

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. IPR2025-00819
U.S. Patent No. 11,154,384

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL**

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I. INTRODUCTION

Discretionary denial under 35 U.S.C. § 325(d) is inappropriate because the Petition presents new prior art not applied by the Examiner, new prior-art combinations, and new arguments not yet presented to the Office. Importantly, the Office's analysis during prosecution suffered from several material errors that warrant referral. While the Petition details these errors and new art and arguments, Patent Owner's Brief in Support of Discretionary Denial ("Request") fails to substantively address them, much less refute the Office's errors or distinguish the art.

The Examiner materially erred by failing to consider the *Porter* reference or any similar prior art. *Porter*, which was not of record, discloses a compelling motivation to modify other prior art to arrive at the claimed invention. Specifically, *Porter* discloses a replacement for polycarbonate polymers, which can leach harmful bisphenol-A chemicals ("BPAs"). BPA was known to be an endocrine system disruptor and cause certain cancers. *Porter* discloses the properties of an innovative, BPA-free alternative—Tritan copolyester—and describes it as suitable for use in applications where the polymer would be exposed to moisture, elevated temperatures, and hydrolytic attack. Patent Owner does not dispute that this would include dental aligners. Tritan's properties, as disclosed in *Porter*, meet the

limitations for the hard layer recited in the '384 patent claims. Other art cited in the Petition confirms that a POSITA would have been well aware of the BPA issue identified in *Porter*. The Examiner erred by failing to consider this motivation in *Porter* for replacing polycarbonate with Tritan.

The Examiner further materially erred by failing to apply the *Tadros* reference, which was of record but never cited in any rejection. As detailed in the Petition, *Tadros* discloses a three-layer dental aligner with a soft-hard-soft layer configuration, wherein the hard layer is a polymeric blend comprising a copolyester and the outer soft layers may be thermoplastic polyurethanes (“TPUs”). Pet., 9-11. The combination of *Tadros* with the Texin 990R TPU disclosed in *Kalili*, which forms the basis of Ground 1 of the Petition, discloses every limitation of nearly all challenged claims, including every independent claim.

This failure to apply *Tadros* was material. Indeed, *Tadros* was later applied in rejecting “parallel” claims in later-filed patent applications in the same family as the '384 patent (U.S. Patent Nos. 11,648,090 and 11,648,091) and Patent Owner was forced to amend those claims to distinguish *Tadros*. In an effort to distinguish the polycarbonate-copolyester blends in the hard layer of *Tadros*, Patent Owner amended the claims to replace language defining the hard layer as “comprising” a copolyester with narrower language requiring the layers to “consist of” single polymers. If the Examiner for the '384 patent had applied *Tadros* consistently across

all the patents, Patent Owner would have been forced to similarly narrow the '384 patent claims. This material error by the Office strongly favors referral.

Patent Owner's silence regarding these material errors by the Office speaks volumes about their significance. Patent Owner does not dispute that the Examiner never considered *Porter*, never applied any art addressing BPAs or replacing polycarbonate with Tritan, and failed to apply *Tadros* consistent with its use in later prosecution. Unable to justify the Office's errors, Patent Owner simply ignores them—the Request does not use the words “BPA” or “Tritan” once and offers no explanation whatsoever of the Office's inconsistent application of *Tadros* to “parallel” claim limitations. And rather than address the new prior art and arguments, Patent Owner wrongly dismisses them as “cumulative.” Patent Owner's failure to address (much less justify) these material errors or rebut the strong, new obviousness grounds weighs strongly in favor of referral under 35 U.S.C. § 325(d).

Many other considerations also favor referral. Patent Owner has no settled expectations for the '384 patent or the other challenged patents in this family given their recent issue dates (the earliest issued in 2021). Instead, it was Patent Owner who delayed in asserting the challenged patents and never asserted other patents in the same family that issued as early as 2017. Patent Owner's delay weighs against discretionary denial.

The *Fintiv* factors also all either weigh strongly in favor of referral or are neutral. The Petition presents strong merits and Petitioner has submitted a *Sotera* stipulation that mitigates concerns regarding duplicative efforts. Further, trial in the related litigation is likely to occur months or even a full year after any final written decision based on the most recent time-to-trial statistics for the Western District of Texas and Judge Albright specifically. Patent Owner's arguments regarding trial date rely on outdated median time-to-trial statistics and a scheduled trial date that has already been pushed back once based on Patent Owner's inability to comply with the discovery and document production schedule.

Referral is appropriate here to correct material errors by the Office and address the Petition's strong merits based on art and arguments not previously considered by the Office. Petitioner thus respectfully asks the Director not to exercise discretion to deny the Petition.

II. EVIDENCE OF EXAMINER ERROR AND NEW, NON-CUMULATIVE PRIOR ART SUPPORTS REFERRAL UNDER *ADVANCED BIONICS*

The Director should refer the Petition and decline to discretionarily deny institution under 35 U.S.C. § 325(d) given: (1) the new prior art, combinations, and arguments in the Petition not previously presented to the Office; and (2) the material errors committed by the Office during prosecution. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (PTAB Feb.

13, 2020) (precedential). Patent Owner's assertions to the contrary rely on unsupported attorney argument and misstate the facts regarding the prior art and prosecution history.

A. Step 1: The Petition Includes New Prior Art and New Arguments That Were Not Previously Presented to the Office

1. *Porter*, Which Was Not of Record, Establishes a Motivation to Replace Polycarbonate in the Prior Art with a Polymer Having the Exact Properties Claimed

Patent Owner concedes that *Porter* was never presented to the Office. Req., 28. As detailed in the Petition and supporting evidence, *Porter* discloses that polycarbonate had been discovered to leach harmful BPAs, which were known to be an endocrine disruptor and cause certain cancers. *See, e.g.*, Pet., 4, 9, 14, 57-58; EX1007, ¶¶ 88-97. *Porter* acknowledges this concern in the art and recommends a specific polymer as a replacement for polycarbonate—an innovative copolyester called “Tritan”—which improved on desirable polycarbonate properties while also being BPA-free. EX1006, 60, 63 (explaining “Tritan was the answer” to health concerns from BPA-containing polycarbonate, by providing a BPA-free polymer with “significantly increased heat resistance and toughness” as compared with polycarbonate). *Porter* also discloses Tritan's properties, which match those recited in the challenged claims.

Porter thus discloses a specific motivation to replace polycarbonate layers in the prior art that was before the Examiner with BPA-free Tritan copolyester, including in applications where the polymer will be exposed to moisture, elevated temperature, and hydrolytic attack (which would include dental aligners). EX1006, 61, 63. The Petition also cited other background references such as *Rafih* (EX1104) addressing this same motivation to eliminate BPA and use Tritan, including in dental aligners. *See also* Pet., 9 (citing EX1068-EX1116). Yet, despite this express motivation, neither BPA nor the health risks of polycarbonate came up during prosecution. The failure by the Office to address the swath of prominent prior art discussing these harms, including *Porter*, was a significant error.

The Examiner's failure to consider *Porter* is particularly relevant here given that Tritan, as expressly disclosed in *Porter*, meets all limitations of the hard layer claimed in the '384 patent. EX1006, 63. The challenged claims do no more than what *Porter* recommends—replace polycarbonate in prior-art dental aligners with a copolyester having the same properties as Tritan. These properties are shown below both in *Porter* and comparative claims 1, 4, 6 and 7 of the '384 patent.¹

¹ As noted in the Petition, Patent Owner argues in the co-pending litigation that datasheets are sufficient to establish a polymer's properties after being processed and combined with other polymers to form a multilayer sheet. Petitioner, thus, relies on the same source of evidence here.

TRITAN COPOLYESTER

Preliminary Data Sheet^a

General Properties	
Specific Gravity	1.18
Mold Shrinkage	0.005 in./in.
Mechanical Properties	
Tensile Strength	
@ Yield	6200 psi
@ Break	7700 psi
Elongation	
@ Yield	6%
@ Break	210%
Flexural Yield Strength	9000 psi
Tensile Modulus	225,000 psi
Flexural Modulus	225,000 psi
Izod Impact Strength	
Notched, 73 F	NB
-40 F	2.4 ft-lb/in.
Unnotched, 73 F	NB
-40 F	NB
Thermal Properties	
HDT @ 66 psi	210 F
@ 264 psi	185 F
Optical Properties	
Total Transmittance	90%
Haze	<1%
Typical Processing Conditions	
Drying Temperature	190 F
Drying Time	4-6 hr
Melt Temperature	500-540 F
Mold Temperature	100-150 F

1. A dental appliance for positioning a patient's teeth from a first arrangement toward a second arrangement, the dental appliance comprising:

...

a hard polymer layer comprising a **copolyester and having a flexural modulus greater than about 150,000 psi**; and

....

4. The dental appliance of claim 1, wherein the hard polymer layer has a **tensile modulus greater than 150,000 psi**.

....

6. The dental appliance of claim 1, wherein the hard polymer layer has a **tensile strength at yield between 4000 psi and 6500 psi**.

7. The dental appliance of claim 1, wherein the hard polymer layer has an **elongation at break of greater than about 70%**.

Tellingly, the Request fails to address *Porter*'s substantive teachings. Instead, Patent Owner attempts to cabin *Porter* as “non-analogous ‘Dishwasher’ art” based on its title. *See, e.g.*, Req., 1, 3, 20, 28. Indeed, the Request does not even mention the word “BPA” or “Tritan” once, despite the Petition’s comprehensive discussion of *Porter*’s disclosures regarding motivation to replace polycarbonate with Tritan to avoid harmful BPAs. Pet., 4 (“*Porter* discloses that . . . Tritan lacks the harmful bisphenol-A (‘BPA’) chemicals present in polycarbonate”), 9 (“*Porter* discloses commercially available Tritan copolyester (an improved, BPA-free polycarbonate replacement)”), 14 (“*Porter* discloses several benefits of replacing polycarbonate with Tritan copolyesters, including to avoid ingesting BPA”), 57-58 (explaining motivation based on *Porter* to replace polycarbonate layer in *Kalili*); EX1007, ¶¶ 88-108.

Patent Owner’s attempt to limit *Porter* to “dishwasher” art is frivolous. *Porter* provides a compelling motivation to replace polycarbonate with Tritan copolyester in applications where the polymer will be exposed to moisture, elevated temperatures, and hydrolytic attack, which Patent Owner does not dispute would include dental aligners. EX1006, 61, 63. *Porter* expressly discusses Tritan’s applicability in “countless applications for clear plastics” in the consumer goods industry, including in “extruded sheet applications” prior to thermoforming into a

mold—the same known manufacturing process Patent Owner uses for fabricating its claimed dental appliance. EX1006, 60, 62-63 (discussing “benefits for molders”); EX1001, Fig. 4 (“providing a sheet” including the hard layer and “thermoforming the sheet” to create the 3D appliance).

Porter thus does not limit Tritan’s applicability to dishwashers, nor is it “unrelated to dental aligners,” as Patent Owner contends. EX1006, 61-63; Req., 20. On the contrary, especially when viewed in the context of the prominent multi-industry shift away from using polycarbonates to avoid BPAs (EX1007, ¶¶ 88-97), *Porter*’s teachings are highly relevant to a variety of plastic applications, including dental aligners. *See, e.g.*, EX1007, ¶¶ 98-99 (discussing shift in the dental industry away from polycarbonate, and prior art, such as *Rafih* (EX1104), using Tritan in dental appliances to avoid BPA leaching); Pet., 9 (citing EX1068-EX1116).

Patent Owner, apparently conceding that *Porter* discloses all the properties of the hard layer recited in the claims, alleges that *Porter* is cumulative because other prior art also disclosed those properties. Req., 28. This misses the point. The Petition relies on *Porter* for its disclosures related to BPAs and motivation to replace polycarbonate with Tritan copolyester, and not only for its disclosure of Tritan’s properties that meet the claimed hard-layer properties. As the Board has explained, mere overlap between the disclosures of prior art asserted in an IPR and art applied during prosecution does not warrant discretionary denial. *See CallMiner, Inc. v.*

NICE Ltd., IPR2020-00221, Paper 11 at 32 (PTAB June 17, 2020) (declining to discretionarily deny petition because “some overlap in arguments will likely always occur because the same claims are being analyzed”).

The Request completely ignores this motivation disclosed in *Porter*, going so far as to assert (wrongly) that “the petition relies on Porter *only for* a teaching of a copolyester with certain properties.” Req., 28 (emphasis added). The Request thus offers no substantive rebuttal to the Petition’s reliance on new art (*Porter*) and new motivation to replace polycarbonate with Tritan copolyester (avoiding BPAs), neither of which was disclosed to the Examiner or addressed in any reference applied during prosecution. Moreover, the prior art that Patent Owner alleges is cumulative (DeSimone) discloses blends containing polycarbonate—the exact material *Porter* recommends eliminating and replacing with Tritan. Req., 28. The Request thus falls well short of the “detailed analysis of the similarities between the disclosures” of *Porter* and the allegedly cumulative references that is required under the “substantially the same art” test of *Advanced Bionics*. See *Geotab USA, Inc. v. Omega Patents, LLC*, IPR2023-00504, Paper 11 at 16 (PTAB July 25, 2023).

The Petition presents new arguments based on *Porter*, which was not of record during prosecution and is not cumulative of any record art. The Examiner never considered *Porter* or the express motivation it discloses to use a specific polymer

(Tritan) having the exact properties claimed. This error weighs strongly in favor of referral.

2. The Examiner Failed to Apply *Tadros*, Which the Office Subsequently Applied in Rejecting “Parallel” Claims in Related Patent Applications

Patent Owner acknowledges that *Tadros* was not applied to the instant claims and that there was no substantive analysis of *Tadros*’s teachings. *See* Req., 27. As the Petition explained, when *Tadros* was later applied to claims of continuation applications in the same patent family—which Patent Owner admits “recit[e] parallel limitations” to the ’613 and ’384 patent claims—Patent Owner was forced to narrow those claims. Pet., 2; Req., 19, 29 (noting ’613 and ’384 claims are substantively similar); ’090 Req., 29; ’091 Req., 29.

The Request fails to address this later prosecution and Patent Owner’s narrowing amendment of “parallel” claims to distinguish *Tadros*. The Request thus fails to justify the Examiner’s failure to apply *Tadros* to the ’384 patent claims or explain how art used to reject “parallel limitations” in later applications could possibly be “cumulative” of the prior art applied during prosecution of the ’384 patent. Indeed, the ’384 patent was a first action allowance, and the Examiner thus did not apply any prior art, including *Tadros*. Pet., 27 (citing EX1016, 167).

The Petition presents new arguments relating to *Tadros*, which discloses three-layer dental aligners with a soft-hard-soft layer configuration, wherein the hard

layer is a polymeric blend comprising a copolyester, and the outer soft layers may be TPUs. Pet., 9-11. Every claim in the '384 patent recites a hard layer that merely “compris[es]” a copolyester rather than a layer “consisting of” a copolyester, and thus the polycarbonate-copolyester blends in *Tadros* meet this limitation. Accordingly, as the Petition details in Ground 1, the soft-hard-soft configuration disclosed in *Tadros*—when the TPU Texin 990R (disclosed as desirable in *Kalili*) is used for the soft outer layers—meets every limitation of claims 1-4, 7-14, 17-24, and 27-30 (i.e., all but three of the challenged '384 patent claims). See, e.g., Pet., 31-38.



The Examiner erred in failing to appreciate *Tadros*’s explicit disclosure and make any rejections based on *Tadros*.

This error is apparent in view of the Office’s treatment of *Tadros* during subsequent prosecution of what Patent Owner calls “parallel” claim limitations in the '090 and '091 patent applications. Like the '384 patent claims, the as-filed claims of those patent applications recited layers “comprising” blends of polymers. The Examiner rejected the '091 patent claims as obvious, noting that *Tadros* disclosed soft TPU outer layers and an inner hard layer comprising copolyester, and that it

would have been obvious to replace the layers in *Tadros*'s soft-hard-soft appliance with "known, commercially available" polymers such as Texin 990R (disclosed in *Kalili*) for the claimed properties. EX1018, 108-112. In response, Patent Owner sought to distinguish *Tadros*'s hard layer, which used polycarbonate-polyester blends, by narrowing the claims to layers "consisting of" a "single polymer" (a copolyester for the hard layer and a TPU for the soft layer). EX1018, 126-29; EX1137, 277-79. The same Examiner had previously rejected the '090 patent claims over *Tadros* in combination with a different TPU, and Patent Owner made the same narrowing amendments to the '090 patent claims that it made to the '091 patent claims. EX1137, 258-59; EX1018, 126-29; EX1137, 277-79.

These narrowing amendments to circumvent *Tadros* were critical to allowance. The Examiner stated in the Notice of Allowance for the '090 patent the apparent lack of prior art disclosing "at least one layer **consisting of** the specified copolyester." EX1137, 298 (emphasis in original).

A comparison of the "parallel" claim limitations in the '384 patent and later continuations, and the inconsistent application of *Tadros* to these limitations is shown below.

Patent Owner: '613/'384 patent claims and '090/'091 patent claims "recit[ed] parallel limitations"	
<i>Tadros</i> not applied ('613 and '384 patent)	<i>Tadros</i> applied ('090 and '091 patent)

<p>1. A method of making a dental appliance for positioning a patient's teeth, the method comprising: providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:</p> <p>a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and</p> <p>a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;</p>	<p>10. (Currently Amended) A multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:</p> <p>a first layer comprising consisting of a co-polyester, <u>the co-polyester having a flexural modulus of greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%,</u></p> <p>a second layer comprising consisting of a thermoplastic polyurethane elastomer, <u>the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D;</u></p> <p>a third layer;...</p>
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The Petition presents new arguments based on *Tadros* that were not previously considered during prosecution of the '384 patent. The fact that Patent Owner was forced to amend around *Tadros* in later continuations with “parallel” claim limitations underscores the Examiner’s error in failing to apply *Tadros* to the '384 patent claims. This weighs strongly in favor of referral.

3. The Petition Presents New Arguments Based on Disclosures of *Kalili*, *Texin 990R*, and *Wen* Not Considered by the Examiner

Kalili, *Texin 990R*, and *Wen* were not substantively considered during prosecution of the '384 patent. They thus form the basis of new combinations and obviousness arguments in the Petition that the Examiner never considered.

Ground 1 combines *Kalili* and *Texin 990R* with *Tadros*. This combination is entirely new and was never considered by the Examiner. By contrast, during prosecution of the related '091 patent, the Examiner rejected claims as obvious over *Tadros* combined with *Kalili*, which the Examiner cited for its disclosure of *Texin 990R* for the TPU layers.

The Petition not only presents new combinations, but also new arguments based on the references that were not considered during prosecution of any of the applications in the '384 patent family. For example, during prosecution of the related '091 patent, the Examiner cited *Kalili* for its disclosure of using *Texin 990R* as a soft outer layer. Ground 2 of the petition, however, cites *Kalili* not only for this disclosure, but also for its disclosure of a 2-layer dental aligner combining a hard polycarbonate layer with a soft TPU layer. The Petition explains based on *Porter* why a POSITA would have been motivated to replace polycarbonate with Tritan copolyester to avoid harmful BPAs and, based on *Wen*, why a POSITA would have been motivated to modify one or both of *Kalili*'s two layers with thinner sublayers.

Ground 2 thus is both a new combination and a new application of *Kalili* compared to how the Examiner applied it during prosecution of the related '091 patent.

The Petition presents two distinct obviousness grounds that were not proposed or addressed during prosecution of the '384 patent. Every ground relies on prior art that was not substantively considered by the Examiner, weighing strongly in favor of referral and against discretionary denial.

B. Step 2: The Office Erred in a Manner Material to the Patentability of the Challenged Claims

Because the Petition presents new prior art, grounds, and arguments not yet presented to the Office, *Advanced Bionics* step 2 is moot and the Director need not consider whether the Office materially erred in its prior evaluation. Even if the Director does reach the second step of *Advanced Bionics*, however, discretionary denial under § 325(d) would still be improper because the record establishes that the Office committed material errors during prosecution of the challenged patent. As a result, it is appropriate for the Office to use its resources to review that material error. *See Microsoft Corp. v. Partec Cluster Competence Center GmbH*, IPR2025-00318, Paper 9 at 3 (Director June 12, 2025) (“discretionary denial of institution is not warranted 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”).

To start, the Petition and supporting exhibits establish that the Examiner never considered the knowledge in the industry, disclosed in *Porter*, that polycarbonate should be replaced to avoid harmful BPAs. *Porter* identifies a preferred replacement material to address this known problem, stating “Tritan was the answer.” EX1006, 60, 63. The Petition cites additional background art establishing that the problem that polycarbonate posed with BPAs was well known, as was the knowledge that Tritan copolyester was a preferred replacement material that avoided BPAs and offered superior properties. Pet., 9. The Examiner did not address any reference during prosecution that contained the same or similar disclosures. This was a material error because *Porter* expressly identifies a motivation to replace the polycarbonate in prior-art multilayer dental aligners with Tritan, which *Porter* discloses as a desirable substitute with the same properties recited in the challenged claims.

Patent Owner cannot excuse the Examiner’s failure to consider this art and motivation, which constitutes a material error. Instead, the Request simply ignores these points in the Petition. *See generally* Req. (no mention of “BPA” or “Tritan”).

Referral is appropriate here so the Board can correct this error by considering for the first time *Porter*’s relevance to the ’384 patent claims. *See, e.g., Yealink (USA) Network Tech. Co., Ltd. v. Barco N.V.*, IPR2025-00491, Paper 18 at 2-3 (Director June 25, 2025) (referring petition based on evidence of material error

where Examiner failed to recognize and discuss well-known prior art relevant to patentability); *Embody, Inc. v. LifeNet Health*, IPR2025-00248, Paper 13 at 2-3 (Director June 26, 2025) (referring petition based on evidence of material error where Examiner did not consider prior-art references which disclosed claim limitation).

The Office committed a separate, independent error by failing to apply *Tadros*. Patent Owner acknowledges that the challenged '384 patent claims recite limitations “parallel” to those in the '090 and '091 patents and does not dispute that *Tadros* was only applied in the later '090 and '091 patents. If the Examiner had applied *Tadros* to the '384 patent, Patent Owner would have been forced to make comparable narrowing amendments. *See* Req., 29; Pet., 2 (discussing failure to address *Tadros* during '384 patent prosecution). Patent Owner's suggestion that the Examiner was aware of *Tadros* simply cannot be squared with the Office's rejection of similar claims over *Tadros* during prosecution of the later patent applications. *See* EX1016, 872 (Notice of Allowance) (listing Examiner Caroline Beha); EX1137, 300 (Notice of Allowance) (listing Examiner Vivian Chen); EX1018, 150 (Notice of Allowance) (same); Req., 32 (incorrectly stating that its patents were prosecuted before the same examiner).

The Examiner's failure to apply *Tadros* during the '384 patent prosecution and the Office's inconsistent application of *Tadros* to “parallel” claim limitations is

a material error. The challenged '384 patent claims more broadly encompass layers *comprising* polymer mixtures, unlike the comparable '090 and '091 patent claims that were narrowed to “consist of” single-polymer layers, because Patent Owner was never forced to address *Tadros*.

The Petition addresses this inconsistency by presenting obviousness grounds similar to those which forced Patent Owner to amend its claims during prosecution of the '090 and '091 patents. *See, e.g., Xencor, Inc. v. Merus N.V.*, IPR2025-00604, Paper 12 at 2-3 (Director July 17, 2025) (referring petition based on evidence of material error where Examiner overlooked reference cited in an IDS during prosecution); *CSPC Pharm. Grp. Ltd. v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11 at 2-3 (Director July 16, 2025) (referring petition based on evidence of material error where Examiner overlooked teachings of prior art references that previously served as basis of rejection); *see also RODE Microphones, LLC v. Zaxcom, Inc.*, IPR2025-00557, Paper 11 at 2-3 (Director July 17, 2025) (referring petition based on evidence of material error where Examiner did not consider related proceedings that could have affected claim scope). Given the inconsistency in how the Office applied *Tadros*, Patent Owner's arguments, which focus on whether the Examiner *might* have considered *Tadros*, are irrelevant. Req., 31-32.

C. Evidence of Material Error Favors Referral

The Director should not discretionarily deny the Petition, even if other considerations support discretionary denial, because it is an appropriate use of Office resources to review the evidence of material error. Thus, even if the Director were to find that discretionary denial is permissible under either of Patent Owner's other arguments—e.g., *Fintiv* and settled expectations—it would still be appropriate to deny Patent Owner's Request. See *Eunsung Glob. Corp. v. HydraFacial LLC*, IPR2025-00445, Paper 14 at 3 (Director July 10, 2025); *Xencor*, IPR2025-00604, Paper 12 at 2-3.

III. THE *FINTIV* FACTORS FAVOR INSTITUTION

The *Fintiv* factors support institution in this case. Petitioner provided a full *Sotera* stipulation, mitigating the risk of duplicative proceedings or inconsistent outcomes. The Petition presents strong arguments and evidence of unpatentability and corrects material errors by the Office—none of which are persuasively rebutted (or even substantively addressed) by Patent Owner. Significant work remains in the parallel litigation—institution would come before expert reports, expert discovery, expert depositions, and pre-trial motions. Further, based on Judge Albright's median time-to-trial statistics, trial in the district court will likely occur months (or longer) after a final written decision is issued. The investment in the district court case has been limited, particularly with respect to the issues raised in the Petition, and

Petitioner acted consistent with the statutory timeline and in reliance on then-operative guidance. The record demonstrates that institution of this Petition will further the Director's and the Office's goals of an efficient, focused proceeding that is not duplicative of efforts by the district court. Each factor either weighs against discretionary denial or is, at worst, neutral. None justifies denying institution.

A. The *Fintiv* Factors Weigh Strongly Against Discretionary Denial

1. Factor 1 (Likelihood of a Stay) Is Neutral

The Board has consistently declined to weigh factor 1 against discretionary denial where a Patent Owner relies on mere speculation, as Patent Owner does here. *See Sand Revolution II, LLC v. Continental Intermodal Grp. – Trucking LLC*, IPR2019-01393, Paper 24 at 7 (PTAB June 16, 2020) (informative) (hereinafter “*Sand*”); *see also Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (PTAB May 13, 2020) (informative); *Western Digit. Corp. v. Kuster*, IPR2020-01391, Paper 10 at 8-9 (PTAB Feb. 16, 2021). In light of this past Board precedent, this factor should be treated as neutral.

2. Factor 2 (Parallel Trial Date) Weighs Against Discretionary Denial

Trial in the parallel district court litigation is likely to occur *after* a final written decision would issue in this IPR. Updated time-to-trial statistics, information regarding Judge Albright's recent reassignment and corresponding substantially

increased caseload, and the Patent Owner's own litigation conduct all confirm the unreliability of the current schedule. As explained below, these factors collectively support the conclusion that trial will take place months—if not a full year—after the Board issues its decision.

According to the 2024 Federal Court Management Statistics (the most recent available), the median time-to-trial in the Western District of Texas as a whole is 33.9 months. EX1119, 37 (National Judicial Caseload Profile). That would place trial here in February 2027—*three months after* any final written decision in this IPR. Judge Albright's own median time-to-trial has been steadily increasing since 2021, reaching 34.6 months in 2024, and now 42.6 months in the first half of 2025, pushing the expected trial date to November 2027—a full year after any final written decision. EX1120, 3 (Legal Metric WDTX Time-to-Trial Statistics).

The increasing delays from case filing to trial are unsurprising and likely to persist given Judge Albright's recent reassignment within the Western District of Texas to the Austin Division, which has more than twice the caseload of the Waco Division, where Judge Albright was previously assigned. EX1121, 3 (WDTX 2024 Statistical Report) (compare 809 case filings in Waco to 1,765 case filings in Austin in 2024). Further, Chief Judge Alia Moses has ordered Judge Albright to retain 100% of the Waco Division docket while simultaneously taking over 40% of the Austin Division docket, along with any additional patent cases filed in the district and

assigned to him according to the standard procedure. EX1122 (Jan. 31, 2025, WDTX Amended Order Assigning Business of the Court), 3; EX1123 (May 30, 2024, WDTX Order Assigning the Business of the Court as it relates to Patent Cases). As of this writing, 400 cases—including 72 patent cases—have been reassigned to Judge Albright since Chief Judge Moses’s order. EX1124 (Lex Machina, Cases Reassigned to Judge Albright); EX1125 (Lex Machina, Patent Cases Reassigned to Judge Albright). This substantial growth in Judge Albright’s docket, unsurprisingly, results in extended trial timelines.

Patent Owner’s reliance on the current trial schedule is misplaced because it ignores the above facts. The scheduled trial date is inconsistent with Judge Albright’s current caseload, the history of the case, and recent median time-to-trial statistics. Where median time-to-trial statistics place trial after the final written decision, the Director has declined to exercise discretion to deny institution even where the scheduled trial date is before the final written decision. *See, e.g., Amazon.com, Inc. v. NL Giken Inc.*, IPR2025-00250, Paper 14 at 2 (Director May 16, 2025) (finding discretionary denial inappropriate where, “[i]n particular,” time-to-trial statistics shifted the likely trial date from before the final written decision to after).

Patent Owner cites outdated statistics that fail to reflect the reality of Judge Albright’s current docket. The median time-to-trial cited by Patent Owner is based

on data that is already five years old and therefore fails to accurately reflect current practices and trends both in the district at large and in cases assigned to Judge Albright. Req., 12-13 (citing median time-to-trial statistics based on data going back five years). As explained above, the most current data available suggest a likely trial date several months, or even a full year, after the final written decision.

The “Patent FAQ” that Patent Owner cites as its only evidence that the current trial date supposedly will not change is outdated and unreliable. Req., 12 (citing five-year-old informal “Patent FAQ”). Specifically, the statement that Patent Owner relies on is from September 2020—five years ago, when Judge Albright’s median time-to-trial was significantly lower than today and before Judge Albright’s reassignment. Req., 12; EX2005.

Judge Albright delays scheduled trial dates when necessary and appropriate. For example, in a recent case, Judge Albright delayed trial by six months despite the case being well into fact discovery and involving only three patents. *Parkervision, Inc. v. NXP Semiconductors N.V.*, No. W-23-CV-00389-ADA, slip op. at 2 (W.D. Tex. May 27, 2025). This example undermines any claim that the current trial schedule in the parallel litigation is set in stone. Indeed, as Patent Owner admits, Judge Albright already delayed trial by several months in the parallel litigation. EX1126 (Fourth Scheduling Order, *Align Tech., Inc. v. ClearCorrect Operating, LLC*, No. 6:24-cv-00187-ADA-DTG (W.D. Tex. June 12, 2025)); Req., 11. This is

particularly relevant given Patent Owner’s ongoing failure to meet discovery obligations and request to stay certain discovery obligations, which Patent Owner argued would be “no small undertaking” and “impractical—if not impossible” to complete on time. EX1127, 5-6 (Redacted Copy of Patent Owner’s Motion to Stay June 17, 2025, Discovery Order Regarding Align’s Production of Customer Contracts, *Align Tech., Inc.*, No. 6:24-cv-00187-ADA-DTG (W.D. Tex. July 8, 2025)). Patent Owner’s stay request was denied, casting further doubt on its ability to meet its discovery obligations. EX1128 (Order, *Align Tech., Inc.*, No. 6:24-cv-00187-ADA-DTG (W.D. Tex. July 8, 2025)).

Even if the parallel district court trial were to occur before the Board’s final written decision, which is unlikely for all the reasons explained above, this factor alone is not dispositive. *See Shenzen Tuozhu Tech. Co., Ltd v. Stratasys, Inc.*, IPR2025-00438, Paper 10 at 2 (Director July 17, 2025) (referring petition despite scheduled trial date and median time-to-trial date being months earlier than final written decision date). More importantly, the weight of the evidence, including up-to-date trial statistics, Judge Albright’s expanded docket, and Patent Owner’s discovery delays in the parallel litigation, indicate that trial will take place several months, and potentially a full year, after the final written decision. In this case, where the current median time-to-trial, both in the district and before Judge Albright, specifically, is well after the expected final written decision, this factor weighs

against discretionary denial. *Amazon.com, Inc.*, IPR2025-00250, Paper 14 at 2 (finding discretionary denial inappropriate because “time-to-trial statistics suggest trial would not begin until” after the projected final written decision date); USPTO Guidance of March 24, 2025 (“Boalick Memo”) (“the Board may consider...median time-to-trial statistics”).

Here, the totality of circumstances—including Patent Owner’s inability to meet deadlines, Judge Albright’s growing case load, and the current median time-to-trial (which puts trial well after the expected final written decision)—strongly supports the conclusion that the IPR will be over well before any trial occurs. Factor 2 therefore weighs against discretionary denial.

3. Factor 3 (Investment in Parallel Proceeding) Weighs Against Discretionary Denial or Is Neutral

Factor 3 weighs in favor of institution because: the investment in the parallel district court litigation has been limited with respect to the issues addressed in the IPR; the Petitions include broad *Sotera* stipulations that mitigate the concern for conflicting decisions and duplicative efforts; the Petition’s filing date both met statutory requirements and comported with prior guidance regarding the effectiveness of a *Sotera* stipulation in the June 21, 2022 Interim Procedure for Discretionary Denials (“Vidal Memo”), which was in force for nearly the entire one-year statutory period.

Much of the district court litigation has focused on issues unrelated to the IPRs, such as infringement, antitrust, false advertising, and unfair competition claims. *See* EX1023 (Complaint); EX1129 (Answer). These issues fall outside the scope of *inter partes* review and do not reflect investment in the invalidity issues raised in the Petition. Most of the district court's investment therefore is irrelevant. *See Sand*, IPR2019-01393, Paper 24 at 10 (informative) (“[M]uch of the district court's investment relates to ancillary matters untethered to the validity issue itself.”).

Even where invalidity has been addressed, the parties and the district court have not needed to engage in substantial work on prior-art-based invalidity issues, further minimizing the relevance of any investment in the district court. For example, the parties have not submitted briefing on any dispositive issues and the district court has not made any determination on the merits of any issues related to invalidity of the '384 patent.

Patent Owner's statement that the district court has issued a final claim construction order is both incorrect and irrelevant with respect to the '384 patent. *First*, no terms from the '384 patent or any related patent were construed or even presented for construction by either party, and thus claim construction in the district court required absolutely no investment on issues related to the '384 patent. *See generally* EX1130 (Claim Construction Order); EX1131 (Joint Claim Construction

Statement); *see Zynga Inc. v. IGT*, IPR2022-00200, Paper 10 at 10-11 (PTAB June 7, 2022) (weighing factor 3 against discretionary denial where “[t]he district court claim construction order does not address any claim terms of the [challenged] patent.”).

Second, the existing claim construction order, issued by Magistrate Judge Gilliland, consists of a table of constructions and is not final. EX1130 (Claim Construction Order). Judge Gilliland has yet to issue the “more-detailed order explaining [the court’s] analysis.” *Id.* at 2. The time period for the parties to file objections to the final constructions has not yet even begun to run. *Id.* Instead, Judge Gilliland’s order must still be reviewed, and then revised or adopted by Judge Albright. In short, claim construction in the parallel proceeding is far from complete.

As to investment beyond claim construction, fact discovery remains ongoing due to Patent Owner’s repeated document production delays. Notably, on July 1, 2025, the Patent Owner sought a stay of a discovery order compelling production of third-party contracts, citing the purportedly significant resources required to comply. EX1127 (Redacted Copy of Patent Owner’s Motion to Stay June 17, 2025, Discovery Order Regarding Align’s Production of Customer Contracts, *Align Tech., Inc. v. ClearCorrect Operating, LLC*, No. 6:24-cv-00187-ADA-DTG (W.D. Tex. Jul. 8, 2025)). This request highlights that significant discovery remains outstanding.

The court has already extended the deadline for substantial completion of document production twice. First, the court delayed the deadline by six weeks, from March 17, 2025, to April 28, 2025, based on agreement by the parties. EX1132, 2 (March 18, 2025, Stipulated Joint Motion to Amend the Case Schedule); EX1133 (March 20, 2025, Third Scheduling Order). The court delayed the deadline again, by nearly 12 additional weeks to July 18, 2025, due to the Patent Owner's inability to meet the prior deadline. EX1126 (June 12, 2025, Fourth Scheduling Order); EX1134, 2 (June 6, 2025, Joint Motion to Amend the Case Schedule). Thus, while even the extended substantial completion deadline has passed, document production is ongoing due to Patent Owner's delays. Patent Owner should not now argue that the litigation has progressed too far to institute review here, while simultaneously failing to meet discovery deadlines and seeking to delay compliance with court orders.

The Board has previously found that, where discovery is ongoing and significant work remains, Factor 3 weighs against denial. *See Bio-Rad Lab 'ys., Inc. v. California Inst. of Tech.*, IPR2024-01451, Paper 11 at 10-11 (PTAB Mar. 27, 2025). Here, opening expert reports are not due until November 14, 2025, after the institution decision, and expert discovery will not close until January 21, 2026. EX1126 (Fourth Scheduling Order), 2. Substantive motion practice will not yet have commenced at institution. *Id.* at 2-3. Accordingly, because much of the investment

relevant to issues of invalidity will occur after institution, this factor weighs against denial. In *Bio-Rad*, a recent Board panel applying *Fintiv* under the 2025 Guidance on Discretionary Denial reached the same conclusion on similar facts. IPR2024-01451, Paper 11 at 10-11 (concluding that Factor 3 “weighs against exercising our discretion to deny institution” where the *Markman* hearing was held, but “much more work remains, including, expert reports, expert discovery, expert depositions, and pretrial motions and disclosures”).

Importantly, Petitioner filed its petitions within the statutory one-year deadline and included a full *Sotera* stipulation, committing that, if the IPRs are instituted, Petitioner would not to pursue in district court any ground that was raised or reasonably could have been raised in the IPRs. 35 U.S.C. § 315(b); Pet., 72. This stipulation, recognized by the Board and the Director as strongly favoring institution, further supports the conclusion that Petitioner acted in good faith and with procedural efficiency.

In preparing the Petitions, Petitioner relied on the Vidal Memo’s assurance that “the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have been reasonably been raised in the petition.” Vidal Memo, 7. The rescission of the Vidal Memo and subsequent replacement with the Boalick Memo

less than three weeks before the petitions were filed eliminated the safe harbor of the *Sotera* stipulation that Petitioner had relied on in setting out its litigation and IPR timeline. EX1136 (Feb. 28, 2025, USPTO Notice); Boalick Memo. The timing of the Petition’s filing—shortly after the guidance was replaced—reflects a prompt and reasonable response to a sudden change in policy.

The Boalick Memo on discretionary denial, despite altering the guidelines regarding the impact of a *Sotera* stipulation, nevertheless maintains the importance of the stipulation in mitigating concerns for duplication between the district court and Board. Boalick Memo, 2-3 (“a timely-filed *Sotera* stipulation ... is highly relevant”). And Board panels applying the Boalick Memo have relied on similar stipulations in instituting review. *See, e.g., Stingray Grp. Inc. v. Hernandez-Mondragon*, IPR2025-00349, Paper 19 at 7-8 (PTAB June 13, 2025) (“Although not dispositive by itself, Petitioner’s stipulation, like the one in *Sotera*, mitigates ‘concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions.’”).

In light of the limited investment in the district court litigation on the issues raised in the IPRs, the ongoing nature of expert discovery, and the Petitioner’s economical approach consistent with the Vidal Memo and subsequent Boalick Memo—including timely filing, reliance on preliminary claim constructions, and a full *Sotera* stipulation—Factor 3 weighs in favor of institution.

4. Factor 4 (Overlap Between Petition and Parallel Proceeding) Weighs Strongly Against Discretionary Denial Because Petitioner Committed to *Sotera* Stipulations

Petitioner provided a full *Sotera* stipulation, committing that “if IPR is instituted for the ’384 patent, it will not pursue in the parallel district court case for the ’384 patent any ground raised or that could have been reasonably raised in this Petition, and all defendants to the litigation have agreed to be bound by this stipulation.” Pet., 72; Paper 6. As the Board explained in *Sotera Wireless, Inc. v. Masimo Corp.* (“*Sotera*”), such a stipulation “mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions,” “ensur[ing] that an *inter partes* review is a ‘true alternative’ to the district court proceeding.” IPR2020-01019, Paper 12 at 19 (PTAB Dec. 1, 2020) (precedential as to relevant part). In light of the stipulation, the Board in *Sotera* found that factor 4 “weighs *strongly* in favor of not exercising discretion to deny institution.” *Id.* (emphasis added).

Numerous panels have since reaffirmed that a full *Sotera* stipulation strongly favors institution. For example, in *LinkedIn Corp. v. eBuddy Technologies B.V.*, where the Petitioner provided a *Sotera* stipulation, the Board emphasized that “[b]ecause of Petitioner’s stipulation, we find this factor weighs *strongly* against exercising discretion to deny *inter partes* review.” IPR2022-00176, Paper 13 at 14 (PTAB May 17, 2022) (emphasis added). And in *Liberty Energy Inc. v. U.S. Well*

Services, LLC, where “Petitioner’s stipulation is similar to that provided in *Sotera*,” the Board recently determined that “the facts underlying this factor *weigh strongly* against exercising our discretion to deny institution.” IPR2025-00139, Paper 14 at 13–14 (PTAB June 11, 2025) (emphasis added).

Current USPTO guidance affirms the precedential nature of *Sotera*, and the “highly relevant” nature of a timely-filed *Sotera* stipulation to the *Fintiv* analysis. Boalick Memo, 1, 2-3. Panels applying the 2025 Guidance have continued to rely on *Sotera* stipulations in declining to exercise discretion under *Fintiv*. In *Stingray Group Inc. v. Hernandez-Mondragon*, for example, the Board found that a *Sotera* stipulation “mitigates ‘concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions,’” leading to the conclusion that “the fourth *Fintiv* factor *weighs strongly* in favor of not exercising discretion to deny institution.” IPR2025-00349, Paper 19 at 7-8 (PTAB June 13, 2025) (emphasis added) (quoting *Sotera*, IPR2020-01019, Paper 12 at 19 (precedential in relevant part)). Likewise, in *Kubota North America Corp. v. Vermeer Manufacturing Co.*, the Board noted that a *Sotera* stipulation mitigates “concerns of duplicative efforts” and “potentially conflicting decisions” and further that it “ensures that an *inter partes* review is a ‘true alternative’ to the district court proceeding.” IPR2025-00170, Paper 15 at 13 (PTAB June 10, 2025) (declining to discretionarily deny the Petition and weighing factor four against denial).

Petitioner’s stipulation here mirrors the language approved in *Sotera* and has the same effect: “mitigat[ing] any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions” and further “ensur[ing] that an *inter partes* review is a ‘true alternative’ to the district court proceeding.” *Sotera*, IPR2020-01019, Paper 12 at 19 (precedential as to relevant part).

Patent Owner admits that a *Sotera* stipulation is in place but asserts (in direct contradiction to Board precedent) that it “does little to mitigate overlap of issues.” Req., 17; *Sotera*, IPR2020-01019, Paper 12 at 19 (precedential as to relevant part) (explaining that a *Sotera* stipulation “mitigates any concerns of duplicative efforts between the district court and the Board.”). Patent Owner’s reliance on *Motorola Solutions, Inc. v. Stellar, LLC* is misplaced. *Motorola* merely confirms that, under recent guidance, a *Sotera* stipulation *alone* does not outweigh *Fintiv* factors 1, 2, and 5, where the invalidity expert report in the parallel litigation includes combinations of the prior art asserted in IPR with unpublished system prior art. IPR2024-01205, Paper 19 at 3-4 (Director Mar. 28, 2025). It does not stand for the proposition that any combination of system art and prior-art publications in a parallel litigation categorically renders a *Sotera* stipulation moot. *Motorola* itself acknowledged as much. *Motorola*, IPR2024-01205, Paper 19 at 4 (recognizing “Petitioner’s *Sotera* stipulation may mitigate some concern of duplication”).

Further, *Motorola* is distinguishable for multiple reasons. There, the Board noted that the petitioner’s invalidity expert report in the parallel litigation “repeats all of the assertions in th[e] Petition.” *Motorola*, IPR2024-01205, Paper 19 at 3. Here, by contrast, any invalidity expert report will not be served until after an institution decision. EX1126 (Fourth Scheduling Order). Patent Owner points to Petitioners’ preliminary invalidity contentions as including system prior art. Req., 16. However, it is common for expert reports to narrow the grounds submitted in initial invalidity contentions, especially after IPR is instituted and consistent with a *Sotera* stipulation. In any event, Align does not allege—because it cannot—that the system art disclosed in Petitioners’ invalidity contentions overlaps with the prior-art references in the Petition.

Patent Owner, without explanation or legal support, suggests that Petitioner’s decision not to challenge the unrelated ’444 Patent in IPR somehow weakens the effect of Petitioner’s *Sotera* stipulation in the ’384 IPR. Req., 18. Not so. The scope and issues presented by the two patents are different, as are the prior-art references asserted against them in the district court. EX1022 (Invalidity Contentions). Thus, even if filed, a petition against the ’444 patent and any corresponding stipulation, would have had no substantial impact on the overlap of issues between the district court and the ’384 IPR proceeding. Instead, Petitioner’s selectivity in bringing IPR

challenges reflects a commitment to efficiency in both forums and respect for Board resources.

Petitioner's comprehensive *Sotera* stipulation ensures that the IPRs will not duplicate district court efforts and will instead serve as a true alternative forum for resolving validity. Consistent with Board precedent and the Boalick Memo, this factor weighs strongly in favor of institution.

5. Factor 5 (Whether the Parties Are the Same) Is Neutral

The parties before the Board and district court are the same, as in almost all IPRs. Although Factor 5 can weigh slightly in favor of discretionary denial under such circumstances, it may also be neutral since it is so frequently true. It is not dispositive, and it must be considered in the context of all other factors. *See, e.g., Kubota N.Am. Corp.*, IPR2025-00170, Paper 15 at 15-16 (refusing to exercise discretionary denial).

6. Factor 6 (Other Considerations)—Including the Strength of the Petition—Weigh Strongly Against Discretionary Denial

Factor 6 weighs strongly against discretionary denial because the Petition presents strong merits and addresses several material errors committed by the Office. *See infra* Section IV.E. The Request does not persuasively rebut these strong merits, and it essentially ignores the Office's material errors. Req., 19-24; *see infra* Section

IV.A, B (describing lack of settled expectations and Patent Owner's misplaced secondary considerations arguments).

Patent Owner's other ancillary arguments likewise are unpersuasive. For instance, Patent Owner incorrectly alleges Petitioner's arguments are inconsistent with prior positions regarding the predictability of the art. To start, the IPR that Patent Owner cites is from a separate proceeding, involving different parties, patents, prior art, and arguments. Further, in that proceeding, Bay Materials was the patent owner, and thus was responding to arguments presented by the petitioner and noting shortcomings in the disclosures of the specific references that petitioner asserted. *See* Req., 24 (citing Bay Materials Patent Owner Response). Patent Owner provides no analysis of how those proceedings analyzing different patent claims and prior-art disclosures bear on the issues here. Regardless, Patent Owner identifies no inconsistency between arguments Bay Materials made previously and Petitioner's positions here.

Petitioner's position here is *not* that every aspect of the art is unpredictable, but rather (as Patent Owner acknowledges) that 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. Every Ground in the Petition relies on express prior-art disclosures that would have motivated a POSITA to make the specific combinations asserted,

reinforcing the strength of the obviousness combinations presented. For example, the Petition identified:

- a specific motivation and expectation of success to use *Texin 990R*, as disclosed in *Kalili*, as the TPU layer in *Tadros*, given *Tadros*'s disclosure of using the TPU layer to increase patient comfort and *Kalili*'s express teachings that *Texin 990R* improves patient comfort, among other “outstanding” properties in dental applications (Pet., 34-38);
- a specific motivation and expectation of success to apply *Wen*'s teachings that thinner sublayers of a material provide advantages when thermoforming multilayer dental appliances such as those disclosed in *Kalili* (Pet., 54-56); and
- a specific motivation and expectation of success to replace *Kalili*'s polycarbonate layer with Tritan copolyester given *Porter*'s express disclosure of the known risks of BPAs and Tritan's desirability as a replacement for BPA-containing polycarbonate in thermoforming applications (like those of *Kalili*'s dental appliance) that require increased heat resistance, chemical resistance, and reduced risk of environmental stress cracking (Pet., 57-59).

Petitioner also pointed to supporting technical background on manufacturing methods, material properties, harms related to BPA, and the compatibility of specific copolyesters and TPUs from the perspective of a POSITA that addressed these specific prior-art disclosures and motivations to combine the art as asserted in the Petition. *See* EX1007, ¶¶ 27-108.

Tellingly, the Request does not present any evidence to the contrary or dispute any of the specific disclosures the Petition cites from the asserted prior art. Instead, the Request blanket-cites the entire unpatentability section of the Petition to support its bare-bones attorney argument regarding purported unpredictability. Req., 24-25. Patent Owner thus presents no plausible rebuttal to the Petition’s reliance on the asserted prior art’s express teachings or the Petition’s detailed explanation of how those disclosures match up to each limitation of the challenged claims. The Board has previously commended this type of meticulous approach to unpatentability. *See T-Mobile USA, Inc. v. Cobblestone Wireless LLC*, IPR2024-00137, Paper 15 (PTAB May 22, 2024) (“[T]he merits here are compelling.... Petitioner presents a detailed limitation-by-limitation comparison of independent claim 9 to the cited prior art, with extensive citations to the prior art and supporting testimony in [its expert’s declaration]. Petitioner also provides a compelling, evidence-supported rationale for combining the teachings of [the prior art].” (internal citations omitted)).

IV. ADDITIONAL FACTORS SET FORTH IN THE DIRECTOR MEMO AND DISCRETIONARY DENIAL DECISIONS FAVOR INSTITUTION

A. Patent Owner Has No Settled Expectations

Patent Owner has no settled expectations of validity for the '384 patent, and referring the Petition here would be consistent with prior Director Discretionary Denial Decisions.

To start, the '384 patent issued recently, on October 26, 2021. Referring the Petition here is in line with past decisions referring petitions challenging patents issued after 2020. *Cambridge Indus., USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00437, Paper 10 at 2-3 (Director June 26, 2025) (referring petitions for two patents issued in 2019 and one issued in 2020); *Yealink (USA) Network Tech. Co., Ltd. v. Barco N.V.*, IPR2025-00491, Paper 18 at 3 (Director June 25, 2025) (patent issued 2020); *Micron Tech. v. Yangtze Memory Tech. Co., Ltd.*, IPR2025-00244, Paper 23 at 3 (Director June 25, 2025) (patent issued 2021); *Amazon.com, Inc. v. SoundClear Techs. LLC*, IPR2025-00565, Paper 11 at 2 (Director July 10, 2025) (patent issued 2021); *Advanced Micro Devices, Inc. v. Concurrent Ventures, LLC*, IPR2025-00479 Paper 10 at 2 (Director July 10, 2025) (patent issued 2021); *Shenzhen Tuozhu Tech., Ltd. v. Stratasy, Inc.*, IPR2025-00438, Paper 10 at 2 (Director July 17, 2025) (patents issued in 2020 and 2021); *see also Xencor, Inc. v. Merus N.V.*, IPR2025-00604, Paper 12 (Director July 17, 2025) at 2-3 (referring patent issued in

2016 based on evidence Office committed material error by overlooking reference cited in an IDS); *Eunsung Global Corp.*, IPR2025-00445, Paper 14 at 2 (denying request for discretionary denial because Petitioner showed material error, despite the challenged patent having issued in 2017). Given the 2021 issue date, Patent Owner’s reliance on a decision where the patent had “been in force since as early as 2012 and Petitioner was aware of it as early as 2013” is misplaced. *iRhythm Techs. Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10 at 3 (Director June 6, 2025) (cited at Req., 21).

Patent Owner attempts to support its settled expectations arguments by asserting that Petitioner’s sister company (Bay Materials) was aware of an early patent in the same family as the ’384 patent, the ’691 patent.² Req., 23. Instead, Patent Owner’s decision not to file suit asserting the ’691 parent patent weighs *against* discretionary denial. That patent, which claims soft-hard-soft aligners, issued on May 23, 2017. *See* EX1002, Cover. At that time, Patent Owner was engaged in a long-running district court litigation against Petitioner that was filed in 2011 and ended in March 2019. *See Align Tech., Inc v. ClearCorrect, Inc. et al*, SDTX-4-11-cv-00695, Complaint (S.D. Tex. Feb. 28, 2011). Yet, rather than assert

² Patent Owner offers no support for its assertion that knowledge of a parent patent by a related company creates any settled expectations for Patent Owner as to the ’384 patent.

the '691 patent in the then-active litigation or a new litigation in 2017, Patent Owner delayed nearly seven years until April 2024 to assert *other*, more recently issued patents in the '691 patent family. If anything, Patent Owner's decision to forgo a suit asserting the '691 patent demonstrates *Petitioner's* settled expectation that it would not be sued on patents in that family, and Patent Owner's decision to delay for years and assert more recently issued patents against *Petitioner's* hard-soft-hard aligners weighs against discretionary denial and in favor of referral. *See BOE Tech. Grp. Co., Ltd. v. Optronix Scis. LLC*, IPR2025-00238, Paper 11 at 2 (Director July 29, 2025); *see also Globus Med., Inc. v. Spinelogik, Inc.*, IPR2025-00225, Paper 8 at 2 (Director June 12, 2025) (referring petition and finding no settled expectations where petitioner "expected non-enforcement of the challenged patent").

Patent Owner's arguments regarding reexamination and IPR challenges to other unrelated patents have minimal relevance to the current proceeding. Req., 4-6, 21-22. To the extent these challenges are relevant, they support *Petitioner*. None of the cited reexaminations relate to the '384 patent or *any* patent that is currently involved in a pending IPR by *Petitioner*. The 26 reexaminations instead involve older technology asserted in the prior litigation Patent Owner filed against *Petitioner*. All patents in these reexaminations are now expired. These challenges therefore do not create any settled expectations for the patents at issue in the current IPRs. Req., 21-22.

Patent Owner's arguments regarding settled expectations are particularly meritless given the Examiner's failure to apply *Tadros*. Patent Owner was aware that the Office applied this reference inconsistently, using *Tadros* to reject claims during prosecution of the '090 and '091 patents but not applying it to the '384 patent claims.

B. Patent Owner's Arguments Relating to Secondary Considerations Misstate the Facts

Patent Owner admits there was no declaration submitted during prosecution of the '384 patent and does not cite any authority for its position that secondary considerations that were never addressed during prosecution must be addressed in an IPR petition. Req., 29. Patent Owner's unsupported arguments regarding the Li Declaration thus should be given no weight.

Patent Owner is also incorrect in asserting that the Petition "ignore[s]," "disregards," or "leave[s] unaddressed" the Examiner's findings regarding alleged unexpected results. Req., 21, 29, 31. On the contrary, the Petition catalogues the prosecution history in detail, including the facts regarding the Li Declarations submitted during prosecution of the '613 patent and its parent and the examiner's treatment of the alleged unexpected results addressed in those declarations. Pet., 24-26. The Petition also expressly noted, citing this summary of the prosecution history, the inconsistency between the characteristics of the soft-hard-soft aligner addressed in the Li Declaration and how Patent Owner is now asserting the '384 patent claims

against Petitioner's hard-soft-hard aligner product (the exact opposite configuration) in the parallel litigation. *See, e.g.,* Pet., 23 n.4 (citing Pet. 24-26). Thus, contrary to the Request's contentions, the Petition squarely addresses the purported unexpected results that the Examiner considered during prosecution.

The Request fails to address these facts and the Petition's substantive engagement with the declaration. This distinguishes the Petition here from those at issue in cases Patent Owner cites, where the petitioner either did not discuss the evidence related to secondary considerations at all or made vague or unsupported assertions regarding this evidence. For example, in *Gilead Sciences, Inc. v. United States*, which Patent Owner cites repeatedly, the petitioner made only "vague assertions about the results being attributable to the prior art and a lack of nexus." IPR2019-01456, Paper 17 at 53 (PTAB Feb. 5, 2020). In *Coalition for Affordable Drugs V LLC, v. Hoffman La-Roche Inc.*, the petitioner asserted that unexpected results evidence was not commensurate in scope with the claims, but provided no substantive analysis and further the panel disagreed based on its own review of the evidence. IPR2015-01792, Paper 14 (Mar. 11, 2016). And in *GlaxoSmithKline Consumer Healthcare Holdings (US) LLC v. Cipla Ltd.*, the petitioner did not even discuss the declaration at issue. IPR2020-00371, Paper 7 at 19 (PTAB Jul. 31, 2020). As noted above, the Petition here substantively addresses the alleged unexpected

results—summarizing the declarations, analyzing their content, and explaining why they conflict with Patent Owner’s assertion of the claims in litigation. Pet., 24-26.

Regardless, the Board has instituted review—even when secondary considerations were a decisive factor during prosecution—where the Patent Owner failed to establish how the purported unexpected results allegedly established nonobviousness or were commensurate with the scope of the claims. In *Mylan Pharmaceuticals, Inc. v. Allergan, Inc.*, for example, the Board instituted review despite expert declarations submitted during prosecution alleging unexpected results. IPR2016-01129, Paper 8 at 21-22 (PTAB Dec. 8, 2016). The Board explained it was “more appropriate to allow further evidence regarding any alleged unexpected results or other secondary considerations to be developed during trial,” and neither expert had been subjected to cross-examination yet. *Id.* Moreover, in *Phigenix, Inc. v. Immunogen, Inc.*, the Board instituted review where Patent Owner failed to address whether declarations cited during prosecution allegedly evidencing unexpected results were commensurate with the scope of the challenged claims, rejecting Patent Owner’s arguments that Petitioner had “fail[ed] to properly account for objective indicia of nonobviousness.” IPR2014-00676, Paper 11 at 16-22 (PTAB Oct. 29, 2014). Additionally, in *Apotex Inc. v. Cellgene Corp.*, the Board instituted after finding a material error where the Office had been “led astray by the

Applicants’ erroneous arguments regarding purported unexpected results.” IPR2023-00512, Paper 7 at 51-52 (PTAB July 20, 2023).

Referral is appropriate and discretionary denial is not warranted here because the Petition expressly addresses the alleged unexpected results and the Request fails to address any of the Petition’s substantive points regarding those results.

C. The Board is Best Positioned to Handle Validity Determinations

The parallel litigation itself involves patents spanning various technology areas, including three other patents in the ’384 patent family. Handling the validity determination at the Board will make the litigation more efficient and ensure review by administrative law judges capable of understanding the scientific arguments in the challenges. *See Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00217, Paper 9 at 2-3 (Director June 13, 2025). Relatedly, since the material errors for these challenged patents occurred at the Patent Office in the first instance (i.e., failure to consider known BPA-related prior art such as *Porter*, the inconsistent application of *Tadros*), these issues are best resolved by the Patent Office.

D. No Forum Has Adjudicated the Validity or Patentability of the Challenged Claims

No forum has yet adjudicated the validity of the ’384 patent. Other than this proceeding, the only case involving the ’384 patent is the district court litigation. No claim of the ’384 patent has been subject to reexamination and the patent has not

been reissued. No Board decision has addressed the combinations or rationales presented in the Petition references or combinations. This is particularly relevant given the material errors during prosecution.

E. The Unpatentability Challenge is Strong

As detailed above, the Petition presents a strong unpatentability challenge based on new prior art, new combinations, and new arguments, including by identifying several material errors by the Office.

For instance, Ground 2 of the Petition describes *Porter*'s disclosure of Tritan copolyester's improved properties and safety compared to BPA-containing polycarbonate. Ground 2 further describes a POSITA's motivation and reasonable expectation of success in modifying *Kalili*'s polycarbonate layer to instead use Tritan. The Request does not dispute the merits of this Ground, and instead inaccurately asserts that *Porter* is cumulative of prior art before the Examiner. Req., 19-20, 28. That is incorrect, as detailed above. The Examiner erred by failing to address the known harms of BPAs and motivation disclosed in the prior art to replace BPA-containing polycarbonate materials. These topics are likewise wholly ignored in the Request.

Similarly, Ground 1 presents strong obviousness arguments. This ground primarily relies on *Tadros*'s soft-hard-soft layer configuration, which discloses or renders obvious every limitation of the independent claims except for certain

properties of the TPU (elongation at break and hardness), which *Texin 990R* discloses. Even here, Patent Owner does not substantively address the merits, instead classifying the prior art as “recycled,” even though it was never applied during prosecution and is non-cumulative of the art that was applied. *See* Req., 19. Indeed, as detailed above, when *Tadros* was later applied to Patent Owner’s admittedly “parallel” claim limitations in later patent applications, Patent Owner was forced to amend to narrow its claims. This reinforces the merits of the Grounds and evidences a significant material error in the Office’s inconsistent application of the same prior art across “parallel” claim limitations in different applications in the same family.

V. CONCLUSION

For the foregoing reasons, Petitioner requests that the Director deny Patent Owner’s request for discretionary denial and refer the Petition to the Board for further consideration on the merits.³

Respectfully submitted,

Dated: August 8, 2025

By: /Charles T. Collins-Chase/
Charles T. Collins-Chase,
Reg. No. 78,019

³ Petitioner reserves the right to challenge the March 26, 2025 Interim Process for PTAB Workload Management at least because it is legally invalid as (1) exceeding the Director’s authority, (2) arbitrary and capricious, and (3) adopted without notice-and-comment rulemaking.

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 10,584 words.

Respectfully submitted,

Dated: August 8, 2025

By: /Charles T. Collins-Chase/
Charles T. Collins-Chase,
Reg. No. 78,019

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Petitioner's Opposition to Patent Owner's Request for Discretionary Denial** was served on August 8, 2025, via email directed to counsel of record for the Patent Owner at the following:

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