

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING, LLC,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Patent Owner.

IPR2025-00821
Patent 11,648,091 B2

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

POWELL, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. BACKGROUND

ClearCorrect Operating, LLC (“Petitioner”) filed a Petition for *inter partes* review of claims 1–23, 25, and 26 of U.S. Patent No. 11,648,091 B2 (Ex. 1001, “the ’091 patent”). Paper 1 (“Pet.”). Align Technology, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). We authorized Petitioner to file a Preliminary Reply and Patent Owner to file a Preliminary Sur-Reply. Paper 15 (“Prelim. 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 to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). To institute an *inter partes* review, we must determine that the information presented in the Petition and the Preliminary Response shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons set forth below, we determine that there is a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim. We institute an *inter partes* review of claims 1–23, 25, and 26 based on the grounds set forth in the Petition.

B. RELATED PROCEEDINGS

The parties note that the '091 patent is involved in *Align Technology, Inc. v. ClearCorrect Operating, LLC*, Case No. 6:24-cv-00187-ADA-DTG (W.D. Tex.). Pet. 78; Paper 3, 2.

C. THE '091 PATENT

The '091 patent relates to dental positioning appliances. Ex. 1001, 1:19–21. The '091 patent explains that such an aligner is “designed to be worn over the teeth” and “exerts force on the teeth and elastically repositions the teeth.” *Id.* at 1:48–53. Describing this as a “considerable advancement in the field of orthodontics,” the '091 patent explains that “additional advancements remain of interest. For example, in some instances it may be advantageous to develop materials that improve properties of the appliances/aligners used for orthodontic treatment.” *Id.* at 1:54–60.

A dental appliance may include cavities for receiving teeth and applying a resilient force on the teeth. Ex. 1001, 3:33–37. The '091 patent shows an exemplary appliance in Figure 1, which is reproduced below.

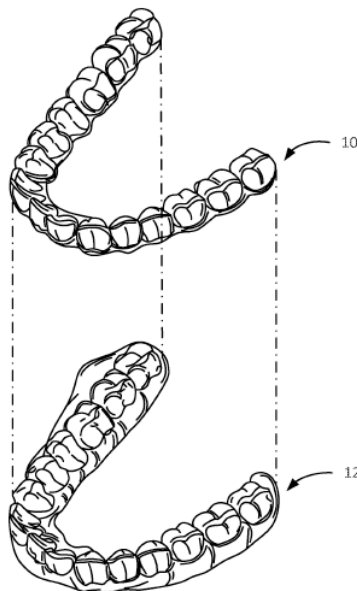


FIG. 1

Figure 1 shows appliance 10 and jaw 12. Ex. 1001, 3:65–67. A patient may wear appliance 10 on the teeth of his or her jaw 12 to incrementally reposition those teeth. *Id.*

The '091 patent discloses that it particularly relates to multilayer dental appliances. Ex. 1001, 1:19–21. It discloses a multilayer appliance constructed of “a hard polymer layer disposed between two soft polymer layers.” *Id.* at 2:5–7. The '091 patent discusses such a configuration in connection with Figure 2, which is reproduced below.

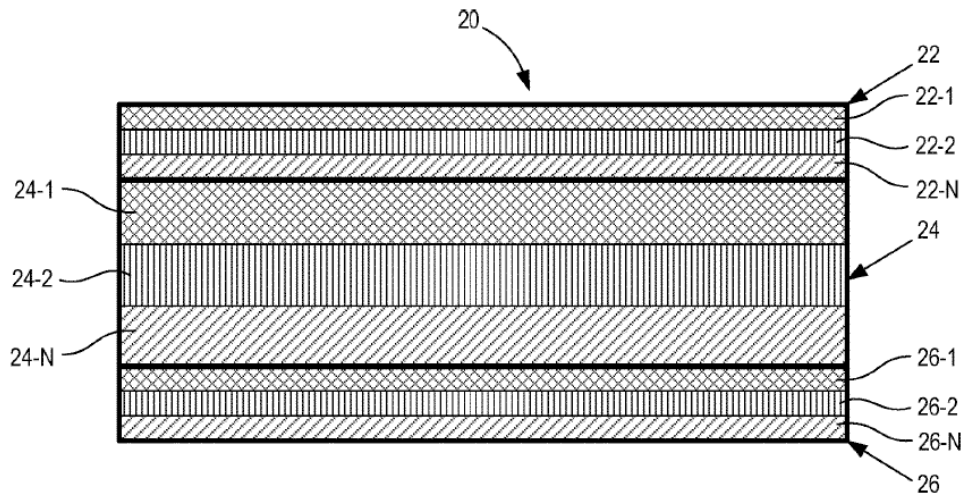


FIG. 2

Figure 2 shows multilayer sheet 20, which includes hard polymer layer 24 sandwiched between soft polymer layer 22 and soft polymer layer 26. Ex. 1001, 5:23–29.

Hard polymer layer 24 can have various thicknesses, material properties, and compositions. Ex. 1001, 5:31–34, 5:44–6:10. In some embodiments, hard polymer layer 24

can have a physical property of at least one of a tensile strength at yield of between about 4000 pounds per square inch (psi) and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than

about 150,000 psi, a stress relaxation at 24 hours testing in a wet environment (e.g., between about 90%-100% relative humidity) is greater than 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

Id. at 5:67–6:10. Additionally, in some embodiments, hard polymer layer may be formed of co-polyester. *Id.* at 5:44–45.

Each of soft polymer layers 22, 26 can also have various thicknesses, material properties, and compositions. Ex. 1001, 5:34–37, 6:11–36. In some embodiments, soft polymer layers 22, 26 may

have a physical property of at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200%, a compression set at about 70° C. of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

Id. at 6:28–36. Additionally, suitable materials for soft polymer layers 22, 26

can include a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) 15 elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof (e.g., a blend of at least two of the listed soft polymeric materials).

Id. at 6:11–19.

D. ILLUSTRATIVE CLAIMS

Of the challenged claims, claims 1, 6, 10, and 18, are independent. Each of claims 2–5, 7–9, 11–17, 19–23, 25, and 26 depends, directly or indirectly, from one of independent claims 1, 6, 10, and 18. Claim 1 is

illustrative for our analysis herein and is reproduced below with certain reformatting:¹

1. [1[pre]] A multilayer sheet comprising:

[1[a]] 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

[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

[1[c]] a third layer;

[1[d]] wherein the multilayer sheet is incorporated into an orthodontic appliance.

Ex. 1001, 9:12–10:6.

E. PETITIONER’S EVIDENCE

Petitioner’s evidence includes:

- U.S. Patent Application Publication No. 2005/0100853 A1 (published May 12, 2005) (Ex. 1003, “Tadros”).
- U.S. Patent Application Publication No. 2011/0020761 A1 (published Jan. 27, 2011) (Ex. 1005, “Kalili”).
- D.S. Porter and R.S. Beavers, Dishwasher Safe, PLASTICS TECHNOLOGY (Dec. 2007) (Appendix 1 to Declaration of Lauren Gluckman) (Ex 1006, “Porter”).

¹ We have added the same labels that Petitioner uses to identify portions of claim 1. *See, e.g.*, Pet. xx.

- International Patent Application Publication No. WO 2006/096558 A2 (published Sept. 14, 2006) (Ex. 1008, “Wen”).
- Bayer Corporation, TEXIN® 990R Thermoplastic Polyurethane Product Information (Nov. 2002) (Ex. 1009, “Texin 990R”).
- A Declaration of Dr. Tim Osswald, Ph.D. (Ex. 1007).
- A Declaration of Lauren Gluckman (Ex. 1012).

F. ASSERTED GROUNDS

Petitioner asserts that claims 1–23, 25, and 26 would have been unpatentable on the following grounds (Pet. 4–5):

Ground	Claims Challenged	35 U.S.C. § ²	References
1	6, 9, 18, 23, 25, 26	103(a)	Kalili, Texin 990R, Porter
2	1, 2, 4–7, 9–14, 16–23, 25, 26	103(a)	Kalili, Texin 990R, Porter, Wen
3	1, 4–7, 9–13, 16–20, 22, 23, 25, 26	103(a)	Tadros, Porter, Kalili, Texin 990R
4	1–23, 25, 26	103(a)	Tadros, Porter, Kalili, Texin 990R, Wen

II. ANALYSIS

A. LEVEL OF ORDINARY SKILL

Petitioner contends that the applicable level of skill in the art is as follows:

A [person of ordinary skill in the art] 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,

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. 4 n.1. Accordingly, we apply the pre-AIA version of § 103; however, our decision would be the same under either version of the statute.

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 (citing Ex. 1007 ¶¶ 13–15). Patent Owner does not dispute Petitioner’s explanation of the level of skill in the art. *See generally* Prelim. Resp.

At this stage of the proceeding and on the present record, we adopt Petitioner’s uncontested proposed level of ordinary skill in the art, which we find consistent with the level of ordinary skill in the art reflected by the ’090 patent and the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

B. CLAIM CONSTRUCTION

In an *inter partes* review, we apply the same claim construction standard as would be used by a district court to construe a claim in a civil action involving the validity or infringement of a patent. 37 C.F.R. § 42.100(b). Under that standard, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . .

that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Neither party indicates that we need to construe expressly any claim terms. Pet. 27–28; Prelim. Resp. 5. Consistent with that, we determine that we need not construe any claim terms expressly in order to resolve the parties’ dispute regarding whether Petitioner has demonstrated a reasonable likelihood of prevailing.

C. GROUND 3 – ALLEGED OBVIOUSNESS OVER TADROS, PORTER, KALILI, AND TEXIN 990R

1. *Tadros Overview*

Tadros discloses “an appliance for use in an oral cavity,” such as the one shown in Figure 3, which is reproduced below. Ex. 1003, code (57), ¶ 21.

FIG. 3

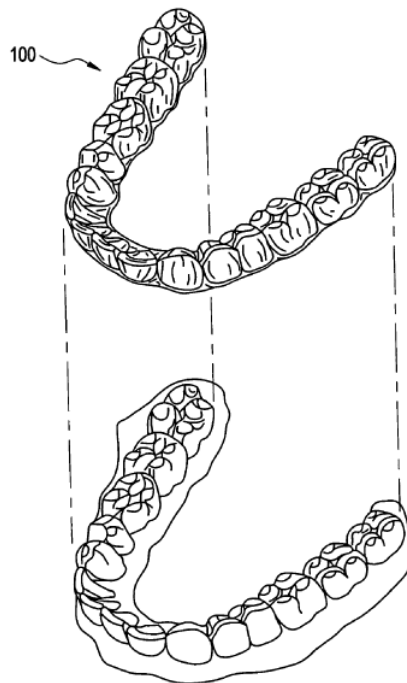


Figure 3 shows a jaw and an incremental position adjustment appliance.
Id. ¶ 12.

Specifically, Figure 3 shows appliance 100, which has “a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one tooth arrangement to a successive tooth arrangement. The polymeric shell will preferably fit over all teeth present in the upper or lower jaw. Ex. 1003 ¶ 21. Appliance 100 may include a layer made of a sheet of a polymeric mixture. *Id.* Among others, Tadros discloses using “polymeric mixtures derived from mixing polycarbonate and polyesters,” such as a “PC—PCCD” mixture. *Id.* ¶ 23. Tadros suggests using material with “a glass transition temperature of less than or equal to about 205° C., preferably less than or equal to about 175° C., and more preferably less than or equal to about 150° C., and most preferably less than or equal to about 95° C.” *Id.* ¶ 54.

Tadros further suggests that the material should also have the following mechanical properties:

an elastic modulus of about 1,500 Newton/square millimeter (N/mm²) to about 2,500 N/mm² when measured in tensile deformation at a rate of 2 millimeter/minute at room temperature prior to insertion in the oral cavity. In general, a tensile strength of greater than or equal to about 1,600 N/mm², preferably greater than or equal to about 1,650 N/mm², and more preferably greater than or equal to about 1,700 N/mm² is suitable.

Id. ¶ 68.

Tadros further discloses that appliance 100 may have additional layers. Ex. 1003 ¶ 73. Specifically, “[t]he additional layers may comprise a first layer disposed upon a surface of the sheet comprising the polymeric mixture, and an optional second layer disposed upon a surface of the sheet opposite the surface in contact with the first layer.” *Id.* “The additional layers generally

comprise an organic polymer having a tensile modulus of less than or equal to about 1,000 N/mm².” *Id.*

2. *Porter Overview*

Porter is an article titled “Dishwasher Safe: New Clear Copolyester is Tougher, More Heat-Resistant, and Processes Easier, Too.” Ex. 1006, 3, 5.³ 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.*

3. *Kalili Overview*

Kalili discloses an “orthodontic repositioning appliance,” such as the example shown in Figure 8, which is reproduced below. Ex. 1005, code (57), ¶ 24.

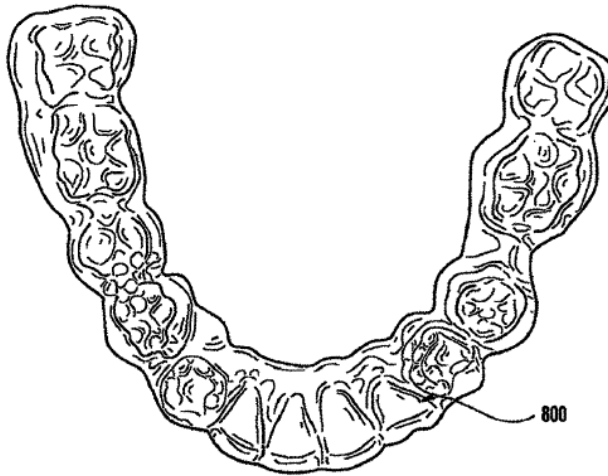


FIG. 8

Figure 8 shows “an occlusal view of [a] mandibular repositioning appliance.” *Id.* ¶ 24.

Kalili discloses using a material called TEXIN® 990R in the construction of the appliance:

³ We cite to the pagination provided by Petitioner.

In an embodiment, the liner may be a polymer such as Thermoplastic Polyurethane that is an aromatic polyether based grade, such as TEXIN® 990R resin with a shore hardness of approximately 90A. The TEXIN® 990R resin may offer outstanding abrasive resistance, impact strength, toughness, structural memory and flexibility. Furthermore, the resin may also provide good hydrolytic stability, microbial resistance, teeth whitening, oral freshness, varied color materials, and exceptional mold release characteristics.

Ex. 1005 ¶ 69.

4. *Texin 990R Overview*

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

5. *Discussion*

Noting that Tadros discloses a multilayer dental aligner, Petitioner argues that it would have been obvious to modify Tadros’s disclosure to use materials within the limitations of the claims. Pet. 7, 15–17, 53–72. For example, when addressing claim 1’s first layer, Petitioner argues that it would have been obvious, in lieu of using Tadros’s polycarbonate hard layer, to adhesively laminate Tritan to the other aligner layers. *Id.* at 54–57. According to Petitioner, an ordinarily skilled artisan would have recognized that Tritan would eliminate harmful BPA present in polycarbonate, as well as provide a number of other desirable characteristics. *Id.* at 55–57. When addressing claim 1’s second layer, Petitioner argues that it would have been obvious to use Kalili’s Texin 990R for the soft layers of Tadros’s aligner. *Id.* at 57–60. Petitioner further contends that an ordinarily skilled artisan would have had a reasonable expectation of success, and that the resulting aligner would meet the challenged claims’ limitations. *Id.* at 53–71.

Patent Owner counters that hindsight taints Petitioner's obviousness contentions. Prelim. Resp. 28. According to Patent Owner, Porter is non-analogous art. *Id.* at 34–35. Patent Owner also argues that Petitioner has not supported its position that it would have been obvious to combine the prior art materials using adhesive lamination. *Id.* at 38–41. Specifically, Patent Owner argues that Petitioner has not shown motivation to use adhesive lamination and tie layers. *Id.* Patent Owner further argues that Petitioner has not addressed sufficiently the expected efficacy of an aligner constructed in the allegedly obvious manner, noting that Petitioner acknowledges unpredictable efficacy of dental aligners with modified material configurations. *Id.* at 28–29. Additionally, noting that allegations of objective indicia of non-obviousness arose in prosecution of patents in the same family as the '091 patent, Patent Owner argues that Petitioner does not sufficiently address objective indicia, such that we should deny institution. *Id.* at 6–8.

Weighing the parties' arguments and evidence, we find Petitioner's arguments and evidence sufficient at this stage to demonstrate a reasonable likelihood of prevailing. Pet. 8–17, 53–71. For example, regarding whether Porter is analogous art, Petitioner sufficiently shows reasonable pertinence of Porter's disclosure to the problem faced by inventor of the '091 patent. Pet. 8; Ex. 1007 ¶¶ 98–108, 125–127, 146–165. The '091 patent illustrates that its inventor faced the problem of selecting desirable materials for an aligner, including selecting a desirable material for an aligner's hard layer. Ex. 1001, 5:44–59. Petitioner and Dr. Osswald provide significant evidence and reasoning tending to show that Porter's discussion of Tritan logically would have commended itself to the attention of an inventor facing the problem of selecting an aligner hard layer. Pet. 8 (citing Ex. 1007

¶¶ 98–108, 125–127, 144–164). For example, Dr. Osswald explains that “because Tritan copolyesters are BPA-free, *Rafih* specifically discloses Tritan EX401 as an exemplary material” for its oral appliance. *Id.* ¶ 99 (citing Ex. 1104, 5:4–64, claims 2, 9, 10). In view of this, Dr. Osswald testifies that “*Rafih* would inform a [person of ordinary skill in the art] that *Porter*’s guidance regarding replacing polycarbonate with Tritan applies to dental appliances.” Ex. 1007 ¶ 147. At this stage, weighing Petitioner’s evidence against Patent Owner’s countervailing attorney argument that Porter focuses on dishware, we determine Petitioner has shown sufficiently that Porter is analogous art. Pet. 8; Ex. 1007 ¶¶ 98–108, 125–127, 146–165; Prelim. Resp. 1–2, 9–10, 34–36.

Petitioner also shows sufficiently that an ordinarily skilled artisan would have been motivated to modify Tadros’s aligner to have a hard layer of Tritan adhesively laminated to the other layers. Pet. 54–57. Petitioner and Dr. Osswald provide persuasive evidence that an ordinarily skilled artisan would have recognized the desirability of replacing Tadros’s BPA-laden polycarbonate with a BPA-free material like Tritan. Pet. 2, 9–10, 55–56; Ex. 1007 ¶¶ 88–108, 125–127, 146–147, 159–165. And, at this stage, Patent Owner does not provide persuasive evidence supporting its characterization of Tadros as suggesting the particular importance of using a polymer blend for its hard layer. Prelim. Resp. 29–30.

Additionally, as Petitioner and Dr. Osswald explain, Tadros specifies that its hard layer should have certain material properties, which match the material properties of Tritan, so long as Tritan’s material properties are preserved, rather than altered in the manufacturing process. Pet. 16, 55; Ex. 1007, ¶¶ 110, 161–163. Petitioner thus provides both a reason why an ordinarily skilled artisan would have used Tritan and a reason why an

ordinarily skilled artisan 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. Pet. 55; Ex. 1007 ¶¶ 161–163. Given this, we do not find persuasive Patent Owner's argument that Petitioner did not separately, expressly refer to the advantages of the adhesive lamination approach as a reason that an ordinarily skilled artisan "would" have used it. Prelim. Resp. 2, 9, 38–41.

At this stage, we also find unavailing Patent Owner's arguments that an ordinarily skilled artisan may not have viewed every characteristic of Tritan as optimal. Prelim. Resp. 30–31. For example, Patent Owner argues that Tritan has a glass transition temperature higher than the "most preferred" temperature noted by Tadros. *Id.* at 31 (citing Ex. 1003 ¶ 56). In our view, this does not undermine Petitioner's observation that Tritan has a glass transition temperature within the range that Tadros expressly describes as desirable. Pet. 55. Rather, considering the glass transition temperature in combination with Tritan's lack of BPA and other desirable properties, Petitioner currently appears to have the better position regarding obviousness of using Tritan for Tadros's hard layer. *Id.* at 54–57. Indeed, to the extent Patent Owner suggests that Tritan may not have been viewed as the best possible material for Tadros's hard layer, that would not undermine significantly Petitioner's position. Even if "better alternatives exist in the prior art," that does not make Petitioner's proposed combination "inapt for obviousness." *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (citing *In re Gurley*, 27 F.3d 551, 553) (Fed. Cir. 1994)).

Petitioner also presents sufficient evidence that an ordinarily skilled artisan would have been motivated to use Texin 990R for Tadros's soft

layers. Pet. 57–60. For example, Petitioner and Dr. Osswald cite Kalili’s express disclosure of the desirability of Texin 990R for soft layer(s) of an aligner. Pet. 58–60; Ex. 1007 ¶¶ 166–170, 267. At this stage, Patent Owner’s argument that Texin 990R is “far softer than Tadros’s materials” does not persuade us of any shortcoming in Petitioner’s evidence that it would have been obvious to use Texin 990R for Tadros’s soft layers. Prelim. Resp. 29. As Patent Owner recognizes, Tadros discloses that its soft layers “generally comprise an organic polymer having a tensile modulus of *less than or equal to* about 1,000 N/mm².” Ex. 1003 ¶ 73 (emphasis added); Prelim. Resp. 29. To the extent Patent Owner implies that this disclosure would suggest only materials with a modulus near 1,000 N/mm², we do not agree on the current record.

Petitioner also sufficiently shows that, in addition to having motivation to use Tritan and Texin 990R, an ordinarily skilled artisan would have had a reasonable expectation of success in doing so. Pet. 53, 56, 59–60. As Patent Owner argues, Petitioner notes unpredictability of an aligner’s efficacy based on the selection and arrangement of constituent materials. Pet. 22 n.4, 43 n.10; Prelim. Resp. 31–32. But Dr. Osswald testifies that, notwithstanding that unpredictability, an ordinarily skilled artisan would have had a reasonable expectation of success. Ex. 1007 ¶¶ 147, 164–165. Dr. Osswald supports his opinion with objective reasoning, including his observation that “Tritan had already been incorporated into layered dental appliances,” elaborating that “*Rafih* discloses using Tritan as a ‘BPA-free’ rigid layer combined with a soft inner layer.” *Id.* ¶ 165. Consistent with Petitioner’s arguments and Dr. Osswald’s testimony, obviousness with a reasonable expectation of success does not require “absolute predictability.” *Soft Gel Techs. v. Jarrow Formulas, Inc.*,

864 F.3d 1334, 1341 (Fed. Cir. 2017) (citing *Noelle v. Lederman*, 355 F.3d 1342, 1352 (Fed. Cir. 2004)).

In addition, to providing sufficient evidence that an ordinarily skilled artisan would have used Tritan and Texin 990R for Tardos's aligner, Petitioner provides sufficient evidence that its proposed combination would result in a multilayer sheet incorporated into an orthodontic appliance and meeting the limitations of at least claim 1. Pet. 53–62. At this stage, Patent Owner does not argue otherwise.

In view of the foregoing, we disagree with Patent Owner's argument that Petitioner's obviousness contentions stem from improper hindsight. Prelim. Resp. 1. Petitioner persuasively maps the limitations of claim 1 to portions of the references relied upon. Pet. 53–62. Petitioner also, on this record, provides adequate statements of motivation to combine with a reasonable expectation of success. *See, e.g., id.* at 54–60 (citing Ex. 1007 ¶¶ 159–165, 256–263). 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).

For the reasons above, having considered both parties' arguments and evidence, we determine Petitioner has demonstrated a reasonable likelihood of prevailing on at least its assertion that claim 1 would have been obvious over Tardos, Porter, Kalili, and Texin 990R.

Moreover, we disagree with Patent Owner's suggestion that Petitioner has overlooked objective indicia in a manner that would support a denial of

institution. As Petitioner notes, it summarized the prosecution history, which addressed unexpected results in the context of the declarations submitted in prosecution. Reply 1.

When addressing the current dispute regarding objective indicia, each party cites prior Board decisions in favor of its position. Prelim. Resp. 7; Reply 2–3. 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, submitted in the form of the declaration submitted during prosecution of the parent application and prosecution of an application that led to another related patent, with a critical eye. Pet. 24–26 (citing Ex. 1010 (prosecution history of parent application); Ex. 1011 (prosecution history of U.S. Patent No. 10,973,613 B2)). 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, 16–22 (PTAB Oct. 29, 2014) (instituting *inter partes* review; rejecting argument that petition failed to address unexpected results). 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 La-Roche Inc.*, IPR2015-01792, Paper 14 at 15–18 (PTAB Mar. 11, 2016) (petitioner failing to establish 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 obviousness 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.

Furthermore, Petitioner notes, “Patent Owner’s arguments are additionally deficient as to the ’384, ’090, and ’091 patents, where no unexpected results declaration was submitted in prosecution. Patent Owner cites no authority for its position that secondary considerations never addressed during prosecution must be addressed in an IPR petition.”

Reply 3. We agree with Petitioner that no such authority is provided; not having been made aware of any such authority, we are unpersuaded that we should deny institution on this basis alone.

D. GROUND 4

Patent Owner argues that Petitioner’s Ground 4 “fails to overcome the shortcomings of” Ground 3. For the reasons discussed in Section II.D above, Petitioner’s Ground 3 shows a reasonable likelihood of prevailing at least in its challenge of claim 1 as allegedly obvious over Tadros, Porter, Kalili, and Texin 990R, and we institute *inter partes* review on all of Petitioner’s grounds.

E. GROUNDS 1 AND 2

In Grounds 1 and 2, Petitioner asserts that it would have been obvious to modify a dental appliance disclosed by Kalili in ways that would have resulted in an appliance meeting the limitations of claims 1, 2, 4–7, 9–14, 16–23, 25, and 26. Pet. 28–53. Patent Owner disputes these contentions, advancing a number of arguments. Prelim. Resp. 6–27. As discussed in Section II.C above, we determine Petitioner has shown a reasonable

likelihood of prevailing on at least its challenge of independent claim 1 as allegedly obvious over Tadros, Porter, Kalili, and Texin 990R in Ground 3, and we institute *inter partes* review of all grounds. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60; *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018); 37 C.F.R. § 42.108(a) (“When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”). The issues raised by Patent Owner’s disputes with Grounds 1 and 2 are well suited for resolution on a fuller record developed during a trial.

III. ORDER

It is:

ORDERED that *inter partes* review of claims 1–23, 25, and 26 of the ’091 patent is instituted on all grounds presented in the Petition; and

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

IPR2025-00821
Patent 11,648,091 B2

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