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 11,648,091

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW PURSUANT TO 37 C.F.R. §42.75

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Pursuant to 37 CFR § 42.75(c), Patent Owner submits this request for Director Review of the Director's Discretionary Denial Decision (DD Decision, Paper 14) and the Decision to Institute Trial (DI, Paper 17).

I. Introduction

This inter partes review arises from an ongoing intellectual property dispute between Straumann Group, a Swiss-based multinational conglomerate, and Align Technology, Inc. (Patent Owner), a U.S.-based dental technology innovator and manufacturer of Invisalign® orthodontic treatment system. Institut Straumann AG, which manages the Straumann Group, is a real party in interest in this proceeding. The petitioner, ClearCorrect Operating LLC, together with Bay Materials, LLC, and Chinese entity AlliedStar Medical Equipment Co., Ltd. (a manufacturer of intraoral scanners) are all part of the Straumann Group. Moreover, Straumann and ClearCorrect have recently announced strategic partnerships and ownership stakes in Shanghai Smartee Denti-Technology Co., Ltd., one of China's largest dental companies.

On July 8, 2025, Patent Owner moved for discretionary denial in light of an early scheduled trial date (May 2026) in the co-pending district court proceedings predating the projected FWD date (November 2026) by nearly six months. Nevertheless, on August 29, 2025, the Director concluded that *Fintiv* did not favor discretionary denial based on Petitioner's argument that time-to-trial statistics

dictated “trial will not begin until November 2027.” DD Decision, 2. The Director then referred the petition to the merits panel.

Petitioner’s argument about the trial’s timing now has been proven to be incorrect. On October 2, 2025, the district court confirmed a “hard” trial date for June 22, 2026—***nearly 5 months before the FWD due date in this case***. This “hard” trial date came at Petitioner’s urging (in conflict with Petitioner’s argument to the Director). Petitioner assured the district court no less than three times that the case was “on track” for a June 2026 trial. As the district court trial undoubtedly will be held well in advance of any FWD, discretionary denial is warranted.

Furthermore, considerations under 35 U.S.C. § 325(d) further support denial. The petition’s grounds rehash the same prior art applied and overcome during prosecution. The only new art advanced in the petition has nothing to do with orthodontics and is cumulative at best. Indeed, the Director’s Discretionary Denial Decision identified no basis for a finding of material error in this case. Nevertheless, the Board instituted review. The panel apparently mistook the Director’s referral as a mandate to institute review despite the deficiencies of the case brought in the petition. Holding a trial to rehash art and argument already considered during prosecution with no showing of material error is a poor use of Office resources.

Finally, denial of institution is warranted due to Petitioner's failure to identify all real parties in interest. As Patent Owner noted in its discretionary denial briefing, the aligners accused in the parallel district court litigation are manufactured using materials from Bay Materials, LLC. Bay Materials is part of the Straumann Group headed by identified real party in interest Institut Straumann AG (*see* EX2008, 18-19 ¶18). The arguments advanced by Petitioner in the present IPR are contrary to arguments previously made by Bay Materials in IPR2022-01214, yet Bay Materials has not been named as a real party in interest.

Recent revelations underscore Patent Owner's concerns regarding unnamed interested parties. The named Institut Straumann AG is a large non-US entity. It has affiliations not just with Bay Materials and ClearCorrect, but with multiple Chinese companies unnamed here. After pre-institution briefing was closed, but before the institution decision, Straumann and ClearCorrect publicly announced "strategic partnerships" and ownership stakes in one of the largest Chinese dental companies, Shanghai Smartee Denti-Technology Co., Ltd. Straumann and ClearCorrect characterized this new relationship with a large Chinese competitor as "a forward-looking initiative aimed at shaping the future of the dental industry." These are precisely the types of "[o]paque investment structures" and foreign entities of concern identified the Director's October 28, 2025, memorandum regarding the Precedential Designation of *Corning Optical Communications*. The

Straumann SIRIOS™ intraoral scanner that is subject to the district court action is manufactured by AlliedStar Medical Equipment Co., Ltd., a Chinese entity that is part of the Straumann Group.

In light of the new *Corning* precedent and Petitioner's failure to identify all real parties in interest, institution of this inter partes review should be vacated.

II. Legal Standard

Director review of an institution decision is appropriate when "to avoid unnecessary trials for patent owners," and particularly where the institution decision involves "(a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law." Director Review Process § 2.B. A Director Review request is appropriate, for example, where trial was instituted based on a *Fintiv* analysis in which the overall weighing of the *Fintiv* factors was erroneous. *See Cisco Sys., Inc. v. WSOU Investments LLC*, IPR2025-00188, Paper 14 (Aug. 22, 2025) (vacating institution decision and denying institution where incorrect weight was assigned to *Fintiv* factors).

III. Changed Circumstances Warrant Denial Under *Fintiv*

The Director previously found *Fintiv* did not favor denial based on a projected November 2027 trial date. The district court, however, has now

confirmed a hard trial date of June 2026. Accordingly, the *Fintiv* analysis strongly favors denial.

In its opposition to discretionary denial, Petitioner argued that trial would take place "potentially a full year, after the final written decision." In support, Petitioner cited "time-to-trial" statistics as predicting a "November 2027" trial date. Paper 10 at 17-21.

Accepting Petitioner's argument, the Director found discretionary denial under *Fintiv* inappropriate based on the assumption that the district court trial would be moved and occur well after the projected final written decision deadline of November, 2026. DD Decision, 2. Although that decision acknowledged that trial had been previously scheduled for May 2026, it credited Petitioner's erroneous and gratuitous argument that "trial w[ould] not begin until November 2027." DD Decision, 2. The Director therefore concluded that considerations arising from overlap with the parallel district court proceedings "neither favor[ed] nor counsel[ed] against discretionary denial." *Id.*

In view of current circumstances, the Director's reliance on Petitioner's assertion of a November 2027 trial date was misplaced. In a hearing on October 2, 2025, the district court stated it was setting a "hard trial date of June 22, 2026, before Judge Albright." *Align Technology, Inc. v. ClearCorrect Operating, LLC*, No. 6-24-cv-00187 (W.D. Tex. Oct. 2, 2025), dkt. 271, Hearing Tr. 44:22-45:2. At

this hearing, Petitioner's counsel thrice asserted that the district court case was "on track" and that Petitioner was "fine with [June 22, 2026] for a trial date":

> we're on track for a trial in June. Align has proposed June 22nd. We're fine with that. You know, we're fine with that for a trial date. … we're on track. We're on track to bring this case to resolution in June, and we'd agree to their trial date….

Id., 44:7-16. As shown, Petitioner's argument before the district court stands in stark contrast to its argument to the Director. Accordingly, and contrary to Petitioner's time-to-trial argument relied on in the Discretionary Denial Decision, there has been no significant delay in the scheduled trial date even after rescheduling. The trial date remains "on track" and will occur nearly five months before the projected final written decision deadline. *See also id.*, dkt. 259 (Oct. 2, 2025) (minute entry) ("The jury trial will be set for June 22, 2026 at 9am"); *id.*, dkt. 264 (Oct. 10, 2025) (scheduling order confirming June 22, 2026, trial date).

In the Discretionary Denial Decision, the Director indicated that the *Fintiv* factors were neutral based on an assumption that the district court trial date would occur in November 2027. DD Decision, 2. Because, at Petitioner's own urging, the district court trial will precede the projected final written decision date by several months, the *Fintiv* factors favor non-institution to eliminate duplicative efforts between parallel proceedings. As the Director recently held, where no stay has been granted and a district court trial is scheduled approximately three months

before the statutory date for the Board's final written decision, discretionary denial is favored even where petitioner has offered a *Sotera* stipulation. *Cisco*, IPR2025-00188, Paper 14 at 3. Here, trial is scheduled almost five months before the statutory date for the Board's final written decision and no stay has been granted; accordingly, the *Fintiv* analysis even more strongly favors non-institution. *Cf. Arm Ltd. v. Daedalus Prime LLC*, IPR2025-00207, Paper 14 at 2-3 (where change of circumstances shifts *Fintiv* factors, revision of discretionary denial decision is appropriate).

IV. Section 325(d) Favors Non-Institution

Prior consideration by the Office favors denial here. As discussed in Patent Owner's briefing, the present petition relies primarily on prior art references not only expressly considered by the Examiner, but also already applied in office actions during prosecution and overcome by the applicant. The petition at best pleads a case where reasonable minds might disagree as to whether the newly raised reference meaningfully impacts the obviousness analysis. But as the Board has explained repeatedly, rehashing prior art and argument already considered during prosecution is a poor use of Board resources and unduly prejudicial to patent owners. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (Feb. 13, 2020) (precedential).

No material error has been identified because none exists. In the Director's Discretionary Denial Decision, potential material error was identified only for IPR2025-00818 and IPR2025-00819 on the basis that those cases did not face an office action applying the prior art combination specifically raised in this case. DD Decision, 4. The Director's decision did not identify any material error in this case, which is the logical conclusion from the potential error identified for the -818 and -819 IPRs.

Indeed, during prosecution, in an office action of Nov. 19, 2022, the Tadros, Kalili, and TEXIN 990R references were applied by the Examiner. EX1018, 108-13; *see also id.*, 159-60 (distinguishing references again in notice of allowance). The petition relies on these same references. *See* Pet., 4-5 (conceding references previously applied). Aware it was recycling the same references faced during *ex parte* prosecution, Petitioner offered the Porter reference (EX1006) as a token "new" reference, but Porter is uncompelling and irrelevant. Porter discusses use of a BPA-free plastic for dishwashable items, but it says nothing about orthodontics or orthodontic appliances, or even incorporation into layers.

Moreover, Petitioner's argument about turning to Porter for a non-polycarbonate option is misplaced, as non-polycarbonate options, too, were already considered by the Examiner. For example, Tadros and Kalili, already considered and applied by the Examiner, disclose numerous non-polycarbonate, BPA-free

options. EX1003, [0022]; EX1005, [0053]. As such, even taking Petitioner's proffered rationale at face value, Porter adds nothing. It is an uncompelling reference directed to unrelated applications of dishwashable kitchenware, and is cumulative at best to the art considered by the Examiner.

In his Open Letter and Memorandum of October 17, 2025, the Director noted that the bifurcated process for discretionary considerations had "inadvertently produced extraordinarily high institution rates," as the Board appeared to have taken referrals as a mandate to institute trial. John A. Squires, *An Open Letter From America's Innovation Agency*, 2 (Oct. 17, 2025). The concerns raised by the Director in his Open Letter and Memorandum apply in this case.

Accordingly, institution should be vacated.

V. Petitioner Has Failed to Identify All Real-Parties in Interest in These Proceedings

A petition for *inter partes* review may be considered only if "the petition identifies all real parties in interest." 35 U.S.C. § 312(a)(2). Under prior precedent, the Board did not enforce the requirement to name all real parties in interest unless an estoppel or time bar was implicated. *See SharkNinja Operating LLC v. iRobot Corp.*, IPR2020-00734, Paper 11 at18-20 (October 6, 2020). On September 26, 2025, the *SharkNinja* case was de-designated, rendering it no longer precedential and restoring the requirement that all real parties in interest be named in the petition.

The newly designated precedential decision in *Corning Optical Communications RF, LLC v. PPC Broadband Inc.* now controls the real-party-in-interest analysis. IPR2014-00440, Paper 68 (PTAB Aug. 18, 2015) (designated precedential except as to § II.E.I, which would have shifted the burden to Patent Owner to show that a party is a real party in interest.). In the memorandum designating *Corning* as precedential and de-designating *SharkNinja*, the Director emphasized the renewed importance of the real-party-in-interest requirements. The Director highlighted the concern that foreign-backed actors have sought to manipulate the U.S. patent system and have entered into improper entanglements with litigants in IPR proceedings. *See* Memorandum, Precedential Designation of *Corning Optical Communications RF, LLC v. PPC Broadband Inc.*, IPR2014-00440, Paper 68 (PTAB Aug. 18, 2015) (except for § II.E.1) ("RPI Memo"), 2-3 (Oct. 28, 2025) (identifying multiple Chinese entities associated with a "substantial and increasing number of IPRs"). As the Director explained, vigorous enforcement of the real-party-in-interest requirements is key to prevent "misuse of AIA proceedings by foreign adversaries." *Id.*, 4.

This IPR is of heightened concern in view of the recent de-designation of *SharkNinja*, the precedential designation of *Corning*, and the entanglements of Institut Straumann AG, the parent company of ClearCorrect.

As Patent Owner noted in its discretionary denial briefing, Straumann is the parent company of Bay Materials, LLC, the manufacturer of the aligners accused in the district court litigation. *See, e.g.*, Paper 7 at 7, 23-24; EX1023, ¶¶4, 42; EX2008, 8-9 ¶18. As Patent Owner has previously explained, Bay Materials has advanced arguments in prior proceedings before the Board that are inconsistent with those Petitioner advances here. These include statements regarding unpredictability in the art as well as arguments regarding objective indicia of non-obviousness. *See* Paper 7 at 24-25; *see 3M Co. v. Bay Materials, LLC*, IPR2022-01214, Paper 21 at 44, 46-47, 51-62 (Apr. 12, 2023).

For example, Petitioner alleges "inconsistency between the characteristics of the *soft-hard-soft* ST30 aligner" for which the Examiner found unexpected results during prosecution and "Petitioner's *hard-soft-hard* aligner product" accused in litigation, suggesting the absence of secondary indicia for Petitioner's product. Paper 15 at 1-2. Yet during the *3M* case, involving a patent with a later priority date, Bay Materials argued that there were secondary indicia of non-obviousness associated with Petitioner's product to claims encompassing a three-layer aligner comprising a hard co-polyester layer, a soft elastomer layer, and a third layer. *See* IPR2022-01214, Paper 21 at 51-62. *Compare id.*, *with* EX1001, claim 1. Despite Bay Materials' entanglement with Petitioner and Straumann, and contrary to Petitioner's duty under 35 U.S.C. § 312(a)(2) and *Corning*, Petitioner has still not

identified Bay Materials as a real party in interest. *See Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996) ("where a party successfully urges a particular position in a legal proceeding, it is estopped from taking a contrary position in a subsequent proceeding"); *cf. Taylor v. Sturgell*, 553 U.S. 880, 894 (2008) (nonparty preclusion triggered by various substantive legal relationships); *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1318 (Fed. Cir. 2018) (estoppel applies between related parties in privity).

Additionally, Straumann, a non-US conglomerate, has been active in acquiring ownership and forming strategic partnerships with various Chinese entities. Industry press and Straumann's own public statements openly confirm this. *See, e.g.*, *Straumann Group acquires AlliedStar, an intraoral scanner provider in China* (Sep. 21, 2023)[1] ("Straumann Group has signed an agreement to acquire AlliedStar, an intraoral scanner (IOS) manufacturer in China"); *Straumann Group delivers strong organic growth and confirms full-year outlook*, (Oct. 29,

[1] https://www.straumann.com/content/dam/data/media-release/en/2023/c6d0c389-f410-49a0-88e7-a1be681d5567/Straumann_Group_Media+release_AlliedStar_EN.pdf

2025)[2] ("A key milestone this quarter was the launch of the SIRIOS X3 intraoral scanner…. serving as the entry point into Straumann Group's digital ecosystem…."); NIH Access GUDID Straumann SIRIOS X3 (06973993440303) (Aug. 22, 2025)[3] (Straumann SIRIOS manufactured by AlliedStar). Recent announcements also confirm that ClearCorrect is equally entangled with these entities, not just Straumann. *See, e.g.*, *Straumann Group transforms its orthodontics business through new strategic partnerships and a sharpened market approach* (Oct. 29, 2025)[4] ("Strategic partnership with Smartee to enhance ClearCorrect's value proposition," including transferring "clear aligner manufacturing to Smartee" by "early 2026"); *Straumann Group refocuses orthodontics unit with new partnerships* (Nov. 6, 2025)[5] (Straumann "has entered a strategic technology partnership with Smartee Denti-Technology, a leading

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[2] https://www.straumann.com/group/en/home/media/newsroom/mr/details.mr-detail.en.0314b136-7f83-4879-8d89-594363e2b7d9.html

[3] https://accessgudid.nlm.nih.gov/devices/06973993440303

[4] https://www.straumann.com/co/es/discover/news/about/archive/news.mr-detail.en.3d40e073-d5ab-441f-b468-17feb328b077.html

[5] https://www.dental-tribune.com/c/straumann/news/straumann-group-refocuses-orthodontics-unit-with-new-partnerships/

provider of aligners and digital orthodontic solutions in China," including an "equity stake in Smartee"). But Petitioner has disclosed none of these material relationships to the Office or identified these Chinese entities as a real party in interest in the present proceedings.

Accordingly, as Petitioner has failed to satisfy its obligation to identify all real parties in interest in this proceeding, institution should be vacated.

VI. Conclusion

For the reasons set forth above, Petitioner respectfully requests Director review and a decision withdrawing institution of trial in IPR2025-00821.

Respectfully submitted,

Dated: November 20, 2025

/ Michael T. Rosato /
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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Director Review Request was served on November 20, 2025, at the following electronic service addresses:

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