

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Patent Owner.

IPR2025-00818
Patent 10,973,613 B2

Before NEIL T. POWELL, KRISTINA M. KALAN, and
CHRISTOPHER L. OGDEN, *Administrative Patent Judges*.

KALAN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner ClearCorrect Operating, LLC requests *inter partes* review of claims 1–22 of U.S. Patent No. 10,973,613 B2 (“the ’613 patent,” Ex. 1001). Paper 1 (“Pet.”). Patent Owner Align Technology, Inc. filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). Additionally, Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 15, “Prelim. Reply”), and Patent Owner filed a Preliminary Sur-reply (Paper 16, “Prelim. Sur-reply”).

Patent Owner filed a Brief in Support of Discretionary Denial (Paper 7), to which Petitioner filed an Opposition (Paper 10), and to which Patent Owner responded with a Reply (Paper 12). Patent Owner’s request for discretionary denial was denied, and the Petition was referred to the Board. Paper 14.

We have authority under 35 U.S.C. § 314(a), which provides that *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” After considering the briefing and cited evidence of record, we institute *inter partes* review because we find that Petitioner establishes a reasonable likelihood that it will prevail with respect to at least one of the claims challenged in the Petition.

A. Real Parties in Interest

Petitioner identifies itself (ClearCorrect Operating, LLC) and ClearCorrect Holdings, Inc., Institut Straumann AG, and Straumann USA, LLC as the real parties in interest. Pet. 74. Patent Owner identifies itself (Align Technology, Inc.) as the real party in interest. Paper 3 (Patent Owner Mandatory Notices), 1.

B. Related Matters

The parties identify as a related matter the following litigation involving the '613 patent: *Align Technology, Inc. v. ClearCorrect Operating, LLC*, Case No. 6:24-cv-00187-ADA-DTG (W.D. Tex.). Pet. 74; Paper 3, 2. Patent Owner also identifies the following *inter partes* reviews: IPR2025-00814; IPR2025-00815; IPR2025-00816; IPR2025-00817; IPR2025-00819; IPR2025-00820; and IPR2025-00821. Paper 3, 1–2.

C. The '613 Patent (Ex. 1001)

The '613 patent, titled “Multilayer Dental Appliances and Related Methods and Systems,” relates to a “dental appliance for positioning a patient’s teeth,” which “includes a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient’s teeth and apply a resilient positioning force to the patient’s teeth.” Ex. 1001, codes (54), (57).

The multilayer appliance of the '613 patent can include “a hard polymer layer” as well as “a soft polymer layer,” and either of these can include additional layers of polymeric material. *Id.* at 5:18–21, 6:39–54. Figure 1 is reproduced below.

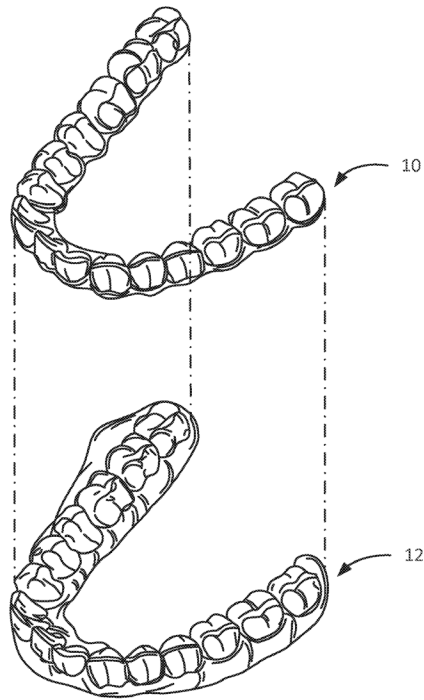


FIG. 1

Figure 1 “illustrates a jaw and an incremental positioning appliance for the jaw.” *Id.* at 2:30–31. Figure 2 is reproduced below.

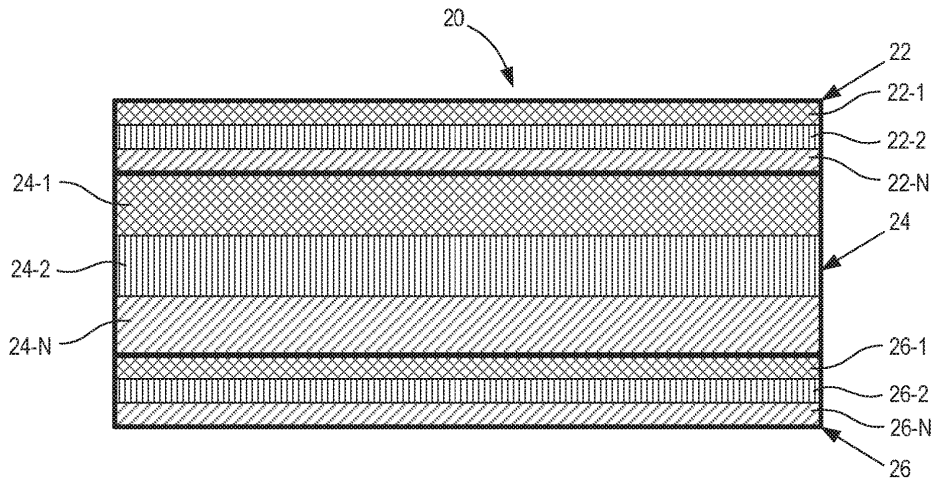


FIG. 2

Figure 2 “shows an arrangement of polymer layers in a sheet having a hard polymer layer disposed between two soft polymer layers.” *Id.* at 2:33–35. In Figure 2, multilayer sheet 20 can include a three layer structure: hard

polymer layer 24 and two soft polymer layers 22, 26. *Id.* at 5:18–21. “The hard polymer layer can be disposed between a first soft polymer layer and a second soft polymer layer.” *Id.* at 5:21–23.

D. The Challenged Claims

Petitioner challenges claims 1–22 of the ’613 patent. Claims 1 and 20 are independent. Claim 1, reproduced below with annotations,¹ is representative of the challenged claims:

1. [1(pre)] A method of making a dental appliance for positioning a patient’s teeth, the method comprising:
 - 1[a] providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:
 - 1[b] a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and
 - 1[c] a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;
 - 1[d] providing a positive model of the patient’s teeth in a target position; and
 - 1[e] fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

Ex. 1001, 9:8–23.

¹ For ease of reference, we use the same bracketed notations Petitioner uses in the Petition. *See, e.g.*, Pet. xvii–xxi.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Ground	Claim(s) Challenged	35 U.S.C. § ²	Reference(s)/Basis
1	1, 2, 4, 6–10, 12–18, 20–22	103(a)	Tadros, ³ Kalili, ⁴ Texin 990R ⁵
2	3, 5, 11, 19	103(a)	Tadros, Kalili, Texin 990R, Wen ⁶
3	1–12, 15, 18– 22	103(a)	Kalili, Porter, ⁷ Wen, Texin 990R

Pet. 6. Petitioner supports its arguments with declarations from Dr. Tim Osswald, Ph.D. (Ex. 1007) and Lauren Gluckman (Ex. 1012), among other evidence.

II. ANALYSIS

A. Principles of Law

In an *inter partes* review, “the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.”

² The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Petitioner applies a priority date of May 14, 2012. *See* Pet. 5 n.1. Accordingly, we apply the pre-AIA version of § 103; however, our decision would be the same under either version of the statute.

³ U.S. Patent Application Publication No. 2005/0100853 A1 (published May 12, 2005) (Ex. 1003, “Tadros”).

⁴ U.S. Patent Application Publication No. 2011/0020761 A1 (published Jan. 27, 2011) (Ex. 1005, “Kalili”).

⁵ Bayer Corporation, TEXIN® 990R Thermoplastic Polyurethane Product Information (Nov. 2002) (Ex. 1009, “Texin 990R”).

⁶ International Patent Application Publication No. WO 2006/096558 A2 (published Sept. 14, 2006) (Ex. 1008, “Wen”).

⁷ D.S. Porter and R.S. Beavers, Dishwasher Safe, PLASTICS TECHNOLOGY (Dec. 2007) (Ex. 1006, “Porter”).

Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Under pre-AIA 35 U.S.C. § 103(a), a claim is unpatentable as obvious if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) any objective indicia of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time the invention was made. *See Graham*, 383 U.S. at 17–18. Petitioner proposes that a person of ordinary skill in the art (sometimes referred to herein as 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. 18 (citing Ex. 1007 ¶¶ 13–15).

At this stage, Patent Owner does not dispute Petitioner’s proposal or offer an alternative proposal. *See generally* Prelim. Resp.

Because Petitioner’s proposed level of ordinary skill in the art appears to be consistent with the cited prior art and is undisputed on this record, we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (indicating that the prior art itself may reflect an appropriate skill level).

C. Claim Construction

The Board interprets a claim using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). Under this standard, we construe a claim “in accordance with the ordinary and customary

meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner argues that no terms require construction, but that “Petitioner applies the prior art consistent with Patent Owner’s assertions in its Infringement Contentions (EX1014, 6-20).” Pet. 26.

Patent Owner does not propose any express claim constructions. Prelim. Resp. 5. Nor does Patent Owner allege that any of Petitioner’s claim interpretations contradict Petitioner’s position in the related district court litigation. *Id.*

Only claim terms in controversy need be construed. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”). For purposes of this Decision, we determine that no claim term requires express construction.

D. Overview of the Asserted Prior Art

1. Tadros (Ex. 1003)

Tadros is titled “Formable Sheets for Medical Applications and Methods of Manufacture Thereof,” and discloses “an appliance for use in an oral cavity, wherein the appliance comprises a polymeric shell that comprises a polymeric mixture, and further wherein the polymeric shell has cavities designed to receive teeth.” Ex. 1003, codes (54), (57).

2. Kalili (Ex. 1005)

Kalili is titled “Orthodontic Repositioning Appliance,” and relates to an “invisible removable orthodontic repositioning appliance with a lower modulus inner lining for systematically aligning teeth from an initial tooth arrangement to a final tooth arrangement while minimizing propensity for

root and bone resorption due to the lower modulus.” Ex. 1005, codes (54), (57).

3. Wen (Ex. 1008)

Wen is titled “Variations of Dental Aligners” and relates to dental appliances “for producing corrective movement in a subject’s teeth,” including “dental aligners which may be worn on a subject’s teeth, gingiva or other region of the oral cavity” and that “include features that enhance the performance and comfort of the appliance, including features for preventing damage or wear on the appliance.” Ex. 1008, codes (54), (57).

4. Porter (Ex. 1006)

Porter is an article titled “Dishwasher Safe: New Clear Copolyester is Tougher, More Heat-Resistant, and Processes Easier, Too.” Ex. 1006, 3, 5.⁸ Porter is directed to describing a new amorphous plastic, i.e., the Tritan copolyester, that aims to fill the gap of durability, design flexibility, and easy processing created by pre-existing plastics. *Id.*

5. Texin 990R (Ex. 1009)

Texin 990R is a product information sheet titled “Texin 990R Thermoplastic Polyurethane Aromatic Polyether-Based Grade.” Ex. 1009, 1.

E. Ground 1 - Alleged Obviousness over Tadros, Kalili, and Texin 990R

Petitioner asserts that claims 1, 2, 4, 6–10, 12–18, and 20–22 would have been obvious over Tadros, Kalili, and Texin 990R. Pet. 27–46. Patent Owner disagrees. Prelim. Resp. 10–20.

⁸ We cite to the pagination provided by Petitioner.

1. Petitioner's Obviousness Argument

Petitioner argues that a POSITA would have been motivated to combine Tadros, Kalili, and Texin 990R to arrive at the claims challenged in Ground 1 with a reasonable expectation of success. Pet. 27 (citing Ex. 1007 ¶¶ 144–150). Petitioner argues that the limitations of independent claim 1 are met by the asserted prior art, as follows:

1. [1(pre)] A method of making a dental appliance for positioning a patient's teeth, the method comprising: (Tadros; Pet. 27–29; Ex. 1007 ¶¶ 31–45, 167)

1[a] providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising: (Tadros; Pet. 29; Ex. 1007 ¶ 168)

1[b] a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and (Tadros; Pet. 30–31; Ex. 1007 ¶¶ 57–87, 169)

1[c] a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D; (Tadros, Kalili, Texin 990R; Pet. 31–35; Ex. 1007 ¶¶ 31, 39–41, 57–87, 146–150, 168, 171, 172)

1[d] providing a positive model of the patient's teeth in a target position; and (Tadros; Pet. 35; Ex. 1007 ¶ 173)

1[e] fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model. (Tadros; Pet. 35–36; Ex. 1007 ¶¶ 27–30, 174)

Petitioner argues that a “POSITA would have been motivated to combine *Kalili*'s TEXIN 990R with *Tadros* with a reasonable expectation of success for several reasons,” including that both references address identical subject matter, that Kalili discloses “numerous advantages of using a specific TPU (Texin 990R) in a layered dental aligner,” and that the

desirable mechanical properties of Texin 990R would be preserved in the combination, by using known manufacturing processes. *Id.* at 32–33.

Petitioner illustrates its proposed combination as follows:



Id. at 34.

A POSITA would have had a reasonable expectation of success, argues Petitioner, because (1) Kalili discloses using Texin 990R for the same application and purpose as Tadros; (2) post-processing Texin 990R meets the claimed properties of the soft layer; and (3) a POSITA “would have been aware of manufacturing techniques such as lamination using a tie layer, which would preserve a polymer’s properties when it is joined to another layer.” *Id.* at 34–35 (citing Ex. 1007 ¶¶ 57–87, 146–150, 172).

Petitioner provides additional arguments mapping the limitations of the remaining claims challenged under this ground, with evidentiary support. *Id.* at 36–46; Ex. 1007 ¶¶ 175–205.

2. Patent Owner’s Arguments

Patent Owner argues that Petitioner’s arguments fail. Prelim. Resp. 9–20.

First, Patent Owner argues that the Ground 1 combination is founded on improper hindsight; more particularly, that “Petitioner does nothing to show the requisite predictability for obviousness, relying instead on hindsight-driven arguments.” *Id.* at 10–11. According to Patent Owner,

despite “expressly arguing that modifications to polymer materials have unpredictable effects on aligner properties and efficiency, the petition advances grounds proposing modifications to aligner materials that are premised on predictability.” *Id.* at 12. Patent Owner also argues that “Petitioner discusses whether substituting TEXIN 990R into Tadros’s aligner to replace a different polymer would have preserved the properties of *TEXIN 990R*, but the petition never discusses the expected effect on the combination beyond its argument that it would be unpredictable.” *Id.* at 13.

Second, Patent Owner argues that Ground 1 requires adhesive lamination, yet fails to motivate its use. *Id.* at 14. More particularly, Patent Owner faults Petitioner for relying on disclosures regarding the constituent layers of the materials when measured on their own, as opposed to when formed into a multilayer sheet. *Id.* at 14–15. Patent Owner argues that Petitioner’s proposal of using adhesive lamination employing tie layers “as a glue” is flawed in that it fails to argue that “a POSITA would be motivated to use adhesive lamination.” *Id.* at 16–17. Patent Owner also faults Petitioner’s “tie layers” argument as “inconsistent with its own assertion that modifying materials and layer arrangements in multilayer appliances is unpredictable.” *Id.* at 18. Finally, according to Patent Owner, Petitioner’s reliance on Patent Owner’s infringement contentions does not salvage Petitioner’s faulty combination. *Id.* at 19.

3. Petitioner’s Reply

Petitioner replies that the Petition puts forward “prior-art materials having the claimed properties of each layer in the claimed multilayer sheet.” Prelim. Reply 3. Petitioner also argues that the Petition establishes motivation to use adhesive lamination, in that the Petition explains “why a

POSITA would have been motivated to use adhesive lamination to combine prior-art polymer materials to achieve the claimed invention” and “*exactly* why and how a POSITA would have been motivated to combine this art to successfully achieve the claimed aligners, including the claimed layer configurations and properties.” *Id.* at 3–5 (citing Pet. 7, 12, 33, 35, 38 n.8, 47, 51, 54, 55, 69; Ex. 1007 ¶¶ 31, 39–42, 45, 51, 116, 120, 122, 123, 140, 153–155, 164, 170 n.5, 211, 239).

4. Patent Owner’s Sur-Reply

Patent Owner responds that the Reply ignores the Petition’s distinction among different types of lamination, and “cherry-picks” adhesive lamination specifically. Prelim. Sur-reply 3–4. Patent Owner reiterates that “mere argument that a POSA would have been aware of adhesive lamination does not suffice for obviousness.” *Id.* at 5.

5. Analysis

In view of the arguments and cited evidence, we find on this record that Petitioner has demonstrated a reasonable likelihood of showing that a person of ordinary skill in the art would have been motivated to combine the teachings of Tadros, Kalili, and Texin 990R to meet the limitations of the claims challenged under this ground.

We disagree that Petitioner fails to meet its burden as to the motivation to combine arguments. Petitioner persuasively maps the limitations of the challenged claims to portions of the references relied upon. Pet. 27–36 (claim 1), 36–46. Petitioner also, on this record, provides adequate statements of motivation to combine with a reasonable expectation of success. *See, e.g., id.* at 32–35 (citing Ex. 1007 ¶¶ 31, 39–41, 57–87, 146–150, 171–172). The Petition’s reliance on supporting testimony and

related corroborating evidence to support the combination does not amount to impermissible hindsight, as that testimony takes into account “knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure.” *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971). Without further clarification or support from Patent Owner, and in the absence of testimony to support the assertion that a POSITA would not have combined the cited references in the manner proposed with a reasonable expectation of success, we are unpersuaded by Patent Owner’s arguments in this regard.

We also disagree with Patent Owner’s arguments about “adhesive lamination” using “tie layers” at this point in the proceeding. Prelim. Resp. 15–18. On this record, we are persuaded that Petitioner has adequately supported its arguments that one of ordinary skill in the art would have been motivated to use adhesive lamination to achieve the proposed combination. *See, e.g.*, Pet. 33–35; Ex. 1007 ¶¶ 39–42, 120, 45, 51, 116, 120. Petitioner relies on Kalili as disclosing a hard layer suitable for combination with Tadros’s soft layers (Pet. 32), and more particularly, doing so in the context of a laminated multilayer aligner (Reply 4). To create the laminated multilayer aligner proposed, Petitioner’s suggested use of a particular type of well-known lamination, i.e. adhesive lamination, is sufficiently developed and supported in the Petition. Pet. 32–35. Here, Patent Owner recognizes that Kalili teaches lamination, but suggests that it does not specifically teach using adhesive lamination. Prelim. Sur-reply 5. We note, however, that the parties have identified limited types of known lamination for aligners: coextrusion, extrusion lamination, and adhesive

lamination. Prelim Sur-reply 4; Pet. 14–15 n.3, 33. In *KSR*, the Supreme Court explained that when “there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR*, 550 U.S. at 421. “If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *Id.*

Having reviewed Petitioner’s proffered arguments as to Tadros, Kalili, and Texin 990R, including motivation to combine the references asserted in this ground, with a reasonable expectation of success, we are persuaded on this record that Petitioner has met its burden for institution with respect to Ground 1.

Having determined that Petitioner has met its burden as to its Ground 1 arguments, and because the Board must institute on all grounds or none, *SAS Institute Inc. v. Iancu*, 584 U.S. 357, 364–65 (2018), we institute trial in on all grounds presented in this proceeding. We nevertheless summarize the parties’ Ground 2 and Ground 3 arguments below.

F. Ground 2 - Alleged Obviousness over Tadros, Kalili, Texin 990R, and Wen

Petitioner asserts that claims 3, 5, 11, and 19 would have been unpatentable as obvious over Tadros, Kalili, Texin 990R, and Wen. Pet. 46–52. Patent Owner disagrees. Prelim. Resp. 20.

Petitioner refers to and relies upon its arguments in Ground 1, and further argues that the addition of Wen would have rendered obvious certain portions of the claims challenged in Ground 2. Pet. 46, 47–52.

Patent Owner argues that “Petitioner does not propose any modifications regarding the limitations of independent claim 1” and, thus, “ground 2 fails to overcome the shortcomings of ground 1.” Prelim. Resp. 20.

For largely the same reasons given above for Ground 1, and for the additional reasons given in Ground 2 supporting the proposed combination of the same references relied on in Ground 1 with Wen, we are persuaded that Petitioner has met its burden on this record for institution on the basis of Ground 2.

G. Ground 3 - Alleged Obviousness over Kalili, Porter, Texin 990R, and Wen

Petitioner asserts that claims 1–12, 15, and 18–22 would have been unpatentable as obvious over Kalili, Porter, Texin 990R, and Wen. Pet. 52–73. Patent Owner disagrees. Prelim. Resp. 20–32.

1. Petitioner’s Arguments

Petitioner argues that a POSITA would have been motivated to combine Kalili with Porter, Wen, and Texin 990R to arrive at the claims challenged in Ground 3 with a reasonable expectation of success. Pet. 52–73 (citing Ex. 1007 ¶¶ 144–145, 151–166, 213–253). Petitioner argues that the limitations of independent claim 1 are met by the asserted prior art, as follows:

1. [1(pre)] A method of making a dental appliance for positioning a patient’s teeth, the method comprising: (Kalili, Pet. 52–53; Ex. 1007 ¶ 213)

1[a] providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising: (Kalili, Wen; Pet. 54–56; Ex. 1007 ¶¶ 31–45, 51–56, 151–156, 214)

1[b] a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and (Kalili, Wen, Porter; Pet. 56–58; Ex. 1007 ¶¶ 88–108, 157–166, 215, 217, 218)

1[c] a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D; (Kalili, Texin 990R; Pet. 59–60; Ex. 1007 ¶¶ 57–87, 219, 220)

1[d] providing a positive model of the patient’s teeth in a target position; and (Kalili; Pet. 60; Ex. 1007 ¶ 221)

1[e] fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model. (Kalili; Pet. 60–61; Ex. 1007 ¶ 222)

Petitioner argues that a “POSITA would have been motivated to modify *Kalili*’s single, higher-modulus hard layer to use two or more thinner layers of the same material (collectively with the same overall thickness) to improve tooth conformity and interlayer bonding,” as taught in Wen. Pet. 55–56 (citing Ex. 1007 ¶¶ 151–154). A POSITA would have had a reasonable expectation of success, argues Petitioner, because of the teachings of Wen and “industry practice of thermoforming polymer sheets with up to seven layers,” and because both Kalili and Wen “disclose the use of multilayer polymer sheets comprising layers of different hardness, thermoformed into dental aligners over a positive model of a patient’s teeth.” *Id.* at 56. Petitioner illustrates its proposed combination as follows:



Id. at 60 (citing Ex. 1007 ¶ 220).

Petitioner also argues that a POSITA “would have been motivated to use TEXIN 990R as the lower-modulus inner lining layer in *Kalili* with an expectation of success given that *Kalili* expressly discloses that material.” *Id.* at 59 (citing Ex. 1007 ¶ 220). Petitioner also argues that a “POSITA would have been motivated to substitute Tritan copolyester, as disclosed in *Porter*, for the polycarbonate layers in the soft-hard-hard polymer sheet and resulting dental aligner suggested by the combination of *Kalili* and *Wen*, to improve product safety and longevity.” *Id.* at 57. Tritan copolyesters were marketed as “a BPA-free alternative to polycarbonate with similar modulus properties,” having “increased heat resistance and toughness,” “superior chemical resistance,” and “reduce[d] [] risk of product failure from environmental stress cracking,” as well as its “proven use in thermoforming processes and extruded-sheet applications, its durability in the “harsh” environments of “heat, hydrolytic and chemical attack, and applied stress,” required for dental aligner materials, and “past industry success in replacing polycarbonate with Tritan.” *Id.* at 57–58.

Petitioner provides additional arguments mapping the limitations of the remaining claims challenged under this ground, with evidentiary support. *Id.* at 61–73; Ex. 1007 ¶¶ 223–253.

2. Patent Owner’s Arguments

Patent Owner argues that “ground 3 suffers from similar deficiencies to ground 1.” Prelim. Resp. 21. More particularly, Patent Owner critiques Petitioner’s alleged hindsight reasoning, reliance on *Porter*, and use of “adhesive lamination.” *Id.* at 21–32.

First, Patent Owner argues that in “addition to Petitioner’s failure to justify why a POSITA would have relied on the Porter reference for this substitution,” Petitioner “again makes no attempt to explain why its substitution would have been selected with a reasonable expectation of success.” *Id.* at 22. According to Patent Owner, this is an “unaddressed unpredictability” that undermines Petitioner’s motivation to combine arguments. *Id.* at 23.

Second, Patent Owner argues that Petitioner’s reliance on Porter is “not justified” because while “Porter describes in great detail the suitability of its plastic for use in kitchenware, nowhere does Porter mention dental applications for its plastics.” *Id.* at 23–24. Accordingly, Patent Owner argues that Porter is non-analogous art. *Id.* at 24–26 (citing *Sanofi-Aventis Deutschland GmbH v. Mylan Pharms., Inc.*, 66 F.4th 1373, 1377 (Fed. Cir. 2023) (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004))). Patent Owner argues that “Porter is not from a field relating to dental aligners,” and that Petitioner fails to explain why a POSITA would have plucked Porter out of the sea of prior art without any guidance from Porter (or other art). *Id.* at 25–26. Whether or not Porter constitutes analogous art, Patent Owner argues, “Petitioner never explains why a POSITA would have looked to Porter’s disclosure of dishwasher-safe polymers for use in a dental aligner when Kalili itself in the same paragraph cited by Petitioner for polycarbonate teaches numerous suitable alternatives to polycarbonate, none of which is a copolyester.” *Id.* at 26.

Third, Patent Owner argues that “ground 3 proposes substitution of different materials into layers of a multilayer appliance,” and proposes using “adhesive lamination,” adding “tie layers” between different layers as a glue

to stick the layers together. *Id.* at 29–30. As with Ground 1, Patent Owner asserts, Petitioner’s focus on “what a POSITA would have been aware of, or on what a POSITA could have done, is inappropriate.” *Id.* at 31.

3. Analysis

Regarding Patent Owner’s first argument, we disagree that Petitioner employs impermissible hindsight. As discussed *supra*, we agree that the Petition does explain “why a POSITA would have been motivated to use adhesive lamination to combine prior-art polymer materials to achieve the claimed invention.” Prelim. Reply 4; *supra* Section II.E.5. On this record, Petitioner provides adequate reasoning and a POSITA would have been motivated to use the references, techniques and combinations proposed in its Ground 3 with a reasonable expectation of success. Pet. 52–73; Ex. 1007 ¶¶ 213–253.

Regarding Patent Owner’s second argument, that Porter is non-analogous art, Petitioner demonstrates sufficiently on this record that Porter would have been reasonably pertinent to the particular problem with which the inventor is involved. The scope of analogous art includes that which is in the same field of the inventor’s endeavor regardless of the problem addressed by the inventor, and that which is outside the field of endeavor yet reasonably pertinent to the particular problem with which the inventor is involved. *Donner Technology, LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1359 (Fed. Cir. 2020). Reasonable pertinence requires only that the teachings of the reference have relevance to “one of the particular problems” addressed by the inventor of the patent. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001–1002 (Fed. Cir. 2016). The patent requires selecting a suitable material for the hard polymer layer (Ex. 1001, 5:39–54),

such as, *inter alia*, a co-polyester or a polycarbonate, identifying additional desirable properties for such a layer (*id.* at 5:55–6:5). Porter discloses that “polycarbonate contains harmful BPAs and should be replaced with BPA-free, Tritan-brand co-polyesters.” Pet. 57 (citing Ex. 1006, 63, 76).

Petitioner provides evidence that “BPAs would be released from a polycarbonate dental aligner, including the aligner in *Kalili*,” indicating that BPA-free materials would be desirable to the creator of a dental aligner. *Id.* (citing Ex. 1007 ¶¶ 88–97). Accordingly, in the realm of selection of a suitable hard layer material as required by the patent, Porter has reasonable pertinence to the particular problem with which the inventor is involved.

Patent Owner’s arguments do not controvert Petitioner’s showing of reasonable pertinence. Based on the foregoing, we determine that Petitioner has sufficiently shown Porter to be reasonably pertinent to the problem faced by the inventor of the ’613 patent, and therefore, that it is analogous art to the ’613 patent.

Regarding Patent Owner’s third argument, we agree with Petitioner that it has met its burden for institution on this record regarding its proposed use of “adhesive lamination” and “tie layers.” As discussed in Section II.E.5, above, we are persuaded that Petitioner has provided sufficient analysis and reasoning, supported by evidence and testimony, that one of ordinary skill in the art would have been motivated to use adhesive lamination in the proposed method, with a reasonable expectation of success.

On this record, we are persuaded that Petitioner has met its burden of demonstrating that the relied-upon references teach the limitations of the challenged claims, and that a person of ordinary skill in the art would have

had an apparent reason to combine the references as proposed by Petitioner, with a reasonable expectation of success.

H. Objective Indicia

Patent Owner argues that a common deficiency across the grounds is that Petitioner argues obviousness, but fails to rebut objective indicia of nonobviousness established during prosecution, namely, unexpected results. Prelim. Resp. 6 (citing Ex. 1011, 602–605, 609; Ex. 1010, 1239–1241, 1245).

Petitioner replies that it has not failed to rebut the objective indicia, but, rather, has detailed the prosecution histories, including the “two declarations allegedly showing unexpected results,” and has addressed “alleged unexpected results in the declarations.” Prelim. Reply 1. Further, Petitioner replies, the Petition expressly notes the “inconsistency between the characteristics of the *soft-hard-soft* ST30 aligner” discussed in the declarations and “how Patent Owner now asserts the challenged claims in parallel litigation against Petitioner’s *hard-soft-hard* aligner product.” *Id.* at 1–2. Accordingly, Petitioner maintains, the Petition presents “arguments addressing objective indicia and there is no basis to deny institution on these facts.” *Id.* at 2–3 (distinguishing cases cited by Patent Owner).

Patent Owner responds that, first, the Petition argues that “soft-hard-soft” would have been obvious, but fails to rebut objective indicia previously credited by the Office, and fails to grapple with unpredictability. Prelim. Sur-reply 1–2. More particularly, Patent Owner argues that the Petition characterizes the art as unpredictable, yet bases its arguments on predictability. *Id.* at 2. This deficiency, according to Patent Owner, “is exacerbated by the petition’s failure to rebut objective indicia recognized

during prosecution” and “still does not dispute the petition’s failure to address nexus.” *Id.*

We disagree that Petitioner has overlooked objective indicia in a manner that would support a denial of institution. As Petitioner notes, it summarized and discussed the prosecution history, which addressed unexpected results in the context of the declarations submitted in prosecution.

We are persuaded that the cases cited by Petitioner in support of its position more closely align with the facts in the case before us. Here, we have determined that, on this record, Petitioner has established a reasonable likelihood of prevailing on its contentions that the challenged claims would have been obvious over the relied-upon art. In addition, Petitioner has acknowledged and characterized the objective evidence, namely, the declarations submitted during prosecution of the parent application and the application leading to the challenged patent, with a critical eye. Pet. 23–26 (citing Ex. 1010 (prosecution history of parent application); Ex. 1011 (prosecution history of ’613 patent)). We agree that the Board should institute “to allow further evidence regarding any alleged unexpected results or other secondary considerations to be developed during trial.” *Mylan Pharms., Inc. v. Allergan, Inc.*, IPR2016-01129, Paper 8 at 21–22 (PTAB Dec. 8, 2016); *see also Phigenix, Inc. v. Immunogen, Inc.*, IPR2014-00676, Paper 11 at 16–22 (PTAB Oct. 29, 2014) (instituting *inter partes* review; rejecting argument that petition failed to address unexpected results); *compare Apotex Inc. v. Cellgene Corp.*, IPR2023-00512, Paper 7 at 51–52 (PTAB July 20, 2023) (instituting where Office was “led astray by . . . erroneous arguments regarding purported unexpected results.”) *with*

Paper 14, 4 (“Petitioner also persuasively demonstrates that the Office erred.”) The cases upon which Patent Owner relies differ sufficiently from the facts at hand so as to be less on point. *See, e.g., Coalition for Affordable Drugs V LLC, v. Hoffman LaRoche Inc.*, IPR2015-01792, Paper 14 at 15–18 (PTAB Mar. 11, 2016) (petitioner failing to establish reasonable likelihood of demonstrating obviousness and also failing to address unexpected results); *Gilead Sciences, Inc. v. United States*, IPR2019-01456, Paper 17 at 53 (PTAB Feb. 5, 2020) (petitioner failing to establish reasonable likelihood of prevailing on asserted grounds and also failing to address unexpected results). We also note that objective indicia are more able to be developed at trial, and the parties may, should they wish, augment the record with further evidence addressing unexpected results and/or other objective indicia.

III. CONCLUSION

After considering the arguments and evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one of the claims challenged in the Petition. Accordingly, we institute *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review is hereby instituted on all challenged claims of the ’613 patent based on the asserted grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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