Paper No. 21
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY,
Petitioner,

v.

BAY MATERIALS, LLC,
Patent Owner.

Case IPR2022-01214
Patent No. 10,946,630

PATENT OWNER'S RESPONSE

ALIGN - EXHIBIT 2025
ClearCorrect Operating, LLC. v. Align Technology, Inc.
IPR2025-00820

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I. Introduction

Neither Hinz nor the Durasoft Data Sheets discloses any flexural modulus for a multilayer composition, much less the flexural modulus of "from about 750 MPa to 2,000 MPa" recited in all challenged claims. Petitioner's reliance on inherency in Grounds 1 and 2 to try to fill this gap fails because the claimed flexural modulus is not the natural result of combining Hinz with the Durasoft Data Sheets.

For all embodiments, Hinz only discloses thickness *ranges* for each of the three polymer layers. Hinz does not disclose a single example specifying thickness for the three layers. It also contains no guidance regarding how to select the thickness of the three layers in combination, much less a motivation to select any particular combination of thickness values from within Hinz's thickness ranges that produce a multilayer sheet having the claimed flexural modulus.

That failure is dispositive where, as here, many of the thickness combinations from within Hinz's preferred ranges would result in a flexural modulus *outside* of the claimed range. Those combinations, which Petitioner fails to address, show that the claimed flexural modulus is not *necessarily present* in, or the *natural result* of, the asserted combination of Hinz with the Durasoft Data Sheets.

Ground 3, which adds the Sun reference, fails to establish a motivation to combine the asserted art to arrive at the claimed flexural modulus. Petitioner improperly uses hindsight to pull Sun's flexural modulus range at 23° C, ignoring

Sun's other requirements for its light-curable polymers. A person of ordinary skill in the art would not have been motivated to combine Sun with Hinz or Durasoft, which disclose fundamentally different polymers, because the Durasoft and Hinz polymers are incompatible with Sun. Specifically, the Durasoft polymers fall outside Sun's flexural strength range and, additionally, lack the substantial temperature dependence required of Sun's polymers (e.g., 20-70% lower flexural modulus at body temperature than at room temperature). These fundamental differences between Sun's polymers and those in Hinz and Durasoft also prevent application of overlapping ranges.

Objective evidence further shows the nonobviousness of the challenged claims. The claimed compositions unexpectedly showed superior ability to exert force (and thus move teeth) for a longer time than the highest selling competitor aligner, despite having a lower initial force that allowed greater patient comfort. Based on these features, Patent Owner's marketed product, Zendura™ FLX, also has shown strong commercial success, with sales increasing substantially each year and far outpacing estimates. Petitioner even tested Zendura™ FLX samples while developing its own multilayer aligner product and has noted Zendura™ FLX's "excellent" properties compared to leading industry competitors. Petitioner's Clarity Flex product uses the hard, outer layers that distinguish Zendura™ FLX from other multilayer aligners.

II. Background

A. Thermoplastic and Thermoset Polymers

Thermoplastic polymers are those that 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). Ex. 2006 ¶¶ 48-51. Thermoplastic polymers have linear and branched structures that associate by intermolecular forces, which weaken upon heating and reform upon cooling. *Id.* ¶¶ 49, 56. Examples include polycarbonate (PC), polyethylene terephthalate (PET), polyethylene terephthalate glycol copolyester (PET-G), thermoplastic polyurethane (TPU), and ethylene vinyl acetate (EVA). *Id.* ¶¶ 50, 56.

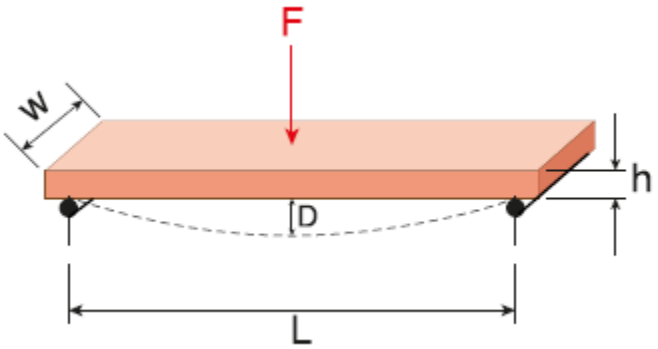
Thermoset polymers are those that are obtained by irreversibly curing a soft solid or viscous liquid prepolymer. Ex. 2006 ¶¶ 52-53. Curing is induced by heat or suitable radiation (e.g., UV light) and results in chemical reactions that create extensive cross-linking between polymer chains. Unlike thermoplastic polymers, thermoset polymers typically do not melt when heated; instead, they usually decompose and do not reform upon cooling. *Id.* ¶ 53. Examples include vulcanized rubber, silicone, and epoxy. *Id.* ¶ 55.

B. Mechanical Properties

Mechanical properties relevant to polymeric sheet compositions used in dental appliances include intensive properties such as flexural modulus and flexural

strength, as well as extensive properties such as stiffness. An intensive property is one that does not change based on the amount of the substance present. Ex. 2006 ¶ 46.

Flexural modulus is the ratio of stress to strain in flexural deformation. *Id.* ¶ 32. It is empirically measured using the ASTM D790 standard test, which employs a three-point bending analysis. *Id.* ¶ 31. As shown below, a rectangular beam of the material being tested is placed on two supports, and a force (F) is applied in the downward direction in between the two supports, creating a displacement (D) in the material, called deflection. *Id.*



Flexural modulus is computed using the equation below. *Id.* ¶ 33.

$$E_f = \frac{FL^3}{4WDh^3}$$

The flexural modulus of a multi-layer polymeric sheet composition may be empirically measured as explained above. It may also be estimated using the known properties of the individual layers making up the composition according to an equation that Patent Owner's expert, Dr. Osswald, derived in connection with this

case. Ex. 2006 ¶¶ 60-69. Petitioner's expert, Dr. Giacomin, relied on Dr. Osswald's derived equation, shown below, to estimate flexural modulus of a three-layer polymeric sheet composition.

$$E_f = \left(\frac{12E_1}{h^3}\right)\left[(n_1h_1d_1^2 + n_2h_2d_2^2 + n_3h_3d_3^2) + \frac{1}{12}(n_1h_1^3 + n_2h_2^3 + n_3h_3^3)\right]$$

Flexural modulus is an intensive property. Ex. 2006 ¶ 46. For a single-layer polymeric sheet composition, the flexural modulus of the sheet remains the same regardless of the sheet's thickness. *Id.* The same is not necessarily true for a multi-layer polymeric sheet composition, where changing the thickness of any individual layer can change overall flexural modulus. *Id.* ¶ 60. In a three-layer sheet with hard outer layers and a soft inner layer, for example, changing thickness of any layer can substantially increase or decrease the sheet's flexural modulus. *Id.* ¶¶ 162-163. For multilayer compositions, modulus will only remain the same when changing thickness *if the individual layers are scaled proportionally* (i.e., each layer's thickness increases or decreases by the same proportion). *Id.* 61-69.

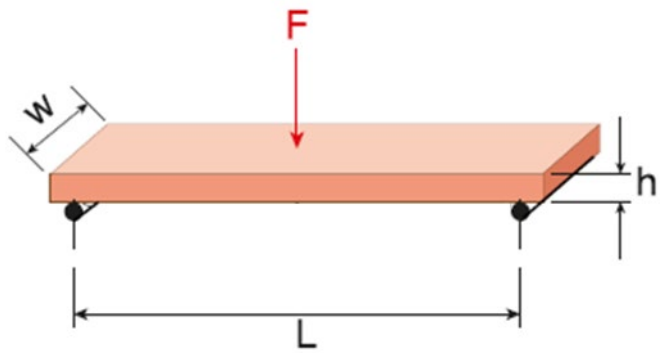
The flexural modulus of any given multi-layer polymeric sheet composition is also affected by the individual layers' respective moduli and location, with the outer layers having a greater impact on overall flexural modulus. Ex. 2006 ¶¶ 60-64, 167. For example, a hard-soft-hard composition will have a markedly higher flexural modulus than a soft-hard-soft polymeric sheet composition even if the materials and

overall thicknesses for the hard and soft layers remain the same. *Id.* ¶ 60. The examples in the table below have 1.0 mm total thickness of both hard (PC) and soft (TPU) material, but the sheet with 0.5 mm PC outer layers has a far higher flexural modulus than the sheet with 0.5 mm TPU outer layers. *Id.* ¶ 60.

PC-Durasoft (h_1)	**TPU-Durasoft (h_2)**	**PC-Durasoft (h_3)**	**Flexural Modulus (MPa)**
0.5 mm	1.0 mm	0.5 mm	**2122**
TPU-Durasoft (h_1)	**PC-Durasoft (h_2)**	**TPU-Durasoft (h_3)**	**Flexural Modulus (MPa)**
0.5 mm	1.0 mm	0.5 mm	**451**

Id. ¶¶ 122, 60-68.

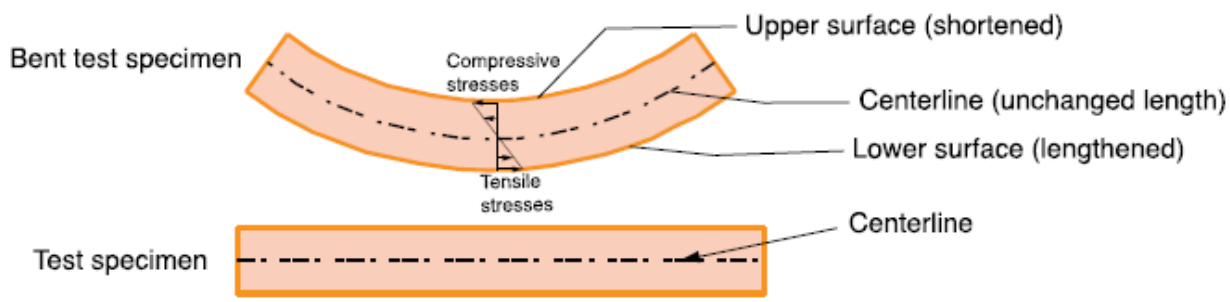
Flexural strength, also known as bending strength, flexural stress at break, or breaking strength, is the stress in a material just before it breaks in a flexural test. Ex. 2006 ¶ 37; *see also id.* ¶ 28. As shown below, a rectangular beam of the material being tested is placed on two supports, and a force (F) is applied in the downward direction in between the two supports until the material fractures. *Id.* ¶ 37.



Flexural strength can be computed using the equation below. *Id.* ¶ 33.

$$\sigma = \frac{3FL}{2Wh^2}$$

For a multi-layer polymeric sheet composition having hard outer layers, the flexural strength of a hard-soft-hard multi-layer polymeric sheet composition will be at least as high as the flexural strength of the composition comprising the outer layer in tension. Ex. 2006 ¶ 144.



Like flexural modulus, flexural strength is an intensive property. *Id.* ¶ 46.

Stiffness is the extent to which an object resists deformation. It is computed using the equation below. Ex. 2006 ¶ 44.

$$k = E\frac{Wh}{L}$$

Unlike flexural modulus and flexural strength, stiffness is an *extensive* property, dependent on both the material's elastic modulus (*E*) and its geometry. For example, a thicker material will be stiffer than the same material with lesser thickness. *Id.* ¶¶ 45-46.

III. The Person of Ordinary Skill in the Art

A person of ordinary skill in the art for the '630 patent would have possessed at least a bachelor's degree in mechanical engineering, biomedical engineering, chemical engineering, materials science, or other similar type of engineering degree, and would have taken courses in polymer processing or polymer materials science, combined with at least two years of experience in the field of design, manufacture, and processing of thermoformable polymer sheets for use in various applications, such as in orthodontic and dental appliances. Ex. 2006 ¶ 13. More relevant experience could compensate for less education, and more relevant education could compensate for less experience. *Id.* This level of education and background provides the necessary training and understanding combined with at least two years of experience in the field of design and manufacturing of polymer orthodontic and dental appliances. *Id.*

Petitioner's proposed level of ordinary skill in the art is incorrect because it ignores the extensive discussion of dental appliances and the unexpectedly good properties of dental aligners made from the novel hard-soft-hard polymer sheets. As

Petitioner concedes, the ’630 patent claims recite both polymeric sheet compositions and dental appliances comprising polymeric sheet compositions. Pet. 10 n.1. The specification similarly focuses on polymeric sheet compositions for use in dental appliances, specifically aligners. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1257 (Fed. Cir. 2007) (evaluating written description to assess level of skill in the art). A person of ordinary skill in the art therefore would also be expected to have some dental appliance experience. Alternatively, he or she would have access to or work with individuals such as orthodontists or dentists with such experience.

Petitioner’s statement that one of skill would not necessarily require *specialized* dental experience acknowledges the relevance of some experience with dental appliances. Pet. 10 n.1. Petitioner’s cited references, which discuss dental appliances and thermoforming machines, further confirm this. Indeed, Petitioner’s witness, Dr. Giacomin affirmatively states that a person of ordinary skill “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. Petitioner’s incomplete definition thus should be rejected.

Dr. Giacomin lacks the requisite experience needed to qualify as a person of ordinary skill in the art because he lacks experience with dental appliances. *See id.* ¶¶ 1-9, 17 & n.1. Thus, his opinion on what a person of ordinary skill in the art would

have understood from the prior art, including Hinz, the Durasoft Data Sheets, and Sun should be afforded little weight. By contrast, Dr. Osswald has the required experience. Ex. 2006 ¶¶ 2-8; Ex. 2007. Dr. Osswald's opinions do not change under either level of ordinary skill in the art. *Id.* ¶ 14.

IV. Grounds 1 and 2: Claims 1-4, 7-11, and 13 Would Not Have Been Obvious Over Hinz and the Durasoft Data Sheets

A. Neither Hinz nor the Durasoft Data Sheets Discloses Any Overall Flexural Modulus, Much Less the Claimed Flexural Modulus

Neither Hinz nor the Durasoft Data Sheets discloses a three-layer polymeric sheet composition or a flexural modulus of from about 750 MPa to 2,000 MPa.[1] Hinz is silent as to flexural modulus. Ex. 1015; Ex. 2006 ¶¶ 72-73, 92. It refers generally to "good mechanical properties" but does not detail any such properties (or even use the word "modulus") or disclose the modulus of any single- or multilayer polymer sheet or dental appliance. Ex. 1015; Ex. 2006 ¶¶ 71-79, 92.

The Durasoft Data Sheets similarly do not disclose the flexural modulus of a multilayer sheet or dental appliance. Ex. 1012; Ex. 1014; Ex. 2006 ¶¶ 80-82, 92-93. While they disclose the modulus of the individual PC, PETG, and TPU layers in the

[1] Hinz also does not disclose a three-layer *sheet*, as recited in claims 1-4 and 7-8; it only discloses a three-layer *dental splint* made by deep-drawing three separate films at one time. Ex. 2006 ¶¶ 77-78, 169-170; Ex. 1015, 40 (Fig. 3).

two-layer Durasoft sheet, they do not disclose the modulus of that two-layer sheet. Ex. 1012; Ex. 1014; Ex. 2006 ¶¶ 80-82, 92-93. Nor do they disclose any three-layer composition, much less the flexural modulus of any three-layer composition. Ex. 1012; Ex. 1014; Ex. 2006 ¶¶ 80-82, 92-93.

Given the lack of express disclosure of the claimed flexural modulus, or even of a three-layer sheet composition, Petitioner's arguments in Grounds 1 and 2 rely on inherency. *See, e.g.*, *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329 (Fed. Cir. 2020) ("When the prior art does not expressly disclose a claim limitation, 'inherency may supply a missing claim limitation in an obviousness analysis.'" (quoting *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014))).

B. A Person of Ordinary Skill Would Not Have Been Motivated by Hinz or the Durasoft Data Sheets to Select a Particular Combination of Thicknesses That Give the Claimed Flexural Modulus

Hinz does not disclose a *single embodiment* that specifies the thickness of the three polymer layers. IPR2022-01214, Paper 16 at 12. Instead, it discloses only thickness *ranges* for each layer. *Id.* Petitioner argues that claims 11-14 of Hinz expressly disclose a pre-thermoformed film having 0.2/1.0/0.8 mm layer thickness, "such that upon thermoforming the thickness of the layers would be 'less than 0.2 mm,' 'less than 1.0 mm,' and 'less than 0.8 mm.'" Pet. 34-36, 57-58. Petitioner is

incorrect. Paper 16 at 12; Ex. 2006 ¶¶ 94-95. Claims 11-14 of Hinz also disclose only *ranges* of thicknesses:

> 13. The dental splint as claimed in claim 11 or 12, characterized in that a hard layer (4, 13) on an outer side of the dental splint facing toward tooth surfaces of the patient in the worn state of the dental splint has a layer thickness of *less than 0.5 mm*, in particular of *less than 0.2 mm*, and a hard layer (5, 10, 12) on an outer side of the dental splint facing away from the tooth surfaces has a layer thickness of *less than 1.2 mm*, in particular of *less than 0.8 mm*.
>
> 14. The dental splint as claimed in any one of claims 11 to 13, characterized in that the soft layer (6, 8, 14) has a layer thickness of *less than 1.3 mm*, in particular of *less than 1.0 mm*.

Ex. 1015, claims 13-14 (emphasis added). Claims 13 and 14 of Hinz no more disclose an embodiment with 0.2/1.0/0.8 mm layer thicknesses than one with, for example, 0.2/0.4/0.5 mm layer thicknesses. Ex. 2006 ¶¶ 74, 95.

Petitioner's reliance on Hinz's generic disclosure of "all intermediate values" of the thickness ranges is misplaced. Pet. 37-38, 59-60. Even if Hinz had disclosed its thickness ranges as individual values, it still does not disclose any combination of those layer thicknesses or particular embodiment that would result in the claimed

flexural modulus when combined with the Durasoft Data Sheets. Ex. 2006 ¶¶ 96-97. Indeed, Petitioner fails to articulate *any* reason why a person of ordinary skill would select, from among the voluminous number of possible three-value thickness combinations suggested by the ranges, any particular combination of layer thicknesses that meets the flexural modulus limitation. Paper 16 at 13.

This failure is dispositive where, as here, it is undisputed that many thickness combinations would yield a flexural modulus outside of the claimed range. *See infra* Section IV.C. The Board should reject Petitioner's impermissible use of hindsight to select thickness values for all three layers that would result in the claimed flexural modulus despite the lack of guidance in Hinz or the Durasoft Data Sheets to do so.

Petitioner similarly ignores the fact that even Durasoft PC/TPU was available in at least three thicknesses: 1.2 mm (0.7 mm PC, 0.5 mm TPU); 1.8 mm (0.8 mm PC, 1.0 mm TPU); and 2.5 mm (1.2 mm PC, 1.3 mm TPU). Ex. 1031 at 3; Ex. 1025 at 15. *All* of these combinations fall within claims 11-14 of Hinz, which recite a first hard layer of "less than 0.5 mm, in particular less than 0.2 mm," a soft layer of "less than 1.3 mm, in particular of less than 1.0 mm," and a second hard layer of "less than 1.2 mm, in particular of less than 0.8 mm." Ex. 1015, 35:326-36:333; Ex. 2006 ¶ 98. Claims 11-14 thus do not counsel a skilled artisan to use any particular thickness of Durasoft. Even Hinz's other disclosures regarding use of a two-layer film similarly do not specify the 1.8 mm version of PC/TPU Durasoft, and instead

expressly state that other thicknesses can be used. Ex. 2006 ¶ 98; Ex. 1015, 29:112-114, 29:121-125, 32:209-211.

Thus, even the Petition's focus on the 1.8 mm version of Durasoft reflects another hindsight-driven selection of thicknesses of two of the three layers. Pet. 34-35 n.8; Paper 16 at 13-14. Petitioner articulates no rationale for selecting the Durasoft product with overall thickness of 1.8 mm rather than the other options. Ex. 1015, claims 11-14; Ex. 2006 ¶ 99.

Moreover, Petitioner provides no evidence regarding the available thicknesses of the PET-G/TPU Durasoft product, but instead assumes that the product was available in the same thickness combinations as the PC/TPU Durasoft. Pet. 34-35 n.8. Neither Durasoft Data Sheet discloses layer thickness, Exs. 1012, 1014, and the other documents Petitioner cites either identify thickness options only for the PC/TPU Durasoft (Ex. 1031 at 3) or do not specify the material (Ex. 1025 at 15). Pet. 34-35 n.8; Ex. 2006 ¶ 100.

Further, Petitioner also provides no rationale for selecting the thickness of the third layer. Indeed, Petitioner identifies no reason why a person of ordinary skill would select a 0.2 mm thickness for the third layer (i.e., 0.8 mm/1.0 mm/0.2 mm), which gives a modulus within the claimed range, rather than one of the numerous thicknesses that gives a modulus *outside* the claimed range (e.g., 0.8 mm/1.0 mm/0.5 mm). Indeed, neither Hinz nor the Durasoft Data Sheets even

mention the overall flexural modulus of a three-layer sheet or dental appliance, much less offer any reason to select thicknesses for each layer that give a certain overall flexural modulus. Ex. 2006 ¶ 101.

Petitioner's picking and choosing thicknesses to achieve the claimed flexural modulus is impermissible hindsight. Accordingly, Petitioner has failed to establish that claims 1-4, 7-11, and 13 would have been obvious over Hinz and the Durasoft Data Sheets. *Id.* ¶ 102.

C. The Claimed Flexural Modulus Is Not Inherent in Hinz and the Durasoft Data Sheets

Because neither Hinz nor the Durasoft Data Sheets discloses the claimed flexural modulus, Petitioner relies on inherency. *See, e.g.*, Ex. 1002 ¶ 160 (incorrectly asserting that "all of" the "exemplary constructions of Hinz's multilayer hard-soft-hard films and dental splints" have a flexural modulus less than 2,000 MPa"); Paper 11 at 4.

Petitioner must "meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis." *Par Pharm.*, 773 F.3d at 1195-96. The limitation at issue "necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Id.* Inherency cannot be established "by probabilities or possibilities." *Id.* at 1196 (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)); *see also Cont'l*

Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) ("The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." (quoting *Oelrich*, 666 F.2d at 581)).

Moreover, the use of inherency in the obviousness context must "be 'carefully circumscribed' because 'that which may be inherent is not necessarily known and that which is unknown cannot be obvious.'" *Vivint, Inc. v. Alarm.com Inc.*, 741 F. App'x 786, 792 (Fed. Cir. 2018) (quoting *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1354-55 (Fed. Cir. 2017)).

As detailed below, Petitioner fails to meet this high standard because it cannot establish that the claimed flexural modulus is *necessarily present* each and every time Hinz and the Durasoft Data Sheets are combined or is the *natural result* of the proposed combination. *See Colas Sols. Inc. v. Blacklidge Emulsions, Inc.*, IPR2016-01031, Paper 38 (PTAB Nov. 2, 2017) (holding claims nonobvious where a claimed property not expressly disclosed in the prior art was not inherent because calculating that property based on the prior art resulted in a small number of values outside the claimed range); Ex. 2001 ¶¶ 19-24; *see also id.* ¶¶ 1-9, 25; Ex. 2006 ¶ 113.

Petitioner's calculations cannot establish that the claimed flexural modulus is the natural result of combining Hinz with the Durasoft Data Sheets. Pet. 37-38 (citing Ex. 1002 ¶ 106); Ex. 2006 ¶¶ 103-111. Petitioner uses hindsight to pick and choose thicknesses for the three layers from within Hinz's preferred ranges and

reports only thickness combinations that result in a three-layer sheet with a flexural modulus within the claimed range. Pet. 37-38; Ex. 1002 ¶ 106; Ex. 2006 ¶¶ 113-114. As detailed below, however, numerous other combinations from Hinz's preferred thickness ranges yield a flexural modulus *greater than* 2,000 MPa, outside the claimed range. Ex. 2006 ¶¶ 97, 101, 110-113, 115-124, 127-128; Ex. 2001 ¶¶ 19-24. Petitioner's witness, Dr. Giacomin, thus is wrong that "all of" the "exemplary constructions of Hinz's multilayer hard-soft-hard films and dental splints" have a flexural modulus less than 2,000 MPa. Ex. 1002 ¶ 160; Ex. 2006 ¶¶ 105-111, 122, 127.

Petitioner's modulus calculations suffer from several flaws. First, as explained above, Hinz does not disclose a single embodiment that specifies the thickness of each layer. Paper 16 at 12. Instead, Hinz discloses potential *ranges* of thickness for each of the two hard layers and the one soft layer. *Id.* Even Hinz's specific embodiments and claims disclose thickness ranges for the various layers, not specific thickness values. *Id.*; Ex. 2006 ¶¶ 104, 114. Petitioner provides no basis for selecting any specific point within these ranges, much less a specific combination of thicknesses for all three layers from within the disclosed ranges. *See, e.g.*, *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1000 (Fed. Cir. 2006) ("[T]he disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points.").

Further, Petitioner's calculations rely on disclosure in Hinz of preferred thickness ranges for just *two* of the three layers, and Petitioner assumes without support that the third layer will have the same thickness as the other rigid, outer layer. Pet. 37-38. Petitioner's tables of calculated flexural modulus values thus omit any configurations where the two hard layers have different thicknesses. Pet. 38, 60; Ex. 1002 ¶ 106; Ex. 2006 ¶ 115. The portion of Hinz that Petitioner cites discusses only the hard and soft layers of the two-layer deep-drawing film, and contains no disclosure regarding the third layer's thickness, much less that it should be the same as the first hard layer. Pet. 37-38 (quoting Ex. 1015, 29:112-117); Ex. 2005 ¶ 115. Regardless, Petitioner cannot establish inherency because, as detailed below, numerous thickness combinations within Hinz's preferred ranges yield a flexural modulus outside the claimed range, *including* many configurations where the outer layers have equal thickness. Ex. 2006 ¶¶ 115, 122, 127. Those combinations, which Petitioner omits from its tables, show that the claimed flexural modulus ("about 750 MPa to 2,000 MPa") is not the natural result of combining Hinz with the Durasoft Data Sheets. *Id.* ¶¶ 115-120, 124-125.

Nor can Petitioner establish inherency even starting with one of the Durasoft materials. As an initial matter, Petitioner fails to identify a reason to choose any specific one of the three thicknesses available for Durasoft PC/TPU (1.2 mm, 1.8 mm, and 2.5 mm), which as discussed above all fall within Hinz's claims 11-14

and disclosed thickness ranges. Ex. 1015, 35:326-36:333, 29:112-114, 29:121-125, 32:209-211. Regardless, even if one accepted Petitioner's choice to start with the 1.8 mm PC/TPU version of Durasoft, Hinz and the Durasoft Data Sheets still provide no reason to pick a third layer thickness that would produce a modulus within the claimed range.[2] And, as shown below, many thicknesses for the third layer from within Hinz's range give a flexural modulus outside the claimed range. Ex. 2006 ¶¶ 116, 122, 127. This defeats Petitioner's argument based on inherency.

Nor do claims 11-14 of Hinz resolve the deficiencies in Petitioner's argument. Numerous thickness combinations within these claims' preferred thickness ranges fall outside the flexural modulus range claimed in the '630 patent. The claims provide no reason to choose a particular *combination* of thickness for the three layers that gives a modulus within the claimed range, or even to select a specific one of three thicknesses of Durasoft. Indeed, the thickness ranges in claims 11-14 encompass any of the three Durasoft thicknesses: "less than 0.5 mm" for the first hard layer; "less than 1.3 mm" for the soft layer; and "less than 1.2 mm" for the second hard layer. Ex. 1015, 35:317-36:333; Ex. 2006 ¶ 117.

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[2] As noted above, Petitioner provides no evidence regarding the available thickness of the PET-G/TPU Durasoft. The only evidence of record address the available thicknesses of the PC/TPU Durasoft. Exs. 1031, 1025.

Petitioner relies heavily on the three narrower thickness ranges in the Hinz claims ("less than 0.2 mm" for the first hard layer, less than 1.0 mm for the soft layer, and less than 0.8 mm for the second hard layer), but even these ranges cannot establish inherency or provide motivation to select any particular thickness combinations. Claims 11-14 of Hinz provide no reason to select the endpoints of those three ranges (i.e., 0.2 mm/1.0 mm/0.8 mm), and numerous thickness combinations within the narrow ranges yield a flexural modulus outside the '630 patent's claimed range. *Atofina*, 441 F.3d at 1000 (holding that disclosure of range is no more a disclosure of the endpoints than of any intermediate point within the range); Ex. 2006 ¶ 118. And these narrower ranges still permit either the 1.2 mm or 1.8 mm thicknesses of Durasoft. Ex. 1031 at 3.

Nor are Hinz claims 11-14 limited to using Durasoft. The claims do not specify using a two-layer sheet as one of the deep-drawing films and they recite a polymer not used in Durasoft as a potential soft layer (specifying either TPU or ethylene vinyl acetate (EVA)). Ex. 1015 at 35. Petitioner's reliance on claims 11-14 of Hinz thus still impermissibly uses hindsight to select not only the thickness for each layer, but also the material used (e.g., using TPU instead of EVA). Ex. 2006 ¶ 119.

Finally, even combining Hinz claims 11-14 with the 1.8 mm PC/TPU version of Durasoft, which already involves extensive picking and choosing, does not

necessarily result in the claimed flexural modulus. Ex. 2006 ¶ 120. Hinz does not guide a skilled artisan to select a third layer thickness that gives a flexural modulus within the claimed range. Indeed, while Petitioner uses a 0.2 mm third layer, Hinz states that "[p]articularly good mechanical properties are additionally achieved" when using a third layer thickness of "approximately 0.5 mm" in combination with a two-layer film having a hard layer of 0.8-1.2 mm and soft layer of 1.0-1.3 mm. Ex. 1015, 29:121-125; Ex. 2006 ¶ 120. Numerous combinations within these ranges give flexural modulus values outside the claimed range. Ex. 2006 ¶¶ 101, 120, 122, 127. For example, using the 1.8 mm PC/TPU Durasoft with a 0.5 mm PC layer (i.e., 0.5 mm/1.0 mm/0.8 mm) gives a flexural modulus of 2,134 MPa. *Id.* ¶ 120. Petitioner fails to address this disclosure in Hinz.

Petitioner's failure to establish inherency here is similar to the facts in *Colas*, where the petitioner argued that the prior art necessarily disclosed the asphalt softening point limitation. *Colas*, IPR2016-01031, Paper 38 at 12-15. The petitioner calculated softening point values based on prior-art disclosure of the asphalt's "penetration index," but some of the calculated values fell outside the claimed softening point range. *Id.* 13-14, 15-19. Here, as in *Colas*, Petitioner calculated modulus values based on various possible combinations of thickness for the three layers, but many of the thickness combinations yield a modulus outside the claimed range. The Board should similarly conclude that Petitioner cannot establish

inherency because the combination of the asserted prior art does not necessarily result in the claimed property. *Id.* at 20-27; Ex. 2006 ¶ 121.

Petitioner fails to meet the high standard required to establish inherency or to identify any motivation in Hinz or the Durasoft Data Sheet to select thicknesses for all three layers that result in the claimed flexural modulus. Ex. 2006 ¶ 121. Petitioner thus fails to establish that claims 1-4, 7-11, and 13 would have been obvious over Hinz and the Durasoft Data Sheets.

Ground 1: Hinz in View of the Durasoft (TPU/PC) Data Sheet

Petitioner's calculations omit any thickness combinations from within Hinz's preferred ranges that produce a flexural modulus outside the claimed range of from about 750 MPa to 2,000 MPa. Ex. 2006 ¶¶ 108-111. The table below reflects a small subset of the omitted combinations, calculated using the same elastic beam theory formula used in Petitioner's witness declaration, which was originally derived by Patent Owner's expert, Dr. Osswald. The calculations use layer thicknesses from within Hinz's disclosed ranges and the individual layer modulus values from the PC/TPU Durasoft Data Sheet (172 MPa for TPU and 2,400 MPa for PC). Ex. 1012 at 6. Additional combinations with flexural modulus values falling outside the claimed range are shown in Dr. Osswald's declarations.

PC-Durasoft (h_1)	TPU-Durasoft (h_2)	PC-Durasoft (h_3)	Combined Thickness (h)	Flexural Modulus (MPa)
0.5	1.2	0.5	2.2	**2038**
0.5	1.1	0.5	2.1	**2080**
0.5	1.1	0.4	2	**2011**
0.5	1	0.5	2	**2122**
0.5	1	0.4	1.9	**2056**
0.5	0.9	0.5	1.9	**2163**
0.5	0.9	0.4	1.8	**2102**
0.5	0.8	0.5	1.8	**2204**
0.5	0.8	0.4	1.7	**2148**
0.5	0.8	0.3	1.6	**2024**
0.5	0.7	0.5	1.7	**2244**
0.5	0.7	0.4	1.6	**2194**
0.5	0.7	0.3	1.5	**2076**
0.5	0.6	0.5	1.6	**2283**
0.5	0.6	0.4	1.5	**2239**
0.5	0.6	0.3	1.4	**2128**
0.5	0.5	0.5	1.5	**2317**
0.5	0.5	0.4	1.4	**2280**
0.5	0.5	0.3	1.3	**2179**
0.4	1.1	0.5	2	**2011**
0.4	1	0.5	1.9	**2056**
0.4	1	0.4	1.8	**2018**

PC-Durasoft (h_1)	TPU-Durasoft (h_2)	PC-Durasoft (h_3)	Combined Thickness (h)	Flexural Modulus (MPa)
0.4	0.9	0.5	1.8	**2102**
0.4	0.9	0.4	1.7	**2069**
0.4	0.8	0.5	1.7	**2148**
0.4	0.8	0.4	1.6	**2122**
0.4	0.8	0.3	1.5	**2031**
0.4	0.7	0.5	1.6	**2194**
0.4	0.7	0.4	1.5	**2174**
0.4	0.7	0.3	1.4	**2090**
0.4	0.6	0.5	1.5	**2239**
0.4	0.6	0.4	1.4	**2225**
0.4	0.6	0.3	1.3	**2149**
0.4	0.5	0.5	1.4	**2280**
0.4	0.5	0.4	1.3	**2273**
0.4	0.5	0.3	1.2	**2207**
0.4	0.5	0.2	1.1	**2017**
0.3	0.8	0.5	1.6	**2024**
0.3	0.8	0.4	1.5	**2031**
0.3	0.7	0.5	1.5	**2076**
0.3	0.7	0.4	1.4	**2090**
0.3	0.7	0.3	1.3	**2052**
0.3	0.6	0.5	1.4	**2128**
0.3	0.6	0.4	1.3	**2149**

PC-Durasoft (h_1)	**TPU-Durasoft (h_2)**	**PC-Durasoft (h_3)**	**Combined Thickness (h)**	**Flexural Modulus (MPa)**
0.3	0.6	0.3	1.2	**2122**
0.3	0.5	0.5	1.3	**2179**
0.3	0.5	0.4	1.2	**2207**
0.3	0.5	0.3	1.1	**2191**
0.3	0.5	0.2	1	**2059**
0.2	0.5	0.4	1.1	**2017**
0.2	0.5	0.3	1	**2059**
0.2	0.5	0.2	0.9	**2018**

Ex. 2006 ¶¶ 122, 61-68.

These calculations show that the claimed flexural modulus is not inherent to Hinz and Durasoft. Petitioner's failure to address *any* of these thickness combinations highlight Petitioner's use of hindsight to cherry-pick data points from Hinz's preferred thickness ranges and the lack of motivation to select the values that produce the claimed flexural modulus. These data also undercut Dr. Giacomin's analysis by showing he is wrong that "all of" the "exemplary constructions of Hinz's multilayer hard-soft-hard films and dental splints" result in a flexural modulus of less than 2,000 MPa. Ex. 1002 ¶ 160; Ex. 2006 ¶¶ 123-124.

Ground 1 is legally deficient because it fails to establish the claimed flexural modulus is *necessarily present* each and every time that Hinz and the Durasoft

(TPU/PC) Data Sheet are combined or that the claimed modulus is the *natural result* of the Hinz-Durasoft (TPU/PC) Data Sheet combination. Ex. 2001 ¶¶ 19-20, 23-24; Ex. 2006 ¶¶ 125-126.

Ground 2: Hinz in View of the Durasoft (TPU/PC) Data Sheet and the Durasoft (TPU/PETG) Data Sheet

Ground 2, which adds the Durasoft (TPU/PETG) Data Sheet, exhibits the same failures because numerous thickness combinations from Hinz's preferred ranges result in a flexural modulus outside the claimed range. Ex. 2001 ¶¶ 21-24. The data below, showing a subset of the combinations Petitioner omits, use layer thicknesses from within Hinz's preferred ranges and the 2,200 MPa flexural modulus reported for PET-G in the second Durasoft Data Sheet. Ex. 1014 at 6.

PC-Durasoft (h_1)	TPU-Durasoft (h_2)	PC-Durasoft (h_3)	Combined Thickness (h)	Flexural Modulus (MPa)
0.5	0.8	0.5	1.8	**2022**
0.5	0.7	0.5	1.7	**2058**
0.5	0.7	0.4	1.6	**2013**
0.5	0.6	0.5	1.6	**2093**
0.5	0.6	0.4	1.5	**2053**
0.5	0.5	0.5	1.5	**2125**
0.5	0.5	0.4	1.4	**2091**
0.4	0.7	0.5	1.6	**2013**
0.4	0.6	0.5	1.5	**2053**

PC-Durasoft (h_1)	**TPU-Durasoft (h_2)**	**PC-Durasoft (h_3)**	**Combined Thickness (h)**	**Flexural Modulus (MPa)**
0.4	0.6	0.4	1.4	**2040**
0.4	0.5	0.5	1.4	**2091**
0.4	0.5	0.4	1.3	**2085**
0.4	0.5	0.3	1.2	**2025**
0.3	0.5	0.4	1.2	**2025**
0.3	0.5	0.3	1.1	**2010**

Ex. 2006 ¶¶ 127-128.

As in Ground 1, the claimed flexural modulus is not necessarily present each and every time Hinz and the Durasoft (TPU/PETG) Data Sheet are combined nor is it the natural result of the Hinz-Durasoft (TPU/PETG) Data Sheet combination. Ex. 2001 ¶¶ 21-24. Accordingly, it is not inherently disclosed by the Hinz-Durasoft (TPU/PETG) Data Sheet combination and Ground 2 fails for the same reasons as Ground 1. Ex. 2006 ¶ 129.

V. Ground 3: Claims 1-4, 7-11, and 13 Would Not Have Been Obvious Over Hinz, the Durasoft Data Sheets, and Sun

A. A Person of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Sun with Hinz or the Durasoft Data Sheets

1. Sun's Disclosures Regarding Mechanical Properties Are Specific to the Disclosed Polymers, and Do Not Apply Generally to All Dental Appliances or Polymers

Sun is a narrow reference directed to preparing dental appliances from specific polymers: light-curable polymers that can be fully or partially cured in the mouth and that have specific mechanical properties that are highly temperature dependent. Ex. 2006 ¶¶ 84-87. Sun explains how to prepare these light-curable polymers and how to form the desired splints and night guards, including how much of each specific polymer to use. Ex. 2006 ¶¶ 87, 130.

Sun gives no indication that the mechanical properties of its light-curable polymers apply to other polymers or dental appliances with different polymers, layers, or layer thicknesses. Ex. 2006 ¶ 131. On the limited institution record, the Board found that "Sun's teachings appear, on this record, to apply generally to multilayer dental structures, including the multilayer structures of Hinz." Paper 16 at 16. As Dr. Osswald explains, however, a skilled artisan would have understood Sun's narrow teachings as limited to its specific polymers. Ex. 2006 ¶¶ 130-131, 135.

Sun discloses a specific approach to achieving dental night guards and splints that are "readily removable from a patient's mouth without discomfort to the patient." Ex. 1018 ¶ [0004]. Specifically, Sun's "invention uses dental compositions, which are adapted to be light cured to form dental night guards and dental splints in patients' mouths." *Id.*; Ex. 2006 ¶ 132.

Sun explains that "light curing polymerizable material allows the user to, at least partially, cure the material in the mouth, when it has the most desired shape." Ex. 1018 ¶ [0005]. By giving the user this "selective control of the curing of the material," the portions that have been polymerized "retain their form, while the remainder of the material may be further shaped and formed to improve the fit of the dental night guard or dental splint to the patient." *Id.*; Ex. 2006 ¶ 133.

Sun connects its desired mechanical properties to the ability of its polymers to be cured in a patient's mouth. Ex. 2006 ¶ 134. It states that the "low Flexural strength and low Flexural modulus of night guards made in accordance with the invention enable them to be at least partially cured in the mouth and then removed from the patient's mouth without hurting the patient." Ex. 1018 ¶ [0040]. The ability to light-cure the polymers thus is an important aspect of Sun because it facilitates shaping the dental appliance while retaining the ability to adjust the fit to the patient. Ex. 2006 ¶ 134.

Sun discloses specific polymers that meet these requirements. Ex. 2006 ¶ 135. Rather than use commercially available polymers, such as the polycarbonate, PET-G, and TPU disclosed in the Durasoft Data Sheets, Sun discloses how to prepare oligomer and monomer, which are then mixed with other ingredients to prepare a range of light-curable polymerizable materials. *Id.*; Ex. 1018 ¶¶ [0021]-[0028]. These materials form thermoset polymers, which differ from the thermoplastic polymers in Hinz and the Durasoft Data Sheets. Ex. 2006 ¶ 135.

Sun's disclosure of certain desirable mechanical properties must be read in the context of these specific polymers that Sun discloses as useful in achieving the invention's goals. Ex. 2006 ¶ 136. Sun states that "[f]lexible dental polymeric material *useful in accordance with the invention* has a flexural modulus in order of increasing preference of less than 350,000; 300,000; 250,000; 200,000; 170,000 psi, and a flexural strength in order of increasing preference of less than 9,000; 8,000; 7,000; or 6,000 psi at 23° C." Ex. 1018 ¶ [0012]. Sun also provides certain minimum flexural modulus and flexural strength values: "[f]lexible dental polymeric material useful in accordance with the invention has a flexural modulus in order of increasing preference of at least 10,000; 20,000; or 50,000 psi, and a flexural strength in order of increasing preference of at least 100; 200; or 500 at 23° C." *Id.* ¶ [0013]; Ex. 2006 ¶ 136.

Sun further specifies that the flexural modulus and flexural strength of the polymers have a strong temperature dependence, decreasing substantially with only a modest temperature increase from room temperature (23° C) to body temperature (37° C). Ex. 2006 ¶ 137. Sun states, for example, that those mechanical properties are preferably 20% less at 37° C, more preferably 50% less, and most preferably 70% less. Ex. 1018 ¶ [0015]. Sun thus specifies different, lower preferred ranges of flexural modulus and flexural strength at 37° C. Ex. 2006 ¶ 137.

A skilled artisan would understand that Sun's specific polymers and temperature-dependent mechanical properties would not necessarily apply to other polymers. Ex. 2006 ¶ 138. As Dr. Osswald opines, numerous polymers used in dental appliances, including those in Hinz and the Durasoft Data Sheets, do not have the mechanical properties or temperature dependence disclosed in Sun. *Id.* Sun contains no disclosure that the temperature-dependent mechanical properties useful for its light-curable polymers would also be desirable for polymers lacking those characteristics. *Id.*

Further, Sun fails to specify other details a skilled artisan would need to know to determine whether Sun's disclosures could be applied to other polymers to make dental appliances with good insertion and removal properties *Id.* ¶ 139. For example, Sun is silent regarding how thickness of the appliance affects insertion and removal behavior, flexural modulus, or flexural strength. *Id.* As Dr. Osswald states and Dr.

Giacomin concedes, a multilayer dental appliance's thickness can affect all these properties. *Id.*; Ex. 2017 at 42:23-44:5, 44:21-25. Sun thus does not disclose whether the same temperature-dependent mechanical properties desirable for its single- or two-layer, light-curable appliances would apply to three-layer aligners made from non-light-curable polymers lacking Sun's temperature-dependent flexural modulus or strength. Ex. 2006 ¶ 139. Sun also discloses appliances that are thicker than those in Hinz. Example 7, for example, discloses a two-layer splint with a thickness of 4 mm, twice as thick as the 2 mm dental sheet Petitioner proposes. *Compare* Ex. 1018 ¶ [0029], *with* Ex. 1002 ¶¶ 101-03; *see also* Ex. 2006 ¶ 139.

Sun's disclosures regarding desirable mechanical properties therefore are limited to the polymers and dental appliances disclosed. A skilled artisan would understand that they could not be applied broadly to dental appliances with different polymers and different layer configurations that are not light curable. Ex. 2006 ¶ 140.

2. The Durasoft Polymers Are Incompatible with Sun Because They Do Not Satisfy Sun's Flexural Strength or Temperature Requirements

A person of ordinary skill in the art would have understood that the polymers disclosed in the Durasoft Data Sheets are incompatible with Sun. Ex. 2006 ¶ 141. First, they fall outside Sun's required range of flexural strength, which is a separate mechanical property from flexural modulus. Second, they do not have significantly

lower flexural strength and flexural modulus at body temperature (37° C.) than at room temperature (23° C.). *Id.* A skilled artisan therefore would not be motivated to combine Sun with the Durasoft Data Sheets because their polymers are incompatible. *Id.*

The Federal Circuit has repeatedly found no motivation to combine where the proposed combination would "require the alteration of the principles of operation" of one of the references or render it "inoperable for its intended purpose." *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1358-59 (Fed. Cir. 2020). The Court recognized that "[f]undamental differences between the references are central to this motivation to combine inquiry." *Id.* at 1359. Similarly, the Court has found no motivation to combine when a ground pulls in one key feature from a reference but omits another. *St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232, 1242 (Fed. Cir. 2020).

Here, Petitioner cites only part of Sun's disclosure regarding maximum flexural modulus, omitting the second half of the sentence discussing flexural strength:

> Flexible dental polymeric material useful in accordance with the invention has a flexural modulus in order of increasing preference of less than 350,000; 300,000; 250,000; 200,000; 170,000 psi [2,413; 2,068; 1,724; 1,379; 1,172 MPa], *and a flexural strength in order of*

> *increasing preference of less than 9,000; 8,000; 7,000; or 6,000 psi [62; 55; 48; or 41 MPa]* at 23° C.

Ex. 1018 ¶ [0012] (emphasis added). Similarly, Petitioner cites only part of Sun's disclosure of minimum flexural modulus, again omitting discussion of flexural strength:

> Flexible dental polymeric material useful in accordance with the invention has a flexural modulus in order of increasing preference of at least 10,000; 20,000; or 50,000 psi [69 MPa; 138 MPa; or 345 MPa], *and a flexural strength in order of increasing preference of at least 100; 200; or 500 psi [0.7; 1.4; or 3.4 MPa]* at 23° C.

Ex. 1018 ¶ [0013] (emphasis added); Ex. 2006 ¶ 142.

The polymers disclosed in the Durasoft Data Sheets fall outside Sun's disclosed flexural strength range of 100-9,000 psi (0.7 to 62 MPa) and most preferred range of 500-6,000 psi (3.4 to 41 MPa). Ex. 1018 ¶¶ [0012]-[0013]; Ex. 2006 ¶ 143. The "bending strength"[3] of 100 MPa for the PC layer and 69 MPa for the PET-G layer exceed Sun's maximum flexural strength disclosed of 62 MPa.

[3] Dr. Osswald opines that "bending strength" is the same mechanical property as the "flexural strength" disclosed in Sun. Ex. 2006 ¶ 143.

Ex. 2006 ¶ 143. In both data sheets, no value is reported for the flexural strength of the TPU layer, indicating that the material did not break during the test. *Id.*

DURASOFT® product data sheet

4.2 Mechanical properties			
Properties	**Test method**	**Value** (TPU)	**Value** (PC)
Tensile strength	ISO 527	32 MPa	59 MPa
Bending strength	ISO 178	-	100 MPa
Impact strength at 23°C	ISO 179/1eU	No breakage	No breakage
Notch impact strength at 23°C	ISO 180/A	No breakage	80 kJ/m^2
Tear strength	ISO 179	43 MPa	65 MPa
Yield stress	ISO 527	7 MPa	65 MPa
Elongation at break	ISO 527	525%	>60%
E-modulus	ISO 527	172 MPa	2400 MPa
Hardness according to Shore A	DIN 53505	88	-
Hardness according to Shore D	DIN 53505	33	88
Rockwell hardness	ISO 2039-1 H358/30	-	110

DURASOFT® product data sheet

4.2 Mechanical properties			
Properties	**Test method**	**Value** (TPU)	**Value** (PET-G)
Tensile strength	ISO 527	39 MPa	53 MPa
Bending strength	ISO 527	-	69 MPa
Impact strength at 23°C	ISO 179/1eA	No breakage	10 kJ/m^2
Notch impact strength at 23°C	ISO 180/1A	No breakage	12 kJ/m^2
Elongation at yield point	ISO 527	-	5%
Yield stress	ISO 527	7 MPa	-
Elongation at break	ISO 527	600%	40%
E-modulus	ISO 527	-	2200 MPa
Hardness according to Shore A	DIN 53505	86	-
Hardness according to Shore D	DIN 53505	35	78
Rockwell hardness	D 785 R scale	-	115

Petitioner and Dr. Giacomin also fail to address the flexural strength of the multilayer polymer composition in their proposed combination of Hinz and the Durasoft Data Sheets. A skilled artisan would have understood that a multilayer sheet with PC or PET-G outer layers surrounding a TPU inner layer would have a flexural strength at least as high as that of rigid material on its own. Ex. 2006 ¶ 144. A composition with a TPU inner layer surrounded by PC outer layers thus would have a flexural strength of at least 100 MPa and a composition with a TPU inner layer surrounded by PET-G outer layers will have a flexural strength of at least 69 MPa. *Id.* The flexural strength of the multilayer sheet Petitioner proposes from the combination of Hinz and the Durasoft Data Sheets therefore would exceed Sun's maximum value. *Id.*

Petitioner also fails to address the fact that the polymers in the Durasoft Data Sheets lack the temperature-dependent mechanical properties identified in Sun. A skilled artisan would have understood that the "Vicat softening temperature" reported in the Durasoft Data Sheets for polycarbonate, PET-G, and TPU shows that those materials would not have a 20%, 50%, or 70% lower flexural strength or flexural modulus at 37° C. than at 23° C. Ex. 2006 ¶ 145. On the contrary, those polymers would not begin to undergo any significant changes in mechanical properties until well above 37° C. *Id.*

Based on the flexural strength and thermal data, a person of ordinary skill would not have been motivated to combine Sun with the Durasoft Data Sheets (and thus with Hinz). Ex. 2006 ¶ 146. The skilled artisan would have understood that the Durasoft polymers fail to meet Sun's requirements of a flexural modulus from 69 MPa – 2400 MPa at 23° C *and* a flexural strength from 0.7 MPa – 62 MPa at 23° C. *Id.*; Ex. 1018 ¶¶ [0012]-[0013]. This is true regardless of whether the skilled artisan was looking at the individual layers, none of which falls within Sun's flexural strength range, or a multilayer composition from Hinz and Durasoft, which similarly would fall outside Sun's range. Ex. 2006 ¶ 146. The skilled artisan also would not have expected the PC, PET-G, or TPU in the Durasoft Data Sheets to be light-curable or have substantially lower flexural modulus and strength in a patient's mouth, and thus would not expect the same insertion and removal behavior for the Durasoft polymers regardless of their flexural modulus at 23° C. *Id.* ¶ 147.

Petitioner fails to address any of these disclosures from Sun. Instead, Petitioner picked only the single property from Sun (flexural modulus at 23° C) that would help Petitioner recreate the claimed flexural modulus range, without regard for whether the Durasoft polymers possessed any of the other properties that Sun identifies as necessary to achieve its desired insertion and removal behavior. The incompatibility between the polymers in Durasoft and Sun reflects Petitioner's improper use of hindsight. Ex. 2006 ¶ 148.

Here, as in *Adidas*, combining Durasoft and Sun would require altering the operation of one or both of the references. A skilled artisan could not retain Durasoft's polymers while still meeting Sun's required flexural modulus and flexural strength, much less Sun's preferred temperature performance. *Id.* ¶ 149. Likewise, a skilled artisan could not retain Sun's mechanical properties using the polymers in Durasoft. *Id.* As the Federal Circuit explained, such "[f]undamental differences between the references are central to this motivation to combine inquiry." *Adidas*, 963 F.3d at 1359.

Similar to *St. Jude*, Petitioner fails to show why a skilled artisan would be motivated to retain just *one* of Sun's mechanical properties (flexural modulus) while omitting the others (flexural strength and temperature dependence). *See, e.g.*, *St. Jude*, 977 F.3d at 1242. Petitioner's hindsight-based approach thus fails to show a motivation to combine these references. For the same reasons, a skilled artisan would not have reasonably expected to succeed in combining the incompatible disclosures from Sun, the Durasoft Data Sheets, and Hinz to arrive at the claimed inventions. Ex. 2006 ¶ 150.

B. Sun Does Not Disclose an Overlapping Flexural Modulus Range

Petitioner's Reply to the Patent Owner Preliminary Response added a new argument that Sun discloses a flexural modulus that overlaps with the claimed range. Paper 11 at 1-2. Petitioner waived this argument by failing to make it in the Petition.

Colas Sols., Inc. v. Blacklidge Emulsions, Inc., 758 Fed. App'x 986, 989 (Fed. Cir. 2019) (finding overlapping ranges theory waived when not presented in the petition, which relied solely on inherency).

1. Overlapping Ranges Do Not Apply Where There Are Fundamental Differences Between the Claims and Prior Art

A *prima facie* case of obviousness "typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). As discussed below, however, *Peterson* and its progeny show that prior art cannot disclose an "overlapping range" where fundamental differences exist between the claims and the prior art.

Where, as here, the differences between the prior art and the claims are substantial enough that a skilled artisan would not expect them to perform the same, overlapping ranges do not apply. *Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 272 (Fed. Cir. 2022). In *Almirall*, for example, the Federal Circuit upheld a Board opinion applying overlapping ranges because, even though the two prior-art references being combined used different polymers, expert testimony established that the two polymers were "interchangeable" and that a skilled artisan "would not have expected any incompatibilities in substituting" the two polymers. *Id.* at 273.

Here, no *prima facie* case exists given the fundamental differences between the polymers disclosed in Sun and those in the Hinz and Durasoft Data Sheets. *See*

Almirall, 28 F.4th at 272. Far from being "interchangeable," the polymers in the Durasoft Data Sheets fail to meet most of Sun's flexural strength and temperature dependence requirements for achieving desirable insertion and removal behavior.

The Board considered similar facts in *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, and declined to apply a presumption of obviousness based on overlapping ranges because the petitioner failed to address "the fundamental differences" between the asserted prior art. IPR2022-01116, 2022 WL 1801878, at *7 (PTAB 2022). Although a prior-art reference disclosed an overlapping range, the Board concluded that the petitioner failed to establish that the prior-art polymers were "interchangeable" and that a skilled artisan "would not have expected any incompatibilities in substituting" one polymer for the other. *Id.* (citing *Almirall*, 28 F.4th at 272-73).

This case differs from *Peterson* and the Federal Circuit's other overlapping range cases, where no fundamental differences existed between the challenged claims and the prior art. In *Peterson*, the claimed "nickel-base superalloy" differed from the prior art only as to the percentage ranges of the elements in the alloy. *Id.* at 1327. Indeed, "each range listed in Peterson's claim . . . lies within the corresponding range disclosed in [the prior art reference]." *Id.* at 1329. The Federal Circuit held it would have been obvious to select the narrower ranges of each element. *Id.*

The Federal Circuit's other overlapping range cases similarly involved no fundamental differences between the claims and prior art. *In re Woodruff*, for example, the prior art's gaseous compositions comprised exactly the same gases claimed (CO_2, O_2, CO, and N_2), and each claimed concentration range fell within the prior-art range except for "overlapping or adjacent ranges of carbon monoxide concentration." 919 F.2d 1575, 1577 (Fed. Cir. 1990). Similarly, in *Titanium Metals Corp. of America v. Banner*, the proportions of nickel and molybdenum in the prior-art titanium base alloy were "so close" to those in the claimed titanium base alloy that the Federal Circuit concluded that "prima facie one skilled in the art would have expected them to have the same properties." 778 F.2d 775, 783 (Fed. Cir. 1985).

Here, the Board should not apply a presumption of obviousness based on overlapping ranges. As discussed above, the asserted art differs in fundamental ways such that a skilled artisan would understand that the modulus for Sun's light-curable polymers would not apply to the polymers in the Durasoft Data Sheets or Hinz. Ex. 2006 ¶ 152. Petitioner cannot simply pluck the flexural modulus at 23° C from Sun while ignoring its flexural strength and temperature dependence requirements, neither of which the Durasoft polymers satisfy. Here, as in *TwinStrand*, those fundamental differences preclude application of overlapping ranges.

2. Overlapping Ranges Do Not Apply Because Sun's Flexural Modulus Range Is Too Broad

Overlapping ranges also should not apply here because Sun's flexural modulus range is extremely broad. The Federal Circuit has clarified that a broad prior-art range does not necessarily render obvious a narrower claimed range falling within the broader range. *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1306 (Fed. Cir. 2011). Where, as here, the disclosed range is "so broad as to encompass a very large number of possible distinct compositions," overlapping ranges do not apply. *Id.* (citing *Peterson*, 315 F.3d at 1330 n.1). The Court in *Genetics Institute* further distinguished the ranges in *Peterson* as "not especially broad," and thus "invite[ing] routine experimentation to discover optimum values." *Id.* The inventors in *Genetics Institute*, by contrast, had "not simply '[s]elect[ed] a narrow range from within a somewhat broader range,'" but rather had created compositions that differed in other significant ways. *Id.* at 1306 (quoting *Peterson*, 315 F.3d at 1329-30).

Here, Sun's specific light-curable, flexible dental polymeric material has a flexural modulus from about 10,000-350,000 psi (about 69-2,413 MPa) at 23° C. Ex. 1018 ¶¶ [0012]-[0013]. At the institution stage, the Board found that this broad flexural modulus range, which encompasses the claimed flexural modulus range, created a *prima facie* case of obviousness. Paper 16 at 18-19; *see* Pet. 67-68.

Sun's range, however, "is so broad as to encompass a very large number of possible distinct compositions," which renders overlapping ranges inapplicable. M.P.E.P. § 2144.05(1) (9th ed. Nov. 2015) (citing *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994)); *see also Genetics Institute*, 655 F.3d at 1306. As Dr. Osswald opines, the vast majority of polymers for use in dental appliances fall within Sun's broad modulus range. Ex. 2006 ¶ 154. Moreover, Sun's polymers differ fundamentally from those in Durasoft and Hinz, and the '630 patent inventors therefore were not simply "[s]electing a narrow range from *within* a somewhat broader range disclosed in a prior art reference." *Peterson*, 315 F.3d at 1329-30.

Moreover, as in *Genetics Institute*, Petitioner identifies no motivation in Sun or the other asserted references to make the claimed compositions with a modulus within the claimed range of 750 to 2,000 MPa, as opposed to some other portion of Sun's broad range (69 to 2,413 MPa). 655 F.3d at 1306; Ex. 2006 ¶ 155.

Given the breadth of Sun's modulus range and the differences between Sun and both the claimed invention and other asserted art, mere overlap of one mechanical property cannot establish *prima facie* obviousness. *Genetics Institute*, 655 F.3d at 1306. This situation is more "analogous to the obviousness of a species when the prior art broadly discloses a genus." *Id.*; Ex. 2006 ¶ 156.

C. Flexural Modulus Cannot Be Routinely Optimized to Achieve "Better Insertion and Removal Behavior"

Even if the Board were inclined to find an overlapping flexural modulus range, Petitioner's obviousness arguments would still fail. A skilled artisan could not routinely optimize flexural modulus to achieve the "better insertion and removal behavior" sought in Hinz because, as conceded by Petitioner's witness, flexural modulus is just one of many properties that affect insertion and removal behavior. Ex. 2017, 37:20-38:14, 39:21-40:6, 46:10-23, 50:21-51:5, 51:23-52:6, 53:16-54:7, 56:4-8. Other relevant properties, including the overall thickness of the dental appliance, affect both modulus and the appliance's rigidity in unpredictable ways. It therefore would not be "routine" to optimize either modulus or insertion and removal behavior, nor would optimizing modulus be sufficient to achieve good insertion and removal. Ex. 2006 ¶ 157.

Sun and Hinz disclose several properties that affect ease of insertion and removal from the mouth. Ex. 2006 ¶ 158. Sun's flexible and soft dental night guards and splints are made from light-curable polymer, which can be partially cured in the mouth and then further shaped to improve fit. Ex. 1018 ¶¶ [0004]-[0005]. Sun discloses certain flexural modulus and flexural strength ranges for the "[f]lexible dental polymeric material useful in accordance with the invention," both of which

preferably are at least 20%, 50%, or 70% lower at body temperature (37°C) than room temperature (23°C). Ex. 1018 ¶¶ [0012]-[0013], [0015].

Hinz discloses dental splints with "increased breaking strength and better insertion and removal behavior due to increased elasticity of the dental splint, which is caused by the internal soft layer having higher elasticity." Ex. 1015, 28:74-76, 32:215-217. Hinz also explains that "the thickness of the film" is based on "the desired structural form and the use of the splint." *Id.*, 26:27-29. Hinz thus identifies elasticity, breaking or flexural strength, and overall appliance thickness as relevant to insertion and removal behavior. Ex. 2006 ¶ 159.

Petitioner's witness, Dr. Giacomin, confirmed that flexural modulus thus is not the only variable relevant to "insertion and removal behavior." Ex. 2017, 37:20-38:14, 39:21-40:6, 46:10-23, 50:21-51:5, 51:23-52:6, 53:16-54:7, 56:4-8; Ex. 2006 ¶¶ 157-160. At minimum, flexural or breaking strength, elasticity, and the overall appliance thickness are also important. A polymer's ability to be partially shaped or cured in a patient's mouth may also be relevant. Ex. 2006 ¶ 160.

Optimizing flexural modulus alone therefore is insufficient to guarantee "good mechanical properties" or desirable insertion and removal behavior. *Id.* ¶ 161. A material with a given flexural modulus may have flexural strength that is too high or may be too thick to have appropriate stiffness or elasticity. *Id.* None of the asserted references explains the interplay between these properties vis-à-vis insertion and

removal, and a skilled artisan therefore could not have simply optimized layer thickness or flexural modulus to obtain good insertion and removal. *Id.*

Furthermore, the thickness of the dental appliance and of each layer of the multilayer sheet affect the above properties in unpredictable ways. *Id.* ¶ 162, Overall thickness can significantly affect the dental appliance's stiffness, and thus ease of insertion or removal, independent of modulus. *Id.* For example, because flexural modulus is an intensive property, a single-layer aligner would be stiffer as its thickness increases even though its flexural modulus would stay the same. *Id.* For a multi-layer aligner, by contrast, increasing overall thickness would still tend to increase stiffness, but it could either increase or decrease overall flexural modulus depending on the layer configuration and what layers were being made thicker. *Id.* The changed flexural modulus in turn could also affect the aligner's stiffness, which depends on both modulus and the aligner's geometry. *Id.*

Nor does thickness have predictable effects on a multilayer sheet's flexural modulus. While increasing the thickness of a multilayer sheet's highest-modulus layer sometimes increases overall flexural modulus, it can also *decrease* overall flexural modulus, depending on the thickness and configuration of the other layers. *Id.* ¶ 163. For example, the flexural modulus of a three-layer, PC/TPU/PC sheet with thicknesses of 0.3mm/1.0mm/0.2mm would *increase* if the first hard layer's thickness increases to 0.4mm (i.e., 0.4mm/1.0mm/0.2mm) but *decrease* if that same

layer's thickness increases again to 0.5mm (i.e., 0.5mm/1.0mm/0.2mm). *Id.* Similar behavior occurs for other materials and thickness combinations. *Id.*

Sun contains no guidance regarding the interplay between flexural modulus, appliance thickness, and layer thickness. It does not explain how a desirable flexural modulus might change when moving from a single-layer material, such as the 2 mm, single-layer sheet in Example 8, to a two-layer embodiment, such as the embodiment in Example 7 with a 2 mm flexible layer and 2 mm rigid layer. *Id.* ¶ 164. Nor does Sun disclose what flexural strength is appropriate for any given flexural modulus. *Id.*

This unpredictability of thickness's effect on modulus, coupled with the other properties that affect insertion and removal behavior, mean that a person of ordinary skill could not "routinely optimize" layer thickness, or even flexural modulus. *Id.* ¶ 165. As in *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, optimizing interdependent variables that interact in unpredictable ways would not have been routine. 18 F.4th 1364, 1375-77 (Fed. Cir. 2021).

VI. Grounds 1-3: The Elastic Beam Theory Calculation Petitioner Relies on to Obtain the Flexural Modulus Limitation Is Not Within the Common Knowledge of Those of Ordinary Skill in the Art

In Grounds 1 and 2, Petitioner uses Dr. Osswald's elastic beam theory calculation to supply the flexural modulus limitation missing from Hinz and the Durasoft Data Sheets. In Ground 3, Petitioner uses the calculation to reverse

engineer the thicknesses of the individual polymeric layers to achieve the flexural modulus values disclosed in Sun and the ’630 patent claims. Neither Petitioner nor Dr. Giacomin, however, cites any prior art evidencing a skilled artisan’s knowledge or use of this calculation. Pet. 36; Ex. 1002 ¶ 102. This deficiency is fatal to the Petition for two reasons.

First, Dr. Osswald’s elastic beam theory calculation is not within the common knowledge of those skilled in the art. Ex. 2006 ¶ 167. Dr. Osswald *derived* the elastic beam theory calculation Petitioner uses, and as he explains, this far exceeds the level of ordinary skill in the art.[4] *Id.* ¶¶ 61-68, 166-167. Indeed, Dr. Giacomin could not recall having used this elastic beam theory calculation prior to his involvement in this case. Ex. 2017 at 33:6-14. Deriving the flexural modulus of a polymeric sheet composition containing three or more layers is complex because the calculation must account for the outer layers’ larger impact on overall flexural modulus. Ex. 2006 ¶ 167. On similar facts, the Federal Circuit has rejected reliance on a mathematical formula derived from the prior art as impermissible use of hindsight. *Zoltek Corp. v. U.S.*, 815 F.3d 1302, 1313 (Fed. Cir. 2016); *see also Hospira, Inc. v. Genentech, Inc.*, IPR2017-00804, 2018 WL 5267374 (PTAB Oct. 3, 2018).

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[4] As Dr. Giacomin notes, Dr. Osswald made a mistake in his original derivation in the district court. Ex. 1002 ¶¶ 168-69, 171.

Second, even if this 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 and the flexural modulus of the three-layer polymeric sheet composition. In *Arendi S.A.R.L. v. Apple Inc.*, the Federal Circuit acknowledged that "common sense and common knowledge have their proper place in the obviousness inquiry" but cautioned that "there are at least three caveats." 832 F.3d 1355, 1361 (Fed. Cir. 2016). "First, common sense is typically invoked to provide a known *motivation to combine*, not to supply a missing claim limitation." *Id.* Second, common sense may supply a missing limitation only when "the limitation in question was unusually simple and the technology particularly straightforward." *Id.* at 1362. Third, "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 when dealing with a limitation missing from the prior art references specified." *Id.*

Here, Petitioner resorts to alleged common knowledge—and in particular, the elastic beam theory calculation derived by Dr. Osswald—to supply the missing link between individual layer thickness and the flexural modulus of the three-layer polymeric sheet composition. But as in *Arendi*, the limitation at issue is not "unusually simple," nor is the technology "particularly straightforward."

Accordingly, alleged common knowledge cannot supply the missing flexural modulus limitation or any alleged motivation to select individual layer thicknesses to achieve the flexural modulus values disclosed in Sun or the claims. Even for Ground 3, Petitioner relies on the elastic beam theory calculations to provide the missing link between Sun's broad flexural modulus range and the thicknesses for each layer in Hinz/Durasoft needed to achieve the claimed flexural modulus range. Use of this calculation thus reflects Petitioner's improper use of hindsight to combine the asserted art in a way that arrives at the claimed compositions and flexural modulus.

VII. Grounds 1-3: Claims 4 and 10 Would Not Have Been Obvious Over Hinz and the Durasoft Data Sheets, with or Without Sun

Dr. Giacomin's calculations for the "lateral restoring force" limitation in claims 4 and 10 contain a unit conversion error that cause them to be off by an order of magnitude. Ex. 2006 ¶ 168. The claims require a lateral restoring force of "less than 100 Newtons per cm^2 (N/cm^2)." Ex. 1001, claims 4, 10. Dr. Giacomin calculates value of either 28 N/cm^2 or 57 N/cm^2, but the true values according to his calculations should be 287 N/cm^2 and 573 N/cm^2 if the math is done correctly. Ex. 2006 ¶ 168. Because Petitioner has failed to establish the presence of this claim limitation, it cannot prove that claims 4 and 10 would have been obvious.

VIII. Objective Evidence of Nonobviousness Supports the Patentability of Claims 1-4, 7-11, and 13

The obviousness analysis must avoid even a hint of hindsight. *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377-78 (Fed. Cir. 2012). Objective evidence of nonobviousness provides a necessary safeguard against hindsight and is part of—not in addition to—the obviousness analysis. *Id.* Objective evidence "may often be the most probative and cogent evidence in the record" and thus "must always when present be considered en route to a determination of obviousness." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)); *see also Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010). Such evidence therefore is not just "icing on the cake" and must be considered as part of evaluating obviousness. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986).

Here, Patent Owner's evidence of unexpected results, commercial success, copying, and industry praise further supports the nonobviousness of the '630 patent claims. When weighed together with the other obviousness factors, it compels a conclusion of nonobviousness.

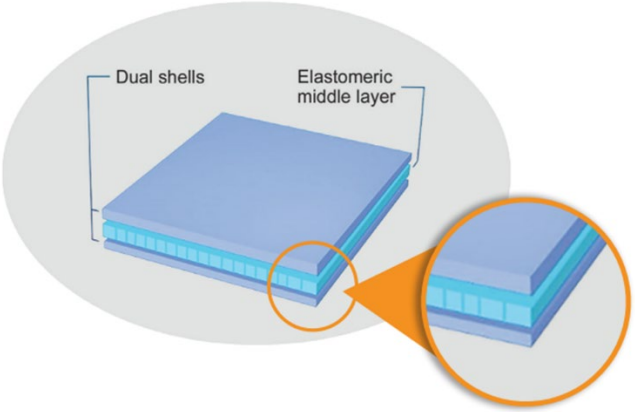
A. Zendura™ FLX Has a Nexus to Claims 1-4, 7-11, and 13

Objective evidence of nonobviousness must have a nexus to the merits of the claimed invention. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)

(citations omitted). Nexus may be presumed when the "asserted objective evidence is tied to a specific product and that product embodies the claimed features, and is coextensive with them." *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (citations omitted).

Here, nexus should be presumed because Patent Owner's Zendura™ FLX, an industry-leading, multilayer polymeric sheet composition used to make clear dental aligners, embodies and is coextensive with the claimed features. Ex. 2006 ¶¶ 171-75. Petitioner does not dispute that the '630 patent claims cover Zendura™ FLX. Pet. 69 (acknowledging that Zendura FLX is an embodiment of the challenged claims). As shown in the claim chart below, Zendura™ FLX embodies and is coextensive with claim 1. Ex. 2006 ¶ 175.

Claim Element	**Zendura™ FLX**
1 [pre]. A polymeric sheet composition, comprising:	Zendura™ FLX is a multilayer polymeric composition. Ex. 2014 at 1.
[1a]. at least two outer layers A and C and an elastomeric inner layer B,	Zendura™ FLX has two hard or rigid polymeric outer layers and a soft elastomeric inner layer, as shown below:

Claim Element	Zendura™ FLX
	 Ex. 2013 at 1. The outer layers shown above are "layers A and C," and the inner layer is "an elastomeric inner layer B." *Id.*
[1b]. 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 hard outer layers of Zendura™ FLX, layers A and C, are copolyesters having a flexural modulus of from 1,000 to 2,500 MPa. Ex. 2015 at 2; Ex. 2010 ¶ 7.

Claim Element	Zendura™ FLX
[1c]. the inner layer B is comprised of an elastomeric material having a hardness from about A80 to D75,	The elastomeric inner layer, layer B, is a thermoplastic elastomer with a hardness between A80 to D75. Ex. 2016 at 4; Ex. 2010 ¶7.
[1d]. and the polymeric sheet composition has a flexural modulus of from about 750 MPa to 2,000 MPa.	Zendura™ FLX is advertised as having an overall flexural modulus between 750 MPa to 2,000 MPa. Ex. 2014 at 1.

Accordingly, nexus between the objective evidence relating to Zendura™ FLX and the claimed invention should be presumed. *WBIP*, 829 F.3d at 1331. Moreover, as discussed below, the objective evidence of nonobviousness is due to the merits of the claimed invention, and thus, nexus exists between the claimed invention and the objective evidence. *Id.*

B. Zendura™ FLX Demonstrates Unexpectedly Superior Properties

When a "claimed invention achieve[s] new and unexpected results nowhere suggested in the prior art," such objective evidence of nonobviousness cannot be

overlooked. *Linemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984). Unexpected results are particularly salient where the prior art teaches that something is necessarily true, but the "inventors determined that the opposite was true." *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1306 (Fed. Cir. 2015); *see also Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1988). Such a determination "is an unexpected difference in kind that supports nonobviousness." *Id.* Unexpected results need not be claimed. *In re Merchant*, 575 F.2d 865, 869 (C.C.P.A. 1978).

Here, Zendura™ FLX demonstrates unexpected superior properties compared to prior aligner materials, including the multilayer aligner material made by competitor Align Technology with a "soft-hard-soft" configuration. *E.g.*, Ex. 1001 at 16:33-17:46, 18:32-19:25, 20:10-22; *see also* Ex. 2006 ¶ 177.

Zendura™ FLX and the '630 patent departed from the conventional wisdom in the industry at the time of the invention that a multilayer aligner's outer layers must be soft to provide patient comfort and overcome the hard layer's propensity for stress cracking and degradation in the wet, humid environment of the mouth. Ex. 1001 at 5:15-20, 19:63-66; Ex. 2011 ¶¶ 12-14; Ex. 2018 at 7:59-66; Ex. 2019 at 7:2-5; Ex. 2020 at 1:39-48; Ex. 2021 ¶ [0009]; Ex. 2022 at 9:48-10:9; Ex. 2023 at 12:43-49; Ex. 2006 ¶ 178. As a result, the multilayer aligners on the market used soft outer layers surrounding a hard inner layer. Ex. 2011 ¶ 14. This included the

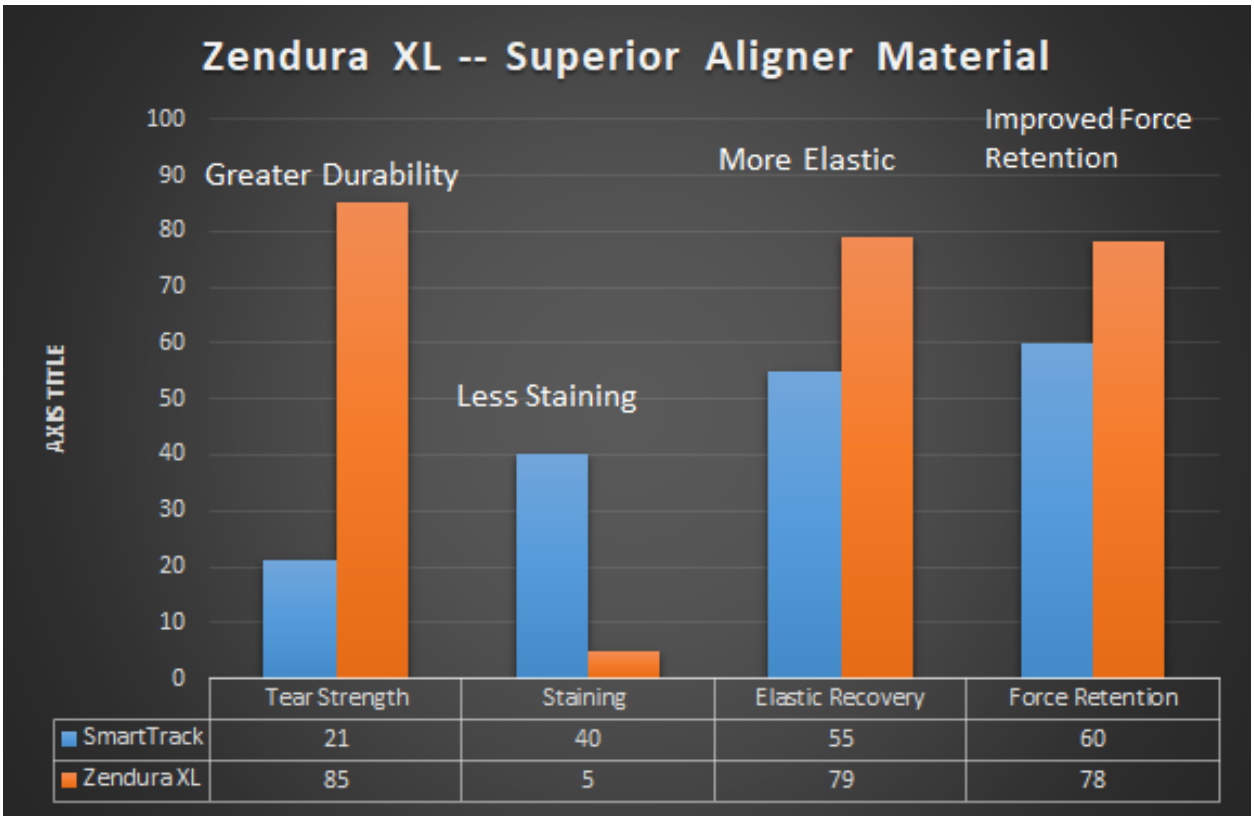
material used in the highest selling aligner at the time of invention—Align Technologies' SmartTrack material, which has a soft-hard-soft configuration. *See* Ex. 2018; Ex. 2011 ¶ 14.

A skilled artisan would not have deviated from this practice. Given this industry belief, it was unexpected that Zendura™ FLX's unique hard-soft-hard layer configuration and other properties produced such favorable results compared to Align's soft-hard-soft material. Ex. 2011 ¶¶ 11-12, 15-20; Ex. 2006 ¶ 179.

Compared to Align's SmartTrack material, Zendura™ FLX exerts similar lower initial forces but retains its ability to exert that force on a patient's teeth over a longer time. Ex. 1001 at Table 3, 17:25-38; Ex. 2011 ¶¶ 17-20; Ex. 2020 at 1:39-48; Ex. 2006 ¶ 180. This force persistence is critical to successfully moving teeth, and the lower initial force makes the aligner more comfortable when inserted in the patient's mouth. *See* Ex. 2020 at 1:39-48; Ex. 2006 ¶ 180. Zendura™ FLX also exhibits improved tear resistance and less stress cracking compared to Align's product. Ex. 1001 at 17:22-24, 17:39-56, 20:10-22. It is also more elastic and stain resistant, which is important because patients directly observe those properties. Ex. 1001 at 17:22-24, 18:32-55.

These improved properties are demonstrated by Patent Owner's internal test data, which compared Zendura™ FLX to a version of SmartTrack. As shown in the

figure below, Zendura™ FLX outperformed SmartTrack in durability, staining, elastic recovery, and force retention. Ex. 2006 ¶ 181; Ex. 2024 at 32.



These improved properties are also disclosed in the ’630 patent. *E.g.*, Ex. 1001 at 15:27-22:5. Examples 1 and 4 disclose three prior-art materials—P1, P2, and P3—and two materials covered by the ’630 patent claims—#1 and #2. P3 is a three-layer, soft-hard-soft material described in Align’s U.S. Patent No. 9,655,693. *See* Ex. 2018; Ex. 1001 at 17:16-22; Ex. 2006 ¶ 182. Compared to prior-art materials, the inventive compositions in Table 3 showed improved tear resistance and less stress cracking, improved force retention, and improved stain resistance. Ex. 1001 at Table 3, 17:22-24, 17:39-56, 18:32-55, 19:63-20:36; Ex. 2006 ¶ 182.

TABLE 3

Monolayer and Multilayer Sheets

	Material Property						
Construction	P1 Monolayer	P2 Monolayer	P3 ABA	1 ABC	2 ABC	3 ABC	4 ABC
P1 layer/ microns	Isoplast 2530	Polyester A 250	Texin 950 75	Polyester B 250	Polyester B 250	Isoplast 2531	Polyester B 175
P2 layer/ microns	Isoplast 2530	Polyester A 250	Polyester A 600	Elastollan 1185A	Texin RxT 50D	Texin RxT 65D	Texin 950 LW
P3 layer/ microns	Isoplast 2530	Polyester A 250	Texin 950 75	Polyester B 250	Polyester B 250	Isoplast 2531	Polyester B 175
Flexural Modulus	1910 Mpa	1750 Mpa	675 Mpa	824 Mpa	968 Mpa	729 Mpa	575 Mpa
Elongation to break (%)	100-130	100-130	100-130	100-130	100-130	100-130	100-130
Impact Strength J/mm	15.2	6.9	—	—	9.2	14	—
Trouser Tear Force (N)	18	48	51	156	165	187	170
Load retention g (1)							
0 days	4244	3956	2664	2638	2739	2567	1598
1 day	707	853	875	1329	1469	1534	1232
2 days	498	601	823	1257	1389	1398	1247
Color change dB(2)	0.97	2.1	44	2.6	2.3	1.1	2.2

* Polyester A is a copolyester marketed by Eastman Chemical (Eastar 6763). Polyester B is cycloaliphatic copolyester marketed by Eastman Chemical under the tradename Tritan
(1) - 5% strain/37° C./water
(2)Mustard/24 hr/22° C.

The ’630 patent also discloses the durability testing that was conducted by subjecting the samples to a mouth wash test. Ex. 1001 at 18:59-19:13. The inventive hard-soft-hard configuration exhibited significantly better recovery properties than

existing aligner materials, including P3. Ex. 1001 at Table 5; 18:59-19:13; Ex. 2006 ¶ 182.

TABLE 5

Shape Recovery of Samples				
	% Recovery			
Minutes	P1	P2	P3	#2
0.01	53	34	51.6	66
60	54	49	53.8	69
1440	61	65	59.4	77

Petitioner incorrectly argues that Zendura™ FLX's superior properties would have been expected based on Hinz's general assertions that its dental splint has "increased breaking strength" and "better insertion and removal behavior" and is "stable against discoloration." Pet. 68-69 (quoting Ex. 1015, 27:54-28:78, 28:82-83). This argument fails, however, because Align's SmartTrack material, and not Hinz, is the appropriate comparator for purposes of assessing unexpected results.

First, Petitioner does not even mention, much less rebut, the full scope of unexpected results from the claimed compositions. The Petition, for example, is silent regarding Zendura™ FLX's unexpectedly superior elastic recovery and force retention, which directly facilitate its improved ability to move teeth.

Second, Petitioner fails to explain how Zendura™ FLX's unexpected results could be compared to Hinz, which does not report data for force persistence, tear resistance, and flexural modulus. Hinz thus does not disclose the specific

performance characteristics or mechanical properties that allow Zendura™ FLX to achieve unexpectedly good results. Ex. 1001, 17:25-38; Ex. 1015, 27:54-59, 29:117-119. And Hinz makes only general assertions regarding other properties (e.g., "increased breaking strength," "stable against discoloration"). Given Hinz's lacking disclosure, Petitioner fails to explain how Patent Owner could compare it to Zendura™ FLX.

Third, Petitioner does not dispute that Hinz discloses a different kind of dental appliance: a dental splint rather than a dental aligner. Pet. 68-69. The '630 patent explains that these appliances "have contradictory requirements." Ex. 1001 at 1:35-36, 1:41-43; *see also In re Stemniski*, 444 F.2d 581, 587 (C.C.P.A. 1971) (reversing obviousness rejection based on unexpected use of the claimed composition compared to known uses of structurally similar prior-art compounds). As the Board noted, Hinz discloses dental splints, including aligners that "maintain teeth in alignment after an active treatment phase." Paper 16 at 9-10. Zendura™ FLX, on the other hand, is designed to move teeth in an active treatment phase.

Petitioner would require Patent Owner to make one or more of the numerous dental appliances that could result from the combination of the asserted art, test those appliances, and then compare the resulting data to the data for the inventive compositions of the '630 patent. The Federal Circuit has rejected precisely this type of argument. In *Millennium Pharmaceuticals, Inc. v. Sandoz, Inc.*, for example, the

Court explained that the patent owner "was not required to create the glycerol ester, when the product had not been created in the prior art." 862 F.3d 1356, 1368 (Fed. Cir. 2017). The Court explained "[u]nexpected results are shown in comparison to what was known, not what was unknown." *Id.* The Court thus rejected the argument that the patent owner should have compared its product to a compound that was only "'generically' encompassed by" the prior art without any disclosure of the relevant chemical properties of the compound. *Id.*

Here, as in *Millennium*, Patent Owner should not be required to compare its product to a non-existent product whose properties are not disclosed in the art. Instead, Patent Owner properly compared Zendura™ FLX to Align's SmartTrack multilayer material, which was both the industry-leading product and could be meaningfully compared based on actual data (unlike Hinz). Indeed, even Petitioner's internal documents compare Zendura™ FLX to Align's product. Ex. 2025 at 4-6.

Petitioner also argues that Patent Owner's evidence of unexpected results is not commensurate with the scope of the challenged claims. Pet. 68. But "absolute identity of scope" is not required. *Genetics Institute*, 655 F.3d at 1308; *In re Merch.*, 575 F.2d at 869. Moreover, contrary to Petitioner's assertions, the '630 patent provides examples of more than just "a single hard-soft-hard embodiment." For example, Table 3 shows two inventive embodiments with different hard-soft-hard configurations, which both demonstrated unexpectedly superior properties over the

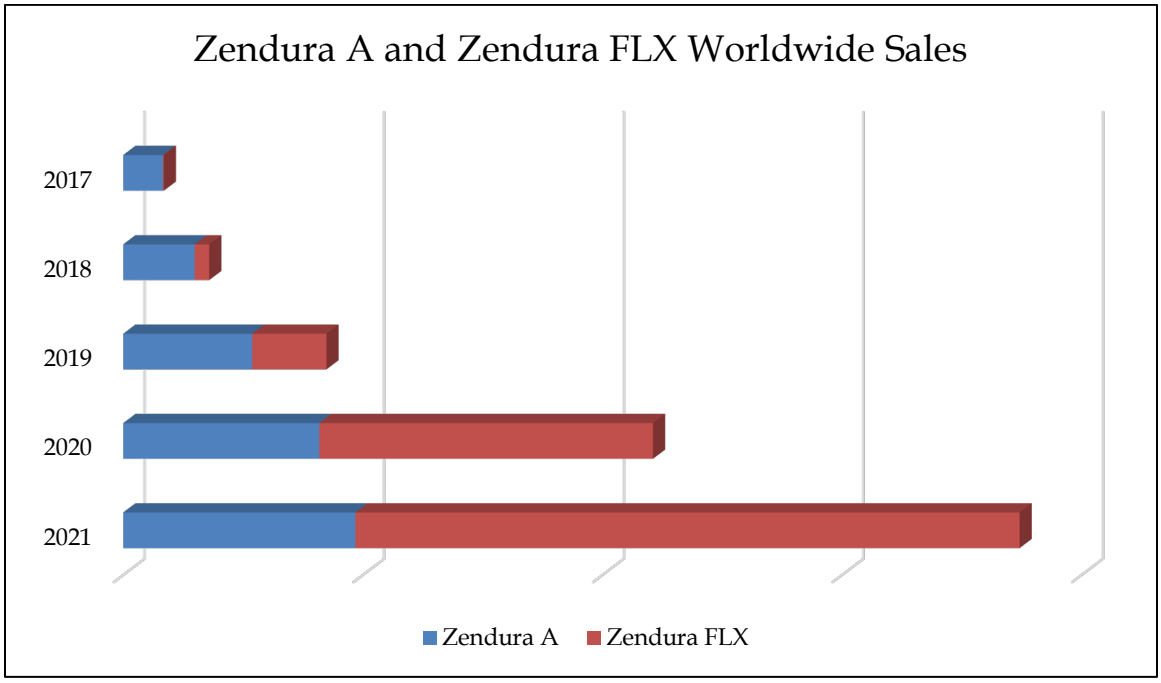
prior art, and Example 7 provides additional inventive embodiments. Ex. 1001 at Table 3, 21:10-30, Table 8. Considered together, the unexpected properties demonstrated by Zendura™ FLX and shown in the ’630 patent are commensurate in scope with the challenged claims. *Genetics Institute*, 655 F.3d at 1308.

C. Zendura™ FLX Is Commercially Successful

Commercial success evidence must be considered “so long as what was sold was within the scope of the claims.” *In re Glatt Air Techniques, Inc.*, 630 F.3d 1026, 1030 (Fed. Cir. 2011) (quotations and citation omitted). Factors that may be relevant to commercial success include displacement of other products in the marketplace, the profitability of the product, and whether the product has met internal performance goals. *Cable Elec. Products, Inc. v. Glenmark, Inc.*, 770 F.2d 1015 at 1026-27 (Fed. Cir. 1985).

Here, Zendura™ FLX falls within the scope of the claims and has demonstrated overwhelming commercial success. Ex. 2006 ¶¶ 171-176; Ex. 2008 ¶¶ 45-48. Its sales have overtaken and far surpassed Patent Owner’s single-layer polymeric sheet composition, Zendura™ A, making Zendura™ FLX Patent Owner’s core product. Ex. 2026; Ex. 2008 ¶¶ 15-22. Patent Owner’s annual sales increased substantially since the release of Zendura™ FLX in 2018. *Id.*; Ex. 2026. Over this same period, sales of Zendura™ FLX to Patent Owner’s largest customers increased substantially and are expected to continue growing. Ex. 2008 ¶¶ 23-26.

Zendura™ FLX sales exceeded even Patent Owner's performance goals, leading to Patent Owner's acquisition by the Straumann Group ("Straumann") in October 2019. Ex. 2008 ¶¶ 22, 32-34; Ex. 2027 at 4, 14; Ex. 2028 at 36. Patent Owner estimated sales of Zendura™ FLX to grow substantially from 2019 through 2022. Ex. 2008 ¶ 22; Ex. 2029. Yet Zendura™ FLX rapidly outpaced even Patent Owner's optimistic anticipated growth, even as sales of Patent Owner's single-layer material (Zendura A) also increased. Ex; 2008 ¶ 22; Ex. 2029; Ex. 2026.



Zendura™ FLX's strong commercial performance led Patent Owner to increase its forecast for the size of the market. Ex. 2008 ¶ 22. In 2018, Patent Owner estimated the Zendura™ FLX market but by the end of 2018 had already doubled that estimate. Ex. 2008 ¶ 22; Ex. 2024 at 28; Ex. 2027 at 10. This commercial success is strong evidence of nonobviousness.

Petitioner wrongly contends that sales of Zendura™ FLX merely cannibalized sales of Zendura™ A. Pet. 70. Contrary to Petitioner's contention, sales of *both* products grew from 2018 to 2022, with Zendura™ FLX sales growth outpacing Zendura™ A. Ex. 2008 ¶¶ 15-22; Ex. 2026. Zendura™ FLX's success was, and remains, attributable to its improved properties over competitors. Ex. 2008 ¶¶ 27-31, 35-44.

Petitioner also wrongly argues that Patent Owner's evidence of commercial success is not commensurate with the scope of the challenged claims. Pet. 68. Evidence from Patent Owner's customers, however, ties Zendura™ FLX's commercial success to the features disclosed and claimed in the '630 patent, including the unexpectedly improved force persistence and comfort made possible by the lower initial force. Ex. 2008 ¶¶ 27-31. Indeed, Patent Owner's customers promote these features to differentiate their aligner products from market competitors. Ex. 2008 ¶¶ 29-31, 38-44.

Regardless, "a patentee need not show that all possible embodiments within the claims were successfully commercialized in order to rely on the success in the marketplace of the embodiment that was commercialized." *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996). As shown above, Zendura™ FLX is covered by and coextensive with at least one claim of the '630 patent.

D. Petitioner Copied Zendura™ FLX

"[E]vidence of copying tends to show nonobviousness." *WBIP*, 829 F.3d at 1336 (quotations and citations omitted); *see also Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1138 (Fed. Cir. 2019); *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1054 (Fed. Cir. 2016); *Transocean*, 699 F.3d at 1352 ("[I]nternal documents expressly tying its copying to the novel [] features of [the] invention" further support a finding of copying.).

Here, Petitioner's internal documents show testing it performed on Patent Owner's Zendura™ FLX product before introducing its Clarity Flex multilayer aligner product. In particular, Petitioner obtained samples of Zendura™ FLX in 2018 and, within months, had assembled a presentation summarizing testing it conducted. Exs. 2030, 2031; Ex. 2006 ¶ 194. Petitioner identified force retention as the most important property and used Zendura™ FLX as the baseline for such measurements. Ex. 2031 at 6-7, 11, 12; Ex. 2006 ¶ 194. Petitioner continued to study Patent Owner's product, even purchasing more samples in January 2020. Ex. 2032. Petitioner also requested a license to the '630 patent. Ex. 2034.

The Clarity Flex product that Petitioner later brought to market has similar attributes to Zendura™ FLX, including a nearly identical flexural modulus, similar layer materials, and hard outer layers rather than the industry-standard soft outer layers used by Align. Ex. 2033; Ex. 2014 at 1. Petitioner's internal consultants noted

the overlap between Zendura™ FLX and Petitioner's product. For example, one consultant rejected the name "Clarity Flex," asking if the name would "be too close to Zendura" and noting the likelihood of "[c]onfusion with [the] product." Ex. 2035. This is substantial evidence of nonobviousness.

Petitioner's argument that it developed a five-layer material rather than a three-layer material does not diminish this copying evidence. Petitioner indisputably tested Zendura™ FLX and developed its Clarify Flex product based on Zendura™ FLX's properties. *See, e.g.*, *Apple*, 839 F.3d at 1054; *Transocean*, 699 F.3d at 1352. Petitioner also was aware of the '630 patent, which it sought to license. *See Liqwd*, 941 F.3d at 1138 ("[W]e have held that even in cases involving claims directed to a product, access to an issued patent coupled with circumstantial evidence regarding changes to a competitor's design is sufficient to support copying."). And Petitioner's product falls within the scope of the challenged claims of the '630 patent. *See Hughes Tool Co. v. Dresser Industries, Inc.*, 816 F.2d 1549, 1556 (Fed. Cir. 1987).

This evidence of copying further supports nonobviousness.

E. Zendura™ FLX Received Praise from Competitors in the Relevant Industry, Including Petitioner

"Praise for the invention, including awards accorded to the inventors for their invention, are further evidence of the [invention's nonobviousness]." *Corning Glass Works v. Sumitoto Elec. U.S.A. Inc.,* 671 F. Supp. 1369, 1398 (S.D.N.Y. 1987), *aff'd*

868 F.2d 1251 (Fed. Cir. 1989); *see also Allen Archery, Inc. v. Browning Mfg. Co.,* 819 F.2d 1087, 1092 (Fed. Cir. 1987).

Here, Zendura™ FLX quickly became the industry baseline material for clear, multi-layer aligners. Competitors, including Petitioner, have praised Zendura™ FLX's desirable performance characteristics. Petitioner's internal documents, for example, state that Zendura™ FLX provides "excellent stain resistance and force retention . . . compared to Invisalign." Ex. 2025 at 6. Petitioner also stated that Zendura™ FLX stains less than Align's product and provides "[i]mproved stress retention." Ex. 2025 at 2. This praise for the features of Zendura™ FLX disclosed and claimed in the '630 patent is additional objective evidence of nonobviousness. Ex. 2006 ¶ 218.

IX. Conclusion

For the foregoing reasons, Patent Owner respectfully request that the Board confirm the patentability of claims 1-4, 7-11, and 13 of the '630 patent.

Respectfully submitted,

Dated: April 12, 2023

/Charles T. Collins-Chase/
Charles T. Collins-Chase
Reg. No. 78,019

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Charles T. Collins-Chase, certify that **Patent Owner's Response** contains 13,846 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: April 12, 2023

/Charles T. Collins-Chase/
Charles T. Collins-Chase
Reg. No. 78,019

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Response** was served electronically via email on April 12, 2023, in its entirety on the following:

Heidi L. Keefe
Adam Pivovar
Reuben Chen
Jennifer Volk-Fortier
Cooley LLP
1299 Pennsylvania Ave. NW, Suite 700
Washington, DC 20004
hkeefe@cooley.com
apivovar@cooley.com
rchen@cooley.com
jvolkfortier@cooley.com

Petitioner has consented to electronic service by email.

Dated: April 12, 2023

/William Esper/
William Esper
Case Manager and PTAB Coordinator
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP