

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Patent Owner.

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

**PATENT OWNER'S PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.107**

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I. INTRODUCTION

The Board should not institute *inter partes* review of claims 1-23 and 25-26 of U.S. Patent No. 11,648,091 (“the ’091 patent”) because petitioner ClearCorrect Operating, LLC (“ClearCorrect” or “Petitioner”) has not met its burden of showing a reasonable likelihood of prevailing on any proposed ground of unpatentability.

The petition advances four obviousness grounds: a three-reference combination of Kalili, Texin 990R, and Porter; a four-reference combination of Kalili, Texin 990R, Porter, and Wen; another four-reference combination of Tadros, Porter, Kalili, and Texin 990R; and a five-reference combination of Tadros, Porter, Kalili, Texin 990R, and Wen.

Each of the petition’s grounds suffer numerous serious deficiencies. To begin with, despite arguing that the relevant field is unpredictable and conceding that objective indicia of nonobviousness were shown during prosecution, the petition advances 3-, 4-, and 5-reference obviousness grounds without addressing unpredictability or objective indicia. In these combinations, the petition provides no motivation for a POSITA to simultaneously select materials for each respective layer with properties as recited in the claim. Instead, the petition proposes grounds driven by hindsight, which reach the recited materials and properties by using the claims as a roadmap to select specific materials for each layer. Worse still, each of the petition’s grounds relies on non-analogous “dishwasher” art to provide missing

limitations in art directed to dental aligners.

Nor are these the limits of the petition's defective motivation arguments. The petition structures its combinations in a way that requires the use of multilayer sheets that are joined using a specific type of adhesive lamination to achieve the claimed properties, yet the petition provides no motivation for a POSITA to use such a process. Indeed, the petition does not even assert that a POSITA would have used adhesive lamination, only asserting that a POSITA would have known that one could have used such a process. An obviousness case built on such a foundation cannot stand.

Accordingly, institution of *inter partes* review should be *denied*.

II. OVERVIEW OF '091 PATENT

The '091 patent describes “[m]ultilayer orthodontic positioning appliances” that “apply forces to a tooth to generate movement of the tooth” to improve the positioning of a patient's teeth. EX1001, 3:6-11. The multilayer appliances can have multiple layers (e.g., three or more) configured to provide improved aligner performance, including improved material performance and stress relaxation properties, longer working range, increased durability, and improved elastic properties, reducing the need for additional aligners or mid-course correction during orthodontic treatment. *See* EX1001, 2:5-15, 3:15-31.

The '091 patent describes that a multilayer appliance can include “a hard

polymer layer” as well as “a soft polymer layer,” and it further describes that either of these can include additional layers of polymeric material. EX1001, 5:23-26, 6:39-59. The layers can be formed of different materials, and in particular, the specification describes appliances that include a hard co-polyester layer, as well as including one or more soft layers formed of a thermoplastic polyurethane elastomer. EX1001, 6:39-44. The ’091 patent describes forming dental aligners by thermoforming a multilayer sheet over “a positive model of the patient’s teeth in a target position” to fabricate an “appliance as a negative of the positive model.” EX1001, 3:51-59; *see id.*, Figs. 3-4.

The claims of the ’091 patent are directed to multilayer dental aligners, with claim 1 reciting a “multilayer sheet” that “is incorporated into an orthodontic appliance,” Claim 1 specifies that the sheet has three layers, including “a first layer containing a single polymer” that is a co-polyester, “a second layer containing a single polymer” that is a thermoplastic polyurethane elastomer, and a third layer, with the first (co-polyester) layer having an elastic modulus greater than the second (thermoplastic polyurethane elastomer) layer. *Id.* The claims further specify that the co-polyester has a “flexural modulus 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%,” and the thermoplastic polyurethane elastomer has “an ultimate tensile

strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D.” *Id.* Independent claim 10 is directed to an orthodontic appliance with similar limitations for each hard and soft layer, as are independent claims 6 and 18, though claims 6 and 18 do not expressly recite a third layer.

During prosecution of the '091 patent's parent applications, Align provided evidence demonstrating that multilayer appliances with the properties recited in the claims of the '091 exhibit unexpectedly positive results relative to the closest prior art. For example, during prosecution of Application No. 13/470,681 and Application No. 15/476,655, Align provided clinical trial data comparing multilayer aligners made with the material “ST30” to aligners made with the prior clinical standard, a single-layer thermoplastic polyurethane material referred to as “EX30.” EX1011, 598-606; EX1010, 1235-42. The ST30 material is a multilayer material comprising hard and soft layers each corresponding to the layers recited in the independent claims of the '091 patent. That is, it includes both a hard layer consisting of co-polyester that matches the properties recited in claim 1 for such a layer and a soft layer consisting of a thermoplastic polyurethane elastomer that matches the properties recited in claim 1 for that layer. EX1010, 1239 (ST30 includes co-polyester hard layer and thermoplastic polyurethane elastomer soft layer); EX1011, 600, 625, 628; *see also* Pet., 22 n.4 (noting correspondence of SmartTrack material to claims). EX30 is a single-layer thermoplastic polyurethane

material and was the standard of care in clear aligner treatment at the time. The clinical study results showed unexpectedly improved performance relative to EX30, including improved On-Track performance and predictability of tooth movement to a degree that would have been surprising and unexpected to persons of ordinary skill. EX1011, 602-05, 609; EX1010, 1239-41, 1245.

The Examiner considered these results and found them persuasive, expressly stating in the '655 application's notice of allowance that the "applicant's affidavit was also found persuasive, in particular attention to the Page 3 statement of 'the appliances recited in the claims of the '655 application exhibit unexpectedly positive results over previously known appliances. These unexpected results are evidenced by clinical studies that were performed comparing the efficacy of orthodontic appliances as described and claimed in the '655 application with that of previously known appliances.'" EX1011, 882; *see also* EX1010, 1376 (crediting declaration evidence showing "unobvious or unexpected advantageous properties" to allow claims).

III. CLAIM CONSTRUCTION

Petitioner has proposed no claim constructions. Pet., 27-28. Petitioner asserts that its claim mappings are informed by Align's infringement contentions (*id.*), but as discussed below, Petitioner's arguments based on these contentions fail.

IV. PETITIONER’S GROUNDS OF UNPATENTABILITY FAIL

The petition advances four grounds alleging obviousness of the claims of the ’091 patent. Ground 1 alleges that claims 6, 9, 18, 23, and 25-26 would have been obvious over U.S. Patent Application Publication No. 2011/0020761 to Kalili et al. (“Kalili”) in view of the TEXIN 990R Product Information (“Texin 990R”), and further in view of “Dishwasher Safe,” by Porter et al. (“Porter”). Pet., 4. Ground 2 alleges that claims 1-2, 4-7, 9-14, 16-23, and 25-26 would have been obvious over Kailili in view of Texin 990R, further in view of Porter, and still further in view of Wen. Pet., 5. Ground 3 alleges that claims 1, 4-7, 9-13, 16-20, 22-23, and 25-26 would have been obvious over U.S. Patent Application Publication No. 2005/0100853 to Tadros et al. (“Tadros”) in view of Porter, further in view of Kailili, and still further in view of Texin 990R. *Id.* And Ground 4 alleges that claims 1-23 and 25-26 would have been obvious over all five references: Tadros, Porter, Kalili, Texin 990R, and Wen. *Id.*

A. Deficiencies Common to All Grounds

To begin with, in each ground, Petitioner advances multi-reference obviousness combinations yet fails to rebut the objective indicia that were established during prosecution. *See supra* §II (objective indicia shown for claimed combination of materials in multilayer appliance); Pet., 23-27 (discussing prosecution history for ’091 patent and conceding, but not rebutting, this objective

evidence of nonobviousness). This evidence was provided in declarations by Dr. Chunhua Li who described clinical trial data showing that aligners made with the ST30 material (corresponding to the claims of the '091 patent) had unexpectedly improved performance relative to EX30, the standard of care. EX1011, 602-05, 609; EX1010, 1239-41, 1245. The Examiner found these results persuasive for both the '655 and '681 parent applications. EX1011, 882; EX1010, 1376.

“Objective indicia of nonobviousness must be considered in every case where present.” *E.g., Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016). Where objective evidence is known by petitioner, such as if the examiner considered such evidence as part of the prosecution history, that evidence must be rebutted *in the petition* to satisfy the petitioner’s burden for institution. *See, e.g., Gilead Sciences, Inc. v. United States*, IPR2019-01456, Paper 17 at 52-53 (Feb. 5, 2020) (“Petitioner’s failure to persuasively address the [unexpected] results in its Petition means Petitioner falls short of its burden to establish a reasonable likelihood of success in prevailing on its challenge.”). Where a petitioner disregards objective indicia the Office had previously considered, or when the petition does not persuasively rebut such evidence, institution should be denied. *See, e.g., id.; Coalition for Affordable Drugs V LLC, v. Hoffman La-Roche Inc.*, IPR2015-01792, Paper 14 at 17-18 (Mar. 11, 2016) (denying institution due to petitioner not addressing the objective indicia of nonobviousness relied upon in

part by the examiner).

There is no question that Petitioner was aware that the Office had considered and credited objective indicia of nonobviousness during prosecution, in both '655 and '681 parent applications. Petitioner concedes both the Office's consideration of these objective indicia and the examiner's crediting of them when discussing the prosecution history. *See* Pet., 23-26. Yet nowhere does the petition rebut these findings. The petition presents no evidence or even argument undermining the objective indicia shown during prosecution, nor does the petition dispute that these indicia have nexus to the claims. None of the grounds ever discusses whether a POSITA would have expected the proposed combination to achieve the type of results shown during prosecution for the claimed multilayer combination of materials. Because the petition fails to factor in or rebut this evidence and the examiner's consideration during prosecution, Petitioner fails to meet its burden of showing unpatentability of the claims under any of its obviousness combinations.

As discussed below for the grounds individually, rather than rebut these objective indicia, Petitioner advances hindsight-infused challenges involving multi-reference combinations that the petition itself argues to be unpredictable. For example, each ground proposes modifying multilayer aligners by replacing particular polymers with different polymers. But Petitioner expressly argues that replacing or modifying polymers has unpredictable effects on the "efficacy of

repositioning teeth using dental aligners.” Pet., 22 n.4. Petitioner cannot have it both ways. Despite advancing “unpredictability” arguments in an attempt to show the claims are inadequately described or enabled, Petitioner never attempts to address unpredictability in the grounds; indeed, Petitioner advances arguments expressly premised on *predictability*. See Pet., 59 (relying on caselaw regarding predictable results). The hindsight-based nature of these challenges is further exemplified by Petitioner’s reliance in every ground on non-analogous “dishwasher” art unrelated to dental aligners to provide limitations missing from the prior art. See Pet., 31-32, 39-40, 54-57 (proposing replacing dental aligner polymer material with copolyester found in “Dishwasher Safe” by Porter et al.); *see also id.*, 77.

Further, each of Petitioner’s combinations relies on using adhesive lamination as an essential part of its combination in order to meet the claim elements. See Pet., 32, 34, 41, 56, 58-60, 77; *see also id.*, 11 n.3 (arguing that techniques other than adhesive lamination would modify properties recited in the claims to an unknown degree, undermining any reasonable expectation of success of achieving the claimed properties using such techniques). Yet Petitioner fails to even allege, much less show, a motivation to employ adhesive lamination for the recited multi-layer aligners.

In sum, despite both arguing unpredictability and failing to rebut objective

indicia of nonobviousness, Petitioner advances obviousness grounds infused with hindsight, relying on non-analogous art, and failing to show why a POSITA would have been motivated to arrive at the claimed invention.

B. Ground 1 Fails

Ground 1 alleges that claims 6, 9, 18, 23, and 25-26 would have been obvious over Kalili in view of Texin 990R and Porter. Pet., 4. Among various modifications Petitioner proposes, ground 3 takes a polymer layer composed of “polymers and plastics including polycarbonates, polyacetates, polyolefins, polyamides, polystyrenes and epoxy resins,” as taught by Kalili, and replaces that layer with a co-polyester (Tritan) disclosed by Porter’s “Dishwasher Safe” article as suitable for kitchenware and the like. EX1005, [0053]; *see* EX1006, 6; Pet., 30-32. Petitioner advances the same arguments against independent claims 6 and 18. *See* Pet., 37.

As discussed below, Petitioner fails to meet its burden to demonstrate the unpatentability of any of these claims in ground 1. In addition to failing to rebut objective indicia shown during prosecution (*see supra* §§II, IV.A), Petitioner advances a hindsight-tainted combination despite simultaneously arguing unpredictability of the field with respect to the changes it proposes. Worse still, to fill in missing disclosure, Petitioner turns to non-analogous art that is incompatible with its primary reference. And Petitioner’s combination also relies on using

adhesive lamination as essential to meet the claim elements, yet Petitioner fails to even allege, much less show, a motivation to employ adhesive lamination for the recited multi-layer aligners.

1. Ground 1's Combination Is Founded on Improper Hindsight, Requiring Modifications Petitioner Argues Would Be Unpredictable

In addition to failing to dispute the presence of objective indicia of nonobviousness, the petition does not show that its proposed combination would be made or would be predictable. Whereas an inquiry focusing on “identified, predictable solutions” may make obviousness a more likely conclusion, it is also essential to avoid the “distortion caused by hindsight bias” and “*ex post* reasoning.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). As the Federal Circuit has observed, “predictability is a vital consideration in the obviousness analysis.” *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1298 (Fed. Cir. 2012). This is not merely predictability in physically combining prior art elements, but also “that the combination would have worked for its intended purpose.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009). In the absence of predictability, the selection of prior art teachings from numerous possible alternatives to arrive at the claims speaks to hindsight reasoning, rather than obviousness. *See, e.g., In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (“[W]here a defendant merely throws metaphorical darts at a

board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.”).

Here, Petitioner does nothing to show the requisite predictability for obviousness, relying instead on hindsight-driven arguments. When discussing the '091 patent, Petitioner argues that “[t]he 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.” Pet., 22 n.4. Petitioner further expounds on this concept in the grounds, stating that “changing layer properties or the relative order of hard and soft layers has unpredictable effects on an aligner’s properties and efficacy.” Pet., 43 n.10.

Despite expressly arguing that modifications to polymer materials have unpredictable effects on aligner properties and efficiency, the petition advances grounds proposing modifications to aligner materials that are premised on predictability. For example, in ground 1, Petitioner proposes replacing polycarbonate with a copolyester described in “Dishwasher Safe” by Porter et al. In addition to Petitioner’s failure to justify why a POSITA would have relied on the Porter reference for this substitution (*see infra* §IV.B.2), Petitioner again makes no attempt to explain why its substitution would have been selected with a reasonable expectation of success. Petitioner points to properties of Porter’s copolyester alone, such as resistance to heat and chemicals and stress cracking in

consumer products such as water bottles when washed in dishwashers. Pet., 31.

This discussion overlooks Petitioner’s own arguments that “replac[ing] layers with other polymers” (e.g., replacing polycarbonate with Porter’s copolyester) and “changing layer properties” (e.g., altering the properties of Kalili’s polycarbonate by substituting Porter’s copolyester having different physical properties) would have “unpredictable effects on an aligner’s properties and efficacy.” Pet., 22 n.4, 43 n.10. Petitioner does not and cannot argue that a POSITA seeking to design an aligner having *properties to efficiently move teeth* would have been unconcerned with the properties and efficiency of that aligner. Accordingly, ground 1 proposes modifications of materials in multilayer aligners yet fails to grapple with the unpredictability that the petition argues would arise from such modifications.

Petitioner’s failure to square its arguments relating to unpredictability and obviousness undermine its argument that a POSITA would have been motivated to arrive at its proposed combination with a reasonable expectation of success. See *DePuy*, 567 F.3d at 1326 (predictability required not merely for combined elements, but also for combination’s operation for intended purpose). This deficiency is particularly severe where, as the petition admits, the Office repeatedly found unexpected results associated with the claimed invention during prosecution. See *supra* §IV.A. Accordingly, the petition fails to meet its burden in ground 1.

2. Ground 1's Reliance on Porter is not Justified

Ground 1's hindsight-based nature is sharply exemplified by its reliance on the Porter reference, despite providing no valid justification for a POSITA to turn to such a reference. As noted above, ground 1 proposes a combination of three references: Kalili, Texin 990R. The last of these, Porter, is an article titled "Dishwasher Safe," and it describes plastics appropriate for goods that will be cleaned in "commercial and residential dishwashers" due to their high "dishwasher durability." EX1006, 6.

Porter describes that its plastic (Tritan) is useful in "commercial and residential kitchenware and small kitchen appliances, including reusable food containers, sports bottles, mugs, pitchers, and containers for food processors and blenders." *Id.* For example, it describes the use of its plastic in CamelBak water bottles, Vita-Mix blenders, and Carlisle soup bowls. EX1006, 8-9. Porter describes properties that make Tritan appropriate for use in dishware and other dishwashable consumer goods, including resistance to "heat, humidity, detergent chemicals," and other properties encountered when dishwashing kitchenware. *Id.* It also describes that dishwashable goods can be made from Tritan using various suitable manufacturing techniques, including "injection molding, injection-blow and stretch-blow molding, sheet and flat-film extrusion, and thermoforming." EX1006, 6.

But while Porter describes in great detail the suitability of its plastic for use in kitchenware, nowhere does Porter mention dental applications for its plastics. Nor does it ever discuss Tritan's suitability to be worn continuously in a mouth or to apply tooth-moving forces for days or weeks on end, as required for effective aligner treatment. Petitioner points to Porter's disclosure describing the properties of its Tritan plastic in consumer products like water bottles (Pet., 31-32), but nowhere does Petitioner identify why a POSITA looking to develop a *dental aligner* would have turned to Porter, which says nothing whatsoever about such devices.

To be analogous art, a reference must be either (1) "from the same field of endeavor" or (2) "reasonably pertinent to the particular problem with which the inventor is involved." *Sanofi-Aventis Deutschland GmbH v. Mylan Pharms., Inc.*, 66 F.4th 1373, 1377 (Fed. Cir. 2023) (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)). There is no question that Porter is not from a field relating to dental aligners. *See* Pet., 8 (asserting only "*Kalili*, *Wen*, and *Tadros* are directed to the field" relevant here). While Petitioner asserts that Porter is "pertinent to the problem of improved aligner materials" (*id.*), Porter never discusses use of its materials in aligners.

To characterize pertinent art, the petition cites to the '091 patent's specification, which describes that "it may be advantageous to develop materials

that improve properties of the appliances/aligners used for orthodontic treatment. As such, there is a need for shell aligners that can, for example, produce more continuous force and better bring a patient's teeth into a desired occlusion." EX1001, 1:54-62; see Pet., 8 (citing EX1001, 1:54-57 to describe pertinent art). Yet to qualify as pertinent art, a reference must be one that "logically would have commended itself to an inventor's attention in considering his problem." *In re ICON Health and Fitness, Inc.*, 496 F. 3d 1374, 1380 (Fed. Cir. 2007) (quoting *In re Clay*, 966 F.2d 656, 659 (Fed.Cir.1992)). Petitioner here fails to explain why a "skilled artisan would have plucked one reference [Porter] out of the sea of prior art," without any guidance from Porter (or other art) to bring Porter to the attention of one seeking to develop dental aligners. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016).

And regardless of whether Porter could constitute analogous art, Petitioner fails to explain why a POSITA would have turned to its teachings. Petitioner asserts that a POSITA would have used Porter's Tritan polymer to replace polycarbonate in Kalili's aligners with "a BPA-free alternative." Pet., 31. Yet Petitioner never explains why a POSITA would have looked to Porter's disclosure of dishwasher-safe polymers for use in a dental aligner when Kalili itself in the same paragraph cited by Petitioner for polycarbonate teaches numerous suitable alternatives to polycarbonate, none of which is a copolyester. See EX1005, [0053]

(“Repositioning appliance 300 may be comprised of a single sheet of material that may be formed from a variety of materials, such as polymers and plastics including polycarbonates, **polyacetates, polyolefins, polyamides, polystyrenes and epoxy resins** among others.... Those skilled in the art will realize that materials such as polycarbonates, **polyacetates, polyolefins, polyamides, polystyrenes and epoxy resins** among others also may be provided in clear forms.”);¹ *see also id.*, [0062] (same list), [0063] (same), [0069] (same). Petitioner’s explanation of the undesirability of polycarbonate thus fails to justify abandoning all of the options listed in Kalili and looking instead to Porter’s dishwasher-safe plastic disclosure that bears no relation to dental aligners. *Cf. Kubin*, 561 F.3d at 1359 (“[W]here a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.”).

Likewise, Petitioner’s description of the purported benefits of Porter’s material also falls short. Petitioner asserts that Porter had described its Tritan material as having “increased heat resistance and toughness,” “superior chemical resistance,” “reduce[d] [] risk of product failure from environmental stress cracking.” Pet., 31 (alterations in original) (quoting EX1006, 60-61). But as

¹ Emphases added unless otherwise indicated.

explained above, Porter is describing these properties for its plastics in the context of dishware—soup bowls, water bottles, blenders, and the like—not in the context of dental aligners. Petitioner has provided no explanation of why the ability of a soup bowl to withstand the heat, stress, and chemicals found in a dishwasher has any bearing on the entirely different conditions found in an aligner worn to apply continuous tooth-moving forces within a patient’s mouth. While Petitioner asserts its combination would “avoid the harmful BPAs released from polycarbonate aligners” (Pet., 31), the absence of BPAs is already satisfied by Kalili’s many alternatives (none of which is the claimed copolyester).

Petitioner also vaguely asserts that using Tritan could “improv[e] performance characteristics” (*id.*), but Petitioner provides no reason why *aligner* performance characteristics would be improved, as the only performance characteristics the petition actually discusses relate to dishwashability. Indeed, as noted above, Petitioner argues the impossibility of predicting any performance improvements for its proposed material substitution. See Pet., 22 n.4. Moreover, with regard to the BPA-related problems Petitioner latches on to, it is improper to conclude that a reference is analogous by “focus[ing] on the problems of alleged prior art references” (such as deficiencies in one of Kalili’s material options) as opposed to focusing on “the problems of the challenged patent” (e.g., improved performance of dental aligners relative to those made with prior art materials).

Sanofi-Aventis, 66 F.4th at 1378.

Nor does Petitioner's discussion of reasonable expectation of success resuscitate its failures of motivation: Petitioner repeats its discussion of Tritan's dishwasher-safe properties (durability to "heat, hydrolytic and chemical attack, and applied stress" of dishwashers) and asserts that there was "past industry success in replacing polycarbonate with Tritan" (Pet., 32), but any such success would be in an unrelated industry (kitchenware) addressing entirely different problems (making dishwasher-safe containers, not force-applying dental appliances). See Pet., 8 (Porter not "directed to the field of polymeric dental aligners"). And while Petitioner asserts that Porter's plastics could be used in "thermoforming processes and extruded-sheet applications" (Pet., 32), Porter describes these processes in the context of making thick plastic containers like blenders, water bottles, and soup bowls, not dental aligners. Any utility of such processes in the context of kitchenware says nothing about the requirements for success in dental aligners, such as the continuous application of tooth moving forces within an oral environment over the course of weeks or longer. And Petitioner points to nothing in Porter (or elsewhere) indicating that its materials would be useful in a multilayer dental appliance in conjunction with different layers, such as the thermoplastic polyurethane elastomer recited in the claims.

3. Ground 1 Requires Adhesive Lamination, Yet Fails to Motivate its Use

To meet its burden when addressing the independent claims in ground 1, Petitioner must show that it would have been obvious to combine the relied-upon references to arrive at the claimed invention. As recited in claim 6, this includes dental appliances comprising hard and soft layers having specified material compositions and properties. In particular, the appliance must include a hard polymer layer containing a single polymer, a co-polyester, with “a flexural modulus 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%”; and a soft polymer layer containing a single polymer, a thermoplastic polyurethane elastomer, with “an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D.” EX1001, claim 6.

In an attempt to satisfy these claim requirements, Petitioner relies on disclosure regarding these materials when measured on their own—that is, when not formed into a multilayer sheet as recited in the claims. *See, e.g.*, Pet., 31-35 (using datasheet properties of TEXIN 990R and properties of Tritan disclosed by Porter to conclude corresponding layers of multilayer sheet forming appliance would have same properties). However, Petitioner also insists that forming a multilayer sheet via certain normal “manufacturing techniques (e.g., coextrusion,

extrusion lamination) would alter the polymer's properties." Pet., 11 n.3; *see also id.*, 34 ("the mechanical properties of a polymer (or free film) can change when combined into a multilayer sheet (e.g., during coextrusion or extrusion lamination)"); EX1007, ¶31 ("certain manufacturing processes (e.g., coextrusion) may lead to molecular diffusion or mixing between the layers, as well as cross-linking, that can change the properties of the polymers within a layer"). Petitioner makes no attempt to assess the degree to which the polymers' properties would change as the result of such processes. For example, Petitioner does not argue that if processes such as coextrusion or extrusion lamination were used, the respective layer's properties (e.g., flexural modulus, elongation at break, or hardness) would remain within the ranges recited in the independent claims. On the contrary, Petitioner completely disavows the use of such processes. *See* Pet., 31-35.

In an effort to reach the claims notwithstanding these problems, Petitioner proposes using "adhesive lamination," and more specifically, adding a "tie layer" between each other polymer layer as a glue to stick the layers together. Pet., 32, 34-35. Petitioner asserts that in contrast to extrusion lamination or coextrusion, in adhesive lamination there would not be "cross-linking or mixing between layers," so that using adhesive lamination "would preserve [a polymer's] reported mechanical properties." Pet., 32, 34; EX1002, ¶31. Petitioner also relies on adhesive lamination instead of coextrusion or extrusion lamination to avoid "inter-

layer mixing” and produce layers that would respectively ““contain[] a single polymer” of pure Tritan copolyester” and ““contain[] a single polymer’ of pure TEXIN 990R TPU as required by the claim.” Pet., 32, 34-35.

Petitioner does not claim that the grounds references teach using such an adhesive lamination process to form an aligner from a multilayer sheet as claimed, as opposed to using extrusion lamination or coextrusion. Instead, throughout the petition, in each ground, Petitioner asserts that “a POSITA **would have known of** suitable techniques for adhering multiple polymer layers together, such as by adhesive lamination using a tie layer.” Pet., 62; *see id.*, 32 (“A POSITA **would have understood** that adhesive lamination would preserve Tritan’s properties within the layer, without cross-linking or mixing of layers.”), 34 (“a POSITA **would have expected** that using tie layers... would preserve TEXIN® 990R’s reported mechanical properties during processing”), 56 (“A POSITA **would have understood** that manufacturing techniques such as adhesive lamination would result in...”), 60 (same), 65 (same), 59 (“a POSITA **would have known** that adhesive lamination, in contrast to coextrusion, would preserve the polymer’s properties....”), 61 (“A POSITA **would have known** that certain manufacturing processes (e.g., adhesive lamination) preserve” polymers’ properties.).

Awareness of an option is not sufficient for obviousness. As the Federal Circuit has repeatedly admonished, it is not sufficient to assert that “one of

ordinary skill in the art *could* combine” references in a particular way; rather one must show that “they *would* have been motivated to do so.” *InTouch Techs., Inc. v. VGo Communs., Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (emphases original); *see, e.g., Polaris Indus. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1068 (Fed. Cir. 2018) (vacating decision where “the Board focused on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated* to do at the time of the invention” (emphases original)). Indeed, an argument focusing on known options in the prior art instead of motivation to use a particular option needed to meet the claims under the proposed combination is “fraught with hindsight bias.” *ActiveVideo Networks, Inc. v. Verizon Communs., Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012). The danger of such hindsight bias is especially acute here, where Petitioner itself has argued the unpredictability of the art and evidence of unexpected results has already been recognized by the Office.

Despite this requirement to address what a POSITA would have—not could have—done, Petitioner does not even try to argue that a POSITA would be motivated to use adhesive lamination. For example, while Petitioner discusses the *option* of including tie layers to adhesively laminate other layers together, Petitioner never discusses how a POSITA would have viewed the benefits and disadvantages of using such a technique. *See* Pet., 32, 34-35. Petitioner cites to a textbook discussing a “glue layer” as an option for certain sheets with “poor

adhesion” and which are prone to “delamination” (EX1019, 150; *see* Pet., 6 (referring to these glue layers as “tie layers”)), yet Petitioner does not assert that such issues would arise in its proposed combination. Petitioner also fails to discuss the suitability of such glue layers in a warm, wet environment like the human mouth in which a dental aligner is continuously worn. Nor does Petitioner address the biocompatibility of such glue layers in the human mouth.

Petitioner’s “tie layers” argument is also inconsistent with its own assertion that modifying materials and layer arrangements in multilayer appliances is unpredictable. Pet., 22 n.4, 43 n.10. Petitioner cannot argue that a person of skill would be motivated to use tie layers and have an expectation of success in doing so without addressing any effect these new layers would have on the appliances’ material properties or efficacy, while simultaneously arguing that the art is “unpredictable” and a person of skill would not know how to modify the layers in a multilayer appliance. *See* Pet., 32, 34-35.

Later in the petition (in ground 3), Petitioner cites to Align’s preliminary infringement contentions as purportedly showing that Petitioner’s combination would satisfy the limitations of the claims. *See* Pet., 59; *see also id.*, 11 n.3. Specifically, Petitioner asserts that because the preliminary infringement contentions cite to “properties of the soft polymer recited in a manufacturer’s datasheet [as] evidence of the properties of that polymer **after** being combined

with other polymers in a multilayer sheet,” that a POSITA would have expected Petitioner’s combination to meet the claims. Pet., 59.

However, Petitioner’s reliance on these contentions cannot salvage its faulty combination. First, it does not remedy Petitioner’s lack of motivation; indeed, Petitioner cites to the contentions only when discussing expectation of success, not in discussing motivation to combine. Second, Petitioner cites to the contentions only to support expectation that its combination (adhesively laminated layers) would be expected to have the same individual layer properties, not to show expectation that the proposed combination would function. Third, Align’s citation to datasheet properties as part of its evidence that aligners manufactured using Petitioner’s process, materials, thickness, and arrangement of layers infringe the claims of the ’091 patent does not speak to whether a different aligner would meet the claims. Petitioner has not argued that *its combination* would satisfy the claims if manufactured using coextrusion or extrusion lamination (indeed, it has argued that the materials’ properties would change to an unknown degree), nor has Petitioner shown that a POSITA would have been motivated to use adhesive lamination in such a multilayer aligner.

In sum, Petitioner advances its combination in a way that critically relies on the use of adhesive lamination to meet the claims’ limitations, yet it has failed even to assert, much less show why a POSITA would have been motivated to use such a

process. Ground 1 is thus incurably fraught with hindsight and cannot sustain Petitioner's burden for institution.

For at least the foregoing reasons, Petitioner fails to meet its burden of demonstrating that claims 6, 9, 18, 23, and 25-26 were obvious Kalili, Texin 990R, and Porter.

C. Ground 2 Fails

Ground 2 alleges that claims 1-2, 4-7, 9-14, 16-23, and 25-26 would have been obvious over Kalili, Texin 990R, Porter, and Wen. Pet., 5. However, when addressing the elements of claim 1 involving hard and soft layers, petitioner relies exclusively on its analysis of claim 6 in ground 1, providing no further analysis as to why these claims would have been obvious over the further combination with Wen or that Wen would be relevant to these limitations. Pet., 39-41.

The only added argument in discussing these elements of claim 1 is a new assertion in the petition that using Tritan would “improve longevity”—something never discussed in ground 1 and not explained in the petition. Pet., 39. To the extent this conclusory assertion is given any consideration, it fails at least because Petitioner has not identified any reason a POSITA would have viewed any of Kalili's aligners as having a longevity problem to be solved. Indeed, the ability of Porter's bowls or water bottles to maintain their shape well enough to continue holding food and drinks over months or years of periodic dishwashing bears no

clear relation to the issues of an aligner typically worn in a mouth for a matter of weeks.

With regard to the remaining independent claims, ground 2 presents no new argument whatsoever, merely referring back to claim 1 when addressing independent claim 10 and to its ground 1 discussion for independent claims 6 and 18. Pet., 47, 53. Thus, ground 2 fails to overcome the shortcomings of ground 1.

Accordingly, Petitioner fails to meet its burden of demonstrating that claims 1-2, 4-7, 9-14, 16-23, and 25-26 were obvious over Kalili, Texin 990R, Porter, and Wen.

D. Ground 3 Fails

Ground 3 alleges that claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26 would have been obvious over Tadros in view of Porter, further in view of Kalili, still further in view of Texin 990R. Pet., 5. For example, ground 1 proposes replacing each layer of a multilayer sheet used to form a dental appliance, taught by Tadros, with different materials—a soft thermoplastic polyurethane elastomer disclosed by Kalili in view of Texin 990R and a hard co-polyester disclosed by Porter—as well as altering the sheet's structure by introducing tie layers to employ adhesive lamination. *See* Pet., 54-60. Petitioner applies the same arguments for independent claims 6, 10, and 18, as for claim 1. *See* Pet., 64-66, 68, 69-70.

As discussed below, ground 3 suffers from similar deficiencies to ground 1.

Ground 3 again advances a hindsight-tainted combination in an unpredictable field while turning to non-analogous art that is incompatible with its primary reference to fill in missing disclosure. And Petitioner again relies on using adhesive lamination as essential to meet the claim elements, despite no showing of a motivation to employ adhesive lamination for the recited multi-layer aligners.

1. Ground 3 Advances a Hindsight-Based Challenge Lacking Predictability and Grounded in Non-Analogous Art

Similar to ground 1, ground 3 not only ignores known objective indicia of nonobviousness but also advances a hindsight-infused combination that the petition confirms lacks the predictability needed for an obviousness challenge. *See supra* §IV.B.1; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (obviousness to be grounded in predictability, not hindsight-biased reasoning); *Otsuka*, 678 F.3d at 1298 (predictability a vital consideration); *DePuy*, 567 F.3d at 1326 (predictability required for achieving aim of whole combination).

Ground 3 fails to show the requisite predictability for obviousness, relying instead on hindsight-driven arguments. As discussed above for ground 1, Petitioner argues that “[t]he 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,” and that “changing layer properties or the relative order of hard and soft layers has unpredictable effects on an aligner’s properties and efficacy.” Pet., 22 n.4, 43 n.10. Yet like with ground 1,

ground 3 proposes modifications to aligner materials without considering any unpredictable effect its combination would have on aligner efficacy.

In ground 3, the petition proposes modifying aligners taught by Tadros by replacing each layer of such an aligner with different materials: TEXIN 990R for the two soft layers and Tritan for the hard layer. Pet., 54-60. For the soft layer, Petitioner begins with a laundry list of possible materials in Tadros, which lists 30 broad categories of organic polymers as well as “mixtures and copolymers thereof,” selected to have a tensile modulus of up to “about 1,000 N/mm²,” only slightly softer than the 1,500 to 2,500 N/mm² polymer mixture layer of Tadros. EX1007, [0073]; *see id.*, [0068]. Petitioner selects one of these broad categories—polyurethanes—and then turns to Kalili and Texin 990R to select the TEXIN 990R material—a thermoplastic polyurethane elastomer that is far softer than Tadros’s materials, having a flexural modulus of just 41.4 MPa (41.1 N/mm²). Pet., 57-61 (noting 6,000 psi flexural modulus—equivalent to 41.4 N/mm²—and arguing equivalence of elastic and flexural modulus) EX1009, 3; *see* EX1007, ¶¶60 (asserting “flexural modulus and tensile modulus...are practically identical under typical use conditions for polymeric materials”), 128 (“6,000 psi (41.4 MPa)”). Petitioner thus proposes a substantial change in the material of the soft layers of Tadros’s appliance.

Petitioner also proposes a substantial and unjustified change to the hard layer

of Tadros's appliance. The central idea of Tadros is to form an appliance of a "polymeric shell that comprises a polymeric mixture." EX1003, Abstract. Tadros's appliance includes "at least one layer manufactured from a sheet of a polymeric mixture," and Tadros lists several types of polymers that can be blended together to form this mixture, especially a mixture of polycarbonates and polyesters. EX1003, [0022]-[0023]. As Petitioner concedes, Tadros's disclosure is centered on using such a mixture of multiple different polymers its "hard layer." Pet., 15-16; *see id.*, 55-56.

Petitioner nevertheless insists that the central idea of Tadros should be abandoned, and that instead of using mixtures of "polycarbonate and polyesters" as taught by Tadros, a POSITA would throw out the entire idea of mixing polymers and instead substitute a single copolyester, using the teachings of Porter. Pet., 55-56. This proposal is pure hindsight. Not only does Petitioner turn to art in an unrelated field which discloses no applicability in aligner treatment (as discussed further in §IV.D.2 below), but Petitioner also contradicts the key teaching of Tadros: to use blends of polymers to produce a mixture with properties that can be adjusted to have the desired effect for moving teeth.

Petitioner's justification for this change is manufactured out of whole cloth. Petitioner asserts that Tadros discloses that "the hard layer should have a glass transition temperature of about 120°C or less." Pet., 55 (citing EX1003, tbl. 3,

[0113]). However, Petitioner's citations do not support its assertion. Paragraph 113 of Tadros merely says that it is desirable for its mixture to have a glass transition temperature less than polycarbonate; it never sets a particular target. EX1003, [0113]. And Table 3 lists five samples and notes their glass transition temperatures as 145°C, 65°C, 65°C, 111°C, and 120°C, but it never indicates that 120°C is a key threshold. EX1003, tbl. 3. Indeed, the "most preferred" thermoforming temperature disclosed by Tadros is "less than or equal to about 95°C," which would exclude Tritan at 108°C. EX1003, [0056]; *see* Pet., 56 (conceding that Tritan has "a glass transition temperature of 108°C," above Tadros's most preferred range).

Petitioner fails to explain why a POSITA would abandon Tadros's blends, which could produce its most preferred glass transition temperature, in favor of Porter's Tritan copolyester. This is unsurprising, as Petitioner is using this temperature (which is not recited in the claims) as an excuse to select Tritan specifically as a hindsight-guided choice to meet claim elements that it does not argue would have motivated a POSITA. *See* Pet., 57 (asserting Tritan would meet claim elements but not arguing a POSITA would be motivated to select materials to achieve these claim elements). While Petitioner vaguely suggests a POSITA would have substituted Tritan to "improve product safety and performance" (Pet., 56), Porter fails to justify this assertion, as discussed further in §IV.D.2.

Petitioner's arguments for the hard and soft layers share similar deficiencies.

Petitioner discusses whether the properties of the Tritan or TEXIN 990R polymers would be changed by its proposed replacements²; however, Petitioner fails to address whether the combination resulting from the selection it proposes would be appropriate for an aligner. *See* Pet., 54-60; *see also id.*, 59 (tying obviousness to *KSR*’s discussion of a “combination of familiar elements” that “does no more than yield predictable results” (quoting *KSR*, 550 U.S. at 416)). In other words, ground 3 proposes “replac[ing] layers with other polymers without guidance to do so,” as well as “changing layer properties” by substituting different materials to make a different multilayer aligner, without providing any reason that a person of skill would be motivated to select this combination or addressing the apparent “unpredictable effects on an aligner’s properties and efficacy.” Pet., 22 n.4, 43 n.10.

Indeed, despite arguing that modifications such as the replacement of a given polymer with another polymer had unpredictable effects on aligner efficacy (*see* Pet., 22 n.4), Petitioner never discusses what a POSITA would have expected with regard to aligner efficacy in its proposed combination. In ground 3, Petitioner discusses whether substituting TEXIN 990R and Tritan into Tadros’s aligner to replace different polymers would have preserved the properties of *TEXIN 990R*

² As discussed below in §0, this discussion is defective as well.

and Tritan, but the petition never discusses the expected effect on the combination beyond its argument that it would be unpredictable. *See* Pet., 54-60; *see also id.*, 57, 60 (discussing expectation of success in *meeting the claim limitations of elements 1[a] and 1[b]*, not in achieving the goals of the invention, such as effective aligner treatment).

Like in ground 1, Petitioner’s failure to square its arguments in ground 3 relating to unpredictability and obviousness undermine its argument that a POSITA would have been motivated to arrive at its proposed combination with a reasonable expectation of success, particularly in light of the Office’s findings of unexpected results. *See supra* §IV.A. Accordingly, the petition fails to meet its burden in ground 3.

2. Ground 3’s Reliance on Porter is not Justified

Like ground 1, ground 3 confirms its hindsight-based nature via its reliance on the Porter reference, despite providing no valid justification for a POSITA to turn to such a reference. As noted above, ground 3 proposes a combination of four references: Tadros, Porter, Kalili, and Texin 990R. The second of these, Porter, is an article titled “Dishwasher Safe,” and it describes plastics appropriate for goods that will be cleaned in “commercial and residential dishwashers” due to their high “dishwasher durability.” EX1006, 6.

As explained above for ground 1, Porter discusses use of its plastic (Tritan)

in “commercial and residential kitchenware and small kitchen appliances, including reusable food containers, sports bottles, mugs, pitchers, and containers for food processors and blenders,” using manufacturing techniques such as “injection molding, injection-blow and stretch-blow molding, sheet and flat-film extrusion, and thermoforming.” EX1006, 6. But while Porter describes in great detail the suitability of its plastic for use in kitchenware, nowhere does Porter mention dental applications for its plastics.

Likewise, Porter discusses its plastic’s suitability to be used for kitchenware and washed in a dishwasher, not suitability to be worn continuously in a mouth or to apply tooth-moving forces for days or weeks on end, as required for effective aligner treatment. Petitioner points to Porter’s disclosure describing the properties of its Tritan plastic like glass transition temperature. Pet., 55-56. But in contrast to Porter’s applications in consumer products like water bottles, nowhere does Petitioner identify why a POSITA looking to develop a *dental aligner* would have turned to Porter, which says nothing whatsoever about such devices.

As explained above for ground 1, analogous art must be either (1) “from the same field of endeavor” or (2) “reasonably pertinent to the particular problem with which the inventor is involved.” *Sanofi-Aventis*, 66 F.4th at 1377 (Fed. Cir. 2023) (quoting *Bigio*, 381 F.3d at 1325). Porter is no more related to the dental aligners of ground 3’s combination than to ground 1’s combination. See Pet., 8 (asserting

only “*Kalili, Wen, and Tadros* are directed to the field” relevant here). Petitioner’s assertion that Porter is “pertinent to the problem of improved aligner materials” is undermined by Porter’s failure to discuss use of its materials in aligners or related applications. *Id.* As explained above, the petition fails to justify its argument, based on the ’091 patent’s disclosure, that Porter would have been relevant to improving shell aligners’ tooth-moving ability. *Supra* §IV.B.2; *see* Pet., 8; EX1001, 1:53-57; *ICON*, 496 F.3d at 1380; *WBIP*, 829 F.3d at 1337.

And regardless of whether Porter could constitute analogous art, Petitioner fails to explain why a POSITA would have turned to its teachings. Petitioner asserts that a POSITA would have used Porter’s Tritan polymer in an unmixed form to replace polymeric mixtures in Tadros’s aligners with “a BPA-free alternative.” Pet., 55. Yet Petitioner never explains why a POSITA would have looked to Porter’s disclosure of dishwasher-safe polymers for use in a dental aligner when Tadros itself in the same paragraph cited by Petitioner for polycarbonate teaches scores of suitable polymers that may be mixed together as alternatives to polycarbonate. *See* EX1005, [0022] (listing polycarbonate as just one among a sea of “Thermoplastic polymers that may be used in the polymeric mixture,” and specifically listing not only polycarbonate, but “polyesters such as cycloaliphatic polyesters and polyarylates, and polycarbonate-polydimethylsiloxane copolymers” as preferred options for its polymeric mixture).

Petitioner’s explanation of the undesirability of polycarbonate thus fails to justify abandoning all of the options listed in Tadros—and indeed abandoning use of a mixture *entirely*—and looking instead to Porter’s dishwasher-safe plastic disclosure that bears no relation to dental aligners. *Cf. Kubin*, 561 F.3d at 1359 (“[W]here a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.”).

Likewise, Petitioner’s description of the purported benefits of Porter’s material also fall short. As explained above, Petitioner’s excuse of relying on Tritan’s glass transition temperature does not hold up to scrutiny. *See supra* §IV.D.1. And while Petitioner asserts its combination would avoid “harmful BPAs” (Pet., 55), the absence of BPAs is already satisfied by Tadros’s many alternatives to polycarbonates (none of which is the claimed copolyester). And ground 3 never even addresses the effect its substitution would have on aligner performance; indeed, as noted above, Petitioner argues the impossibility of predicting any performance improvements for its proposed material substitution. *See* Pet., 22 n.4. Moreover, with regard to the BPA-related problems Petitioner latches on to, it is improper to conclude that a reference is analogous by “focus[ing] on the problems of alleged prior art references” (such as deficiencies in one of Tadros’s material options) as opposed to focusing on “the problems of the

challenged patent” (e.g., improved performance of dental aligners relative to those made with prior art materials). *Sanofi-Aventis*, 66 F.4th at 1378.

Nor does Petitioner’s discussion of reasonable expectation of success resuscitate its failures of motivation: Petitioner repeats its discussion of Tritan’s dishwasher-safe properties (durability to “heat, hydrolytic and chemical attack, and applied stress” of dishwashers) and asserts that there was “past industry success in replacing polycarbonate with Tritan copolyester” (Pet., 56), but any such success would be in an unrelated industry (kitchenware) addressing entirely different problems (making dishwasher-safe containers, not force-applying dental appliances). See Pet., 8 (Porter not “directed to the field of polymeric dental aligners”). And while Petitioner asserts that Porter’s plastics could be used in “thermoforming processes and extruded-sheet applications” (Pet., 56), Porter describes these processes in the context of making thick plastic containers like blenders, water bottles, and soup bowls, not dental aligners. Any utility of such processes in the context of kitchenware says nothing about the requirements for success in dental aligners, such as the continuous application of tooth moving forces within an oral environment over the course of weeks or longer. And Petitioner points to nothing in Porter (or elsewhere) indicating that its materials would be useful in a multilayer dental appliance in conjunction with different layers, such as the thermoplastic polyurethane elastomer recited in the claims.

Accordingly, Petitioner fails to justify its reliance on Porter in ground 3.

3. Ground 3 Fails to Justify Its Use of Adhesive Lamination

As with ground 1, ground 3 proposes substitution of different materials into layers of a multilayer appliance (e.g., layer(s) of Porter's Tritan copolyester in combination with layer(s) of TEXIN 990R) and attempts to show that the properties recited in the '091 patent's claims would be present in its proposed combination. In particular, Petitioner seeks to show these properties' presence based on disclosure regarding these materials when not part of a multilayer sheet. *See, e.g.*, Pet., 55-60 (using datasheet properties of TEXIN 990R and properties of Tritan described in Porter to conclude corresponding layers of multilayer sheet forming appliance would have same properties). However, as noted above, Petitioner insists that forming a multilayer sheet via certain normal "manufacturing techniques (e.g., coextrusion, extrusion lamination) would alter the polymer's properties." Pet., 11 n.3; *see also id.*, 34 ("the mechanical properties of a polymer (or free film) can change when combined into a multilayer sheet (e.g., during coextrusion or extrusion lamination)"); EX1007, ¶31 ("certain manufacturing processes (e.g., coextrusion) may lead to molecular diffusion or mixing between the layers, as well as cross-linking, that can change the properties of the polymers within a layer"). Petitioner does not argue that if processes such as coextrusion or extrusion lamination were used, the respective layer's properties (e.g., flexural

modulus, elongation at break, or hardness) would remain within the ranges recited in the independent claims. On the contrary, Petitioner completely disavows the use of such processes. *See* Pet., 56, 58-60.

As in ground 1, to avoid these problems in ground 3, Petitioner proposes using “adhesive lamination,” adding “tie layers” between different layers as a glue to stick the layers together, which Petitioner asserts would preserve each polymer’s reported mechanical properties. Pet., 56, 58-60. Petitioner does not claim that its grounds’ references teach using this type of adhesive lamination process to form an aligner from a multilayer sheet as claimed, as opposed to using extrusion lamination or coextrusion. Instead, Petitioner asserts that “**would have known of** suitable techniques for adhering multiple polymer layers together, such as by adhesive lamination using a tie layer.” Pet., 62; *see also id.*, 32, 34, 56, 59, 60, 61, 65 (insisting on mere awareness throughout petition).

As explained above for ground 1, Petitioner’s focus on what a POSITA would have been aware of, or on what a POSITA could have done, is inappropriate: obviousness depends on what a POSITA *would have done*. *See InTouch*, 751 F.3d at 1352; *Polaris*, 882 F.3d at 1068. By focusing only on options POSITAs would have known of without addressing whether they would have employed those options, ground 3’s combination is “fraught with hindsight bias” and fails to satisfy the standard for obviousness. *ActiveVideo*, 694 F.3d at 1327.

As in ground 1, ground 3 does not argue that a POSITA would be motivated to use adhesive lamination. Ground 3 never discusses how a POSITA would have viewed the benefits and disadvantages of employing adhesive lamination instead of coextrusion or extrusion lamination. *See Pet.*, 56-62. And ground 3 relies on the same textbook teachings of glue layers as ground 1, without showing that the issues it identifies for using adhesive lamination would have been present in its proposed combination. *See Pet.*, 6, 62; EX1019, 150. Nor does ground 3 discuss the suitability of such glue layers in a warm, wet environment like the human mouth in which a dental aligner is continuously worn, or the biocompatibility needed for such added glues in an appliance worn in the human mouth.

Ground 3 also fails to address the effect of inserting tie layers into a dental appliance. The Petition asserts that modifying materials and layer arrangements in multilayer appliances is unpredictable. *Pet.*, 22 n.4, 43 n.10. Yet it proposes inserting tie layers between each layer of its proposed dental appliances without any regard for the effect these new layers of different materials would have on the appliances' material properties or efficacy. *See Pet.*, 56, 58-60, 62.

In sum, the use of adhesive lamination is essential for Petitioner's mapping in ground 3 to meet the elements of the independent claims, yet Petitioner fails even to assert, much less show why a POSITA would have been motivated to use adhesive lamination. Thus, Petitioner fails to show obviousness of any of the

claims challenged in ground 3.

For at least the foregoing reasons, Petitioner fails to meet its burden of demonstrating that claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26 would have been obvious over Tadros, Porter, Kalili, and Texin 990R.

E. Ground 4 Fails

Ground 4 asserts that claims 1-23 and 25-26 would have been obvious over five references: Tadros, Porter, Kalili, Texin 990R, and Wen. Pet., 5. However, with regard to each independent claim as well as each dependent claim previously addressed in ground 3, Petitioner uses Wen for nothing, instead relying exclusively on its arguments from ground 3. Pet., 77. In other words, despite being styled as addressing all challenged claims, ground 4 actually addresses only dependent claims 2-3, 8, 14-15, and 21. *See id.*, 72-77. Petitioner provides no new arguments or evidence regarding why any independent claim would have been obvious over the further combination with Wen or that Wen would be relevant to any limitation of these claims. Thus, ground 4 fails to overcome the shortcomings of ground 3.

Accordingly, Petitioner fails to meet its burden of demonstrating that claims 1-23 and 25-26 were obvious over Tadros, Porter, Kalili, Texin 990R, and Wen.

V. CONCLUSION

Accordingly, for at least the reasons set forth above, institution of *inter partes* review should be denied.

Respectfully submitted,

Date: August 8, 2025

/ Michael T. Rosato /

Michael T. Rosato, Lead Counsel

Reg. No. 52,182

CERTIFICATE OF COMPLIANCE

Pursuant to § 42.24(d), 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 9,347 words.

Respectfully submitted,

Date: August 8, 2025

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CERTIFICATE OF SERVICE

I certify that the foregoing Patent Owner's Preliminary Response Pursuant to 37 C.F.R. § 42.107 was served on this 8th day of August, 2025, on Petitioner at the following electronic service addresses:

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