 patent, relative to the closest prior art aligners. EX1011, 600, 602-05.⁶ The examiner indicated in the reasons for allowance that

⁶ As discussed above, Bay Materials, LLC, made similar arguments to the Board in IPR2022-01214 of U.S. Patent No. 10,946,630 in defending its own patent, and these statements are attributable to Petitioner and its real-parties-in-

the affidavit was found persuasive, especially regarding the showing of aligners with the claimed configurations showing “unexpectedly positive results over previously known appliances.” EX1011, 847. “Objective indicia of nonobviousness must be considered in every case where present.” *E.g., Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016); *see Gilead*, Paper 17 at 52-53 (unexpected results previously found by Office must be persuasively addressed in petition); *Coalition*, Paper 14 at 17-18 (same). Thus, while the petition advances the same art and arguments, it does so in an improper, artificially limited manner compared to the more expansive consideration by the Office previously.

Petitioner concedes that the Office had considered and credited the presence of objective indicia showing nonobviousness of the claims during prosecution of the '091 patent's parent, the '655 application. Pet., 25-26. Yet the petition presents neither argument rebutting the examiner's reasoning nor evidence showing the absence of the unexpectedly positive properties described by Dr. Li. To the

interest (e.g., Institut Straumann AG) as both Petitioner and Bay Materials are co-owned as members of the Straumann Group. *See supra* §III.A.6; EX2008, ¶¶139-41.

contrary, Petitioner concedes that the field is unpredictable, including with respect to the specific types of material substitutions Petitioner proposes. *See* Pet., 22 n.4 (“The efficacy of repositioning teeth using dental aligners that either alter the relative placement of the hard and soft layers, or replace layers with other polymers without guidance to do so, is unpredictable...”); *see also id.*, 43 n.10. Accordingly, the multi-reference obviousness grounds not only seek to recycle the same prior art, but improperly do so by ignoring the objective indicia previously recognized during prosecution.

In sum, the petition presents grounds relying on art and arguments already considered by the Office. As a result, step 1 of *Advanced Bionics* weighs in favor of discretionary denial and the Director should exercise discretion not to institute the petition under §325(d).

2. Advanced Bionics Step 2

Discretionary denial is further warranted under the second step of the *Advanced Bionics* framework because the petition has failed to sufficiently point out how the Office erred in its evaluation of the asserted prior art and the eligibility of the challenged claims. *See Advanced Bionics*, Paper 6 at 10-11. The petition does not argue that the examiner erred, nor does the petition present evidence addressing the examiner’s consideration of the art or the arguments made during prosecution. The petition concedes that it relies on art previously disclosed during

prosecution and considered by the Office, yet it identifies no error in the Office's consideration of that evidence. Pet., 4. Indeed, far from contending that the examiner was unaware of the teachings of this art, the petition it concedes that the Examiner substantively considered the teachings of each of Tadros, Kalili, and Texin 990R. See Pet., 4; see also *id.*, 26-27 (noting examiner had considered combinations including all three references).

The petition asserts that the “Examiner did not apply any prior art disclosing pure copolyester layers, such as *Porter*.” Pet., 27. This assertion is doubly false: First, Porter never discloses a material with *pure copolyester layers*; Porter discusses use of a copolyester (Tritan) for various types of dishware, water bottles, and the like, but has no discussion of use of a multilayer material with copolyester layers in any application, much less multilayer appliances. See generally EX1006; Pet., 9-10, 31-32, 38-40, 55-57 (not relying on Porter for a teaching of *layers*, only for teaching the existence of Tritan copolyester). Second, DeSimone was expressly considered by the examiner, who noted its teachings regarding use of copolyester in aligners and expressly discussed whether it would have been obvious to use such teachings in a layer of a multilayered appliance. See EX1017, 256-57.

Moreover, as noted above, objective indicia of nonobviousness, where present, must be addressed. See *Apple*, 839 F.3d at 1048. The petition itself admits that such objective indicia were found persuasive by the examiner during

prosecution of the '091 patent's parent, the '655 application. Pet., 26-27 (citing EX1011, 846-47). The petition's failure to address or present evidence rebutting the objective indicia recognized during prosecution is not only a fatal defect in its *prima facie* case, but it is also fatal under §325(d). *See, e.g., GlaxoSmithKline Consumer Healthcare Holdings (US) LLC v. Cipla Ltd.*, IPR2020-00371, Paper 7 at 18-21 (denying institution under §325(d) where petition failed to rebut examiner's findings of secondary indicia).

To the extent Petitioner's reply includes a belated attack on the objective indicia found by the examiner, such argument would be untimely, unsubstantiated, and misplaced. Such arguments would be untimely because the time to address objective indicia found during prosecution is in the petition, as part of its threshold burden. *See Gilead*, Paper 17 at 52-53; *Coalition*, Paper 14 at 17-18; Patent Trial and Appeal Board Consolidated Trial Practice Guide 73 (Nov. 2019) ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a *prima facie* case of unpatentability."). Moreover, without expert analysis of the examiner's findings, any reply by Petitioner would be no more than unsubstantiated attorney argument. And in any event, such argument would be misplaced, as it would be directed to the weight the examiner attributed to the evidence, contrary to the Board's admonition that "[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be

said that the Office erred in a manner material to patentability.” *Advanced Bionics*, Paper 6 at 9. The weight given to evidence of nonobviousness might be the type of issue about which reasonable minds can disagree, but such disagreement is insufficient to demonstrate material error. Thus, having failed to advance evidence or arguments countering the examiner’s finding of objective indicia of nonobviousness, Petitioner cannot now show that the Office materially erred in a manner reasonable minds could not disagree.

In sum, Petitioner advances its grounds of unpatentability with no evidence or argument undermining the Office’s prior consideration of the same art or the Office’s findings of objective indicia of nonobviousness. Accordingly, *Advanced Bionics* weighs in favor of discretionary denial and the Director should exercise discretion not to institute the petition under §325(d).

IV. CONCLUSION

For at least the reasons above, Patent Owner respectfully requests that the Director exercise discretion to deny institution of the petition.

Respectfully submitted,

Date: July 8, 2025

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
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CERTIFICATE OF COMPLIANCE

Pursuant to §42.24(d) and the Director's Memorandum on Interim Processes for PTAB Workload Management, the undersigned certifies that this paper contains no more than 14,000 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 7058 words.

Respectfully submitted,

Date: July 8, 2025

/ Michael T. Rosato /

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V. APPENDIX

Exhibit No.	Description
2001	Claim Construction Order, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 5, 2025)
2002	Scheduling Order, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Aug. 5, 2024)
2003	Fourth Scheduling Order, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , 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, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 6, 2025) (ECF No. 187)
2007	Preliminary Claim Constructions, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jan. 21, 2025)
2008	Defendants’ Answer, Affirmative Defenses, and Counterclaims (Public Version), <i>Align Technology, Inc. v. ClearCorrect Operating LLC</i> , 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	U.S. Patent Pub. No. 2006/0078841 to DeSimone et al.

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Patent Owner's Brief In Support of Discretionary Denial and accompanying Exhibits 2001-2012 were served on July 8, 2025, on the Petitioner at the electronic correspondence address of the Petitioner as follows:

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