

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY,
Petitioner,

v.

BAY MATERIALS, LLC,
Patent Owner.

IPR2022-01214
Patent 10,946,630 B2

Before GRACE KARAFFA OBERMANN, CHRISTOPHER L. CRUMBLEY,
and KRISTINA M. KALAN, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

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

I. INTRODUCTION

3M Company (“Petitioner”) filed a Petition (Paper 2, “Pet.”) for *inter partes* review of claims 1–4, 7–11, and 13 of U.S. Patent No. 10,946,630 B2 (Ex. 1001, “the ’630 patent”). Bay Materials, LLC (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). With Board pre-authorization, Petitioner filed a Reply (Paper 11) and Patent Owner filed a Sur-reply (Paper 13) limited to addressing Patent Owner’s alleged “mischaracterization of the Petition’s arguments and the law regarding inherency in the context of obviousness.” Ex. 1039, 2.

The information presented in the Petition, Preliminary Response, Reply, and Sur-reply forms the basis for our preliminary findings and conclusions of law, which are provided for the sole purpose of explaining our reasons for instituting an *inter partes* review. Any final determinations shall be based on the full trial record.

A. Real Parties-in-Interest and Related Matters

Petitioner asserts 3M Company is the real party-in-interest. Pet. 2. Patent Owner asserts the real party-in-interest is Bay Materials, LLC, a wholly-owned subsidiary of Straumann Manufacturing, Inc. Paper 4, 1. Both parties identify as a related matter co-pending district court litigation in *Bay Materials LLC v. 3M Company*, No. 1:21-cv-1610-RGA (D. Del.) (“the District Court action”). Pet. 3; Paper 4, 1.

Concurrently herewith, we enter a decision instituting review in IPR2022-01215, involving U.S. Patent No. 10,870,263 B2 (“the ’263 patent”). Petitioner avers that “the ’630 patent and ’263 patent are related through their shared parent application, U.S. Patent Application No. 16/211,176.” Pet. 3; *see* Paper 4, 1; *see also* Ex. 1001, code (63).

II. BACKGROUND

A. The '630 Patent (Ex. 1001)

The '630 patent, titled “Dual Shell Dental Appliance and Material Constructions,” relates to “[a] polymeric sheet composition” having “at least two outer layers” and “an elastomeric inner layer.” Ex. 1001, code (54) (Title), 22:8–9 (claim 1, the sole independent challenged claim). In particular, one or more outer layers “is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa.” *Id.* at 22:10-12. The term “flexural modulus” relates “to the rigidity of a material and/or resistance of the material to deformation in bending” or “stretching.” Ex. 1001, 6:54–56; 7:3–5. “The higher the flexural modulus of the material, the more resistant to bending it is.” *Id.* at 6:56–57.

The sole independent claim also specifies that the elastomeric inner layer has “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.” *Id.* at 22:13–34. The term “hardness” relates “to a Shore hardness scale.” Ex. 1001, 6:60–61. “A durometer measures the penetration of a metal foot or pin into the surface of a material. There are different durometer scales, but Shore A and Shore D are commonly used.” *Id.* at 6:62–65. Materials with a higher durometer value “will be harder compared to materials with a lower durometer value.” *Id.* at 6:65–67. The written description explains that “hardness and modulus are generally correlated and can be converted by approximation if only one value is known by methods” known in the art. *Id.* at 6:67–7:2.

We reproduce below Figure 1A from the '630 patent, which illustrates a three-layer sheet composition of the claimed invention.

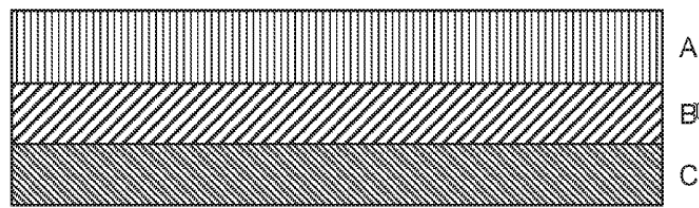


FIG. 1A

Figure 1A depicts “a cross sectional view of a three-layer sheet of the invention with a simple ABC construction.” *Id.* at 3:41–43. The two outer layers are labeled A and C, and the inner layer is labeled B.

The '630 patent illustrates “exemplary test samples for determining displacement,” in Figure 2A, “and lateral restoring force” in Figure 2B. *Id.* at 3:56–58. We reproduce those figures below.

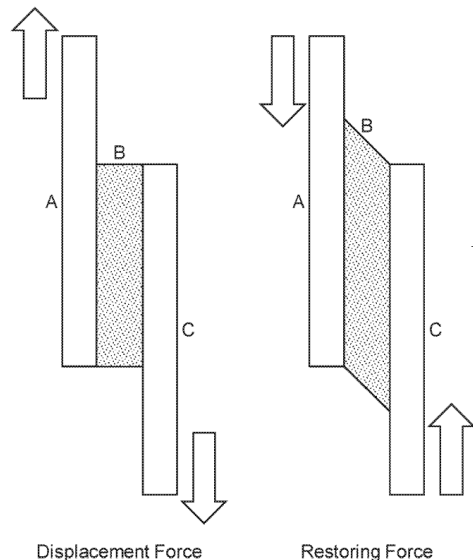


FIG. 2A

FIG. 2B

Figures 2A and 2B illustrate “a simple 3-layer sheet comprised of two rigid outer layers,” labeled A and C, “and an inner elastomeric layer,” labeled B. *Id.* at 3:59–61. “In this example, layers A and C are reversibly translated relative to each other and layer B provides a restoring force.” *Id.* at 3:61–63.

The '630 patent identifies “a need for improved orthodontic and dental appliances capable of facilitating orthodontic tooth movements,

stabilizing tooth positions or protecting teeth from potentially damaging outside forces.” *Id.* at 1:28–30. For example, “aligners” are dental appliances fabricated as “plastic shells which fit over teeth” that are “designed to apply translational or rotational forces to teeth.” The ability of aligners “to accurately move teeth is limited by their effective modulus, elasticity and ability to resist creep and stress relaxation.” *Id.* at 1:35–38. In addition, aligners “generally should be resistant to staining and environmental stress cracking.” *Id.* at 1:39–40. The ’630 patent discusses requirements for other dental appliances, including sports guards and dental splints. *Id.* at 1:41–46.

The ’630 patent indicates that the polymeric sheets of the invention “are useful, for example, in a dental appliance, and are constructed of layers that impart flexibility and strength and stain resistance.” *Id.* at 1:19–23.

B. Challenged Claims

The Petition challenges claims 1–4, 7–11, and 13. Claim 1, which we reproduce below, is the sole independent claim challenged in the Petition and illustrates the subject matter of the invention.

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.*

Ex. 1001, 22:8–34 (Board’s emphasis). We adopt Patent Owner’s convention and refer to the emphasized feature as the “flexural modulus limitation.” See Prelim. Resp. 12 (citing claims 1–4, 7–11, 13).

C. Asserted Grounds of Unpatentability

The Petition advances four grounds, each of which is based on obviousness under 35 U.S.C. § 103.¹ We provide below a chart that sets forth the grounds identified in the Petition.

Ground	Claims Challenged	References
1	1–4, 7–11, 13	Hinz ² , Durasoft (TPU/PC) Data Sheet ³
2	1–4, 7–11, 13	Hinz, Durasoft (TPU/PC) Data Sheet, Durasoft (TPU/PETG) Data Sheet ⁴

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (September 16, 2011), includes revisions to Section 103 that became effective on March 16, 2013. The challenged claims are entitled to an earliest priority date of May 31, 2017, therefore, the AIA provisions apply in this proceeding. *See* Pet. 12; Ex. 1001, code (60).

² WO 20010/043419 A1, published Apr. 22, 2010, with English Translation (Ex. 1015).

³ Produktdatenblatt DURASOFT with English Translation, available at https://web.archive.org/web/20160808102931/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenblätter/Produktdatenblatt-DURASOFT_bis-LOT-1614A.pdf (Ex. 1012). Petitioner avers, and Patent Owner does not contest at this juncture, that this reference “was publicly available at least as of August 8, 2016.” Pet. 19; *see, e.g.*, Prelim. Resp. 1–2, 12–13 (addressing merits of reference without contesting its prior art status).

⁴ Produktdatenblatt DURASOFT with English Translation, available at https://web.archive.org/web/20160808110356/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenblätter/Produktdatenblatt-DURASOFT_ab-LOT-1714A.pdf (Ex. 1014). Petitioner avers, and Patent Owner does not contest at this juncture, that this reference “was publicly available at least as of August 8, 2016.” Pet. 19; *see, e.g.*, Prelim. Resp. 1–2, 12–13 (addressing merits of reference without contesting its prior art status).

Ground	Claims Challenged	References
3	1–4, 7–11, 13	Ground 1 or Ground 2 further in view of Sun ⁵

Pet. 3. The Petition is supported by the Declaration of Dr. Alan Jeffrey Giacomini. Ex. 1002. The Preliminary Response is supported by the Declarations of Dr. Tim A. Osswald, Mr. John Lahlough, Mr. Tom Ross, and Mr. W. Todd Schoettelkotte. Exs. 2001, 2002, 2004, and 2005.

III. ANALYSIS

A. Level of Ordinary Skill in the Art

The level of ordinary skill in the art at the time of the invention is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

The parties disagree about whether the ordinarily skilled artisan would have had specific “experience with dental appliances or access to individuals with such experience.” Prelim. Resp. 9; see Pet. 10–11 n.1 (disagreeing with that proposition). Neither party explains why a resolution of that dispute is necessary to this Decision to institute review. See, e.g., Prelim. Resp. 9 n.2 (“even under Petitioner’s proposed definition, the Petition fails to show a reasonable likelihood that any claim is unpatentable”); Pet. 14–15 & n.1 (arguing about the issue without explaining how a resolution of the dispute would change the outcome of the decision on institution). If either party believes that the difference in level of skill would have a material effect on

⁵ US Pub. 2004/0224283 A1, published Nov. 11, 2004 (Ex. 1008).

the analysis of the patentability of the challenged claims, that issue should be specifically addressed in briefing during the trial. We will resolve that dispute only to the extent necessary in any final written decision.

Based on the information presented, we find that the asserted prior art itself is sufficient to demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (prior art itself can reflect the appropriate level of ordinary skill in the art).

B. Claim Construction

In an *inter partes* review, the Board construes the terms of a patent 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.” 37 C.F.R. § 42.100(b). Under that standard, claim terms generally are given their plain and ordinary meaning as would have been understood by the ordinarily skilled artisan at the time of the invention and within the context of the entire patent disclosure. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

We construe terms in controversy only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Petitioner discusses certain terms at issue in the District Court action, such as “layer A,” “layer B,” “layer C,” “inner layer B,” and “flexural modulus” ranges, without proposing any express constructions. Pet. 12–15. Patent Owner does not provide arguments directed specifically to proposed claim constructions. *See generally* Prelim. Resp.

Taking account of the information presented, we determine that no claim term requires express construction for purposes of deciding whether to institute review. *Compare* Pet. 12–15 (addressing issues of claim construction, without demonstrating that an express construction is necessary to resolve whether to institute review), *with* Prelim. Resp. 12–39 (addressing the merits of Petitioner’s challenges, without asserting an express claim construction).

C. The Patentability Challenges

On the record before us, we determine that Petitioner is reasonably likely to prevail at trial in showing that the subject matter of at least one challenged claim would have been obvious over the combined disclosures of Hinz, the Durasoft Data Sheets,⁶ and Sun. For example, as explained below, Petitioner shows sufficiently that an ordinarily skilled artisan would have combined the teachings of the references, and that the combined teachings would have suggested a polymeric sheet composition that meets every limitation of claim 1. Pet. 23–68 (Petitioner’s art-based rationale), 68–71 (Petitioner’s assessment of secondary indicia of nonobviousness).

1. Hinz and the Durasoft Data Sheets

Hinz discloses a method for producing a multilayer dental splint. Pet. 15, 29–30; Ex. 1002 ¶¶ 90–92; Ex. 1015, Fig. 3, 1:3–4, 8:240–244. Hinz explains that deep-drawing, also known as thermoforming, can be used to produce dental splints for use in removable orthodontic treatment apparatuses, including aligners that maintain teeth in alignment after an

⁶ We adopt Patent Owner’s convention and refer to Exhibits 1012 and 1014 collectively as the “Durasoft Data Sheets.” Prelim. Resp. 1.

active treatment phase. Pet. 15; Ex. 1015, 1:6–8, 1:24–26, 3:73–76, 3:89–90, 9:278, 10:323. Hinz discloses an embodiment in which the dental appliance is constructed from three bonded layers in a hard-soft-hard configuration—that is, a soft layer inside two hard outer layers. Pet. 15, 30–32; Ex. 1002 ¶¶ 93–96; Ex. 1015, Fig. 3, 2:61–3:70, 7:215–217, 8:240–243.

Both outer hard layers “preferably” are “made of the same plastic material,” such as polycarbonate (known as PC) or polyethylene terephthalate (known as PET). Pet. 17; Ex. 1015, 3:80–93. Hinz teaches that thermoplastic polyurethane (known as TPU) is a preferred soft inner material. Pet. 18; Ex. 1015, 3:89–90. Hinz also expressly teaches the use of commercially-available, two-layer materials, marketed under the tradename Durasoft and “supplied by Scheu Dental,” as useful in producing hard-soft-hard multilayer dental splints according to the method of Hinz. Pet. 18, 23–24; Ex. 1015, 6:177–7:206; *see especially id.* at 7:205–207; Ex. 1002 ¶¶ 80–83.⁷ In other words, the ordinarily skilled artisan would have “recognized the suitability of the hard and soft polymeric materials” disclosed in the Durasoft Data Sheets as suitable “for use within the teachings of Hinz.” Pet. 24; Ex. 1002 ¶ 81.

Petitioner shows sufficiently that Hinz’s disclosure, explaining “that ‘[t]he dental splint according to the invention preferably has hard layers

⁷ Patent Owner attempts to divorce Hinz’s disclosure of Durasoft materials from the description of Hinz’s Figure 3 embodiment. Prelim. Resp. 36–38. Patent Owner, however, does not explain why an ordinarily skilled artisan would understand Hinz’s disclosure, regarding the usefulness of the two-layer Durasoft materials, to apply only to the “three-layer structure” of Figure 1 and exclude the “three-layer structure” of Figure 3. Ex. 1015, 7:205–217, 8:240.

made of the same plastic material” would have prompted an ordinarily skilled artisan to bond a third hard layer of PC to the soft TPU layer of the material disclosed in the Durasoft (TPU/PC) Data Sheet (Ex. 1012), or a third layer of PETG to the soft TPU layer of the material disclosed in the Durasoft (TPU/PETG) Data Sheet (Ex. 1014), to create a hard-soft-hard polymeric sheet composition. Pet. 25; Ex. 2015, 3:86–87; *see id.* at Fig. 3, 8:240–244; *see also* Ex. 1002 ¶ 83.

2. Layer Thicknesses

Here is where the question of whether to institute review becomes a much closer call. In this section, we detail our concerns about the sufficiency of Petitioner’s showing that the asserted prior art references would have led an ordinarily skilled artisan to select a combination of layer thicknesses from among the broad ranges disclosed in Hinz, to create a multilayer sheet having a flexural modulus that falls within the specified range “of from about 750 MPa to 2,000 MPa.” Ex. 1001, 22:34–35 (claim 1).

Petitioner relies on Hinz’s disclosure of broad ranges for the individual thicknesses of the three layers that make up a hard-soft-hard dental structure. Pet. 33–34. Specifically, Petitioner directs us to Hinz’s claims, which, according to Petitioner, disclose:

a three-layer embodiment wherein the thickness of one outer hard layer is “less than 0.5 mm, in particular of less than 0.2 mm,” the soft [inner] layer has a thickness of “less than 1.3 mm, in particular of less than 1.0 mm[,]” and the other hard outer later has a thickness of “less than 1.2 mm, in particular of less than 0.8 mm.”

Id. (quoting Ex. 1015, 10:317–11:333 (claims 11–14 from Hinz)).

There is no genuine dispute that some, but not all, of the three-layer thickness combinations encompassed by those claimed ranges would result in a multilayer structure that meets the flexural modulus limitation. *Compare* Pet. 36–38, 59–60 (Petitioner identifying three-layer embodiments that meet the flexural modulus limitation), *with* Prelim. Resp. 19–27 (Patent Owner using the same methodology as Petitioner to identify other three-layer embodiments that do not meet the flexural modulus limitation). Our main concern, on this record, is whether Petitioner accounts adequately for the fact that Hinz discloses and claims thickness *ranges* for each of the layers in a multilayer dental structure, but not a single *example* of a thickness *value* for any layer, much less an example of a multilayer combination having specific thickness values assigned to each layer. Ex. 2015, 4:112–119 (Hinz’s disclosure of preferred thickness ranges), 10:317–333 (Hinz’s claims 11–14, specifying thickness ranges). In other words, we agree with Patent Owner that “Hinz does not disclose a *single embodiment* that specifies the thickness of the three polymer layers” but discloses only “a thickness *range* for each layer.” Sur-reply 1 (Patent Owner’s emphasis)).

We also agree with Patent Owner that Petitioner overstates the record by asserting that Hinz “expressly” discloses a PC-TPU-PC, hard-soft-hard embodiment in which the layer thicknesses are 0.2 mm, 1.0 mm, and 0.8 mm, respectively. Pet. 34; Reply 4–5. To the contrary, Hinz discloses and claims only thickness ranges, never specific thickness values, for each of the three layers in a multilayer dental structure. Ex. 1015, 4:112–119, 10:317–11:333. Petitioner incorrectly asserts that “examples” in Hinz teach any thickness *value* for any layer. Reply 3–4 (quoting *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 343 F. Supp. 3d 823, 845–846 (N.D. Ill. 2018), *aff’d*, 946

F.3d 1322 (Fed. Cir. 2020) (providing that the calculated property can render a limitation obvious when it is “the natural result of the combination of elements explicitly disclosed by the prior art”)).

Petitioner instead relies on a statement in Hinz that indicates a broad intent to capture “all intermediate values of the” relatively broad thickness ranges set forth in the reference. Ex. 1005, 4:115–116; Pet. 37–38; Reply 5. Petitioner does not articulate a clear reason, however, why Hinz’s general reference to “all intermediate values” would have led an ordinarily skilled artisan to select, from among the voluminous number of possible three-value combinations suggested by the ranges, any particular combination of layer thickness values that meets the flexural modulus limitation. That failure is problematic where the parties agree, on this record, that some of the possible combinations would meet the limitation, and others would not. *Compare* Pet. 36–38, 59–60 (identifying three-value combinations from Hinz’s ranges that meet the flexural modulus limitation), *with* Prelim. Resp. 19–27 (identifying three-value combinations from Hinz’s ranges that do not meet the flexural modulus limitation, without meaningfully contesting Petitioner’s evidence that other combinations, in fact, would result in a multilayer structure having a flexural modulus that falls within the range specified in the flexural modulus limitation).

Petitioner, however, does articulate a rational reason why Hinz’s disclosure, in light of Durasoft, would have led an ordinarily skilled artisan to select specific thickness values for two of the three layers in a hard-soft-hard multilayer combination: Petitioner explains that Hinz recommends choosing Durasoft materials, sold as TPU/PC or TPU/PETC two-layer sheets, which have discrete properties and values identified in their

respective data sheets, as starting materials to form three-layer sheets. Pet. 18, 34–34 & n.8; Ex. 1015, 7:205–207. For example, Petitioner shows sufficiently, on this record, that the Durasoft TPU/PC material would have been available in three overall thicknesses, including one having an 0.8 mm PC hard layer bonded to a 1.0 mm TPU soft layer. *See* Ex. 1034, 22 (“properties section”).

A much closer question arises as to whether, and why, an ordinarily skilled artisan would have been led by the asserted references to select a third layer of 0.2 mm thickness for bonding to the two-layer Durasoft material. Pet. 34–35 n.8 (selecting the 0.2 mm value from Hinz’s preferred range “of less than 0.5 mm, in particular of less than 0.2 mm”); Ex. 1005, 10:326–11:330 (claim 11), 4:112–114 (disclosing a range for the two hard layers “of less than or equal to 3.0 mm, preferably of 1.0 to 1.5 mm, more preferably of less than or equal to 0.5 mm, in particular of 0.2 to 0.5 mm”).

In Patent Owner’s view, Petitioner engages in impermissible “hindsight to cherry-pick the data points within Hinz’s preferred thickness ranges” to arrive at structures that meet the flexural modulus limitation. Prelim. Resp. 22; *see id.* at 27 (same); *see also* Pet. 33–38, 56–60 (Petitioner’s alleged picking and choosing). On that point, we agree with Patent Owner that neither Hinz nor the Durasoft Data Sheets make any mention of “the overall flexural modulus of a three-layer dental sheet or dental appliances, much less offer any reason to select thicknesses for each layer that give a certain overall flexural modulus.” Prelim. Resp. 27; *see generally* Ex. 1012, 1014, 1015 (asserted prior art references).

Accordingly, we have concerns about Petitioner’s showing in connection with the grounds that do not assert Sun. Pet. 6 (Grounds 1 and 2).

At this juncture, we need not address those concerns in greater detail because, for reasons explained below, Petitioner meets the threshold showing, necessary to support institution of review, in connection with the ground that asserts Sun. *Id.* (Ground 3). Any final determinations on the sufficiency of the patentability challenges will be based on the full trial record and provided only as necessary in a final written decision.

3. The Ground that Asserts Sun

The third ground stated in the Petition is to “Ground 1 or Ground 2 further in view of Sun.” Pet. 6 (grounds chart). Petitioner shows sufficiently, in connection with this third ground, that the ordinarily skilled artisan would have recognized that the thickness values selected for the layers in a multilayer dental structure affect the flexural modulus property of the structure and, moreover, would have chosen those values with an eye toward preparing a polymeric sheet composition characterized by a desirable flexural modulus. Pet. 6, 65–67.

On this record, we agree with Petitioner that Sun and Hinz “both are directed to the interrelated construction of dental splints with ‘improved mechanical properties’ that ‘may be inserted into and removed from patients easily.’” *Id.* at 66 (quoting 1002 ¶ 158; Ex. 1015, 2:54–59; Ex. 1018 ¶ 4). Petitioner also shows sufficiently that, “[a]lthough Sun teaches a different polymeric composition for forming a dental splint than Hinz,” the ordinarily skilled artisan “would still look to the specific teachings of the flexural modulus of dental splints of Sun as guidance for achieving (at least) the ‘better insertion and removal behavior due to increased elasticity of the dental splint’ taught by Hinz.” *Id.*; Ex. 1015, 3:74–75.

Petitioner directs us to evidence sufficient to show that Sun would have led an ordinarily skilled artisan to select a combination of “flexible and rigid layers” to create multilayer dental structures with a flexural modulus to “ensure they are readily removable without discomfort.” Pet. 22–23 (citing Ex. 1018, ¶¶ 2–4, 11–12, 29–40). A close question arises, however, as to whether Petitioner shows sufficiently that this selection would have been within the level of ordinary skill in the art.

We preliminarily find that Hinz would have alerted the ordinarily skilled artisan that the choice of “layer thicknesses” in a multilayer dental structure “ensure[s] very good mechanical properties.” Ex. 1002 ¶ 100; Ex. 1015, 4:116–119. Where Sun teaches that the flexural modulus of dental structures would have been recognized as one such mechanical property (*id.* ¶ 160; Ex. 1018 ¶ 12), we further accept, at this preliminary stage, that an ordinarily skilled artisan would have understood how variations “in the relative thicknesses of the respective layers” desirably impact the flexural modulus (*id.* ¶ 105). Furthermore, in view of Sun’s disclosure of advantages associated with dental structures having a preferred flexural modulus, and the fact that those exact same advantages expressly were of interest to Hinz, we are not persuaded by Patent Owner’s argument, on this record, that it makes a difference that Sun discusses two-layer structures, whereas Hinz discusses three-layer structures. Pet. 65–66 (citing Ex. 1002 ¶¶ 158–160; Ex. 1015, 3:74–76; Ex. 1018 ¶ 4); see Sur-reply 5 (Patent Owner, identifying distinctions without a difference in Sun). In other words, Sun’s teachings appear, on this record, to apply generally to multilayer dental structures, including the multilayer structures of Hinz.

For the above reasons, although the issue is a close one, we find that Petitioner shows sufficiently for purposes of trial institution that the ordinarily skilled artisan would have had a reason, and possessed the technical acumen, to select combinations of layer thickness *values*, from among the *ranges* disclosed in Hinz, to attain a multilayer dental structure having a desirable flexural modulus, as suggested by Sun. Patent Owner may address that preliminary finding in a timely response to the Petition.

4. Inherency

Patent Owner argues that Petitioner must “meet the high standard” of inherency to showing that the specified “flexural modulus is *necessarily* present each and every time Hinz and the Durasoft Data Sheets are combined or is the *natural result* of the Hinz-Durasoft Data Sheet combination.” Prelim. Resp. 2 (Patent Owner’s emphasis), 14. That argument is misplaced, at least as to the sufficiency of Petitioner’s third ground, in which Petitioner shows sufficiently that the combined disclosures of those references, when read in view of Sun’s teachings, would have led an ordinarily skilled artisan to select the individual layer thicknesses in a multilayer sheet to attain a desirable flexural modulus.

There is no genuine dispute that some of the combinations of layer thicknesses suggested by Hinz’s preferred ranges would have resulted in multilayer structures that satisfy the specified flexural modulus range “of from about 750 MPa to 2,000 MPa,” albeit inherently. Ex. 1001, 22:34–35; see Pet. 36–38, 59–60 (identifying embodiments that meet the flexural modulus limitation). It is worth repeating here: Patent Owner does not genuinely dispute that the specific embodiments advanced by Petitioner meet the flexural modulus limitation. See *generally* Prelim. Resp.

Instead, Patent Owner comes forward with evidence that certain other embodiments suggested by Hinz’s preferred thickness ranges do not meet the flexural modulus limitation when calculated using the same methodology employed by Petitioner. *Compare* Pet. 36–38, 59–60 (advancing embodiments that meet the flexural modulus limitation), *with* Prelim. Resp. 19–27 (advancing embodiments that do not meet the flexural modulus limitation, without contesting that Petitioner’s embodiments, in fact, meet the flexural modulus limitation).

We are not persuaded that Petitioner’s showing is nullified by Patent Owner’s countervailing showing. Petitioner shows sufficiently, for purposes of trial institution, that the prior art would have led the ordinarily skilled artisan to some embodiments of a polymeric sheet composition characterized by a flexural modulus that falls within the specified range “of from about 1,000 MPa to 2,500 MPa.” Ex. 1001, 22:12 (claim 1, the only independent challenged claim).

“The legal principal at issue in this case is old. For decades,” our reviewing court has “recognized that ‘where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.’” *E.I. DuPont De Nemours & Co. v. Synvina C.V.*, 904 F.3d 966, 1006 (Fed. Cir. 2018). Significantly, the burden falls on Patent Owner to come forward with evidence sufficient to rebut Petitioner’s “*prima facie* case of obviousness” by showing, for example, “a new and unexpected result which is different in kind and not merely in degree from the results of the prior art” or that the flexural modulus “parameter was not recognized as ‘result effective.’” *E.I. DuPont De Nemours*, 904 F.3d at 1006 (identifying these and other

categories of effective rebuttal evidence and making crystal clear that the burden of producing such evidence falls on the patent owner in an *inter partes* review). At this preliminary stage, Patent Owner does not present evidence sufficient to rebut the *prima facie* case of obviousness made by Petitioner in connection with the third ground, which asserts Sun. Patent Owner may raise rebuttal evidence in a timely response to the Petition.

5. Secondary Considerations of Nonobviousness

Secondary considerations can be the most probative evidence of nonobviousness in the record, enabling the decisionmaker to avert the trap of hindsight. *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310 (Fed. Circ 2010). Accordingly, “evidence rising out of the so-called ‘secondary considerations’ must always when presented be considered en route to a determination of obviousness.” *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Petitioner directs us to Patent Owner’s contentions in the District Court action regarding secondary considerations of non-obviousness, and advances reasons why, in Petitioner’s view, those considerations do not undercut the sufficiency of the information supporting institution of review. Pet. 68–71. Patent Owner, for its part, asserts that substantial objective indicia of nonobviousness, including unexpected results, commercial success, and copying, undercuts Petitioner’s obviousness contentions and provides a reason to deny institution. Prelim. Resp. 41, 46.

As an initial matter, we disagree with Petitioner’s suggestion that the current record reflects a particularly “strong case of obviousness.” Pet. 68. To the contrary, for reasons explained above, the current record reflects a very close question on the case of obviousness. Furthermore, we are not

persuaded that the objective indicia of nonobviousness advanced by Patent Owner at this stage of the proceeding, including the declaration testimony of Messrs. John Lahlough, Tom Ross, and W. Todd Schoettelkotte, is insubstantial. Prelim. Resp. 40–46 (citing Exs. 2002, 2004, and 2005).

Genuinely disputed issues of material fact, best resolved on a full trial record, surround the objective indicia, at least as to unexpected results and commercial success. *Compare* Pet. 68–71, *with* Prelim. Resp. 40–46. For example, the issue of unexpected results requires resolution of conflicting opinion testimony provided by the parties’ opposing declarants—testimony untested by cross-examination at this juncture. *Compare, e.g.*, Pet. 69 (citing Ex. 1002 ¶¶ 163–165), *with* Prelim. Resp. 41 (citing Ex. 2002 ¶ 13).

Given that those same disputed issues are a focus of the co-pending District Court action, we reiterate that these issues are best resolved on a full trial record in our proceeding. *See, e.g.*, Exs. 2002, 2004, 2005 (redacted public versions of declarations filed in the District Court action). We will provide detailed findings to the extent that the issues are preserved in a timely response to the Petition, and only as necessary to a final written decision. At this stage of the proceeding, we determine only that the information before us supports trial institution. *See* Pet. 68–71; Prelim. Resp. 40–46.

6. Conclusions on the Sufficiency of Petitioner’s Information

Petitioner shows sufficiently that the subject matter of at least one challenged claim would have been obvious based on the ground that asserts Sun. *See* Pet. 6 (Ground 3). We have concerns about the sufficiency of Petitioner’s showing with respect to the grounds that do not assert Sun. *See id.* (Grounds 1 and 2). We institute an *inter partes* review of all challenged

claims based on all grounds asserted in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019)⁸ (“The Board will not institute on fewer than all claims or all challenges in a petition.”).

D. Notices

The Board shall deem waived any issue not raised in a timely response to the Petition, or as permitted in another manner during trial, even if asserted in the Preliminary Response or discussed in this Decision.

Nothing in this Decision authorizes Petitioner, in a manner not otherwise permitted by the Board’s rules, to supplement the information supporting any ground advanced in the Petition.

IV. CONCLUSION

For the above reasons, we institute an *inter partes* review of all challenged claims based on all asserted grounds of unpatentability set forth in the Petition. 35 U.S.C. § 314(a)(1) (2018).

V. ORDER

It is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–4, 7–11, and 13 of the ’630 patent is hereby instituted based on all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), an *inter partes* review of claims 1–4, 7–11, and 13 of

⁸ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

IPR2022-01214
Patent 10,946,630 B2

the '630 patent shall commence on the entry date of this Decision, and notice is hereby given of the institution of trial.

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