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Paper 77
Entered: January 16, 2024

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, KRISTINA M. KALAN, and JULIA HEANEY, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDERS
Denying Petitioner's First and Second Motions to Exclude (Papers 52, 68)
Denying Patent Owner's Motion to Exclude (Paper 54)
37 C.F.R. § 42.64(c)

Denying Patent Owner's Motion to Strike (Paper 33)
Denying Petitioner's Motion to Strike (Paper 62)
37 C.F.R. § 42.23(b)

ALIGN - EXHIBIT 2033
ClearCorrect Operating, LLC. v. Align Technology, Inc.
IPR2025-00818

I. INTRODUCTION

This is a Final Written Decision in an *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"). We have jurisdiction under 35 U.S.C. § 6 and enter this Decision pursuant to 35 U.S.C. § 318(a). This Decision is based on the information presented in the Petition (Paper 2, "Pet."), Patent Owner's Response to the Petition (Paper 21, "Resp."), Petitioner's Reply (Paper 30, "Reply"), Patent Owner's Sur-Reply (Paper 41, "Sur-reply"), and the evidence of record.

Petitioner's Sur-sur-reply (Paper 45) relates solely to asserted objective indicia of nonobviousness, which we do not consider in this Decision because, for reasons that follow, we determine that no challenged claim is proven unpatentable on this record.[1]

A. Real Parties-in-Interest

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.

B. Related Matters

Both parties identify *Bay Materials LLC v. 3M Company*, No. 1:21-cv-1610-RGA (D. Del.) ("the District Court action") as a related matter. Pet. 3; Paper 4, 1. Petitioner also points out that IPR2022-01215 ("IPR1215") involves the same parties and is directed to U.S. Patent

[1] The parties filed papers and exhibits containing confidential information under seal pursuant to a protective order. *See* Paper 48. We refer in this Decision exclusively to the public versions of the documents.

No. 10,870,263 B2, which shares a common parent application with the ’630 patent. Pet. 3; *see* Paper 4, 1; *see also* Ex. 1001, code (63).

This proceeding is not joined or consolidated with IPR1215. In a single hearing, we heard final oral arguments in both proceedings by videoconference on October 20, 2023. *See* Paper 76 (“Tr.”). Concurrently with this Decision, we enter a final written decision in IPR1215.

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), 22:8–10 (claim 1, the sole independent challenged claim). 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.” *Id*. at 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. Patent Owner’s witness, Dr. Osswald, provides a cogent and extensive overview of the flexural modulus characteristic and how it relates to other mechanical properties of a multilayer polymeric sheet composition. Ex. 2006 ¶¶ 27–69.

The sole independent claim specifies a polymeric sheet composition having “a flexural modulus of from about 750 MPa to 2,000 MPa.” Ex. 1001, 22:13–34 (claim 1). We refer to this feature of claim 1 as the “flexural modulus limitation.” Each of the other challenged claims inherits that limitation by dependence from claim 1. Our analysis of the flexural

modulus limitation, as recited in claim 1, is dispositive in this proceeding. Because that feature of the invention is critical to this Decision, it is worth repeating here that the flexural modulus limitation of the challenged claims applies to a multilayer ***composition*** made up of at least three individual polymeric layers, not any particular layer within the composition.

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

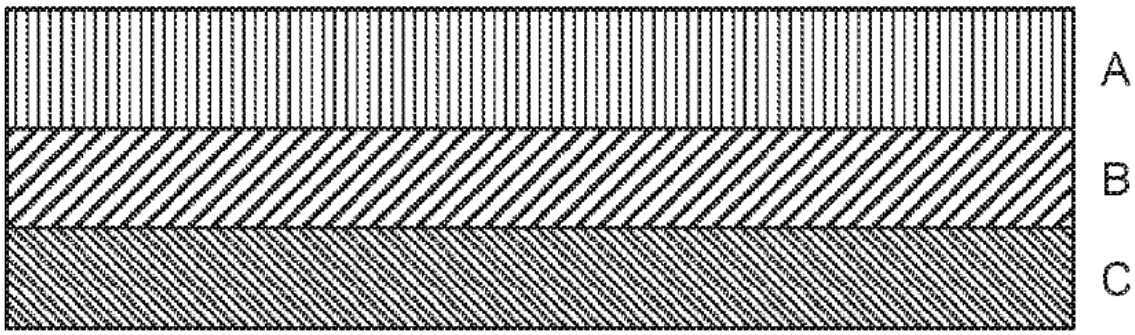

FIG. 1A

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.

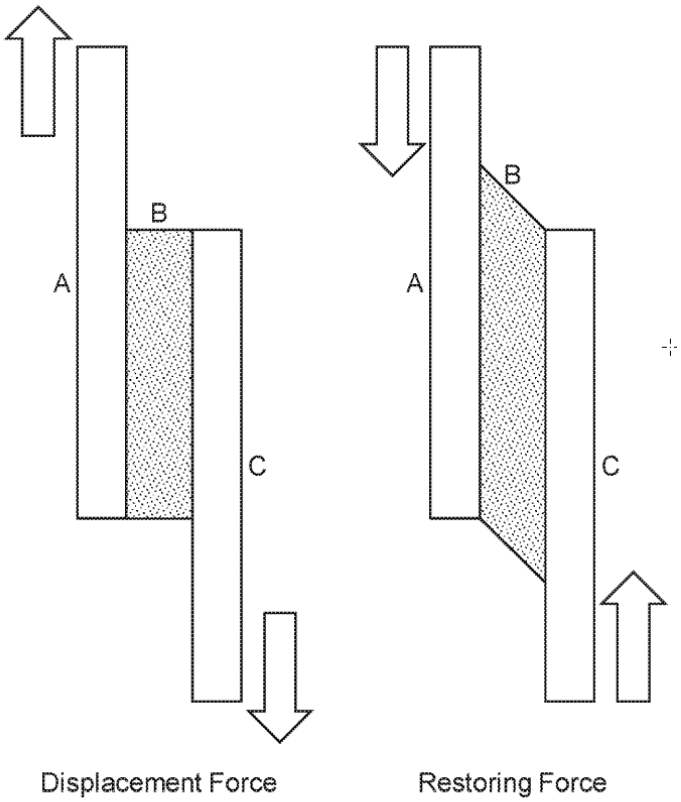

FIG. 2A FIG. 2B

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 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. 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 1:28–31. 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." *Id*. at 1:35–38. The ability of aligners "to accurately move teeth is limited by their effective modulus, elasticity and ability to resist creep and stress relaxation." *Id*. 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.

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).

C. Asserted Grounds of Unpatentability

The Petition advances three grounds, each of which is based on obviousness under 35 U.S.C. § 103.[2] We identify those grounds in the chart that follows.

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[2] 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).

Ground	Claims Challenged	References
1	1–4, 7–11, 13	Hinz[3], Durasoft (TPU/PC) Data Sheet[4]
2	1–4, 7–11, 13	Hinz, Durasoft (TPU/PC) Data Sheet, Durasoft (TPU/PETG) Data Sheet[5]
3	1–4, 7–11, 13	Ground 1 or Ground 2 further in view of Sun[6]

Pet. 3. The Petition is supported by the Declaration of Dr. Alan Jeffrey Giacomin. Ex. 1002. Patent Owner's Response is supported by the First and Second Declarations of Dr. Tim A. Osswald, as well as the Declarations of Mr. John Lahlough, Mr. Tom Ross, and Mr. W. Todd Schoettelkotte. Exs. 2001, 2002, 2004, 2005, and 2006. The Reply is supported by the Reply Declaration of Dr. Alan Jeffrey Giacomin. Ex. 1040.

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

[4] 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, that this reference "was publicly available at least as of August 8, 2016." Pet. 19; *see generally* Resp. (declining to address the prior art status of this reference).

[5] 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, that this reference "was publicly available at least as of August 8, 2016." Pet. 19; *see generally* Resp. (declining to contest the prior art status of this reference).

[6] US Pub. 2004/0224283 A1, published Nov. 11, 2004 (Ex. 1018).

D. Preview of Our Analysis

On the preliminary record, we expressed our concerns that the first and second grounds of unpatentability, which are based on Hinz and the Durasoft Data Sheets alone (without Sun), are deficient. Paper 16 ("Dec."), 14–15, 20. We instituted review, nevertheless, based on the apparent sufficiency of the third ground, which adds Sun to the mix. *Id*. In our Institution Decision, however, we identified a number of "close" factual questions even with respect to the third ground, which includes Sun. *Id*. at 11, 14, 16, 17. We made plain that the preliminary "record reflects a very close question on the case of obviousness." *Id*. at 19.

On the full trial record, the case is clear. A host of reasons, provided in the analysis that follows, independently support our determination that Petitioner does not prove any challenged claim unpatentable on this record.

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 the appropriate definition of the ordinarily skilled artisan and, in particular, whether that artisan would have had experience or familiarity with processing "thermoformable polymer sheets" to form "orthodontic and dental appliances." Resp. 8; *see* Pet. 10–11 n.1 (disagreeing with that proposition). We agree with Patent Owner for the following reasons.

Six of the challenged claims pertain to multilayer polymeric sheet compositions, whereas the remaining four challenged claims specify dental appliances manufactured from those multilayer polymeric sheet compositions. *Compare* Ex. 1001, 22:8–46, 22:53–23:9 (claims 1–4, 7, 8), *with id*. at 23:10–23:21, 24:1–24:2 (claims 9–11 and 13). The subject matter of the claims supports Patent Owner's position that the hypothetical person of ordinary skill in the art at the time of the invention would have been familiar with manufacturing processes for dental appliances.

On the other hand, the description of the technical field of the invention, provided within the four corners of the '630 patent, refers only to "polymeric sheets" without reference to dental appliances. *Id*. at 1:20–47. Nevertheless, the title of the patent, the written description of the invention, and the unambiguous words that appear in the challenged claims persuade us that the field of the invention pertains to dental appliances made from thermoformable polymeric sheets. *See id*. at code (54) (Title, "Dual Shell Dental Appliance and Material Constructions"), 5:4–13, 5:59–6:6 (written description of conditions and methods for thermoforming dental appliances from the polymeric sheets described in the '630 patent), 23:9–23:21, 24:1–24:2 (claims 9–11 and 13, all directed to a "dental appliance").

The '630 patent is concerned with manufacturing processes for thermoforming polymeric sheets to produce multilayer polymeric sheet compositions. *Id*. at 5:4–13, 5:59–6:6, 8:16, 9:6–7, 11:30–12:52, 18:45–55, 20:10–14, 20:34–21:8. 21:42, 21:51. Furthermore, every ground asserted in the Petition relies on Hinz, which focuses on manufacturing processes for thermoforming a multilayer dental splint from layers of thermoformable polymeric materials. Ex. 1015, code (57); Pet. 23–68 (challenges).

The sole ground of unpatentability that we found sufficient to support institution of review relies on Sun. Dec. 20. The central dispute in this case is whether an ordinarily skilled artisan would have viewed one of the flexural modulus ranges disclosed by Sun, for two-layer dental appliances made by light-curing an oligomer-based preparation to generate thermoset polymers in a thermosetting process, as applicable without modification to Hinz's three-layer dental appliances made by thermoforming sheets of thermoplastic polymers. Ex. 1015, code (54); Ex. 1018, code (54); Resp. 28–47; Reply 8–15. That circumstance strongly supports Patent Owner's view that the ordinarily skilled artisan at the time of the invention would have been familiar with various methods of forming dental appliances from polymeric materials.

The claims and written description of the '630 patent, the disclosures of the asserted prior art references, and the nature of the central dispute in this proceeding together persuade us to adopt Patent Owner's position that an ordinarily skilled artisan, at minimum, would have had some familiarity or experience with known processes for thermoforming dental appliances. Resp. 8; *see Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (prior art itself can reflect appropriate level of skill in the art).

Any remaining doubt is dispelled because Petitioner's own witness, Dr. Giacomin, opines that an ordinarily skilled artisan "would have been familiar with various machines and methods that would have enabled the thermoforming of multilayer dental sheets into shapes that conform with the teeth (i.e., creating a dental appliance)," thereby supporting Patent Owner's proposed level of ordinary skill in the art. Resp. 9 (quoting Ex. 1002 ¶ 25).

On this complete record, we find that a person of ordinary skill in the art would have had at least some experience or familiarity with methods of thermoforming dental appliances from polymeric materials. *See* Ex. 1002 ¶ 25 (opinion of Petitioner's own witness, Dr. Giacomin); *see, e.g.,* Ex. 1001, code (54), 5:4–13, 5:59–6:6, 23:9–23:21, 24:1–24:2 (written description and claims of the '630 patent, supporting this determination).

B. Conflicting Opinion Testimony

Petitioner's own witness, Dr. Giacomin, opines that an ordinarily skilled artisan "would have been familiar with various machines and methods that would have enabled the thermoforming of multilayer dental sheets into shapes that conform with the teeth (i.e., creating a dental appliance)." Ex. 1002 ¶ 25. Nonetheless, Petitioner does not contest Patent Owner's evidence that Dr. Giacomin himself lacks that qualification. *Compare* Resp. 9–10 (citing Ex. 1002 ¶¶ 1–9, 17 & n.1), *with* Reply (nowhere contesting that evidence). Petitioner also leaves uncontested Patent Owner's evidence that Dr. Osswald, by contrast, possesses "the required experience" with dental appliances, including thermoforming processes for their manufacture. *Compare* Resp. 10 (citing Ex. 2006 ¶¶ 2–8; Ex. 2007), *with* Reply (nowhere contesting that evidence).

Dr. Giacomin possesses excellent qualifications in the field of polymer rheology, but on this record, he demonstrates no, or inadequate, familiarity or experience with methods of thermoforming dental appliances from polymeric materials, which by his own admission is a minimum qualification of the hypothetical person of ordinary skill in the art. Ex. 1002 ¶¶ 1–11 (statement of qualifications), App'x A (curriculum vitae). Patent Owner's witness, Dr. Osswald, by contrast, has "experience with polymer

materials used in dental appliances" and "shaping operations, including thermoforming" processes for such applications. Ex. 2006 ¶¶ 5, 6.

Against that backdrop, where the two witnesses' opinions differ about the level of ordinarily skill in the art of thermoforming processes for dental appliances at the time of the invention, we credit Dr. Osswald's opinions over those of Dr. Giacomin. We take note, moreover, that Dr. Osswald's opinions would not change under Petitioner's somewhat different definition of the level of ordinary skill in the art. Ex. 2006 ¶ 14.

C. Claim Construction

Claim terms are given their ordinary and customary meaning, as understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). We construe only terms in controversy and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

No claim term requires express construction for purposes of this Decision.

D. The Asserted Prior Art

1. Overview of Hinz

Hinz is titled "Method for producing a multilayer dental splint in a deep-drawing device and dental splint." Ex. 1015, 1:1. Hinz relates to a method of deep-drawing, or thermoforming, multilayer polymeric orthodontic treatment devices for insertion and removal from a patient's mouth, including aligners that maintain teeth in alignment after an active treatment phase. *Id*. at 1:6–8, 1:24–26, 3:73–76, 3:89–90, 9:278, 10:323; Pet. 15. Hinz discloses a dental splint constructed from three bonded

polymeric layers in a hard-soft-hard configuration—that is, a soft inner layer embedded between two hard outer layers. Ex. 1015, Fig. 3, 2:61–3:70, 7:215–217, 8:240–243; Pet. 15, 30–32; Ex. 1002 ¶¶ 93–96. Hinz explains that "the properties of 'hard' and 'soft' in the meaning of the invention relate to different Shore hardnesses of the layers."[7] Ex. 1015, 3:73–74.

Both outer hard layers "preferably" are "made of the same plastic material," such as polycarbonate (known as PC) or polyethylene terephthalate (known as PET). Ex. 1015, 3:80–93; Pet. 17. Hinz teaches that thermoplastic polyurethane (known as TPU) is a preferred material for the soft inner layer. Ex. 1015, 3:89–90; Pet. 18.

Hinz informs that commercially-available, two-layer materials sold under the tradename "DURASOFT" would have been useful in thermoforming three-layer dental splints. Ex. 1015, 7:205–207; Pet. 18, 23–24; Ex. 1002 ¶¶ 80–83. We agree with Petitioner that, from these express disclosures, an ordinarily skilled artisan would have recognized that the two-layer materials disclosed in the Durasoft Data Sheets are suitable for preparing a hard-soft-hard dental splint according to the thermoforming method of Hinz. Pet. 24; Ex. 1002 ¶ 81.

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[7] The '630 patent similarly describes hardnesses, in terms of a Shore hardness scale, for each individual layer that makes up a hard-soft-hard composition. Ex. 1001, 6:60–61, 22:14, 22:41–42. "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.

Hinz does not refer to the flexural modulus property; not for any individual polymeric layer, much less any multilayer polymeric sheet composition. *See generally* Ex. 1015.

2. Overview of the Durasoft Data Sheets

The Durasoft Data Sheets are product sheets for the DURASOFT materials discussed in Hinz. Ex. 1012; Ex. 1014. The Durasoft Data Sheets describe two-layer soft-hard materials: One reference refers to a material having a hard PC layer and a soft TPU layer (Ex. 1012), whereas the other reference refers to a material having a hard layer of polyethylene terephthalate glycol (known as PETG) and a soft TPU layer (Ex. 1014).

The Durasoft Data Sheets report "elastic modulus" values for the individual TPU and PC or PETG polymeric layers, but do not provide, or suggest how to discern, a value or range for the modulus property of any two-layer composition of PC-TPU or PC-PETG. *See generally* Ex. 1012; Ex. 1014; *see also* Pet. 22 (Petitioner's own description of these references).

3. Overview of Sun

Sun is concerned with prepolymers that are "adapted to be light cured to form dental night guards and dental splints in patients' mouths." Ex. 1018 ¶ 4. Sun's prepolymers are made by reacting the monomers trimethyl-1,6-diisocyanatohexane, bisphenol A propoxylate, and 2-hydroxyethyl methacrylate under catalytic conditions to generate "TBDMA oligomer" preparations. *Id*. ¶¶ 4, 21–28.

Sun describes a thermosetting (as opposed to a thermoforming) process whereby prepolymer TBDMA oligomer preparations are shaped using finger pressure onto a mold or directly on a patient's teeth. *Id*. ¶¶ 30–34. The prepolymer composition is partially or fully cured in a light unit or

in the patient's mouth by a handheld light. *Id*. ¶¶ 32, 34. Sun describes two-layer dental appliances made by this thermosetting process. *Id*. ¶¶ 32, 33.

Sun's dental appliances, which include thermoset polymers made by partially or fully light-curing the TBDMA oligomer preparations, exhibit temperature-dependent flexural modulus values. *Id*. ¶¶ 11, 12; Resp. 28; Ex. 2006 ¶¶ 84–87, 130, 131. Those dental appliances exhibit a "flexibility and softness" that "enables them to be readily removable from a patient's mouth without discomfort to the patient." Ex. 1018 ¶ 4.

E. Grounds 1 and 2: Asserted Obviousness Over Hinz and the Durasoft Data Sheets Alone

Petitioner argues the subject matter of claims 1–4, 7–11, and 13 would have been obvious over Hinz and the Durasoft Data Sheets. Pet. 6 (grounds chart), 23–65 (argument pertaining to those grounds). Petitioner, in the Petition, submits that these grounds are "based at least on the express disclosures within the references themselves." Pet. 23, 51. During the final oral hearing, by contrast, Petitioner's counsel stated that these grounds rely on an inherent disclosure of the flexural modulus limitation. Tr. 27:2–29:5. We discuss both theories below, but first provide an overview of the proposed modified dental splint of Hinz as advanced in the Petition.

1. The Modified Dental Splint of Hinz

Hinz informs that commercially-available, two-layer "Durasoft" materials would have been useful in producing three-layer, hard-soft-hard dental splints. Ex. 1015, 7:205–207; Pet. 18, 23–24; Ex. 1002 ¶¶ 80–83. We agree with Petitioner that this disclosure would have prompted an ordinarily skilled artisan to prepare a three-layer, hard-soft-hard polymeric dental splint of PC-TPU-PC or PETG-TPU-PETG. Pet. 24; Ex. 1002 ¶ 81. To be clear,

that suggestion flows from the description in the Durasoft Data Sheets of two-layer sheet compositions of hard-soft PC-TPU (Ex. 1012, 5) and hard-soft PETG-TPU (Ex. 1014, 5) combined with Hinz's teaching that the hard polymeric layers in its three-layer, hard-soft-hard dental splints preferably are made of the same polymeric material (Ex. 1015, 3:86–3:87).

In the next two sections, we address Petitioner's further view that Hinz and the Durasoft Datasheets, taken together, expressly or inherently disclose a PC-TPU-PC or PETG-TPU-PETG composition characterized by an overall flexural modulus value that falls within the range of "from about 750 MPa to 2,000 MPa" as recited in claim 1. Ex. 1001, 22:34.

2. No Express Disclosure of Individual Layer Thickness Values

Petitioner argues that Hinz expressly discloses thickness ***values***, not merely thickness ***ranges***, for the individual polymeric layers from which its three-layer dental splint is thermoformed. Pet. 33–34. In Petitioner's view, when Hinz's expressly disclosed layer thickness ***values*** are applied to the individual TPU and PC or PETG layers taught by the Durasoft Data Sheets, the thermoforming process results in three-layer PC-TPU-PC and PETG-TPU-PETG compositions that meet the flexural modulus range of claim 1.

The problem with this argument is that Hinz discloses thickness ***ranges***, but never thickness ***values***, for its three-layer, hard-soft-hard polymeric compositions. Petitioner relies on these words from Hinz's claim 13 to support its opposite view:

> 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.; Ex. 1015, 10:326–11:330 (Hinz's claim 13) (Board's emphasis). We find no merit in Petitioner's view that the above-emphasized language would have been understood to indicate thickness ***values***, as opposed to thickness ***ranges***, for any layer used to form Hinz's three-layer dental splint. Reply 6.

In that regard, Petitioner argues that an ordinarily skilled artisan "would have readily recognized [that] a uniform layer within a pre-thermoformed film with a thickness of 'approximately 0.5 mm' is correlated with that layer having a thickness of 'less than 0.5mm' in the thermoformed splint." *Id*. (quoting Ex. 1040 ¶ 19). In Petitioner's further view, that artisan "would have understood this correlation because the pre-thermoformed multilayer films taught by Hinz are made with specific and uniform layer thicknesses; whereas the resulting thermoformed dental splint made from the film would have layers with unspecific and variable thicknesses that are generally 'less than' their pre-thermoformed thicknesses." *Id*. (quoting Ex. 1040 ¶¶ 20, 21); *see* Sur-reply 1–7 (Patent Owner's persuasive and well-supported counterarguments on point).

Those arguments run counter to the plain language of Hinz's claim 13, in which the phrase "less than 0.5 mm, in particular of less than 0.2 mm" is instructive. We cannot reasonably construe those words to supply specific thickness values because they unambiguously convey a preferred range (less than 0.5 mm) and more preferred range (of less than 0.2 mm). Any doubt is eliminated by the straightforward, corresponding disclosure in the written description of Hinz's invention. Ex. 1015, 4:112–4:128 (making clear that ranges, not values, are under discussion).

We view Petitioner's argument that the ordinarily skilled artisan "would immediately understand" from Hinz's thickness ***ranges*** to select individual, pre-thermoformed layers having specific and particular thickness ***values*** (namely, a hard outer layer "of 0.2 mm," a soft middle layer "of 1.0 mm," and a hard outer layer "of 0.8 mm") as a hindsight-driven attempt to circumvent the showing required to support an obviousness ground based on prior art ranges, as opposed to values. Pet. 34. We agree with Patent Owner that "Petitioner's reliance on Hinz's disclosure of 'all intermediate values' of the thickness ranges is misplaced." Resp. 12 (citing Pet. 37–38, 59–60).

Petitioner demonstrates that the commercially-available PC-TPU Durasoft product 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"). Petitioner provides no hindsight-free rationale, however, as to why an ordinarily skilled artisan would have selected the value of 0.2 mm for the third layer in the modified dental splint of Hinz. 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"). Nor does Petitioner identify evidence establishing the thicknesses of the layers in the PETG-TPU Durasoft product, but instead simply assumes that the product would have been available in the same thickness combinations as the PC-TPU Durasoft product. *Id*. at 34–35 & n.8; Resp. 14; Ex. 2006 ¶ 110. Petitioner makes assumptions that, on this record, appear to be driven by the disclosure of the '630 patent and, in particular, the flexural modulus limitation of claim 1.

Petitioner improperly works backwards from the challenged claims to cherry pick sets of layer thickness values, from among Hinz's layer

thickness ranges, that result in PC-TPU-PC or PETG-TPU-PETG three-layer compositions that meet the flexural modulus limitation of claim 1 when calculated by an "elastic beam theory."[8] Pet. 36; *see id*. at 38, 60; Resp. 11–15. That exercise bears the unmistakable taint of impermissible hindsight reconstruction. "Hinz is completely silent as to flexural modulus and suitable values of flexural modulus" for its three-layer compositions and, furthermore, provides no guidance for selecting thickness values, from within the ranges provided, that would improve any mechanical property of a three-layer composition after thermoforming. Resp. 10; *see id.* at 12–13; Ex. 2006 ¶¶ 73–76, 96, 97; *see generally* Ex. 1015 (Hinz).

The Durasoft Data Sheets disclose modulus values for individual PC, PETG, and TPU layers, but are not shown, on this record, to suggest an overall flexural modulus value for any two-layer material, much less provide guidance for ensuring a desirable overall flexural modulus in a three-layer composition thermoformed according to Hinz's process. Resp. 10–11; Ex. 2006 ¶¶ 80–82, 92, 93; *see generally* Exs. 1012, 1014.

For the above reasons, we determine that Petitioner does not persuasively demonstrate an express disclosure of the flexural modulus limitation in the combined disclosures of Hinz and the Durasoft Data Sheets.

3. No Inherent Disclosure of the Flexural Modulus Limitation

During the final oral hearing, upon questioning of counsel, Petitioner for the first time asserted that the obviousness grounds based on Hinz and the Durasoft Data Sheets alone (without Sun) rely on an inherent disclosure

[8] We discuss the elastic beam theory, and modulus values calculated by that theory, in a subsequent section of our analysis.

of the flexural modulus limitation. Tr. 27:2–29:5. Nowhere in Petitioner's briefs, however, do we find any discussion of the showing required to make out that inherent disclosure. Pet. 23–65; Reply 1–8.

Inherency in the obviousness analysis requires a showing that "the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014). As explained above, Hinz discloses thickness ***ranges*** for individual layers in a three-layer polymeric composition, but never thickness ***values*** for those layers. Ex. 2006 ¶ 74. Furthermore, Hinz provides no guidance that would have informed how to select a thickness value for any given layer, or a set of thickness values for each individual layer, to ensure, after thermoforming, a three-layer composition that exhibits a particular overall flexural modulus or any other desirable mechanical property. *Id*. ¶¶ 75, 76 (citing Ex. 1015 36:177–188; 37:205–217, 37:224–38:238).

There is agreement that, when the overall flexural modulus is resolved by the elastic beam theory calculation,[9] some combinations of individual layer thicknesses, selected from among Hinz's preferred ranges, would result in a three-layer composition characterized by an overall flexural modulus that falls within the claimed range "of from about 750 MPa to 2,000 MPa,"

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[9] *See supra* 19 n.8 In our analysis below of the ground based on Sun, we discuss the elastic beam theory calculation, its origins, and Petitioner's arguments that an ordinarily skilled artisan would have possessed the technical skill and know-how to thermoform a three-layer PC-TPU-PC or PETG-TPU-PETG composition according to Hinz's process that exhibits a flexural modulus, when calculated by the elastic beam theory, that meets Sun's preferred range for dental appliances at 23° C made by a different process from materially different polymers.

but other combinations would not. Ex. 1001, 22:34–35; *see* Pet. 36–38, 59–60 (identifying embodiments that meet the flexural modulus limitation when calculated according to the elastic beam theory); Resp. 16–22; Ex. 2006 ¶¶ 101, 120, 122, 127 (identifying embodiments that do ***not*** meet the flexural modulus limitation when calculated according to the same elastic beam theory). To be clear, Petitioner does not contest Patent Owner's evidence that some of the proposed modified dental splints would ***not*** meet the flexural modulus limitation. Reply 1–8. Instead, in the Reply, Petitioner doubles down on its view that Hinz ***expressly*** discloses an embodiment that meets the flexural modulus limitation. *Id*.

On this record, we agree with Patent Owner that a multilayer polymeric sheet composition that meets the flexural modulus limitation is not the necessary or natural result of the proposed combination of prior art references. *See* Resp. 10–27. Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (emphasis in original) (quoting *In re Oelrich*, 666 F.2d at 581).

For the above reasons, we determine that Petitioner does not establish in Hinz and the Durasoft Data Sheets an inherent disclosure of the flexural modulus limitation.

F. Ground 3: Asserted Obviousness Over Hinz, the Durasoft Data Sheets, and Sun

We next address the ground based on the combined disclosures of Hinz, the Durasoft Data Sheets, and Sun. Pet. 6 (grounds chart), 65–68 (entirety of the four-page argument on this ground set forth in the Petition).

Petitioner submits that an ordinarily skilled artisan would have known how to prepare a PC-TPU-PC or PETG-TPU-PETG composition according to the thermoforming process of Hinz, as modified by the Durasoft Data Sheets, to ensure an overall flexural modulus that meets "the preferred flexural modulus values taught by Sun." *Id*. at 67–68.

On the preliminary record, with some reservations, we accepted Petitioner's view 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." Dec. 17 (Board's emphasis). We made clear, however, that "the issue is a close one." *Id*. Nevertheless, it was that preliminary determination, tied to the ground that asserts Sun, that supported our decision to institute review, notwithstanding clear deficiencies in the grounds based on Hinz and the Durasoft Data Sheets alone. *Id*. at 14–15.

Viewed through the lens of the full trial record, that preliminary determination is an oversimplification. In the next sections, we provide four alternative rationales why the ground that includes Sun is deficient to establish the unpatentability of any challenged claim:

(1) Petitioner glosses over fundamental differences between the polymers and processes of Sun and Hinz;

(2) The ground based on Sun, like those based on Hinz and the Durasoft Data Sheets alone, rests on the faulty premise that Hinz's disclosed layer thickness ***ranges*** somehow teach express thickness ***values*** for the individual layers that make up a three-layer dental splint;

(3) Petitioner's overlapping range argument, presented in the Petition, is unpersuasive for three alternative reasons; and

(4) Petitioner's new overlapping range argument, presented in the Reply, is untimely and, for six alternative reasons, unpersuasive.

1. Petitioner Glosses Over Fundamental Differences Between the Polymers and Processes of Sun and Hinz

Sun employs light-curable (as opposed to thermoformable) prepolymer "TBDMA oligomer" preparations to make dental appliances that include thermoset polymers. Ex. 1018 ¶¶ 4, 5, 21–28; Resp. 3. Sun's TBDMA oligomer preparations, in turn, are made by reacting the monomers trimethyl-1,6-diisocyanatohexane, bisphenol A propoxylate, and 2-hydroxyethyl methacrylate. Ex. 1018 ¶¶ 21–28. Dental appliances prepared according to Sun's process have temperature-dependent mechanical properties, including a temperature-dependent overall flexural modulus. *Id*. ¶¶ 11, 12; Resp. 28; Ex. 2006 ¶¶ 84–87, 131, 130.

Sun shapes the prepolymer TBDMA oligomer preparation on a dental mold by finger pressure, then partially or fully converts the oligomers to thermoset polymers by light-curing. Ex. 1018 ¶¶ 29–37. Alternatively, Sun applies the prepolymer TBDMA oligomer preparation directly to a patient's teeth, shapes the preparation by finger pressure, partially polymerizes the preparation in the mouth with a handheld light, then further polymerizes the resulting material in a curing unit. *Id*.

In other words, Sun concerns "thermoset polymers . . . obtained by irreversibly curing a solid or viscous liquid ***prepolymer***." Resp. 3 (Board's emphasis). It is in that context that Sun describes dental appliances having a "flexibility and softness" that "enables them to be readily removable from a patient's mouth without discomfort or pain." Ex. 1018 ¶¶ 2, 4. Significantly, moreover, Sun describes soft and flexible dental appliances formed in two layers, but not three layers. *Id*. ¶¶ 30, 37.

Sun sets forth two different flexural modulus ranges for its dental appliances, one that is preferable at a room temperature of 23˚ C and another that is preferable at a body temperature of 37˚ C. *Id*. ¶¶ 11,12; Resp. 31. In other words, Sun describes a dental appliance having a temperature-dependent flexural modulus. Resp. 31. Petitioner does not acknowledge anywhere in the Petition that Sun discloses two ranges. Pet. 22, 23, 65–68. Instead, Petitioner selectively quotes the room temperature (23˚ C) range from Sun and omits the body temperature (37˚ C) range that is recited in the very same paragraph. *Id*. at 65–66 (selectively quoting material from Ex. 1018 ¶ 12). Similarly, Petitioner's witness, Dr. Giacomin, echoes that selectively-quoted flexural modulus range from Sun, without acknowledging that an ordinarily skilled artisan would have had to choose from among two ranges reported in Sun. Ex. 1002 ¶ 157.

Like Sun, Hinz relates to a method of forming dental appliances that "have improved mechanical properties," which an ordinarily skilled artisan would have recognized to include the ability "to be inserted into and removed from patients easily." Ex. 1015, 2:54–57. That is where, in our view, the relevant similarity between the polymers and processes of Sun and Hinz ends.

Hinz has nothing to do with irreversibly light-curing prepolymer formulations of an oligomer to form thermoset polymers. Resp. 3; Ex. 2006 ¶¶ 52, 53; *see generally* Ex. 1015. Hinz is concerned with thermoplastic TPU, PC, and PETG polymer sheets, which unlike Sun's TBDMA oligomer-based thermoset polymers, "can be softened or melted with increased temperatures and processed in the heat-softened state (e.g., by

thermoforming) or in the liquid state (e.g., by extrusion and injection molding)." Resp. 3; Ex. 2006 ¶¶ 48–51; *see generally* Ex. 1015.

Thermoplastic polymers, including TPU, PC, and PETG, "have linear and branched structures that associate by intermolecular forces, which weaken upon heating and reform upon cooling." Resp. 3; Ex. 2006 ¶¶ 49, 52, 53, 56. We find, on this complete record, that Hinz's thermoplastic polymers fundamentally differ from Sun's thermoset polymers, which have extensive cross-linking between polymer chains, are "obtained by irreversibly curing a soft solid or viscous liquid prepolymer," and typically do not melt when heated. Resp. 3; Ex. 2006 ¶¶ 52–55.

In other words, Sun and Hinz relate to fundamentally different polymers and processes. Hinz's process has nothing to do with shaping prepolymers on a mold or a patient's teeth, "at least partially" light-curing them to generate thermoset polymers, or making dental appliances that exhibit different flexural modulus ranges at different temperatures. Ex. 1018 ¶¶ 4, 5 (Sun); *see generally* Ex. 1015 (Hinz). Petitioner does not address adequately the fact that Sun's dental appliances "have a strong temperature dependence, decreasing substantially with only a modest temperature increase from room temperature (23˚ C) to body temperature (37˚ C)." Resp. 31; Ex. 2006 ¶ 137; Ex. 2018 ¶¶ 12, 15.

In the absence of explanation by Petitioner, we are left to wonder why either of those two ranges reported in Sun would have been recognized as applicable, without modification, to the three-layer dental splint of Hinz. Starting with a commercially-available, two-layer sheet of hard-soft PC-TPU or hard-soft PETG-TPU thermoplastic polymers, Hinz bonds a third layer, consisting of hard PC or hard PETG, to the soft TPU layer of the two-layer

material by a process of thermoforming. No prior art reference explains how that process would have been understood to affect the overall flexural modulus of the resulting three-layer, hard-soft-hard composition.

Petitioner does not supply an adequate reason for combining Sun's preferred flexural modulus range, reported for Sun's dental appliances at a temperature of 23˚ C, to dental splints formed by Hinz from fundamentally different polymers and a fundamentally different process. *See* Pet. 65–68 (entirety of four-page analysis on this ground); Resp. 32–38; Sur-reply 7–14 (well-supported explanation of those fundamental differences); Reply 8–16 (Petitioner's unpersuasive responsive positions).

The flexural modulus of Sun's dental appliance not only is temperature dependent but also varies with the flexural strength of the polymeric material at hand. Ex. 1018 ¶ 12. Too late in the Reply, Petitioner raises fact-intensive reasons why those differences would not have mattered to an ordinarily skilled artisan. Reply 8–16. In any event, we agree with Patent Owner that Petitioner glosses over "[f]undamental differences" between the polymers and processes of Sun and Hinz, differences that "are central to [the] motivation to combine inquiry" and undercut Petitioner's view that an ordinarily skilled artisan would have understood either of Sun's flexural modulus ranges to apply, without modification, to Hinz's polymers and process. Resp. 33 (quoting *Adidas AG v. Nike, Inc*., 963 F.3d 1355, 1359 (Fed. Cir. 2020)) (first alteration in original); *see* Sur-reply 8–16 (Patent Owner's persuasive arguments and evidence on point).

The ground based on Sun is deficient for the above reasons.

2. Faulty Premise Regarding an Alleged Express Disclosure in Hinz

Petitioner devotes a mere four pages of analysis in the Petition to the ground that includes Sun. *See* Pet. 65–68. Although not deficient for brevity alone, the analysis glosses over material differences between the references as discussed above. *Id*. Those differences are not material, in Petitioner's view, because "Hinz expressly discloses" embodiments of a dental splint, defined by layer thickness ***values***, not merely layer thickness ***ranges***, for each of the three polymeric layers that make up the modified PC-TPU-PC or PETG-TPU-PETG composition as thermoformed according to the process of Hinz. *Id*. at 66–67 (citing Ex. 1002 ¶ 159). In other words, the ground based on Sun, just like the grounds based on Hinz and the Durasoft Data Sheets alone, rests on the faulty premise, echoed by Dr. Giacomin, that Hinz expressly discloses layer thickness ***values***.

In the Petition, Petitioner avers that expressly disclosed embodiments in Hinz are characterized by a flexural modulus, when calculated according to the elastic beam theory, that meets Sun's preferred flexural modulus range for dental appliances at a temperature of 23˚ C. *See* Pet. 65–68 (entirety of Petition analysis as to the ground that asserts Sun); Ex. 1002 ¶ 159. In the Reply, Petitioner doubles down on its view that Hinz discloses specific layer thickness ***values*** that necessarily result in three-layer embodiments in which the overall flexural modulus satisfies that preferred range in Sun. Reply 1–8.

To the contrary, Hinz discloses thickness ***ranges***, never thickness ***values***, for the layers that make up the three-layer dental splint. Ex. 1015, 10:326–11:330. The reasoning above, provided in our discussion of the grounds based on Hinz and the Durasoft Data Sheets alone, applies with equal force to the ground that includes Sun.

3. The Overlapping Range Argument, as Presented in The Petition, is Unpersuasive for Two Independent Reasons

Petitioner raises an alternative argument in the Petition that an ordinarily skilled artisan would have understood "how to follow the teachings of Hinz to make multilayer hard-soft-hard films and dental splints with the polymers of Durasoft" to ensure that their flexural modulus values "overlap and fall within" the preferred range of Sun for two-layer, TBDMA oligomer-based dental appliances having specific flexural strengths at 23˚ C. Pet. 66 (citing Ex. 1002 ¶¶ 159, 160). That argument fails for two independent reasons, both of which flow from the prohibition against impermissible hindsight reconstruction.

First, Petitioner focuses on a particular set of embodiments that satisfy Hinz's layer thickness ranges, and also happen to meet the flexural modulus limitation of claim 1, while ignoring other embodiments that similarly satisfy Hinz's ranges but do ***not*** meet the claimed flexural modulus limitation. *Id*. at 65–68. Petitioner, without adequate explanation, begins its analysis with an assumption that the artisan would have been led to focus on embodiments from Hinz that are cherry-picked to meet the flexural modulus limitation. *Id*. at 66 (referring back to embodiments of Hinz's dental splint that meet the flexural modulus limitation when calculated according to the elastic beam theory (*see id*. at 36–38, 59–60 for a listing of those embodiments)); *but see* Resp. 16–22; Ex. 2006 ¶¶ 101, 120, 122, 127 (identifying embodiments that do ***not*** meet the flexural modulus limitation when calculated according to the same elastic beam theory). Petitioner works backwards from the disclosure of the '630 patent in an exercise of impermissible hindsight reconstruction.

Second, we agree with Patent Owner that Sun's dental appliances display flexural modulus values that "have a strong temperature dependence, decreasing substantially with only a modest temperature increase from room temperature (23˚ C) to body temperature (37˚ C)." Resp. 31; Ex. 2006 ¶ 137; Ex. 2018 ¶¶ 12, 15. Petitioner identifies no persuasive reason why an ordinarily skilled artisan would have recognized Sun's flexural modulus range, reported for dental appliances at 23˚ C, as applicable, without modification, to the proposed modified dental splint of Hinz. Pet. 66.

In the Petition, Petitioner does not even acknowledge that Sun reports two flexural modulus ranges that vary with both the temperature and the flexural strength of the polymeric composition. Pet. 65–68. In the Reply, Petitioner for the first time argues that the ordinarily skilled artisan would have selected the range reported in Sun for dental appliances at 23˚ C (room temperature) because that is the temperature at which Hinz's dental appliance is ***inserted into*** a patient's mouth. Reply 13.

That is too little too late, particularly where Sun's other preferred range applies to the ***removal*** of a dental appliance at body temperature (37˚ C). *See* Resp. 31 (explaining these issues cogently); Ex. 1018 ¶ 12. Selecting the room temperature range makes little sense where, in Petitioner's view, the whole point of the combination is to optimize Hinz's dental splint to achieve desirable mechanical properties during "***remov[al]*** from a patient's mouth," that is, at a body temperature of 37˚ C. Pet. 65 (Board's emphasis); Reply 13; Ex. 1018 ¶¶ 11, 12. We detect impermissible hindsight reconstruction in Petitioner's selection of Sun's room temperature range, where the impetus for the modification is keyed to a dental appliance at body temperature. *See* Pet. 65–66.

For the above reasons, Petitioner's overlapping range argument, as presented in the Petition, is unpersuasive.

4. The Overlapping Range Argument, as Presented in the Reply, Is Untimely and, for Six Independent Reasons, Unpersuasive

Petitioner shifts gears in the Reply, emphasizing that the preferred modulus range reported by Sun for dental appliances at 23˚ C overlaps the range recited in claim 1 of the '630 patent. Reply 8–16; *see* Pet. 67 (solitary sentence in the Petition that touches upon that alleged overlap, but only in the context of the faulty proposition that Hinz ***expressly*** discloses embodiments that meet Sun's range). On that basis, Petitioner for the first time argues in the Reply that an ordinarily skilled artisan would have been led, and known how, to optimize Hinz's three-layer composition through routine experimentation in order to identify a set of embodiments (***not*** expressly disclosed in Hinz but suggested by Hinz's layer thickness ranges) that exhibit flexural modulus values which ***both*** meet Sun's preferred flexural modulus range for two-layer appliances at 23˚C ***and*** overlap the flexural modulus range recited in claim 1. *Compare* Pet. 65–68 *with* Reply 13–14 (citing Ex. 1040 ¶ 40).

Because that argument materially alters the thrust of the challenge, we agree with Patent Owner that Petitioner waived it "by failing to make it in the Petition." Resp. 38; *see* Pet. 65–68 (totality of Petitioner's four-page argument pertaining to the ground that includes Sun, nowhere advancing this argument about routine optimization, but instead referring back to alleged ***express*** embodiments taught by Hinz). In any event, this new argument in the Reply is unpersuasive for six alternative reasons.

First, as Patent Owner observes, differences between the thermoset, TBDMA oligomer-based, two-layer dental appliances of Sun and the thermoformed, PC-TPU-PC and PETG-TPU-PETG, three-layer dental splints of Hinz "are substantial enough that a skilled artisan would not expect them to perform the same," therefore, Petitioner's new overlapping range argument is inapplicable. Resp. 39 (citing *Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 272 (Fed. Cir. 2022)); *see* Sur-reply 11–13 (Patent Owner's additional persuasive arguments). Petitioner does not explain adequately why an ordinarily skilled artisan would have set out to distinguish, through routine experimentation, a subset of Hinz's three-layer dental splints that meet Sun's preferred flexural modulus range at 23˚ C for fundamentally different polymeric compositions or, *ipso facto*, which satisfy the overlapping flexural modulus range recited in claim 1. Pet. 66; Reply 13–14; Ex. 1040 ¶ 40. That new argument relies on an impermissible hindsight reconstruction of the claimed invention.[10]

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[10] Petitioner also raises new evidence in the Reply, namely, "Sun-2," U.S. Pub. No. 2009/0130624, in an effort to belatedly explain why an ordinarily skilled artisan would have been led to combine Sun and Hinz in the manner claimed. Reply 9–13. We reject that new evidence as untimely because it goes to the heart of the rationale for combining the references and, in fairness to Patent Owner, should have been raised in the Petition. Sur-reply 7–8. Alternatively, Sun-2 is not persuasive to salvage this ground. Petitioner advances Sun-2 to show a preference in the art for dental guards made from "material with a low flexural modulus" so "that a relatively low amount of force is required to deform or deflect the material" when inserted or removed from a patient's mouth. Reply 10 (quoting Ex. 1042 ¶ 57). Neither Sun nor Sun-2 is shown on this record to supply an adequate reason why Sun's preferred modulus range at 23˚ C would have been viewed as applicable, without modification, to the fundamentally different polymers and process of Hinz. *Id*. at 9–13; Sur-reply 8–14.

Second, Petitioner directs us to no persuasive evidence that the ordinarily skilled artisan would have possessed the technical skill or know-how to optimize the process of Hinz to obtain a dental splint characterized by a flexural modulus that falls within Sun's preferred range for dental appliances at 23˚ C. Instead, Petitioner advances embodiments in which the flexural modulus values are assigned by Dr. Giacomin using an elastic beam theory calculation—a calculation that was derived by Patent Owner's witness, Dr. Osswald, and employed by Petitioner in the District Court action in an attempt "to supply the flexural modulus limitation missing from Hinz and the Durasoft Data Sheets." Resp. 47.

We agree with Patent Owner that Petitioner, in similar fashion here, employs the elastic beam theory calculation "to reverse engineer the thicknesses of the individual polymeric layers" prior to thermoforming in Hinz's process, in a hindsight-driven exercise "to achieve the flexural modulus values disclosed in Sun and the '630 patent claims." *Id*. at 47–48. Significantly, in the Petition, Petitioner directs us to ***no*** argument or evidence that the elastic beam theory calculation, or any other method for reliably predicting or measuring the overall flexural modulus characteristic of a three-layer thermoformed polymeric sheet composition, would have been within the level of ordinary skill in the art at the time of the invention. *See* Pet. 65–68 (entirety of four-page analysis in Petition, pertaining to the ground that asserts Sun, nowhere touching upon that essential factual issue).

We find persuasive Patent Owner's evidence that the elastic beam theory calculation would ***not*** have been "within the common knowledge of those skilled in the art" at the time of the invention. Resp. 48; Ex. 2006 ¶ 167; *see* Pet. 36; Ex. 1002 ¶ 102 (identifying no evidence to the contrary).

Patent Owner's own witness, Dr. Osswald, "*derived* the elastic beam theory calculation" and explains persuasively why his method of calculation "far exceeds the level of ordinary skill in the art" at the time of the invention. Resp. 48 (Patent Owner's emphasis); Ex. 2006 ¶¶ 68, 167.

In the Reply, Petitioner comes forward with extensive new arguments and a significantly more robust new Reply Declaration from Dr. Giacomin geared toward undercutting Dr. Osswald's opinions on that point. Reply 9, 16; Ex. 1040 ¶¶ 27, 28, 51, 52. For example, for the first time in the Reply, Petitioner proposes that an ordinarily skilled artisan would have possessed the technical skill or know-how "to measure" the flexural modulus of a three-layer PC-TPU-PC or PETG-TPU-PETG composition thermoformed by the process of Hinz "or use calculations to predict it." Reply 9.

The Petition, however, does not include that, or any similar, factual assertion. *See generally* Pet. Instead, in the Petition, Petitioner simply sets forth elastic beam theory calculations—without any argument or evidence aimed toward establishing that those calculations would have been within the reach or technical acumen of an ordinarily skilled artisan. *See id*. at 25–29, 33–38, 53–54, 56–60, 65–67 (relevant portions of analysis in the Petition); *see generally* Ex. 1002 (entirety of Dr. Giacomin's original declaration in support of the Petition, nowhere opining on that essential point).

The closest Petitioner comes to addressing that issue in the Petition is to argue, in conclusory fashion, that the ordinarily skilled artisan, when thermoforming a hard-soft-hard composition of PC-TPU-PC or PETG-TPU-PETG by the process of Hinz, "would have reasonably expected success in achieving the preferred flexural modulus values taught by Sun." Pet. 67. By

way of support, Petitioner directs us to Dr. Giacomin's declaration in which he echoes that conclusory assertion but does ***not*** opine, much less identify objective evidence, that the elastic beam theory calculation, or any other technique for predicting or measuring the flexural modulus of Hinz's composition, would have been within the technical reach of an ordinarily skilled artisan. *Id*. (citing Ex. 1002 ¶ 159 (Dr. Giacomin's opinions, tethered to the faulty premise that Hinz "expressly" discloses embodiments that satisfy Sun's preferred flexural modulus range). Those arguments and evidence are insufficient to support a finding that an ordinarily skilled artisan would have known how to measure or predict the flexural modulus of Hinz's three-layer PC-TPU-PC or PETG-TPU-PETG dental splint.

The new argument and evidence presented in the Reply, directed to making out that essential aspect of the challenge, is untimely. Reply 9, 16; Ex. 1040 ¶¶ 27, 28, 51, 52. Even if we set aside its untimeliness, the new argument and evidence presented in the Reply is unpersuasive because it focuses on a task that "can be" carried out by Patent Owner's witness, Dr. Osswald, based on his own current level of skill, without any showing that the same level of skill would have been ***ordinary*** at the time of the invention. Reply 8; Ex. 1041, 26:7–18. Petitioner relies on cross-examination testimony from Dr. Osswald about his own current abilities—evidence tethered inadequately, if at all, to the level of ordinary skill in the art at the time of the invention. Reply 9, 16; Ex. 1040 ¶¶ 27, 28; Ex. 1041, 26:7–18, 101:5–14; *see id*. at 100:1–7 (driving home that point); *see also* Sur-reply 16–17 (Patent Owner's persuasive counterarguments) (citing Ex. 2006 ¶¶ 166, 167; Ex. 1043, 227:2–228:11).

Third, even if the elastic beam theory calculation "were within the common knowledge of a skilled artisan, this is not a scenario where 'common knowledge' may be used to supply the missing link between the thicknesses of the individual polymeric layers" used to form a modified dental appliance of Hinz "and the flexural modulus of" that appliance. Resp. 49. Patent Owner here aptly directs us to an instruction, set forth by our reviewing court, that "references to 'common sense'—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially" where, as here, a party advances opinion testimony to make out "a limitation missing from the prior art references." *Id*. (quoting *Arendi S.A.R.L. v. Apple Inc.,* 832 F.3d 1355, 1362 (Fed. Cir. 2016)); *see* Reply 15–16 (citing Ex. 1002 ¶¶ 168, 169, 171; Ex. 1040 ¶¶ 51, 52)).

Fourth, Dr. Osswald and Dr. Giacomin express conflicting or diverging opinions on the question of whether the task of adapting Hinz's process, through routine experimentation, to optimize the overall flexural modulus of the resulting dental splint, would have been within the level of ordinary skill in the art. *Compare* Ex. 2006 ¶¶ 68, 167*, with* Ex. 1040 ¶¶ 27, 28, 51, 52. We credit Dr. Osswald's opinion that the task would have required more than an exercise of mere ordinary skill. Dr. Osswald not only derived the elastic beam theory calculation, but Dr. Osswald also, unlike Dr. Giacomin, demonstrates familiarity with thermoforming processes for preparing dental appliances from polymeric materials. *See supra* 11–12.

On this record, we credit Patent Owner's evidence that Dr. Osswald "derived the [elastic] beam theory equation himself" and, although "the underlying equations he used in his derivation appear in a textbook, the

[elastic] beam theory equation does not" and calculations based on that theory "exceed the level of ordinary skill" in the art. Sur-reply17 (citing Ex. 2006 ¶¶ 166, 167; Ex. 1043, 227:2–228:11); *see* Reply 16 (Petitioner's contrary and unpersuasive view that Dr. Osswald "testified that the equations for calculating the flexural modulus of a multilayer sheet are 'just basic mechanics'" that "came from a textbook").

Fifth, the unpredictability of the process by which Hinz thermoforms three-layer compositions of thermoplastic polymers--namely, hard-soft-hard combinations of PC-TPU-PC or PETG-TPU-PETG—fully supports our determination that this challenge is deficient. Like Hinz and the Durasoft Data Sheets, "Sun contains no guidance regarding the interplay between flexural modulus, appliance thickness, and layer thickness." Resp. 47; Ex. 2006 ¶ 164. Sun does not "explain how a desirable flexural modulus might change when moving from a single-layer material" of thermoset TBDMA oligomer-based polymers as in Sun's Example 8 "to a two-layer embodiment" of thermoset polymers as in Sun's Example 7, much less when moving to a three-layer composition of thermoplastic polymers that are thermoformed according to the process of Hinz. Resp. 47; Ex. 2006 ¶ 164.

We agree with Patent Owner, on this complete record, that the "unpredictability of thickness's effect on modulus, coupled with the other properties that affect insertion and removal behavior" of dental appliances, "mean that a person of ordinary skill could not 'routinely optimize' layer thickness" or, in so doing, optimize the "flexural modulus" of Hinz's three-layer composition. Resp. 47; Ex. 2006 ¶¶ 157–165.

It is worth observing here that Petitioner comes close to admitting that an ordinarily skilled artisan would have recognized that Hinz's

thermoforming process affects the overall flexural modulus of the resulting three-layer composition in unpredictable ways. Reply 6; Ex. 1040 ¶¶ 20, 21 (in connection with Petitioner's argument that the "less than" ranges in Hinz represent specific values, admitting that, although the individual layers used by Hinz have specific and uniform layer thicknesses, the three-layer compositions of post-thermoformed PC-TPU-PC and PETG-TPU-PETG "would have layers with unspecific and variable thicknesses").

Specifically, Petitioner acknowledges that an ordinarily skilled artisan "would not have expected to be able to predict the specific amount and distribution of thinning that occurs upon thermoforming" the polymeric layers that make up Hinz's three-layer composition. Reply 2. Petitioner continues, "[T]he overall extent of thinning upon thermoforming is inherently variable across applications because it is highly dependent on many different process parameters." *Id*. Moreover, referring to the three-layer polymeric sheet or film of Hinz, Petitioner states, "a single thermoformed 3-dimensional shape would also have variable and irregular layer thicknesses, dependent on the contours and complexity of the mold onto which the film is thermoformed." *Id*.

Those facts are uncontested and supply additional support for Patent Owner's view, which we adopt on this record, that the task of optimizing Hinz's three-layer, thermoformed composition of PC-TPU-PC or PETG-TPU-PETG to identify, through routine experimentation, a subset of dental splints having flexural modulus values that fall within the preferred range reported by Sun for dental appliances at 23˚ C (and, thereby, overlap the flexural modulus limitation of the claimed invention) would have implicated "interdependent variables that interact in unpredictable ways" and "would

not have been routine." Resp. 47 (citing *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1375–1377 (Fed. Cir. 2021)); *see id*. at 44–47 (and evidence cited therein).

Sixth, even if we were to accept that an ordinarily skilled artisan would have known how to predictably obtain, through routine experimentation, a set of embodiments prepared according Hinz's thermoforming process that are optimized to meet Sun's preferred flexural modulus range for dental appliances at 23˚ C, Petitioner does not explain why or how that artisan would have further winnowed down that set to identify those embodiments that also meet the flexural modulus range recited in claim 1. Pet. 67 (arguing that express embodiments from Hinz meet Sun's range and overlap the range recited in claim 1); Reply 8–16 (for the first time arguing that an ordinarily skilled artisan, through routine experimentation, would have arrived at a set of specific embodiments of Hinz's three-layer composition that meet Sun's range ***and*** overlap the range recited in claim 1).

On that point, Patent Owner argues, and Petitioner does not contest, that Sun's preferred flexural modulus range spans "from about 10,000–350,000 psi (about 69–2,413 MPa)." Resp. 42 (citing Ex. 1018 ¶¶ 12, 13); *see* Reply 14 (acknowledging, but declining to oppose, that factual proposition). We agree with Patent Owner that "Sun's flexural modulus range is extremely broad." Resp. 42. We further agree with Patent Owner that Petitioner identifies "no motivation in Sun or the other asserted references to make" Hinz's three-layer compositions "with a modulus within the claimed range of 750 to 2,000 MPa, as opposed to some other portions of

Sun's broad range (69 to 2,413 MPa)." *Id*. at 43 (including citations to persuasive evidence and supporting authority); Ex. 2006 ¶¶ 154–156.

For the above reasons, Petitioner's overlapping range argument, as presented for the first time in the Reply, is untimely and unpersuasive.

G. Consideration of Objective Indicia of Nonobviousness

Objective indicia of nonobviousness "must always when present be considered en route to a determination of obviousness." *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). No "determination of obviousness" is made here, because no challenged claim is proven unpatentable by Petitioner on this record. Accordingly, we need not and do not consider the objective indicia of nonobviousness advanced by Patent Owner. *See* Pet. 68–71; Resp. 51–67; Reply 16–26.

H. Pending Motions

We address in turn five pending motions, which involve requests to strike or exclude material from the record. Papers 33, 52, 54, 62, 68.

1. Patent Owner's Motion to Strike (Paper 33)

Patent Owner moves to strike three arguments from the Reply, portions of Dr. Giacomin's Reply Declaration (Ex. 1040), and Exhibit 1034. Paper 33. First, Patent Owner argues, the Board should strike portions of the Reply and Dr. Giacomin's Reply Declaration that rely on Sun-2 to support Ground 3. *Id*. at 1. Second, Petitioner moves to strike arguments and opinions aimed at showing the "less than" phrases in Hinz's claim 13 refers to specific thickness values as opposed to thickness ranges. *Id*. at 2. Third, Patent Owner moves to strike portions of the Reply and Exhibit 1034, which

allegedly advance a new claim construction as to whether claim 1 encompasses a hard-soft-hard configuration. *Id*. at 2–3.

Petitioner filed an opposition to the motion. Paper 35. Patent Owner filed a reply to the opposition. Paper 65.

Rather than striking any material from the record, we adopt a practical approach that preserves the record for appeal and allows for alternative arguments in our analysis, taking full account of the parties' differing views on the matters at hand. The Board is adept at identifying new arguments raised in a reply that truly are improper or unfairly impede the other party's ability to respond, and we flag in this Decision where we have done so in connection with the first issue, concerning Sun-2, raised by Patent Owner. *See supra* 31 n.10. The second issue, pertaining to the "less than' phrases in Hinz's claim 13, concerns a matter that, in our view, was raised in the Petition, opposed in the Response, and argued responsively in the Reply. *Compare* Pet. 34, 57*, and* Resp. 1, 11, 13, 17, *with* Reply 5–8. The third issue relates solely to objective indicia of nonobviousness, which are not necessary to and, therefore, not assessed in this Decision.

For these reasons, we deny Patent Owner's Motion to Strike (Paper 33).

2. *Petitioner's First Motion to Exclude (Paper 52)*

Petitioner moves to exclude Exhibits 2088 and 2092, which Patent Owner submits in support of its Sur-reply. Petitioner filed also a confidential version of this motion. Paper 51. Patent Owner opposes the motion (Paper 58) and files also a confidential version of its opposition (Paper 57).

Exhibits 2088 and 2092 pertain exclusively to Patent Owner's proffered objective indicia of nonobviousness, which we do not address in

this Decision. To preserve the record for appeal, and because retaining the exhibits in the record is unlikely to prejudice Petitioner as to an issue not addressed in this Decision, we deny Petitioner's motion to exclude (Paper 52).

3. Patent Owner's Motion to Exclude (Paper 54)

Patent Owner moves to exclude as pages 14–19 and 23–53 of Exhibit 1034 (an affidavit of Nathaniel E Frank-White, Records Request Processor at the Internet Archive) as well as paragraphs 79 and 80 of Exhibit 1040, which is Dr. Giacomin's Reply Declaration. Paper 54. Petitioner opposes the motion. Paper 60.

Patent Owner argues that the pages 14–19 and 23–53 of Exhibit 1034 should be excluded as "irrelevant, prejudicial, confusing, and/or a waste of time" because they are not relied upon by Petitioner and "could be used to newly raise a forfeited issue now or on appeal." Paper 54, 3–4. As for paragraphs 79 and 80 of Exhibit 1040, Patent Owner moves to exclude material that pertains exclusively to Patent Owner's proffered objective indicia of nonobviousness, which we do not address in this Decision.

To preserve the record for appeal, and because retaining the exhibits in the record is unlikely to prejudice Petitioner with respect to issues not addressed in this Decision, we deny Petitioner's motion to exclude (Paper 54).

4. Petitioner's Motion to Strike (Paper 62)

Petitioner moves to strike portions of Patent Owner's Sur-reply as well as Exhibit 2088. Paper 62. Patent Owner opposes the motion, arguing, among other things, the motion is untimely, and improperly moves to strike Exhibit 2088, which was not mentioned in the request for authorization.

Paper 71, 1 (Patent Owner filed a confidential version of this opposition as Paper 70).

Petitioner seeks to strike information that pertains exclusively to objective indicia of nonobviousness advanced by Patent Owner. We do not address that information in this Decision. To preserve the record for appeal, we deny this motion without prejudice to Petitioner as the material at hand does not bear on any issue addressed in this Decision. In so doing, we take note of Petitioner's arguments that the motion is untimely and requests relief that exceeds the scope of authorization. *Id*. We decline to address those issues because their resolution is not necessary to this Decision.

5. *Petitioner's Second Motion to Exclude (Paper 68)*

Petitioner moves to exclude Exhibits 2088 and Exhibit 2093. Paper 68 (confidential version filed as Paper 67). Patent Owner filed an opposition. Paper 71 (confidential version filed as Paper 70). Both exhibits pertain exclusively to objective indicia of nonobviousness advanced by Patent Owner. To preserve the record for appeal, we deny this motion without prejudice to Petitioner as the material at hand does not bear on any issue addressed in this Decision.

IV. CONCLUSION

For the above reasons, we determine that no challenged claim of the '630 patent is proven unpatentable on this record. We summarize our decision in the following chart.

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 7–11, 13	103	Hinz, Durasoft (TPU/PC) Data Sheet		1–4, 7–11, 13
1–4, 7–11, 13	103	Hinz, Durasoft (TPU/PC) Data Sheet, Durasoft (TPU/PETG) Data Sheet		1–4, 7–11, 13
1–4, 7–11, 13	103	Ground 1 or Ground 2 further in view of Sun		1–4, 7–11, 13
Overall Outcome				**1–4, 7–11, 13**

V. ORDER

It is

ORDERED that none of claims 1–4, 7–11, and 13 of the ’630 patent is proven unpatentable on this record;

FURTHER ORDERED that Patent Owner’s Motion to Strike (Paper 33) is *denied*;

FURTHER ORDERED that Petitioner’s First Motion to Exclude (Paper 52) is *denied*;

FURTHER ORDERED that Patent Owner’s Motion to Exclude (Paper 54) is *denied*;

FURTHER ORDERED that Petitioner's Motion to Strike (Paper 62) is *denied*;

FURTHER ORDERED that Petitioner's Second Motion to Exclude (Paper 68) is *denied*; and

FURTHER ORDERED that, because this is a Final Written Decision, any party to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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