

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
Patent 10,791,936

**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 13) and the Decision to Institute Trial (DI, Paper 16).

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.—the manufacturer of the accused intraoral scanner infringing U.S. Patent No. 10,791,936—are all part of the Straumann Group. Moreover, Straumann and ClearCorrect have recently announced strategic partnerships and ownership stake 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, findings made by the merits panel in the institution decision regarding the cited prior art actually confirm that denial was warranted all along. Petitioner had argued material error on the basis that the Boerjes reference relied upon in all IPR grounds was not before the Examiner. Per Petitioner, Boerjes supplied the limitation the Examiner found missing from the art—that is, building a composite digital model from a pre-modification scan and a later scan after physical modification of teeth (e.g., partial tooth removal for crown preparation). The merits panel disagreed, expressly finding Boerjes lacked this disclosure. DI, 18-19.

Nevertheless, the Board instituted review. The panel apparently mistook the Director’s referral as a mandate to institute review despite the actual facts. But

patentability of the '936 patent was already adjudicated in prior IPR2021-01241, which failed on the merits. Conducting another review based on indisputably deficient art is unduly prejudicial to Patent Owner and 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. Unnamed Bay Materials is part of the Straumann group headed by identified real party in interest Institut Straumann AG (*see* EX1039, 18-19 ¶18).

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 infringing Straumann SIRIOS™ intraoral scanner 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* not favoring 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 8 at 25, 27-28.

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. The Board Erred in Granting Institution

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.” 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.

The merits panel determined that the newly asserted Boerjes reference, in fact, did not disclose limitation 1(h) or the corresponding limitations of the other independent claims. DI, 18-19. Although Petitioner cited Boerjes for this limitation in its petition challenge (**and** as the basis of alleged material error in prior reviews), the merits panel recognized that Boerjes does not teach or suggest “stitch[ing] together before-and-after models that have undergone an intervening physical

change,” as the claims require. DI, 19. Thus, the panel’s own findings dispel any concerns of material error.

Although the Board found that grounds 2 and 4 (which added the Geng reference) had a reasonable likelihood of success, the Board did not find that Geng supplied the missing limitation. Instead, the panel found only that Geng taught replacing a surface portion of a scan with additional data—not stitching together *before-and-after models that have undergone an intervening physical change*. DI, 24. Petitioner did not argue—and the panel did not find—that Geng taught limitation 1(h), whether alone or in combination with Boerjes. As grounds 2 and 4 did not remedy the deficiency in grounds 1 and 4 (*see* DI, 19, 24-25), the decision to institute based on those grounds was erroneous.

Given the recognized deficiency of the cited art, it appears the Board here mistook the Director’s referral as a signal that institution was required. But no such instruction is found in that decision. After incorrectly judging the *Fintiv* factors to be neutral, the Discretionary Denial Decision also addressed considerations under 35 U.S.C. § 325(d). DD Decision, 3-4. The Director indicated that discretionary denial under Section 325(d) was not appropriate because the Examiner may have erred during prosecution of the ’936 patent. *Id.*, 3. Specifically, the Director noted that different claims of a different family member patent had been found

unpatentable in IPR2019-00134.¹ The Examiner was aware of that IPR, and while he did not expressly mention the IPR in the reasons for allowance, he did expressly find that the art applied in the IPR did not teach the independent claims' limitations directed to "where the intra-oral cavity (e.g. dentition) is modified in between the scans (e.g. subjected to a surface preparation)," and also that the prior art taught away from this limitation. EX1002, 96-97.

Of course, the claims in the '936 patent are materially different compared to the claims of the '192 patent addressed in IPR2019-00134—the claims in that latter case do not recite the specific limitation at issue here. The '936 patent's claims require generating a composite model from two structurally distinct scans, before and after a physical change. By contrast, the '192 patent's claims could be met by stitching together old and new data of the same structure, without an intervening physical change. See Paper 15 at 2; EX1026, 29, 46-47. No party disputes this distinction. Indeed, Petitioner here does not rely on the art at issue in the IPR2019-00134. The Institution Decision also did not find the -00134 IPR or the different combination of references advanced in that IPR had any bearing on this case. See *generally* DI.

¹ As discussed, the '936 patent itself was previously challenged in IPR2021-01241. That IPR was denied on the merits.

As limitation 1(h) is now undisputedly lacking in the art, any attempt by Petitioner to rely on expert opinion to supply it falls short. Such argument is precisely the type of case that the Director has identified as ripe for denial—particularly as validity has already been adjudicated on the merits in a prior, unsuccessful IPR challenge. See Memorandum, *Interim Processes for PTAB Workload Management* (USPTO Dir. Mar. 26, 2025) (“Workload Memo”), 2 (denial appropriate where improper reliance on expert opinion implicated); see also *3Shape A/S v. Align Tech., Inc.*, IPR2021-01241, Paper 16 (denying institution on merits for failing to teach this limitation).

In sum, the ’936 patent has been reviewed multiple times. In each case, no identified prior art taught the claim requirement to stitch together before-and-after models that have undergone an intervening physical change. First, during prosecution, the Examiner found the prior art lacked this disclosure. Second, in IPR2021-01241, the Board reached the same conclusion. And third, the merits panel here acknowledged that the Boerjes reference lacks this limitation and identified no other prior art reference supplying it.

Accordingly, far from favoring institution, the merits favor non-institution. The panel’s determination that Boerjes does not disclose limitation 1[h] undermines Petitioner’s material error argument advanced in opposition to

discretionary denial. Further, the panel’s decision to institute in the absence of prior art disclosing the limitation recited in claim 1[h] was erroneous.

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 at 18-20 (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; EX1038, ¶4; EX1039, ¶141. As Patent Owner has previously explained in companion proceedings, 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* IPR2025-00818, Paper 7 at 23-24; *see* *3M Co. v. Bay Materials, LLC*, IPR2022-01214, Paper 21 at 44, 46-47, 51-62 (Apr. 12, 2023). 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.

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)² (“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, 2025)³ (“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)⁴ (Straumann SIRIOS manufactured by AlliedStar). Recent

² https://www.straumann.com/content/dam/data/media-release/en/2023/c6d0c389-f410-49a0-88e7-a1be681d5567/Straumann_Group_Media+release_AlliedStar_EN.pdf

³ <https://www.straumann.com/group/en/home/media/newsroom/mr/details.mr-detail.en.0314b136-7f83-4879-8d89-594363e2b7d9.html>

⁴ <https://accessgudid.nlm.nih.gov/devices/06973993440303>

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)⁵ (“Strategic partnership with Smartee to enhance ClearCorrect’s value proposition,” including manufacturing of dental aligners by Smartee); *Straumann Group refocuses orthodontics unit with new partnerships* (Nov. 6, 2025)⁶ (Straumann “has entered a strategic technology partnership with Smartee Denti-Technology, a leading 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 IPR2025-00817.

⁵ <https://www.straumann.com/co/es/discover/news/about/archive/news.mr-detail.en.3d40e073-d5ab-441f-b468-17feb328b077.html>

⁶ <https://www.straumann.com/clearcorrect/en/doctors/digital-workflow.html>

Respectfully submitted,

Dated: November 13, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Director Review Request was served on November 13, 2025, at the following electronic service addresses:

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