

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 RESPONSE

TABLE OF CONTENTS

I. INTRODUCTION	1
II. OVERVIEW OF '091 PATENT.....	3
III.CITED PRIOR ART	6
A. Tadros (EX1003).....	6
B. Kalili (EX1005) and Texin 990R (EX1009).....	7
C. Porter (EX1006)	8
D. Wen (EX1008)	9
IV.PERSON OF ORDINARY SKILL IN THE ART	10
V. CLAIM CONSTRUCTION	11
VI.PETITIONER’S GROUNDS OF UNPATENTABILITY FAIL	11
A. Ground 1 Fails to Show that Claims 6, 9, 18, 23, and 25-26 Were Obvious over Kalili, Porter, and Texin 990R	12
1. Ground 1’s Reliance on Porter is not Justified	13
2. Petitioner’s Hindsight Combination is Contradictory and Self- Defeating Regarding Mechanical Properties	24
3. Petitioner Combines Kalili, Porter, and Texin 990R Based on False Assertions and Hindsight, not Logical Motivation	27
B. Ground 2 Fails to Show that Claims 1-2, 4-7, 9-14, 16-23, and 25-26 Were Obvious over Kalili, Porter, Texin 990R, and Wen	31
1. Ground 2 Fails to Cure the Deficiencies of Ground 1	31
2. Wen Fails to Support Ground 2’s Subdivision of Layers of a Multilayer Sheet.....	32
C. Ground 3 Fails to Show that Claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26 Were Obvious over Tadros, Porter, Kalili, and Texin 990R	38

1. Ground 3 Fails to Justify Replacing Tadros’s Polycarbonate Mixture with Porter’s Copolyester	39
2. A POSITA Would Not Have Been Motivated to Combine the Tadros with Kalili and Texin 990R	48
3. Petitioner’s Hindsight Combination is Contradictory and Self-Defeating Regarding Mechanical Properties	52
D. Ground 4 Fails to Show that Claims 1-23 and 25-26 Were Obvious over Tadros, Porter, Kalili, Texin 990R, and Wen	53
E. Objective Evidence of Nonobviousness Supports the Patentability of Claims 1-11	53
1. Aligners Made with SmartTrack Have Nexus to the Challenged Claims	54
2. SmartTrack Aligners Show Unexpectedly Superior Performance	57
3. SmartTrack Aligners Are Commercially Successful.....	60
4. Petitioner Copied Align’s SmartTrack Aligners.....	61
VII.THE PETITION FAILS TO NAME ALL REAL PARTIES-IN-INTEREST	66
VIII.CONCLUSION	68
IX.APPENDIX – EXHIBIT LIST.....	69

I. INTRODUCTION

ClearCorrect Operating LLC (“ClearCorrect” or “Petitioner”) challenges claims 1-23 and 25-26 of U.S. Patent No. 11,648,091 (“the ’091 patent,” EX1001) based on four grounds. Pet., 4-5. Align Technology, Inc. (“Align” or “Patent Owner”) respectfully requests the Board issue a final written decision rejecting Petitioner’s grounds of challenge and affirming the patentability of the challenged claims.

The challenged claims here were the result of over five years of development and the testing of over two hundred potential materials. Align, a company founded by two Stanford graduates, revolutionized the dental world by developing Invisalign® aligners that were an alternative to braces, despite deep skepticism from the dental community. But Align did not stop there – instead it continued to be on the bleeding-edge of developing aligners that would address a myriad of desired characteristics. Now, with widespread adoption of Align’s patented breakthroughs by Petitioner and others, Petitioner raises obviousness challenges that are an exercise in contradictions, misinterpret the relied-upon references, and are easily overcome by the strong secondary considerations set forth in the developed record.

As to contradictions, the petition takes inconsistent positions regarding predictability in multilayer aligner materials. On the one hand, the petition argues

that alterations to materials in a multilayer aligner had unpredictable effects on aligner properties and efficacy, but then treats multilayer materials as though their components could be predictably varied at will. Petitioner's expert asserts that replacing a layer of polycarbonate with any other polymer would be unpredictable, but that his own proposal would have been predictable. Petitioner's contradictions reflect a fundamental misunderstanding of prior-art polymers and techniques, and Petitioner proposes hindsight-driven combinations with features that would have discouraged, not motivated, a POSITA from pursuing them.

While Petitioner's grounds all have intrinsic fatal flaws, objective indicia additionally confirm the claims' non-obviousness. Align's SmartTrack material, used to manufacture its Invisalign® aligners embodying the claims, showed unexpected superiority over the best-performing prior-art aligner material, including superiority to the asserted prior-art material. The commercial success of these Invisalign® aligners made with SmartTrack material (herein, "SmartTrack aligners") further confirms the non-obviousness of the claims, as does the widespread industry adoption of the patented invention, including copying of SmartTrack by Petitioner and its related companies. Petitioner's hindsight-based, internally contradictory attack cannot withstand record evidence showing Align's SmartTrack material, as recited in the challenged claims, was a significant and innovative advancement in the field of dental aligner treatment.

For these reasons, and as discussed below, the Board should find that Petitioner has not met its burden to prove that the challenged claims are unpatentable.

II. OVERVIEW OF '091 PATENT

The '091 patent and its family members are the product of an intensive research and development process. Align pioneered the field of clear plastic orthodontic appliances called “aligners,” a substitute for braces. Since its launch in 1997, Align has been the segment leader in the United States and throughout the world. EX2016, ¶¶5-9, 38.

Align’s early aligners were manufactured using a polycarbonate material called Proceed30 (or PC30). However, in 2001 Align moved to aligners made from a polyurethane material called EX30. EX30 performed better than PC30, with better stress-strain curves and greater force-delivery capacity. Accordingly, from 2001 until 2013, polyurethane aligners dominated the market. EX2016, ¶¶7-9.

In an effort to further improve upon EX30, Align engaged in an extensive development process for next-generation aligners. Align’s objective was to identify materials providing improved overall properties including increased stress-relaxation and comparable or superior performance in other parameters including modulus of elasticity, elongation, polymer thermal-mechanical properties, durability, environmental stress cracking, transparency, thermoforming adaptation,

and thermoformability. EX2016, ¶¶10-13, 21-25.

Over more than five years, Align tested over two hundred fifty candidate materials sourced from numerous commercial suppliers across the polymer industry, comparing them to EX30 and to each other. Eventually, Align identified certain material combinations—with certain properties—that had strong performance as compared to EX30. Its chosen commercial product, SmartTrack (or “ST30”), exhibited excellent properties when testing candidate materials and further demonstrated substantial improvement in orthodontic treatment relative to the best prior aligner material, EX30, in clinical trials. EX2016, ¶¶21-37. The ’091 patent claims encompass SmartTrack. EX2014, ¶¶125-38; EX2016, ¶¶14-20.

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 three or more layers configured to provide improved aligner performance, reducing the need for additional aligners or mid-course correction during treatment. *See* EX1001, 2:5-15, 3:15-31; EX2014, ¶¶24-25.

The ’091 patent describes that a multilayer appliance can include “a hard polymer layer” and “a soft polymer layer,” and 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, including a hard co-polyester layer and 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; EX2014, ¶¶26-27.

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.

III. CITED PRIOR ART

Petitioner relies on five references (Tadros, Kalili, Texin 990R, Porter, and Wen) to challenge the '091 patent claims. Petitioner's obviousness conclusion is contaminated by repeated misunderstandings of the applied references and reliance on "teachings" absent from the cited art. By understanding what each reference teaches and importantly, what it does not teach, Petitioner's errors become readily apparent. EX2014, ¶28.

A. Tadros (EX1003)

Grounds 3 and 4 rely on Tadros as allegedly disclosing "a 'soft-hard-soft' dental appliance with a rigid inner layer surrounded by soft, elastomeric outer layers," further asserting that Tadros's examples use "copolyester materials in the rigid layer" and that the "soft layers" are "preferably 'elastomers' such as 'polyurethanes.'" See Pet., 3, 57. As will be detailed more below, these contentions regarding Tadros's disclosure are riddled with errors, including a false assertion that PCCD is a copolyester, which infect and render deficient the entirety of Petitioner's obviousness case.

Tadros describes "an appliance for use in an oral cavity" comprising "a polymeric shell that comprises a polymeric mixture," which Tadros explains is a mixture of "two or more thermoplastic polymers." EX1003, Abstract, [0022]. This "polymeric mixture" is what the petition claims contains copolyester. See Pet., 54.

To tie Tadros to the claims’ recited “co-polyester” layers, the petition relies exclusively on Tadros’s “PCCD variations,” which it calls “comparative copolyesters.” *Id.* (citing EX1003, [0097], [0113]).

Tadros describes PCCD as a “cycloaliphatic polyester.” EX1003, [0022], [0024] (“polycarbonate-cycloaliphatic polyester mixture”), [0050]-[0051] (“A preferred cycloaliphatic polyester is PCCD....”). Tadros describes PCCD as being formed by “recurring units of” a single monomer, making PCCD a homopolymer, not a copolyester.

The petition also relies on Tadros’s disclosure that “the appliance may comprise additional layers disposed upon the sheet comprising the polymeric mixture.” EX1003, [0073]. The petition claims Tadros describes these layers as “preferably ‘elastomers’ such as ‘polyurethanes’” (Pet, 57), but Tadros never describes polyurethanes as preferred. The only elastomer Tadros calls preferred is the copolyester ether “ECDEL 9966.” EX1003, [0073]. Tadros mentions polyurethane once among 30 different categories of elastomers that are “[s]uitable.” *Id.*; EX2014, ¶¶29-31.

B. Kalili (EX1005) and Texin 990R (EX1009)

Kalili describes “[a]n invisible removable orthodontic repositioning appliance” having a soft inner lining and a hard outer lining (i.e., two layers). *See, e.g.*, EX1005, Abstract, [0007], [0009]. Kalili identifies Texin 990R as a

polyurethane material that can form the inner lining. *Id.*, [0069]. Relying on a product datasheet for Texin 990R, Petitioner alleges that Texin 990R satisfies the material properties of the claimed second thermoplastic polyurethane elastomer layer. *See Pet.*, 33-35.

For its outer lining, Kalili discloses that while this layer may be formed of polycarbonates, numerous other materials alternatively may be used, including BPA-free materials. *See EX1005*, [0053] (identifying “polyacetates, polyolefins, polyamides, polystyrenes” and others). Nowhere does Kalili describe copolyesters as suitable for an aligner. *EX2014*, ¶¶32-33.

C. Porter (EX1006)

Porter is an article titled “Dishwasher Safe: New Clear Copolyester Is Tougher, More Heat-Resistant, and Processes Easier, Too.” *EX1006*, 60. Porter describes a particular copolyester material, Tritan TX 1000, as suitable for kitchenware and other consumer products. *See EX1006*, 5-6, FIG. 2. Porter identifies Tritan as particularly suitable for thick-walled consumer products designed for holding food and water, such as CamelBack water bottles, Vita-Mix blenders, and a “thick-walled soup bowl,” all of which are injection-molded. *EX1006*, 8-9. Porter also highlights Tritan’s improved resistance to heat, hydrolytic and chemical attack, and applied stress in response to environmental conditions found in dishwashers. *Id.*, 6.

While Porter mentions in passing that Tritan can be thermoformed or extruded into a sheet or flat film, it never discusses forming Tritan into multilayered sheets or combining Tritan with other polymers. *See* EX1006, 6, 7. Porter also never mentions any orthodontic or dental applications. Indeed, Porter's Tritan TX1000 was known only as a consumer-grade plastic, not a medical-grade plastic. *See* EX1118, 7-8; EX2014, ¶¶34-35.

D. Wen (EX1008)

Wen describes a particular manufacturing approach to thermoforming a multilayer dental aligner. *See* EX1008, [0205]-[0213]. The process involves vacuum-forming a heated sheet of a first layer over a patient's physical tooth model such that the softened sheet conforms to the shape of the physical model. EX1008, [0205]. A heated sheet of a second layer can then be vacuum-formed on top of the first to produce a two-layered aligner. EX1008, [0206], Figs. 13-14.

Petitioner relies on Wen as allegedly teaching that if a multilayer sheet has thinner sublayers, this will improve conformance to tooth models and help layers bond to each other. *See* Pet., 2-3, 41-42. However, this is inaccurate, as the disclosure Petitioner cites to (paragraphs 212-13) is not discussing thermoforming a multilayer sheet, but a different approach using multiple thinner single-layer sheets.

Wen teaches that "rather than forming a dental aligner by a thick layer of the

same aligner-making material, the aligner is formed by a plurality of thinner layers of aligner-making material using vacuum-forming.” EX1008, [0212]. In other words, Wen teaches successively heating and vacuum-forming thin sheets onto a tooth model, one atop the other. Because each individual thin layer has greater flexibility, Wen explains the thinner layers will “more easily conform[] to the physical tooth models than a single thick layer.” EX1008, [0212]. Wen notes that this process can include forming an appliance using sheets of different materials since “[t]hinner films allow more intimate contact between polymer sheets and therefore help bond the films to one another.” EX1008, [0213]; EX2014, ¶¶36-37.

IV. PERSON OF ORDINARY SKILL IN THE ART

Petitioner contends:

A POSITA would have had at least a four-year undergraduate degree in materials science, mechanical engineering, chemical engineering, or a related field and at least two years of experience in the field of polymer science, combined with at least two years of experience in the field of design, manufacture, and processing of thermoformable polymer sheets for use in various applications, such as in orthodontic and dental appliances. Additional education could substitute for professional experience and vice versa.

Pet., 17. Patent Owner’s expert, Dr. Robert Kimmel, met and exceeded this level of ordinary skill by May 14, 2012. EX2014, ¶¶1-14, 38-40.

On cross-examination, Dr. Osswald confirmed that under his definition, the

POSITA would not need experience with orthodontic and dental appliances. *See* EX2017, 80:7-81:22 (qualifying experience encompasses whole territory of thermoforming). In IPR2022-01214, the patent owner there (Bay Materials, a real party-in-interest here (*see infra*, section VII.)) argued a POSITA would further have “some dental aligner experience” or access to “orthodontist or dentists with such experience.” EX2025 (POR) at 8-9; *see also* EX2033 (FWD) at 8-11 (agreeing). In contrast to Dr. Osswald, Dr. Kimmel’s opinions are informed by the declaration of Yan Chen, a co-inventor of the ’091 patent with approximately 20 years of experience in orthodontic-appliance development. EX2014, ¶41; *see* EX2016, ¶¶1-4, 11-12.

V. CLAIM CONSTRUCTION

A claim subject to *inter partes* review receives its plain and ordinary meaning, interpreted in light of the specification. *See* 37 C.F.R. § 42.100(b); EX2014, ¶42. Petitioner proposes no claim constructions. Pet., 27-28. Petitioner asserts its claim mappings are informed by Align’s infringement contentions (*id.*), but as discussed below, Petitioner’s arguments based on these contentions fail.

VI. PETITIONER’S GROUNDS OF UNPATENTABILITY FAIL

The petition advances three grounds alleging obviousness of the ’091 patent claims. Ground 1 addresses independent claims 6 and 18, alleging that claims 6, 9, 18, 23, and 25-26 would have been obvious over Kalili in view of Texin 990R and

further in view of Porter. Pet., 4-5. Grounds 2 and 3 address independent claims 1, 6, 10, and 18. Ground 2 alleges that claims 1-2, 4-7, 9-14, 16-23, and 25-26 would have been obvious over Kalili in view of Texin 990R, further in view of Porter, and still further Wen. *Id.* Ground 3 alleges that claims 1, 4-7, 9-13, 16-20, 22-23, and 25-26 would have been obvious over Tadros in view of Porter, further in view of Kalili, and still further Texin 990R. As discussed below, each of Petitioner's grounds fails.

A. Ground 1 Fails to Show that Claims 6, 9, 18, 23, and 25-26 Were Obvious over Kalili, Porter, and Texin 990R

Ground 1 alleges that claims 6, 9, 18, 23, and 25-26 would have been obvious over Kalili, Porter, and Texin 990R. Pet., 4-5. Ground 1 proposes multiple modifications to Kalili's two-layer sheet. First, Petitioner proposes further modifying Kalili's outer layer by replacing polycarbonate with a co-polyester (Tritan) disclosed by Porter. EX1005, [0053]; *see* EX1006, 6; Pet., 31-32. And second, Petitioner proposes further modifying Kalili by using adhesive lamination to join each layer together.

As discussed below, ground 1 fails to justify these modifications. Petitioner's reliance on Porter is ill-founded, as Porter is not only non-analogous art but also would not have motivated a POSITA to make the proposed combination. Moreover, Petitioner relies on adhesive lamination as essential to meet the claim elements, despite no showing of a motivation to employ adhesive

lamination, and without showing that a combination employing adhesive lamination would satisfy the required material properties, even though it argues generally that manufacturing would change the mechanical properties of the layers.

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

Petitioner contends that a POSITA would have looked to Porter to substitute Tritan copolyester into Kalili's dental aligner. *See* Pet., 31-32. However, the petition neither establishes Porter as analogous art nor that a POSITA would have been motivated to make the proposed substitution. Rather, Porter contains nothing indicating relevance to dental aligners.

a. Petitioner fails to show Porter is analogous art

To be analogous art, a reference must be (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). To be 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). 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 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).

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 [relevant] field”). Instead, Petitioner asserts that Porter and Texin 990R are analogous art because they are “pertinent to the problem of improved aligner materials as they describe polymers explicitly identified by the other references or within a class of polymers identified as suitable for dental aligners,” generally citing to the ’091 patent and over sixty paragraphs of its expert declaration. *Id.*¹ (citing EX1001, 1:54-57; EX1007, ¶¶98-128, 145-76). The petition doesn’t identify which of these two categories applies to Porter, doesn’t explain which “other references” identify Porter’s polymer, and doesn’t explain who or what Petitioner contends “identified” a class of polymers suitable for dental aligners that Porter falls within. Pet., 8. These bald, unexplained assertions fail to meet Petitioner’s burden to show that Porter was analogous art.

Petitioner’s citations also fail to clarify Petitioner’s theory. Petitioner never explains how the over sixty cited declaration paragraphs apply. Pet., 8. As to the citation to the ’091 patent, it merely states 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

¹ Emphasis added unless otherwise noted.

more continuous force and better bring a patient's teeth into a desired occlusion."

EX1001, 1:54-62. Identification of a problem is not an explanation why Porter would be viewed as relevant to that problem. Petitioner fails to show how Porter "logically would have commended itself to an inventor's attention in considering his problem" (i.e., why a POSITA would have turned to Porter in seeking a material for a dental aligner). *ICON Health*, 496 F. 3d at 1380. EX2014, ¶¶91-94.

While Petitioner's cursory assertion regarding analogous art wholly fails to meet its burden, even the most minimal examination reveals Porter lacks pertinence. Porter never mentions any orthodontic or dental applications. EX1006. Indeed, Porter's Tritan copolyester, Tritan TX1000, is not even a medical-grade polyester. EX2014, ¶¶70, 92; *see* EX1006, Fig. 2 ("Tritan TX 1000"); EX1118, 7-8 (Tritan TX1000 for use in appliances, durable consumer goods, and houseware, not medical applications). An orthodontic aligner is a Class II medical device, and a POSITA would look to medical-grade materials, not non-medical materials like Porter's TX1000. EX2014, ¶92; EX2016, ¶22. Petitioner's suggestion that a POSITA would have looked to Porter for an aligner material thus fails to present a realistic depiction of what a POSITA would look for.

The examples discussed in Porter also differentiate it from dental appliance applications. Porter's only example products are thick-walled plastic containers for holding food and water (e.g., water bottles, blenders, a "thick-walled soup bowl").

EX1008, 8-9. The structure and purpose of Porter's examples are thus dissimilar to aligners. EX2014, ¶92.

Further, each of these products is injection-molded, not thermoformed. EX2014, ¶93. Indeed, Porter only briefly mentions that Tritan is capable of being thermoformed, and never discusses thermoforming Tritan into any kind of orthodontic, dental, or other medical device. *See* EX1008, 6 (“Thus far, it has been shown to be suitable for injection molding, injection-blow and stretch-blow molding, sheet and flat film extrusion, and thermoforming.”), 7 (“It molds well with hot runners and small gates. It also thermoforms well with deep draws.”); EX2014, ¶93.

Porter also never discusses incorporating Tritan into multilayer sheets. While Porter mentions that Tritan can be extruded into a sheet or flat film, it never discusses combining Tritan with other polymers. *See* EX1008, 6, 7. In sum, nothing about Porter's description of its Tritan TX1000 material indicates that a POSITA would have looked to Porter for a dental aligner material. EX2014, ¶94.

b. Petitioner fails to establish motivation to combine Porter with Kalili

Petitioner's arguments regarding motivation to combine similarly fail to show why a POSITA would have turned to Porter as relevant to dental aligners. Petitioner argues a POSITA would have turned to Porter “to avoid the harmful BPAs released from polycarbonate aligners” as in *Kalili. Pet.*, 31. Yet Petitioner

never attempts to reconcile this alleged motivation with its argument IPR2025-00818 and IPR2025-00819 that propose a dental aligner containing polycarbonate. *See, e.g.*, IPR2025-00818, Paper 1 at 30 (proposing using “one of Tadros’s exemplary hard polymeric [polycarbonate-PCCD] mixtures.”). Petitioner’s argument here directly contradicts its combination in those cases. *See* EX2014, ¶96

Even setting aside these inconsistencies, identification of an undesirable aspect of polycarbonate dental aligners fails to define a relevant “class of polymers” (Pet., 8), let alone provide a reason to turn to Porter. The only polymer Petitioner identifies as containing BPAs is polycarbonate. Pet., 31-32. Seeking a polymer other than polycarbonate is not enough to bring Porter to the attention of someone developing dental aligners, as Petitioner’s arguments identify no reference teaching the use of Tritan in a dental aligner, or even a reference teaching a co-polyester as an alternative to a polycarbonate in dental aligners. In fact, Kalili discloses many BPA-free alternatives to polycarbonates in dental aligners, none of which is a co-polyester. EX1005, [0053] (materials include “polyacetates, polyolefins, polyamides, polystyrenes...”). Lacking BPAs is thus not a sufficient basis to bring Porter to the POSITA’s attention. EX2014, ¶¶95, 97.

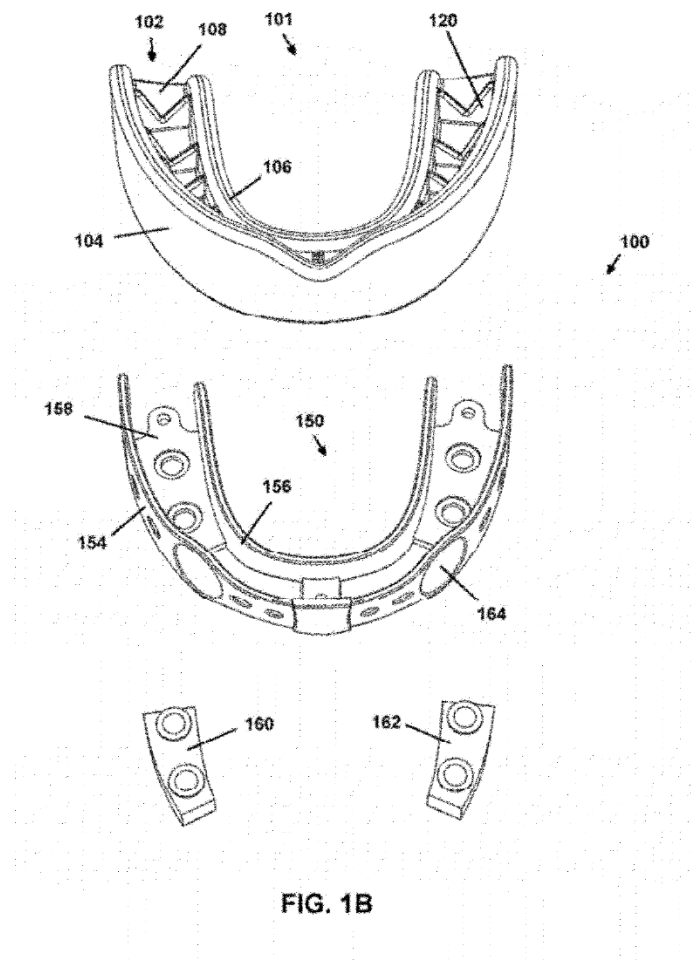
Moreover, Dr. Osswald himself cites to references teaching numerous known non-copolyester, BPA-free polymers. *See* EX1007, ¶97 (citing EX1106, EX1108, EX1109, EX1110, EX1113); EX2014, ¶98 (no disclosure of

copolyesters). Yet despite insisting that adding Tritan—a polymer with no disclosed orthodontic use—would have been predictable, he insists using *other* BPA-free polymers “would have entered a domain of unpredictability.” EX2017, 99:5-18. Dr. Osswald’s view that only Tritan would have been predictable, while BPA-free polymers with known orthodontic uses (like those in Kalili) would be unpredictable, throws his hindsight reasoning into sharp relief. See EX2014, ¶¶96-97.

Attempting to bridge the gap between Porter’s “Dishwasher Safe” disclosure and the dental aligner context, Dr. Osswald cites to a single reference (Rafih, EX1104) as involving use of a BPA-free Tritan material in an oral appliance. EX1007, ¶¶97, 99, 147. As an initial matter, Rafih is not discussed anywhere in the petition and should be disregarded on that basis. To the extent Petitioner intended to rely on Rafih merely by virtue of its inclusion in cited paragraphs of Dr. Osswald’s declaration and its generic citation to it for reasonable expectation of success (Pet., 32), such reliance would constitute improper incorporation by reference. 37 C.F.R. §42.6(a)(3).

Beyond that, Dr. Osswald glosses over important distinctions between Rafih’s subject matter and a dental aligner, such that it would not serve as the missing link between Porter and Kalili. Dr. Osswald asserts “Rafih would inform a POSITA that Porter’s guidance regarding replacing polycarbonate with Tritan

applies to dental appliances where Tritan is used in combination with a soft inner layer.” EX1006, ¶147. But this is not true. Rafih does not use layers in a multilayer sheet, or any sheet at all for its appliance. EX2014, ¶¶99-100. Rafih’s appliance is formed from separate plastic pieces, shown most clearly in Fig. 1B below.



EX1104, Fig. 1B.

As shown above, the upper part (channel 102) is made of a soft polymer that the patient can bite into and deform upon boiling, so that it takes the shape of the teeth like a dental impression. EX1104, 5:1-6. The middle part (150) is a “frame”

that merely reinforces the oral appliance against undesirable deformation. EX1104, 5:30-64. Rafih teaches this part may be made of Tritan. EX1104, 5:57-64; EX2014, ¶¶99-100. Neither Rafih's frame nor Rafih's channel is a layer of a sheet, much less are they layers of a multilayer sheet. EX2014, ¶101. The two components are clearly shown as separate parts that can be placed together into Rafih's mouthguard. *Id.* Thus, Dr. Osswald's characterization of this configuration as one where "Tritan is used in combination with a soft inner layer" is simply inaccurate. *Id.*

Other characteristics of Rafih further eliminate any relevance to a thermoformed dental aligner. Rafih describes neither dental aligners nor tooth-moving forces, does not involve thermoforming sheets, and does not use Tritan in either thermoforming or sheets. EX2014, ¶102. For example, Rafih is directed to a type of mouthguard that keeps the jaws apart, not a dental aligner aimed at producing a force to bring a patient's teeth into a desired occlusion. *See* EX1104, 4:21-42. Indeed, Dr. Osswald admitted that Rafih's appliance fails to provide any tooth-moving forces. EX2017, 96:24-97:2; *see also* EX2014, ¶99. Moreover, a POSITA would have understood that Rafih's frame 150 is not made by thermoforming. EX2014, ¶102. Rafih never says the frame is thermoformed. Rather, from the shape shown, a POSITA would have concluded that Rafih's frame was most likely formed by a molding process (e.g., injection molding) that

produces a fixed shape independent of the shape of the patient's mouth, which further distinguishes Rafih from dental aligner references like Tadros and Kalili.

Id.

Simply put, Rafih (1) does not use Tritan to apply tooth-moving forces; (2) does not involve sheets of Tritan; (3) does not involve multilayer sheets; and (4) does not teach thermoforming Tritan, confirming Rafih was irrelevant to the problem the '091 patent inventors were seeking to solve. EX2014, ¶103. Thus, Dr. Osswald's reliance on Rafih further highlights the lack of evidence supporting Petitioner's assertion that a POSITA would have turned to Porter when developing a thermoformed multilayer dental aligner. *Id.* Regardless of whether Rafih or Porter describes Tritan as BPA-free, neither reference addresses other critical threshold issues for consideration in dental aligners, such as the material's ability to apply tooth-moving forces.

Furthermore, even if a POSITA were to consider Porter, the reasons given for selecting Porter's copolyester also fall short. First, as discussed above, whether a POSITA had an interest in avoiding BPA in a dental aligner, Petitioner provides no reason to ignore the numerous BPA-free alternatives in Kalili and instead turn to an article having nothing to do with a medical-grade material or dental appliances. Petitioner also argues that a POSITA would have turned to Porter "to improv[e] performance characteristics," suggesting that POSITAs would select

Porter's Tritan because Porter describes Tritan as having "durability in the 'harsh' environments of 'heat, hydrolytic and chemical attack, and applied stress' required for dental applications," as well as avoiding "product failure from environmental stress cracking." Pet., 31-32 (quoting EX1006, 6). However, as Dr. Kimmel explains, a POSITA would not view Porter's description as providing good reasons to use Tritan in a dental aligner. EX2014, ¶¶104-07.

With regard to heat, chemical, hydrolytic attack, and stress, Porter expressly describes these properties in relation to what "kitchenware is exposed to the dishwasher." EX1006, 6. A POSITA would not have viewed the dishwasher environment as bearing a meaningful relationship to a dental aligner worn in the mouth. EX2014, ¶105. Porter describes the ability of thick, plastic dishware to withstand intermittent hot temperatures and detergents. EX1006, 8. This does not address the ability of very thin materials, like the layers of a multilayer aligner, to withstand weeks in a continuous warm, wet environment, including both continuous stress from applying tooth-moving forces as well as the continual forces from biting. EX2014, ¶105.

Petitioner's discussion of environmental stress cracking also mischaracterizes Porter. EX2014, ¶106. Porter refers to improved resistance to environmental stress cracking as arising from the material's "lower residual stress level." EX1006, 6. However, as Porter notes, this residual stress arises from the

injection molding process, not from forming materials in sheets by processes like extrusion. *Id.* (“Products molded from Tritan have less residual stress....”). Dental aligners are made by thermoforming sheets, not a molding process, so the type of residual stress contemplated by Porter is simply not present. EX2014, ¶106. Thus, a POSITA would have viewed this teaching of Porter as having little relevance to thermoforming aligners. *Id.*

Moreover, as discussed in section VI.E, whereas Petitioner describes that a POSITA would have relied on Porter for a hard material in a dental aligner because “materials for dental aligners ... must be durable” (Pet., 10), Align’s testing showed that aligners formed from Tritan did not exhibit strong durability, such that they were substantially outperformed by aligners made according to the instant claims. EX2014, ¶107. Thus, testing confirms that Tritan lacks the property Petitioner says was needed in dental aligners, confirming Petitioner’s reasoning as a flawed application of hindsight, rather than an accurate description of Tritan’s properties.

Accordingly, Petitioner fails to meet its burden in establishing the obviousness of the claims in ground 1 because Petitioner fails to show that a POSITA would have modified Kalili to include a layer of co-polyester based on Porter. While Petitioner has failed to make a plausible *prima facie* showing, as explained below in section VI.E, Align’s evidence of surprising results and

commercial success further demonstrates nonobviousness.

2. Petitioner's Hindsight Combination is Contradictory and Self-Defeating Regarding Mechanical Properties

Claim elements 6[b]/18[b] and 6[c]/18[c] recite layers respectively containing co-polyester and thermoplastic polyurethane elastomer, each with multiple specified mechanical properties. Petitioner's assertion that its proposed combination of different layers cherry-picked from Kalili, Texin 990R, and Porter would provide the claimed mechanical properties fails as self-defeating.

Throughout the petition materials, Petitioner argues that mechanical properties of individual layers change significantly and unpredictably based on both layer configuration as well as methods to combine and fabricate the multilayer sheet. *See, e.g.*, Pet., 1 (discussing “the layer configuration’s impact on aligner properties and efficacy”), 34 (“the mechanical properties of a polymer (or free film) can change when combined in a multilayer sheet”); *see also* EX1007, ¶¶31, 104 n.2, 170. In its obviousness challenge, however, Petitioner proposes combining different layers of Kalili, Texin 990R, and Porter specifically using “adhesive lamination,” which Petitioner conveniently claims would “preserve” the mechanical properties of the individual polymer layers. Pet. 32, 34; EX1007, ¶¶31, 39-41. This artificially crafted litigation argument fails to withstand scrutiny.

Petitioner distinguishes between adhesive lamination and other multilayer fabrication methods by arguing that adhesive lamination “would preserve [the

polymer’s] properties within the layer, without cross-linking or mixing of layers.” Pet. 32; *see id.*, 34; EX1007, ¶31. But this lacks any supporting evidence. The petition cites to ¶31 of Dr. Osswald’s declaration, which offers nothing beyond conclusory, *ipse dixit* commentary—no evidence is identified in support. 37 C.F.R. § 42.65(a); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000) (expert testimony lacking factual support is “of little probative value”).

Elsewhere, Dr. Osswald offers contradictory testimony and evidence. For example, Dr. Osswald cites Ebnesajjad (EX1042) as discussing adhesive lamination (e.g., EX1007, ¶¶40-41) but omits that Ebnesajjad discusses such lamination as including processes such as chemical bonding including “**cross-linking**.” EX1042, 8, 11-14. Yet at ¶35, Dr. Osswald contends that this type of “**crosslinking**, molecular diffusion, or molecular entanglement, can influence the mechanical properties of both the polymer layers and the overall multilayer polymer sheet.” EX1007, ¶35; *see id.*, ¶31. Similarly, while Dr. Osswald cites “**molecular diffusion**” as another factor that can “change the properties of polymers within a layer,” Ebnesajjad discusses developing adhesion through “**interdiffusion of molecules** between the adhesive and adherend.” *Compare id. with* EX1042, 12; *see also* EX1042, 13 (“The interactions that hold the adhesive and the adherends together may receive contributions from ... diffusion.”); EX2014, ¶¶109-10.

Petitioner's argument and evidence further contradict its concocted narrative. For example, the petition cites ¶¶39-41 of Dr. Osswald's declaration where he discusses certain aspects of adhesive lamination. Pet., 34 (citing EX1007, ¶¶39-41). Notably absent, however, is discussion of the prior assertion regarding adhesive lamination and mechanical properties of adhered layers. Instead, Petitioner's cited art, Ebnesajjad (EX1042), describes adhesive lamination as including harsh surface modification techniques, mechanical blasting and material removal, chemical etching using corrosive chemicals, as well as heat melting and scorching. *See, e.g.*, EX1042, 8-9, 59. Ebnesajjad specifically identifies aspects such as surface modification and preparation as altering the properties of the polymer materials. *See, e.g., id.*, 72 ("This technique can alter the physical and chemical properties of the surface."), 59 ("Bulk methods involve additives, blending, or recrystallization, all of which affect the bulk properties of plastics."); EX1019, 155-56 (interlayer interactions affect material properties); EX2014, ¶111.

Accordingly, Petitioner and its expert offer conflicting argument that does little beyond sabotage the petition assertion that the multilayer configuration would provide the mechanical properties recited in the challenged claims. Petitioner chose to construct an obviousness case based on walking a concocted tightrope between assertions of mechanical property alterations and convenient (though unsupported) exceptions. Petitioner's narrative collapses under the weight of its own argument

and evidence and should be rejected as such. And the corresponding obviousness assertion should now be recognized as self-defeating.

3. Petitioner Combines Kalili, Porter, and Texin 990R Based on False Assertions and Hindsight, not Logical Motivation

Petitioner also fails to show that a POSITA would have been motivated to make the further combination with Kalili and Texin 990R as proposed. Petitioner proposes combining, using adhesive lamination, a polyurethane layer of Kalili together with Porter's Tritan TX1000 material in a two-layer configuration. Pet. 31-35. Such argument is unsupported, self-defeating, and ultimately fails.

The proposal of adhesive lamination specifically to preserve mechanical properties serves as the lynchpin of Petitioner's challenge but is unsupported and even contradicted by Petitioner's own argument and evidence. Furthermore, Petitioner's admissions regarding unpredictability also undermine its challenge. 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., 22-23 n.4. Petitioner further states 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. Yet Petitioner inexplicably proposes just this, replacing layers with other polymers (e.g., Kalili's outer layer with Porter's Tritan), and suggesting its change was predictable. Pet., 31-32. Petitioner cannot have it both ways: its

insistence that substituting layers is unpredictable is inconsistent with its claim that it would have yielded predictable results. EX2014, ¶¶54-57, 115.

Moreover, while Petitioner proposes a combination specifically using adhesive lamination, it never addresses or factors in known **disadvantages** of adhesive lamination. This alone is reason enough to find an incomplete and faulty obviousness inquiry. *Arctic Cat Inc. v. Polaris Indus.*, 795 F. App'x 827, 833 (Fed. Cir. 2019) (“The Board must weigh the benefits and drawbacks ... to determine whether there would be a motivation to combine.”); *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *see* EX2014, ¶58.

Petitioner's submitted evidence includes a long list of disadvantages of adhesive lamination ignored in the petition. *See, e.g.*, EX1042, 9-10. Particularly salient considerations in the context of orthodontic aligners are unwanted “bacteria, mold” contamination and unwanted exposure to chemicals and solvents that “may present health problems.” EX1042, 9-10. Petitioner's own proposal of construction by adhesive lamination would undermine many, if not all, of the alleged “advantages” of Porter's Tritan. Moreover, as Dr. Kimmel explains, known disadvantages to using adhesive lamination would dissuade a POSITA from pursuing what the petition proposes. EX2014, ¶¶112-17; EX2016, ¶¶40-42. The petition materials address none of this.

Notably, Petitioner never provides any affirmative reason why a POSITA

would have pursued adhesive lamination specifically. Instead, throughout the petition, 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.*, 34 (similar). Nowhere does Petitioner identify a reason why a POSITA would have chosen to use the adhesive lamination that its combination relies on. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations” (emphasis original)); EX2014, ¶108.

At bottom, Petitioner’s argument does little beyond raising the specter of improper hindsight. It is 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. *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.”).

As is well-known, petitioner bears the unshifting burden of proving the obviousness case they chose to construct. *See In re Magnum Oil Tools International, Ltd.*, 829 F. 3d 1364, 1375-76. Here, Petitioner’s own argument and evidence undermines its assertion a POSITA would be motivated to reach the claimed subject matter with a reasonable expectation of success. Petitioner’s failure to square its arguments relating to unpredictability and obviousness, in combination with Petitioner’s mischaracterization of the art (e.g., adhesive lamination), disregard of known disadvantages, and sheer enormity of different material combinations not addressed in the petition, shows that the petition’s argument is impermissibly tainted with hindsight—not logically grounded in objective evidence. The hindsight-based nature of Petitioner’s challenge is further highlighted by objective indicia discussed in section VI.E below, including surprising results and commercial success as well as copying by Align’s competitors, including Petitioner.

Accordingly, Petitioner fails to meet its burden to show that claims 6, 9, 18, 23, and 25-26 were obvious over Kalili, Porter, and Texin 990R.

B. Ground 2 Fails to Show that Claims 1-2, 4-7, 9-14, 16-23, and 25-26 Were Obvious over Kalili, Porter, Texin 990R, and Wen

Ground 2 proposes at least three modifications to Kalili's two-layer sheet.

First, as with ground 1, Petitioner proposes modifying Kalili's outer layer by replacing Kalili's polycarbonate with the co-polyester (Tritan) disclosed by Porter. EX1005, [0053]; *see* EX1006, 6; Pet., 40-41. Second, Petitioner then proposes modifying this layer layer by splitting it into two smaller layers each half as thick as the original, citing Wen. Pet., 41-43. And like ground 1, Petitioner proposes using adhesive lamination to join each layer.

As discussed below, ground 2 fails to justify these modifications. First, ground 2 fails to cure the deficiencies identified above for ground 1. That is, Petitioner's reliance on Porter and adhesive lamination is ill-founded. Second, Petitioner arrives at its theory of duplication of layers by misreading Wen to produce a layer configuration that the prior art neither disclosed nor gave reason to use.

1. Ground 2 Fails to Cure the Deficiencies of Ground 1

As an initial matter, ground 2 contains the same deficiencies identified above with respect to ground 1. First, Petitioner argues that "a POSITA would have been motivated to replace Kalili's polycarbonate layer with a single-polymer layer of Tritan co-polyester (disclosed in Porter)," referring to its ground 1 analysis. Pet., 39-40 ("As detailed above for claim 6[b] in Ground 1....").

However, as explained above, Petitioner fails to show that Porter is analogous art and fails to show that a POSITA would have been motivated to combine Porter with Kalili. *Supra*, section VI.A.1. Moreover, Petitioner again relies on adhesive lamination as essential to meet the claim elements (Pet., 41), despite no showing of a motivation to employ adhesive lamination, and without showing that a combination employing adhesive lamination would satisfy the required material properties, even though it argues generally that manufacturing would change the mechanical properties of the layers. *Supra*, sections VI.A.2-3. Thus, for the same reasons why Petitioner’s ground 1 fail, ground 2 also fails.

2. Wen Fails to Support Ground 2’s Subdivision of Layers of a Multilayer Sheet

Ground 2 further proposes modifying one layer of a multilayer sheet used to make Kalili’s aligner by splitting it into two sublayers, each half the width of the original, then gluing the two layers together again. *See* Pet., 41-43 (“two or more thinner layers of the same material (totaling the same overall thickness as the single layer)”). As Petitioner illustrates, this would take a two-layer sheet and replace it with a three-layer sheet like the one shown below:



Pet., 42. Petitioner asserts that Wen teaches doing this to “improve tooth conformity and inter-layer bonding.” Pet., 41-42. However, Petitioner mischaracterizes Wen, which does not support the proposed change. EX2014, ¶¶73-76.

Petitioner cites two paragraphs of Wen as allegedly supporting this modification: paragraphs 212 and 213. *See* Pet., 41-42. Regarding paragraph 212, Petitioner relies on Wen’s statement that “thinner layers can be more easily conformed to the physical tooth models than a single thick layer.” *Id.* (quoting EX1008, [0212]). However, as confirmed by Dr. Kimmel, Wen’s discussion refers to an entirely different process than found in Petitioner’s proposal. EX2014, ¶80.

Specifically, in paragraph 212, Wen describes that “the aligner is formed by a plurality of thinner layers of aligner-making material using vacuum forming.” EX1008, [0212]. This type of process is described earlier in paragraphs 205 and 206, where a first sheet is vacuum-formed onto a tooth model and then a second sheet is vacuum-formed atop the first. EX2014, ¶81; EX1008, [0205]-[0206]. This is illustrated in Figs. 13-14, shown below, with a first sheet 1410 placed over a tooth model and a second sheet 1510 placed over the first:

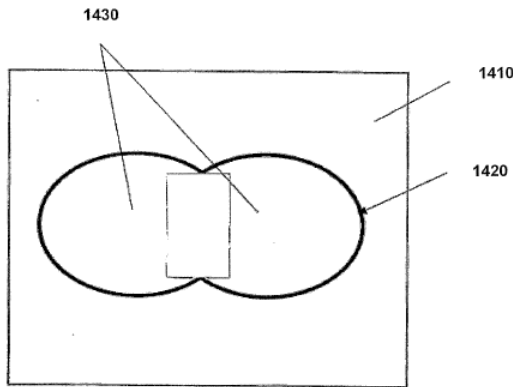


Figure 13

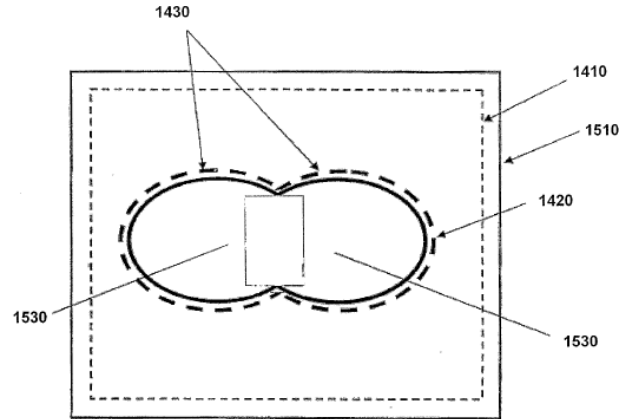


Figure 14

EX1008, Figs. 13-14; EX2014, ¶81.

Thus, paragraph 212’s description of thinner layers conforming to tooth models that Petitioner cites is not describing thermoforming a single multilayer sheet containing thin sublayers over a tooth model (as in Petitioner’s proposal) but assembling an appliance by forming separate thin sheets on a dental model, one atop the other (inconsistent with Kalili and in contradiction to the claims).

EX2014, ¶81. Indeed, Dr. Osswald readily admitted that paragraph 212 discusses a process with separate sheets for each layer like that in paragraphs 205-206, not his proposed multilayer sheet. EX2017, 27:13-28:8.

Petitioner’s reliance on the next paragraph of Wen also fails. Paragraph 213 describes forming an appliance using sheets of different materials, noting that thicker films may delaminate while “[t]hinner films allow more intimate contact between polymer sheets and therefore help bond the films to one another.”

EX1008, [0213]. Coming as it does right after paragraph 212, paragraph 213 is naturally referring to the same process of sequentially laying separate sheets atop one another, and thus fails to support Petitioner's claim that thinner layers **combined to form a thicker multilayer sheet prior to thermoforming** will conform better. EX2014, ¶87.

Dr. Osswald again conceded that this refers to sequentially placing sheets atop one another. *See* EX2017, 28:20-29:4 (“[T]his is talking about sequentially laying the films one on top of the other on top of the physical tooth model, as in Paragraph No. 212 and consistent with Paragraphs 205 and 206, right? Well, yeah....”). While Dr. Osswald imagines that this teaching might not necessarily apply only to this process (*id.*, 29:8-21), he fails to explain why a POSITA would read Wen this way. *See also id.*, 41:18-42:24 (unsure whether paragraph 231 also supported his argument); EX2014, ¶¶84-85 (no support in paragraph 231).

Indeed, Dr. Kimmel explains the better conformance to the tooth model arises because individual, thinner sheets are laid one atop the other in Wen. EX2014, ¶¶88-89. For example, when laying plastic sheets over an irregular tooth surface like that shown below in Fig. 6, individual thin layers will shape more easily because they are more flexible, and thus easier to bend than a thick sheet. *Id.*

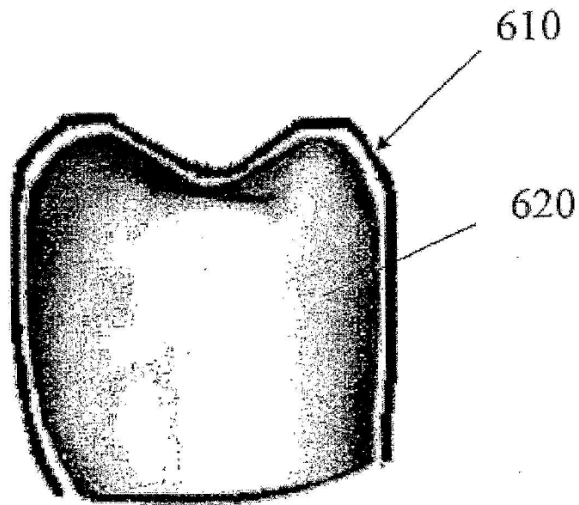


Figure 6

EX1008, Fig. 6. In contrast, a multilayer sheet comprising multiple thinner layers would not be expected to conform any better to a tooth mold than would a sheet of the same thickness made up of just two, thicker layers. *Id.* Thus, a POSITA would not have read Wen as providing any reason to construct a polymeric sheet by laying multiple identical thin layers together as Petitioner suggests. EX2014, ¶¶82-83, 88-90.

Petitioner and Dr. Osswald also cite to Bedard (EX1051) and Schrenk (EX1019), but neither supports their proposal. *See* Pet., 5-6; EX1007, ¶¶52-53 (citing EX1051, 3:55-67; EX1019, 155-56). Regarding Bedard, the cited portion describes forming a sheet with multiple layers that collectively behave as though they were a single combined layer. EX2014, ¶¶77-79. The cited paragraph says

nothing about thinner layers conforming better to tooth models or providing better tooth positioning. *Id.* Indeed, Bedard expressly describes that multiple soft or hard (“strengthening”) materials put together act as a soft or hard layer equivalent. *See* EX1051, 3:55-57. A POSITA would thus conclude that Petitioner’s proposal would not only fail to provide the benefit Petitioner identifies but would incur needless cost and risk introducing points where the material can fail along the new interface. EX2014, ¶79.

Petitioner’s citation to Schrenk fares no better. The cited portion of Schrenk describes that when layers are thin, one layer “can more easily influence the response of its neighbor.” EX1019, 155-56. As Dr. Kimmel explains, this refers to “interlayer interactions,” in which adjacent layers of different materials alter each other’s material properties over extremely short distances. EX2014, ¶86. Indeed, the next sentence of Schrenk describes such interactions as occurring in a “microlayer film, with hundreds of very thin layers.” EX1019, 156. Such arrangements have nothing to do with Petitioner’s proposal, which involve just two thin layers of the **same material** next to each other, and further separated by a glue layer. EX2014, ¶86. Indeed, Petitioner asserted that a POSITA would avoid changing layer properties (e.g., via interlayer interactions) using adhesive lamination, directly opposed to Schrenk’s stated purpose of using thin layers. *Id.* Schrenk thus also fails to provide a reason to subdivide layers in an aligner sheet as

Petitioner proposes.

Accordingly, Petitioner has failed to show that Wen supports its proposed modification in ground 2.

For at least the foregoing reasons, Petitioner fails to meet its burden of demonstrating that claims 1-2, 4-7, 9-14, 16-23, and 25-26 would have been obvious over Kalili, Porter, Wen, and Texin 990R.

C. Ground 3 Fails to Show that Claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26 Were Obvious over Tadros, Porter, Kalili, and Texin 990R

Ground 3 proposes taking a multilayer sheet used to form a dental appliance, taught by Tadros, and replacing every layer with different materials. *See* Pet., 53-60. Specifically, Petitioner proposes replacing Tadros's layer of mixed polycarbonate and polyester with a pure copolyester disclosed by Porter and replacing Tadros's other two layers with a soft thermoplastic polyurethane elastomer disclosed by Kalili in view of Texin 990R. *Id.* Petitioner also proposes altering the process by which the sheet is formed by introducing polymeric tie layers to employ adhesive lamination. *See id.* The petition illustrates how it picks and chooses among different references to produce its proposed combination as reproduced below:



Pet., 59.

Petitioner fails to meet its burden to demonstrate the unpatentability of these claims. To begin with, Petitioner’s combination relies on misreading the prior art, proposing modifications contrary to the primary reference’s teachings, and relying on non-analogous prior art that a POSITA would not have been motivated to use. Petitioner also fails to show that result of its combination satisfies the recited mechanical properties. Moreover, the petition advances a hindsight-tainted combination inconsistent with its admission that the change it proposes would have been unpredictable. Petitioner’s combination also relies on using adhesive lamination as essential to meet the claim elements, yet Petitioner fails to show that a POSITA would have been motivated to employ adhesive lamination.

1. Ground 3 Fails to Justify Replacing Tadros’s Polycarbonate Mixture with Porter’s Copolyester

To meet limitations 1[a]/6[b]/10[b]/18[b], ground 1 proposes replacing the polymeric mixture described in Tadros paragraphs 97 and 113 with a copolyester from Porter. However, the petition mischaracterizes Tadros, fails to justify why a POSITA would make the proposed substitution, and fails to show that a POSITA

would have looked to Porter.

a. Petitioner's arguments rest on a mischaracterization of Tadros

In describing Tadros, the petition cites to polycarbonate mixtures described in paragraphs 97 and 113 of Tadros, stating “Tadros highlights comparative copolyesters (specifically, PCCD variations) as materials with better thermoforming capabilities than polycarbonate but insufficient modulus properties.” Pet., 54 (citing EX1003, [0097], [0113]).

This assertion is wrong. The materials disclosed in the cited paragraphs are (1) polycarbonate, (2) PCCD (poly(1,4-cyclohexane-dimethanol-1,4-cyclohexanedicarboxylate)), and (3) mixtures containing both polycarbonate and PCCD. EX1003, [0097], [0113]; *see id.*, [0022]. Petitioner's bare claim that PCCD is a copolyester finds no support in the petition. Paragraph 50 of Tadros describes PCCD as a “cycloaliphatic polyester,” not a copolyester. EX1003, [0050]. Other paragraphs similarly characterize PCCD only as a polyester, not a copolyester. *See, e.g.*, EX1003, [0022] “polyesters such as...PCCD”), [0024] (“polycarbonate-cycloaliphatic polyester mixture”). Nowhere does Tadros identify PCCD as a copolyester, because it is not a copolyester. EX2014, ¶¶43-46.

Like the petition, Dr. Osswald asserts that Tadros's “PCCD variations” are “comparative copolyesters,” but he cites no evidence for this claim. EX1007, ¶257. Cross-examination confirmed, however, that Dr. Osswald's conclusory statement

in his declaration was based on a false and erroneous assumption that not only PCCD, but all cycloaliphatic polyesters were copolyesters:

22	Q	Is it your understanding that all cycloaliphatic
23		polyesters are copolyesters?
24	A	To my knowledge, yes.

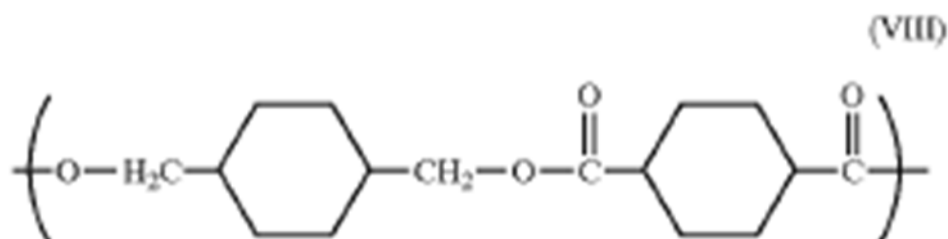
EX2017, 22:22-24. When further pressed, Dr. Osswald insisted that this assumption applied to “the specific examples from Tadros that” he cited, and that “What I do know is Tadros’s mixtures do contain polycarbonate and copolyesters.” EX2017, 23:18-24:8; EX2014, ¶48.

However, as Dr. Kimmel explains, PCCD is not a copolyester. EX2014, ¶49. A polyester is a polymer formed of repeating monomer units, with each monomer formed from the reaction of a dicarboxylic acid (or an esterified dicarboxylic acid) and a diol. *Id.*; see EX1003, [0048] (describing this process). A copolyester is a copolymer of a polyester that may be formed by using multiple different kinds of diacids or diols, producing different monomer units. EX2014, ¶¶49-50. By contrast, a polyester that is a homopolymer, meaning a polymer not composed of different kinds of monomer units, is not a copolyester. *Id.*; see EX2020, 173 (distinguishing homopolymers and copolymers).

When asked regarding his understanding of polyesters and copolyesters, Dr. Osswald conceded that a copolyester must be “polymerized with different

monomers.” EX2017, 104:7-105:17. He also confirmed that not all polyesters were copolyesters, and that a copolyester must have a “molecular structure is more complex than just a single type of molecule.” EX2017, 104:7-105:17. As discussed below, this testimony is inconsistent with his assertion that PCCD, shown by Tadros with only one type of monomer unit, is a copolyester. EX2014, ¶¶50-53.

Tadros describes PCCD as a “cycloaliphatic polyester...having recurring units of formula (VIII),” which is reproduced below:



EX1003, [0050]. As Dr. Kimmel explains, this recurring unit is a single monomer, meaning that PCCD is a homopolymer, not a copolymer, and accordingly not a copolyester. EX2014, ¶50. Indeed, the prior art specifically confirms that PCCD is a homopolymer, in contrast to a copolymer. *See* EX2019, 4101, table 6; EX2014, ¶50; *see also* EX1003, [0073] (describing separate examples of a “copolyester ether” elastomer and “PCCD,” which is not described as a copolyester).

As Dr. Kimmel further describes, Tadros’s description of the process of forming PCCD confirms that it is only a polyester, not a copolyester. EX2014, ¶51. Indeed, Tadros specifically describes producing PCCD not only as a homopolymer

made of monomer units of the same kind, but also as one in which each monomer unit is stereochemically identical. *Id.*; see EX1003, [0045] (describing all-trans PCCD as “especially preferred”). And as Dr. Kimmel explains, even PCCD formed from different isomers of the monomer unit shown in formula VIII would be considered a homopolymer (for example, an isotactic homopolymer), and thus a polyester, but not a copolyester. EX2014, ¶¶51-52. Indeed, the prior art specifically characterized such mixed-isomer embodiments of PCCD as a “homopolymer,” not a copolymer, and thus not a copolyester. *Id.*

At bottom, Tadros never indicates that the PCCD used in its samples involves a mix of monomer units. To the contrary, Tadros expressly describes PCCD as having a single recurring unit according to formula VIII. EX1003, [0050]. Tadros describes PCCD, including the PCCD used in samples 4 and 5, only as a polyester, not a copolyester. EX2014, ¶¶50-52; see EX1003, [0050]-[0051], [0093], claim 5. Petitioner’s first step leading to substituting a copolyester into Tadros is thus unfounded. EX2014, ¶¶46, 53.

Petitioner goes on to state that “Tadros sought to create a material that combined the best features of the pure polycarbonate and pure copolyester.” Pet., 55 (citing EX1007, ¶257); see also *id.* (claiming Tadros “used polycarbonate-copolyester mixtures” to combine “polycarbonate’s modulus properties and copolyester’s thermoforming properties”). Again, this assertion fails, as it is based

on the mistaken assumption that PCCD is a copolyester. The cited declaration paragraphs discuss no examples beyond Tadros's PCCD mixtures, which are not and do not contain copolyesters. *See* EX1007, ¶¶257-59; EX2014, ¶¶49-53, 59. Indeed, Petitioner provides no evidence whatsoever showing that pure copolyesters were commonly used in the art in any type of aligner, either as a pure copolyester aligner or as a layer in a multilayer aligner. This fundamental misunderstanding undermines Petitioner's entire basis for selecting copolyester in the first place.

b. Petitioner fails to justify abandoning Tadros's mixture

Regardless of Petitioner's misrepresentations of Tadros's materials, the petition ignores critical aspects of Tadros's overall teachings that undermine Petitioner's proposed combination. Specifically, Petitioner alleges that a POSITA would have been motivated "to substitute a single-polymer layer of" Porter's Tritan copolyester for the "polycarbonate-containing hard layer" of Tadros. Pet., 56. However, Tadros consistently describes throughout its disclosure that its hard layer is formed by a polymeric mixture. EX2014, ¶¶64-65. The petition provides no logical, evidence-based rationale showing why a POSITA would have abandoned Tadros's express teachings of using a mixture in favor of a layer of pure copolyester, such as Porter's Tritan material, instead.

Tadros repeatedly makes clear, throughout the entire specification, that its primary objective is forming aligners with a layer formed by a polymeric mixture.

EX2014, ¶65. For example, its abstract expressly ties the focus of its disclosure to aligners that “comprise[] a polymeric mixture.” EX1003, Abstract. Tadros’s summary reaffirms this objective. *See* EX1003, [0006] (“an appliance for use in an oral cavity, wherein the appliance comprises a polymeric shell that comprises a polymeric mixture”), [0007] (“polymeric mixture”), [0008] (“polymeric mixture”). The use of a polymeric mixture is echoed over and over again throughout the detailed description. *See, e.g.*, EX1003, [0015] (“Disclosed herein is an appliance made from a sheet comprising a polymeric mixture that may be advantageously used for repositioning teeth from an initial tooth arrangement to a final tooth arrangement.”), [0016] (“polymeric mixtures”), [0022] (“polymeric mixture”), [0023] (listing “[p]referred polymeric mixtures”), [0024] (“a preferred polymeric mixture”). EX2014, ¶65.

The specific examples that Petitioner cites in Tadros as an exemplary hard layer (samples 4 and 5) are both polymeric mixtures. *See* Pet., 55 (citing Tables 2-3); EX1003, [0093] (samples 4 and 5 containing polycarbonate and PCCD mixture); *see also id.*, tables 9, 10, 12 (polycarbonate-PCCD mixtures); EX2014, ¶65. Indeed, where Tadros describes non-mixtures, it is as components to be mixed or as comparative samples. *See, e.g.*, EX1003, [0097], [0108]-[0110], tables 2, 7; EX2014, ¶65.

Petitioner ignores these plain teachings that polymeric mixtures form a

fundamental aspect of Tadros's aligner layer. EX2014, ¶¶65-66. Petitioner's proposed modification to Tadros wrongfully assumes that a POSITA would have abandoned polymeric mixtures in favor a single-polymer layer, despite Tadros's teachings to the contrary. *Id.* None of Petitioner's reasons support the conclusion that a POSITA would have been motivated to make such a modification. *Id.*

Specifically, the petition argues that a POSITA would have substituted Porter's Tritan copolyester for Tadros's polycarbonate mixture to avoid exposure to BPAs released by the polycarbonate component. Pet., 55. However, even assuming that a POSITA would have seen this as a reason to turn away from using polycarbonate as an aligner material, this still would not have directed the POSITA to Tritan in particular. EX2014, ¶¶60, 67. Tadros teaches about 75 different types of material that can be mixed to produce its main aligner layer, only one of which is polycarbonate. *See id.*; EX1003, [0022]. Even eliminating polycarbonate as a candidate material leaves over 2701 different mixtures of just any two material categories. EX2014, ¶60. Naturally, a POSITA deciding to avoid polycarbonate would have turned to any one of the thousands of other mixtures of materials taught by Tadros as an appropriate substitute, rather than looking to abandon Tadros entirely along with its central concept of polymer mixtures in favor of an entirely different material. EX2014, ¶67.

Petitioner also suggests that a POSITA would have turned to Tritan because

its glass transition temperature was not so high that it would prevent thermoforming. *See* Pet., 55. However, this again does not explain why a POSITA would be led away from Tadros's polymeric mixtures, which already provide the properties desired for its main aligner layer, including glass transition temperatures as well as other properties like tensile modulus and stress relaxation. *See, e.g.*, EX1003, [0022] (listing alternative materials mixable to meet stated goals), [0068], [0115], tables 2, 4, 9; EX2014, ¶68. And as discussed above, Petitioner's basis for considering pure copolyesters in the first place rests on its mischaracterization of Tadros's PCCD. Thus, Petitioner fails to show a POSITA would have adopted its proposal.

c. Petitioner fails to show a POSITA would turn to Porter

As also discussed above for ground 1, the petition neither establishes Porter as analogous art nor that a POSITA would have been motivated to make the proposed substitution.

Regarding analogous art, the Petition provides no further discussion for ground 3 than for ground 1. Porter is not in a field relating to dental aligners, and it is no more pertinent to the substitution in ground 3 than the substitution in ground 1. For example, Porter is directed to injection-molded consumer products, rather than disclosing a medical-grade polymer for use in thermoformed dental appliances, and it has no disclosure regarding use in multilayer sheets or

combination with other polymers. *See supra* §VI.A.1.a; EX1006, 6-9.

Likewise, ground 3's arguments regarding motivation to combine fail for similar reasons to ground 1. Petitioner's arguments regarding selecting BPA-free materials (Pet., 55-56) fare no better in pointing to Porter in relation to Tadros than they do in relation to Kalili. As noted above, Tadros, similar to Kahili, discloses numerous alternative mixtures, only one of which is polycarbonate. *See* EX1003, [0022]; EX2014, ¶97; *supra* §VI.A.1.b. Dr. Osswald's arguments regarding Rafih likewise apply no more to Porter's use here than in ground 1. EX2014, ¶¶99-102; *supra* §VI.A.1.b. And Petitioner's arguments regarding Porter's properties still have no shown application to the context of dental aligners, and indeed are undermined by testing data showing Tritan's poor durability in intraoral environments. EX2014, ¶¶104-07; *supra* §VI.A.1.b.

Accordingly, Petitioner fails to meet its burden in establishing the obviousness of the claims in ground 3 because Petitioner fails to show that a POSITA would have modified Tadros to include a layer of co-polyester based on Porter. While Petitioner has failed to make a plausible *prima facie* showing, as explained below in section VI.E, Align's evidence of surprising results and commercial success further demonstrates nonobviousness.

2. A POSITA Would Not Have Been Motivated to Combine the Tadros with Kalili and Texin 990R

Petitioner also fails to show that a POSITA would have been motivated to

make the further combination with Kalili and Texin 990R as proposed. Petitioner proposes combining, using adhesive lamination, two polyurethane layers of Texin 990R and Kalili together with Porter’s Tritan TX1000 material in a three-layer configuration from Tadros to produce the arrangement shown below:



Pet. 59. As to alleged motivation, the petition argues 1) Tadros and Kalili address similar subject matter, 2) Tadros expresses preference for “polyurethanes” and Texin 990R is a polyurethane that would offer “numerous advantages,” and 3) combining by adhesive lamination would preserve mechanical properties of individual layers. Pet. 57-60. Such argument ultimately fails.

First, the starting premise of Petitioner’s argument mischaracterizes Tadros. The proffered reason for selecting polyurethane in the first place is the false assertion Tadros identifies polyurethanes as preferred “elastomers.” Pet., 57 (quoting EX1003, [0073]). Tadros says no such thing. Tadros generically refers to elastomers, but the only preferred elastomer it identifies is not polyurethane: “[a] preferred elastomer for the first layer is a copolyester ether,” specifically “ECDEL 9966.” EX1003, [0073]; *see* EX2021, 4:25-31. Polyurethanes only appear as one

category in a laundry list of approximately thirty different broad categories of elastomers described as “[s]uitable examples.” EX1003, [0073]; EX2014, ¶¶61-63. As the petition’s only reason for turning to polyurethanes in the first place is its false characterization of them as “preferred,” the petition fails to justify its additional pivot to a particular polyurethane from Kalili.

Moreover, as in ground 1, Petitioner proposes using “adhesive lamination” to glue layers together, which Petitioner asserts would preserve each polymer’s reported mechanical properties. Pet., 56, 58-60. Petitioner does not contend that its grounds’ references teach using this type of adhesive lamination process to form an aligner from a multilayer sheet as claimed. Nor does ground 3 remedy the failure of ground 1 to argue or satisfy the requirements for an obvious-to-try rationale. See *KSR*, 550 U.S. at 406. Petitioner asserts mere awareness of adhesive lamination as an option.

As explained above for ground 1, Petitioner’s focus on what a POSITA would have been aware of, or 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 have been 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., 55. And ground 3 relies on the same textbook teachings of glue layers as ground 1, without showing that the issues the book identifies as reasons for using adhesive lamination would have been present in the proposed combination. *See* Pet., 6, 56-57; EX1019, 150. Nor does ground 3 discuss the suitability of such glue layers in a warm, wet environment in which a dental aligner is continuously worn, or biocompatibility.

At institution, the Board suggested that Petitioner had argued that a POSITA would have used adhesive lamination “to ensure Tritan’s material properties are preserved with adhesive lamination, thereby providing a BPA-free hard layer meeting Tadros’s specified material properties.” DI, 14-15 (citing Pet., 55). However, Petitioner did not argue this as a reason to use adhesive lamination. Rather, Petitioner argued that a “POSITA would have understood that manufacturing techniques such as adhesive lamination would result in a first layer ‘containing a single polymer’ pure Tritan copolyester.” Pet., 56. Whether a POSITA would have understood this—which Petitioner has not shown to be the case—it does not explain why a POSITA would have selected adhesive lamination in the first place.

Ground 3 also fails to address the effect of its proposed modifications. The petition asserts that modifying materials and layer arrangements in multilayer appliances is unpredictable. Pet., 22-23 n.4, 43 n.10. Yet it proposes (1) replacing Tadros's polycarbonate-PCCD layer with Porter's pure copolyester Tritan material, (2) replacing Tadros's soft layers with Kalili's TEXIN 990R, and (3) inserting tie layers to adhere the layers, all without any regard for the effect these new layers of different materials would have on the appliances' material properties or efficacy. See Pet., 55, 60, 62.

Therefore, like ground 1, Petitioner's own argument and evidence undermines its assertion a POSITA would be motivated to reach the claimed subject matter with a reasonable expectation of success.

3. Petitioner's Hindsight Combination is Contradictory and Self-Defeating Regarding Mechanical Properties

As with ground 1, Petitioner offers conclusory and conflicting argument and evidence regarding its ground 3 assertion that the proposed combination utilizing adhesive lamination would satisfy the mechanical properties recited in the independent claims. See *supra*, §VI.A.2. Even if the Board credits Petitioner's arguments that a POSITA would have used adhesive lamination in the ground 3 combination (see, e.g., Pet., 56, 58-60), the petition's arguments that these limitations would be satisfied fail for the same reasons discussed above.

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 were obvious over Tadros, Porter, Kalili, and Texin 990R.

D. Ground 4 Fails to Show that Claims 1-23 and 25-26 Were Obvious over Tadros, Porter, Kalili, Texin 990R, and Wen

Ground 4 asserts that claims 1-23 and 25-26 would have been obvious over Tadros, Porter, Kalili, Texin 990R, and Wen. Pet., 5. However, Petitioner provides no further argument regarding the elements of claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26, instead realleging its arguments for ground 3. See Pet., 77. Ground 4 thus fails to remedy ground 3's deficiencies regarding any of claims 1, 4-5, 6-7, 9-13, 16-20, 22-23, and 25-26.

Additionally, ground 4's arguments regarding claims 2, 3, 8, 14-15, and 21 rely on Wen to propose dividing a single layer into two or more layers. Pet., 72-77. However, as explained above regarding similar arguments made in ground 2, Petitioner misreads Wen and fails to justify its proposed combination. See *supra* §VI.B.2.

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

E. Objective Evidence of Nonobviousness Supports the Patentability of Claims 1-11

“Objective indicia of nonobviousness must be considered in every case where present.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir.

2016). Objective indicia can “serve to ‘guard against slipping into use of hindsight,’ and to resist the temptation to read into the prior art the teachings of the invention in issue.” *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966).

As explained below, the nonobviousness of the ’091 patent is further supported by Patent Owner’s evidence unexpected results, commercial success, and widespread adoption by the industry including copying by others.

1. Aligners Made with SmartTrack Have Nexus to the Challenged Claims

To be accorded substantial weight, objective evidence “must have a ‘nexus’ to the claims, *i.e.*, there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.” *Henny Penny*, 938 F.3d at 1332. The nexus analysis evaluates “the correspondence between the objective evidence and the claim scope.” *Id.*

The aligners manufactured and sold by Align under the name SmartTrack embody the ’091 patent claims, including each element of independent claims 1, 6, 10, and 18 as illustrated in the chart below. EX2014, ¶¶124-27, 138; EX2016, ¶¶14-20.

'091 Patent Claims	ST30 Aligners
1[pre] A multilayer sheet comprising:	SmartTrack aligners are made from a multilayer sheet of SmartTrack material. EX2014, ¶138.
1[a] a first layer containing a single polymer, wherein the single polymer of the	The multilayer sheet includes a first layer that contains a single polymer: a co-polyester. That layer has a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater

'091 Patent Claims	ST30 Aligners
first layer is a co-polyester, and wherein the first layer 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	than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%. <i>Id.</i>
1[b] a second layer containing a single polymer, wherein the single polymer of the second layer is a thermoplastic polyurethane elastomer, and wherein the second layer 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; and	The multilayer sheet includes a second layer that contains a single polymer: a thermoplastic polyurethane elastomer. That layer 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. <i>Id.</i>
1[c] a third layer;	The multilayer sheet includes a third layer. <i>Id.</i>
1[d] wherein the first layer has an elastic modulus greater than the second layer; and	The elastic modulus of the first layer is greater than the elastic modulus of the second layer. <i>Id.</i>
1[e] wherein the multilayer sheet is incorporated into an orthodontic appliance.	In a SmartTrack aligner, a sheet of SmartTrack material is incorporated into the aligner (an orthodontic appliance) by thermoforming the sheet into the shape of the aligner. <i>Id.</i>

'091 Patent Claims	ST30 Aligners
6[pre] A multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the multilayer dental aligner comprising:	SmartTrack aligners are multilayer dental aligners made for positioning a patient's teeth from a first arrangement toward a second arrangement. <i>Id.</i>
6[a] a multilayer sheet comprising:	<i>See</i> 1[pre]. <i>Id.</i>
6[b] a first layer containing a single polymer, wherein the single polymer of the first layer is a co-polyester, and wherein the first layer 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	<i>See</i> 1[a]. <i>Id.</i>
6[c] a second layer containing a single polymer, wherein the single polymer of the second layer is a thermoplastic polyurethane elastomer, and wherein the second layer has an ultimate tensile strength	<i>See</i> 1[b]. <i>Id.</i>

'091 Patent Claims	ST30 Aligners
of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and	
6[d] wherein the multilayer sheet forms a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement.	<i>See</i> 1[e]. The aligner has multiple tooth-receiving cavities shaped to receive and reposition the patient's teeth from the first arrangement toward the second arrangement. <i>Id.</i>

EX2014, ¶138; *see* EX2016, ¶¶15-20. As the above chart shows, SmartTrack aligners embodies independent claims 1 and 6. Independent claims 10 and 18 are embodied for the same reasons. *See id.*

As discussed below, the objective evidence of nonobviousness arises from the merits of the claimed invention, thereby confirming nexus between the objective evidence and the invention as claimed.

2. SmartTrack Aligners Show Unexpectedly Superior Performance

Objective evidence showing unexpected results for the claimed invention supports nonobviousness. *E.g., In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011). Unexpected results are “particularly probative” where there is “a difference between the results obtained and those of the closest prior art, and that the

difference would not have been expected by one of ordinary skill in the art at the time of the invention.” *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). This can include demonstrating a “significant difference in degree” in a property relevant to the claimed invention, such as one amounting to “marked superiority.” *Id.*

As discussed above in section II, the SmartTrack material was developed over a multi-year process, seeking to identify an improvement over the leading prior aligner material, EX30. Align’s objectives included improvement in stress-relaxation relative to EX30, as well as comparable or improved performance in multiple other properties important for effective aligner treatment. This process evaluated hundreds of candidate materials and ultimately identified SmartTrack (or ST30) as the preferred commercial candidate among all tested materials.

SmartTrack showed substantial improvement over EX30 and met Align’s design objectives. EX2014, ¶¶139-44; EX2016, ¶¶5-10, 21-22, 23-25, 27.

Align subsequently conducted a clinical trial comparing SmartTrack to EX30 in patients. The trial provided SmartTrack aligners to all new patients for participating doctors over a one-month period and compared to a group consisting of patients treated by those doctors over the prior six months using EX30 aligners. The study found that relative to EX30, SmartTrack provided a substantial increase in percentage of patients who were “on-track,” with teeth moving as intended (26%

improvement, $p < 0.001$). The study also found a substantial decrease in patients who were “off-track” (-17%, $p < 0.001$) or very substantially off-track (-34%, $p < 0.001$). EX2014, ¶¶145-47; EX2016, ¶¶26-29.

These clinical results were highly surprising, showing such a marked improvement in performance that Align promptly replaced all of its EX30 aligners with SmartTrack, which since 2013 has been the top-performing material for clear plastic aligners. EX2014, ¶148; EX2016, ¶30.

Subsequent analysis confirmed SmartTrack’s superiority relative to EX30 and other known materials. A retrospective analysis conducted comparing 110,000 patients treated with either EX30 or SmartTrack showed that SmartTrack produced substantially improved tooth movement predictability along each of fourteen different measures to a highly significant degree, with an average of 75% improvement across all categories. EX2014, ¶149; EX2016, ¶¶31-35. Align reported this 75% improvement in a 2018 brochure along with other results showing significant increases in durability, capacity to sustain force, and ability to revert to shape after deformation than EX30 or other candidate materials tested by Align. *See* EX2027; EX2014, ¶149; EX2016, ¶34.

Further clinical testing, reported in a study published by Dr. Timothy Wheeler et al., showed that SmartTrack aligners provided significantly more tooth movement as a percentage of targeted movement than EX30 aligners, with

SmartTrack aligners producing an average of over 73% of intended movement in two weeks of treatment compared to under 43% provided by EX30 aligners. See EX2028; EX2014, ¶150; EX2016, ¶36.

These testing results show that aligners made with SmartTrack were unexpectedly superior at providing orthodontic treatment relative to the closest prior art. As the market-leading aligner material prior to the invention of SmartTrack, EX30 represented the appropriate comparator. EX2014, ¶¶151-53; EX2016, ¶¶22-23, 27, 37.

Considered together, the evidence relating to the development of SmartTrack and its surprising performance shows unexpected properties that are commensurate in scope with the challenged claims. *Id.*

3. SmartTrack Aligners Are Commercially Successful

As courts have long recognized, “the commercial success of a patented invention is clearly important.” *Truswal Sys. Corp. v. Hydro-Air Eng’g, Inc.*, 813 F.2d 1207, 1212 (Fed. Cir. 1987). Evidence of commercial success must be considered “so long as what was sold was within the scope of the claims.” *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008). Align’s aligners made with SmartTrack material are unquestionably within the scope of the claims (*supra* §VI.E.1) and they exhibit clear commercial success.

Prior to the introduction of SmartTrack in 2013, all aligners on the market were single-layer, and no company was able to produce a successful multilayer aligner. EX2016, ¶38. After SmartTrack’s introduction, multilayer aligners became the industry standard, with numerous other companies now selling multilayer aligners. EX2016, ¶¶38-39.

Since their introduction, SmartTrack aligners represent nearly all aligner sales made by Align, and growth in aligner sales has been substantial. EX2018, ¶¶4-6. Between 1999 and 2012, Align treated just 2 million total patients. In the period from 2013 to 2025, Align treated over 20 million patients, including over 2 million patients in 2025 alone. EX2018, ¶5.

Over this same period, Align’s annual clear aligner revenue increased substantially, from just over \$500 million the year before SmartTrack’s introduction to \$3.2 billion today. EX2018, ¶6. This aligner sales revenue consists almost exclusively of SmartTrack sales. See EX2016, ¶14, 38; EX2018, ¶6. SmartTrack has thus substantially contributed to Align’s dramatic growth in aligner sales revenue. See EX2018, ¶6. This commercial success is strong evidence of non-obviousness.

4. Petitioner Copied Align’s SmartTrack Aligners

“The fact that a competitor copied technology suggests it would not have been obvious.” *WBIP, LLC v. Kohler Co.*, 829 F. 3d 1317, 1336 (Fed. Cir. 2016).

Copying may be shown where a party had “access to the patented product combined with substantial similarity to the patented product.” *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Petitioner manufactures aligners made with a multilayer material called Zendura FLX, which Petitioner sells under the name “ClearQuartz.” *See, e.g.*, EX1023, ¶4; EX2008, ¶4 at 5, ¶18 at 8-9; EX2014, ¶154; EX2016, ¶38. Zendura FLX is manufactured by Bay Materials LLC (“Bay Materials”), and ClearCorrect and Bay Materials are both members of the Straumann Group, headed by real-party-in-interest Straumann AG. *See* EX1023, ¶4; EX2008, ¶4 at 5. As explained below, Petitioner’s aligners are substantially similar to Align’s SmartTrack aligners, and ClearCorrect had access to the patented product as a competitor as well as via their related company and supplier, Bay Materials. EX2014, ¶154.

Bay Materials owns U.S. Patent No. 10,946,630 (the “’630 patent”). EX2010. In IPR2022-01214, Bay Materials argued its Zendura FLX material embodied and was coextensive with at least claim 1 of that patent. EX2025, 51-54; *see also* EX2026, ¶¶171-76 (Osswald declaration arguing same). Claim 1 recites:

1. A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B,

wherein one or more of the outer layers A and C is a polyester or co-polyester

having a flexural modulus of from about 1,000 MPa to 2,500 MPa,

the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75, and the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.

EX2010, claim 1.

As Dr. Kimmel explains, the claims of the '630 patent as well as the argument of Bay Materials and Dr. Osswald indicate that Zendura FLX is a multilayer sheet with three polymer layers, including a hard co-polyester layer with flexural modulus of from about 1,000 MPa to 2,500 MPa and an elastomeric layer with a hardness from about A80 to D75. EX2014, ¶¶155-57. These aspects of Zendura FLX match those recited in at least claim 1 of the '091 patent, and are also substantially similar to the composition of the sheets from which SmartTrack aligners are made. EX2014, ¶157.

ClearCorrect's website advertises that its aligners are made from Bay Materials's Zendura FLX product. EX2022; *see also* EX2023 (ClearCorrect aligners made by thermoforming Zendura FLX). Bay Materials's website further confirms that Zendura FLX's elastomeric layer is a thermoplastic polyurethane elastomer. EX2024; *see* EX2014, ¶159.

In the district court litigation, ClearCorrect stands accused of infringing the '091 patent as well as its family members in IPR2025-00818, -00819, and -

00820 via manufacture and sales of aligners with the Zendura FLX material that includes hard layers of Tritan copolyester and a soft layer of thermoplastic polyurethane elastomer according to the claims of these patents. *See, e.g.*, EX1023, ¶¶70, 87-88, 92, 108-09, 111, 126-27, 134, 148-49; EX2014, ¶158. Indeed, the petition equates ClearCorrect's aligners to Align's SmartTrack, characterizing their accused aligners as differing only in layer arrangement, being "the opposite configuration ('hard-soft-hard')." Pet., 1.

In addition to substantial similarity to Align's SmartTrack product and the patent claims it embodies, Petitioner also had access to both the patented product and the patents. ClearCorrect, at least via Bay Materials, was aware of Align's SmartTrack aligners and its family of patents including the '091 patent. For example, Bay Materials's '630 patent specifically cites to U.S. Patent No. 9,655,693 as prior art. EX2010, 17:16-24. The '091 patent claims priority to U.S. Patent No. 9,655,693. *See* EX1001, cover. Bay Materials and ClearCorrect thus had access to the '091 patent and its family member, U.S. Patent No. 9,655,693. Indeed, Bay Materials confirmed that its '630 patent specifically describes and compares Zendura FLX to Align's SmartTrack material, removing any question of access to Align's SmartTrack aligners by Bay Materials and ClearCorrect. EX2025, 57; EX2014, ¶160.

Moreover, in IPR2022-01214, Bay Materials and Dr. Osswald specifically

identified Align's SmartTrack aligners as the best-selling aligners on the market and the appropriate comparator for purposes of secondary considerations. EX2025, 56-59; EX2026, ¶¶179-82. This not only supports the conclusion that ClearCorrect, as a competitor, was aware of Align's SmartTrack aligners but also confirms their commercial success.

Contrary to the position taken here, Bay Materials (a Straumann company) and Dr. Osswald both asserted in IPR2022-01214 that Zendura FLX, the aligners of which are encompassed by the multilayer material patents' claims, showed unexpected results. EX2025, 56-59; EX2026, ¶¶179-82; EX2014, ¶161.

These arguments confirm that ClearCorrect, by making aligners using Bay Materials's Zendura FLX material, copied Align's SmartTrack aligners and the associated '091 patent claims. EX2014, ¶¶161-62. Furthermore, since aligners made with Bay Materials's Zendura FLX material fall within the scope of the claims, Bay Materials's arguments in IPR2022-01214 that such aligners show unexpected results further support the presence of secondary indicia of nonobviousness associated with the present claims. *Id.*; see EX2025, 51-62.

Accordingly, ClearCorrect's awareness of Align's SmartTrack aligners and the substantial similarity of ClearCorrect's aligners to SmartTrack aligners confirms that ClearCorrect copied Align's SmartTrack aligners and their methods of manufacture. This copying, as well as the arguments made by Bay Materials and

Dr. Osswald before the Board of unexpected results related to SmartTrack and Zendura FLX, further confirm the nonobviousness of the '091 patent.

In addition to ClearCorrect, other competitors includingOrmco Spark and Angel Align—and even individual dental labs and dental offices—now offer aligners using the Bay Materials Zendura FLX material, while yet more competitors have flooded the market with multi-layer aligners after Align introduced SmartTrack aligners. EX2016, ¶38. Conversely, very few aligner companies remain that make only single layer material aligners. EX2016, ¶39. The widespread industry adoption of Align’s patented technology offers yet more evidence of nonobviousness.

VII. THE PETITION FAILS TO NAME ALL REAL PARTIES-IN-INTEREST

A petition for *inter partes* review may be considered only if “the petition identifies all real parties in interest.” 35 U.S.C. §312(a)(2). As Align has previously explained, while the petition lists multiple ClearCorrect and Straumann entities as real parties in interest (RPI), other RPI remain unnamed. Paper 7 at 22-24; Paper 19 at 10-14.

For example, Straumann is the parent company of not only ClearCorrect but also Bay Materials. *See, e.g.*, EX1023, ¶¶4, 42; EX2008, ¶18 (ClearCorrect and Straumann asserting that accused aligners are “the direct result of years of research by ClearCorrect **and related company Bay Materials**”); EX2029 (Bay Materials

is “part of the Straumann Group”). As explained above, Bay Materials previously has advanced arguments regarding unpredictability and objective indicia—using the same expert Petitioner relies on here—that are inconsistent with Petitioner’s positions in this IPR. EX2025, 44, 46-47, 51-62. Despite this, or perhaps because of it, Petitioner has not identified Bay Materials as an RPI here. Yet Bay Materials is unquestionably “a clear beneficiary that has a preexisting, established relationship with the petitioner,” both as a supplier to ClearCorrect and as member of the Straumann corporate family. *Applications in Internet Time, LLC, v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018).

Additionally, Straumann, a non-US conglomerate, has been active in acquiring ownership and forming strategic partnerships with various Chinese entities, entanglements in which ClearCorrect is also implicated. Paper 19 at 12-14. Yet none of these Chinese entities, including AlliedStar and aligner manufacturer Smartee, has been disclosed to the Office by Petitioner let alone named as an RPI.

Accordingly, as Petitioner has failed to satisfy its obligation to identify all RPI in this proceeding and the one-year time bar has passed, the institution decision should be vacated and the petition dismissed. *See Corning Optical Communications RF, LLC v. PPC Broadband Inc.*, IPR2014-00040, Paper 68 (Aug. 18, 2015) (precedential).

VIII. CONCLUSION

Accordingly, for at least the reasons set forth above, the petition fails to meet its burden of establishing the unpatentability of claims 1-23 and 25-26 of the '091 patent.

Respectfully submitted,

Date: February 20, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

IX. APPENDIX – EXHIBIT LIST

EXHIBIT NO.	DESCRIPTION
2001	Claim Construction Order, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 5, 2025)
2002	Scheduling Order, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Aug. 5, 2024)
2003	Fourth Scheduling Order, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 12, 2025)
2004	DocketNavigator Median Time-to-Trial Statistics for Judge Alan D. Albright and for W.D. Tex. Overall, July 1, 2020 – July 1, 2025
2005	Judge Albright Patent FAQ, https://www.txwd.uscourts.gov/for-attorneys/judge-albright-courtroom-faq/ (accessed July 3, 2025)
2006	Joint Request to Amend the Claim Schedule, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jun. 6, 2025) (ECF No. 187)
2007	Preliminary Claim Constructions, <i>Align Technology Inc. v. ClearCorrect Operating LLC</i> , et al., No. 24-cv-00187-ADA-DTG (W.D. Tex. Jan. 21, 2025)
2008	Defendants’ Answer, Affirmative Defenses, and Counterclaims (Public Version), <i>Align Technology, Inc. v. ClearCorrect Operating LLC</i> , Case No. 6:24-CV-00187 (W.D. Tex. Jul. 16, 2024) (ECF No. 56)
2009	International Application Publication No. WO 2018/222864 to Stewart et al.
2010	U.S. Patent No. 10,946,630 to Stewart et al.
2011	U.S. Patent No. 7,641,828 to DeSimone et al.
2012	U.S. Patent No. 2006/0078841 to DeSimone et al.
2013	ClearCorrect Prior Art Narrowing Disclosure, <i>Align Technology, Inc. v. ClearCorrect Operating, LLC</i> , Civil Action No. 6:24-cv-00187-ADA-DTG
2014	Declaration of Dr. Robert Kimmel

2015	Curriculum Vitae of Dr. Robert Kimmel
2016	Declaration of Yan Chen – Parties and Board Only
2017	Osswald Deposition Transcript
2018	Declaration of Naga Kusima
2019	Daniel J. Brunelle et al., “Optimization of poly(1,4-cyclohexylidene cyclohexane-1,4-dicarboxylate (PCCD) preparation for increased crystallinity,” 47(11) <i>Polymer</i> 4094 (2006)
2020	James L. Throne, Understanding Thermoforming, Ch. 11 (2008)
2021	U.S. Patent No. 8,178,647 (Hawkins)
2022	ClearCorrect Support – Aligner FAQs, https://support.clearcorrect.com/hc/en-us/articles/204800937-Aligner-Material-FAQs
2023	ClearCorrect – The Premier Aligner Clinical Evidence Summary, https://www.straumann.com/content/dam/sites/clearcorrect/xy/landing/aao-2025/113896_ClearCorrect_PremierAligner_SummaryClinicalEvidence_Superside_V3.pdf
2024	Zendura Dental – Why Zendura, https://www.zenduradental.com/pages/why-choose-zendura
2025	3M Co. v. Bay Materials LLC, IPR2022-01214, Paper 21 (Patent Owner’s Response) (Apr. 12, 2023)
2026	3M Co. v. Bay Materials LLC, IPR2022-01214, Exhibit 2006 (Osswald Declaration, Public Version) (Excerpt) (Apr. 12, 2023)
2027	Align Technology, “SmartTrack: Technology that’s made to move” (2018)
2028	Timothy Wheeler et al., “Effect of aligner material on orthodontic tooth movement,” 1(1) <i>Journal of Aligner Orthodontics</i> 21 (2017)
2029	Zendura Dental – The Zendura Story, https://www.zenduradental.com/pages/the-zendura-story
2030	Align Technology 2013 Q1 Financial Slides
2031	Align Technology 2012 Q4 Financial Slides
2032	Align Technology 2025 Q5 Financial Slides

2033	<i>3M Co. v. Bay Materials LLC</i> , IPR2022-01214, Paper 77 (Final Written Decision) (Jan. 16, 2024)
------	---

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 13, 995 words.

Respectfully submitted,

Date: February 20, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

CERTIFICATE OF SERVICE

I certify that the foregoing Patent Owner's Response and Exhibits 2014-2033 were served on this 20th day of February, 2026, on Petitioner at the following electronic service addresses:

Charles Collins-Chase
Luke McCammon
Melanie Magdun
Kyle Howarth
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
Charles.Collins-Chase@finnegan.com
Luke.McCammon@finnegan.com
Melanie.Magdun@finnegan.com
Kyle.Howarth@finnegan.com

Respectfully submitted,

Date: February 20, 2026

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182