

Petition for *Inter Partes* Review of
U.S. Patent No. 10,870,263

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY,
Petitioner

v.

BAY MATERIALS, LLC,
Patent Owner

Case No. IPR2023-00243

U.S. Patent No. 10,870,263

Filing Date: December 18, 2019

Issue Date: December 22, 2020

Title: Dual Shell Dental Appliance and Material Constructions

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OF U.S. PATENT NO. 10,870,263**

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List of Exhibits

Exhibit No.	Description of Document
1101	U.S. Patent No. 10,870,263 B2 to Ray F. Stewart, et al. (filed December 18, 2019, issued December 22, 2020) (“’263” or “’263 patent”)
1102	Declaration of Alan Jeffrey Giacomini (“Giacomini”)
1103	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Complaint (D.I. 1)
1104	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Summons (D.I. 24)
1105	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Order Staying Case (D.I.)
1106	Service rejection letter to Bay Materials (November 16, 2021)
1107	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Plaintiff’s Identification of Asserted Claims
1108	File Wrapper of U.S. Patent No. 10,870,263
1109	Claim Listing of Challenged Claims
1110	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), 3M’s Answering Brief in Opposition to Plaintiff’s Motion for Preliminary Injunction (D.I. 87)
1111	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Reply Brief in Support of Plaintiff’s Motion for Preliminary Injunction (D.I. 101)
1112	U.S. Patent No. 10,946,630 (“’630 patent”)
1113	U.S. Provisional Pat. Appl. No. 62/512,786 (“’786 provisional”)
1114	U.S. Provisional Pat. Appl. No. 62/590,627 (“’627 provisional”)

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Exhibit No.	Description of Document
1115	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Opening Brief in Support of Plaintiff’s Motion for Preliminary Injunction (D.I. 14)
1116	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Declaration of Dr. Tim A. Osswald in Support of Plaintiff’s Motion for Preliminary Injunction (D.I. 17)
1117	WO 2010/043419 A1 to Rolf Hinz (filed Oct. 19, 2009, published Apr. 22, 2010) and English translation thereof (“Hinz”)
1118	Affidavit of Nathaniel E Frank-White (Internet Archives)
1119	Produktdatenblatt DURASOFT® with English Translation (“Durasoft (TPU/PC) Data Sheet”) available at https://web.archive.org/web/20160808102931/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenbl%C3%A4tter/Produktdatenblatt-DURASOFT_bis-LOT-1614A.pdf
1120	Screenshot of archived Durasoft (TPU/PC) Data Sheet web page at: https://web.archive.org/web/20160808102931/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenbl%C3%A4tter/Produktdatenblatt-DURASOFT_bis-LOT-1614A.pdf
1121	Produktdatenblatt DURASOFT® with English Translation (“Durasoft (TPU/PETG) Data Sheet”) available at: https://web.archive.org/web/20160808110356/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenblätter/Produktdatenblatt-DURASOFT_ab-LOT-1714A.pdf
1122	Screenshot of archived DURASOFT (TPU/PETG) Data Sheet web page at:

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Exhibit No.	Description of Document
	https://web.archive.org/web/20160808110356/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenblätter/Produktdatenblatt-DURASOFT_ab-LOT-1714A.pdf
1123	Produktdatenblatt Produktdatenblatt IMPRELON® S pd with English Translation (“Imprelon S (Copolyester) Data Sheet”) available at: https://web.archive.org/web/20160809214649/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenbl%C3%A4tter/Produktdatenblatt-IMPRELON-S_ab-LOT-3615A.pdf
1124	U.S. Pub. No. 2004/0224283 A1 to Benjamin J. Sun, et al. (filed: Nov. 26, 2003, published November 11, 2004) (“Sun”)
1125	Handbook of Thermoplastics, Second Edition, Chapter 9: Thermoplastic Polyesters (“Kannan”)
1126	Declaration of Sylvia Hall-Ellis
1127	U.S. Patent No. 9,655,691 (“Li”)
1128	Int’l Pat. Publ. No. WO2017/007962 (“Boronkay”)
1129	U.S. Patent No. 8,758,009 (“Chen”)
1130	Int’l Pat. Publ. No. WO2013/130552 (“Stewart”)
1131	Dr. Henry C.A. Lim, Ch. 20, Thermoplastic Polyesters (2017)
1132	Wiley Encyclopedia of Packaging Technology (2009) - Sheet, PETG
1133	Drobny, <i>Handbook of Thermoplastic Elastomers</i> (2014)
1134	WO 2013/172812 A1 Craig Pehlert, et al. (filed May 14, 2012, published Nov. 21, 2013) (“Pehlert”)

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Exhibit No.	Description of Document
1135	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Deposition of Dr. Tim A. Osswald (D.I. 88-1)
1136	Mix, A. W., & Giacomini, A. J. (2011). Standardized polymer durometry. <i>Journal of Testing and evaluation</i> , 39(4), 696-705
1137	Qi, H. J., Joyce, K., & Boyce, M. C. (2003). Durometer hardness and the stress-strain behavior of elastomeric materials. <i>Rubber chemistry and technology</i> , 76(2), 419-435
1138	Beer, <i>Mechanics of Materials</i> (2001)
1139	Dr. Giacomini's CV

I. INTRODUCTION

Petitioner 3M Company respectfully submits this Petition for *Inter Partes* Review of claims 1-4, 7, 11-14, 16, 18, and 31 (“the Challenged Claims”) of U.S. Patent No. 10,870,263 (“’263 patent”) (Ex.1101).

Multilayer polymeric sheets for use in forming dental appliances were well known and disclosed within the prior art. The allegedly inventive hard-soft-hard configuration of the ’263 patent was already expressly disclosed, and other variations are natural consequences of the recipes found within that art. The Challenged Claims recite nothing more than obvious aspects of the disclosures and teachings of the prior art, which were never considered by the examiner. Accordingly, Petitioner requests institution of *Inter Partes* review (“IPR”) and a finding that all Challenged Claims are unpatentable.

II. MANDATORY NOTICES UNDER § 42.8(A)(1)

A. Real Parties-In-Interest under § 42.8.(b)(1)

3M Company is the real party-in-interest to this IPR petition.

B. Related Matters under § 42.8(b)(2)

The ’263 patent, together with U.S. Patent No. 10,946,630 (“’630 patent”), is the subject of pending litigation involving the Petitioner and Patent Owner in *Bay Materials, LLC v. 3M Company*, Case No. 21-cv-1610-RGA (D. Del.). The presently challenged ’263 patent, along with the related ’630 patent, was first

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asserted in Patent Owner's Complaint, served on Petitioner on December 6, 2021.
(Ex.1103; Ex.1104.) The district court case was stayed on November 1, 2022.
(Ex.1105.)

The '263 patent is a continuation-in-part of U.S. Patent Application No. 16/211,176 ("'176 application"), which issued as U.S. Patent No. 10,549,511 ("'511 patent"). (*See* Ex.1101, Cover Page.) The parent '176 application is a continuation in part of PCT/US2018/035384, filed on May 31, 2018, and the '263 patent further asserts priority to provisional Patent Appl. No. 62/590,627 (filed on November 26, 2017) and provisional Patent Appl. No. 62/512,786 (filed on May 31, 2017). (*Id.*, Page 2.) The '630 patent is related to the '263 patent through their shared '176 parent application. Other related child patents and applications to the '263 patent are U.S. Patent Nos. 10,987,907 and 11,325,358 and pending U.S. Patent Appl. No. 17/564,857, which published as U.S. Publ. No. 2022/0118747. All of these foregoing parent and child patents and applications, in addition to the pending litigation, are related matters.

In addition to the present Petition, Petitioner has filed IPR petitions challenging asserted claims of the continuation-in-part '263 patent based on a lack of an effective filing date earlier than the actual December 18, 2019 filing date of

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the application that issued as the '263 patent (IPR2022-01215),¹ and has also filed an IPR challenge to the related '630 patent (IPR2022-01214). IPR2022-01214 challenges claims of the '630 patent with Grounds that rely on prior art references similar to those included in Grounds 1-2 herein.

C. Lead and Back-Up Counsel under § 42.8(b)(3)

Petitioner provides the following designation of counsel.

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¹ Pursuant to the PTAB Trial Practice Guide, Petitioner is submitting a separate paper with this Petition explaining the need for parallel filed IPR petitions challenging the '263 patent.

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D. Service Information

This Petition is being served by Federal Express to the attorney of record for the '263 patent, Leydig, Voit & Mayer, The Atrium Building, 1981 N. Broadway, Suite 375, Walnut Creek, CA 94596-5083. A courtesy copy of this Petition is also being served electronically on Patent Owner's counsel of record in the pending case *Bay Materials, LLC v. 3M Company*, Case No. 21-1610-RGA (D. Del.).

Petitioner consents to electronic service at the addresses provided above for lead and back-up counsel.

III. FEE PAYMENT UNDER § 42.103

Petitioner requests review of 12 claims of the '263 patent. A payment of \$41,500 is being submitted herewith.

IV. REQUIREMENTS UNDER §§ 42.104 AND 42.108 AND CONSIDERATIONS UNDER §§ 314(A) AND 325(D)

A. Grounds for Standing

Petitioner certifies that the '263 patent is available for IPR and that Petitioner is not barred or otherwise estopped.²

B. Identification of Challenge and Statement of Precise Relief Requested

Petitioner requests institution based on the following Grounds:

Ground	Claims	Basis for Challenge under 35 U.S.C. § 103
1	1	Hinz in view of Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet
2	2-4	Hinz in view of Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet and Sun
3	7, 31	Hinz in view of Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet, Sun, and Handbook of Thermoplastics
4	11	Li, Boronkay and Chen
5	12-14, 16, 18	Li, Boronkay, and Chen in view of Stewart

This Petition is supported by a Declaration from Dr. Alan Jeffrey Giacomini

² Patent Owner did not properly serve Petitioner with the district court complaint until December 6, 2021. (*See* Ex.1106.)

(Ex.1102) (“Giacomin”), a qualified technical expert.

C. The Board Should Not Exercise Its Discretion Under 35 U.S.C. § 314(a) to Deny Institution

Petitioner will stipulate that if this Petition is instituted, Petitioner will not rely on any grounds in the district court that were raised or reasonably could have been raised herein. Additionally, with the exception of claims 1 and 2, the Challenged Claims are presently asserted in the parallel district court litigation, which has already been stayed pending IPR petitions. (*See* Ex.1107; Ex.1105.) The *Fintiv* factors strongly weigh against exercising discretion to deny institution

D. Considerations under 35 U.S.C. §§ 315(d) and 325(d)

The '263 patent issued from a continuation-in-part application that was filed on December 18, 2019, but claims priority to the earlier filed parent applications. The PTAB recognizes that “more than one petition may be necessary . . . when there is a dispute about priority date requiring arguments under multiple prior art references.” Trial Practice Guide Update, 26. In IPR2022-01215, Petitioner is relying on intervening prior art to challenge the claims of the '263 patent, contending that Patent Owner cannot establish an effective filing date earlier than December 18, 2019. Here, Petitioner is presuming (without conceding) an effective filing date of May 31, 2018, which would disqualify the intervening references in IPR2022-01215. As such, the Grounds presented herein rely on prior art references different

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from those presented in IPR2022-01215 and all such references pre-date May 31, 2017, the earliest filed provisional application.³

This Petition does not present a situation in which “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). Neither Hinz nor the other references on which Grounds 1-3 rely nor the Chen and Stewart references on which Grounds 4-5 rely were considered by the examiner. Although Li and Boronkay, are identified on the face of the ’263 patent, they were not cited by the examiner during prosecution, and their combination was never considered. Rather, the examiner relied on only one prior art reference, U.S. Patent 5,318,737 to Trabert, which is substantially different from any of the references herein. (Ex.1108, Pages 101-105, 212-216.) After a final rejection, an Examiner Interview was held during which “[a]greement was reached with respect to the lack of obviousness of the pending claims over Trabert” and the claims issued. (*Id.*, Pages 227-228, 237-240, 253-254.)

V. OVERVIEW OF THE ’263 PATENT

The ’263 patent is directed to multilayer, polymeric sheet compositions “useful for making dental appliances having outer layers comprised of a material

³ For further explanation, please see the separately filed Petitioner’s Statement Regarding Parallel IPR Petitions Challenging the ’263 Patent.

having a modulus of from about 1,000 MPa to 2,500 MPa ('hard') and an inner core comprised of elastomeric material or materials having a modulus of from about 50 MPa to 500 MPa ('soft')[.]” (Ex.1101, Abstract).

In addition to referring to the “modulus” of the layers, the '263 patent also refers to them by “hardness.” (*E.g.*, Ex.1101, 6:60-67.) The term “hardness” refers to a “Shore hardness scale,” such as Shore A or Shore D, which is measured using a durometer. (*Id.*) “Materials with higher durometer values will be harder compared to materials with a lower durometer value.” (*Id.*)

The disclosed multilayer polymeric sheet compositions are “comprised of at least two outer layers A and C and a middle layer B...” (Ex.1101, 1:51-52.) “Each layer A, B and C, may be a [*sic*] comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.” (Ex.1101, 3:48-51.)

Figure 1A depicts “a cross sectional view of a three-layer sheet with a simple ABC construction” where each of layers A, B, and C are single layers:

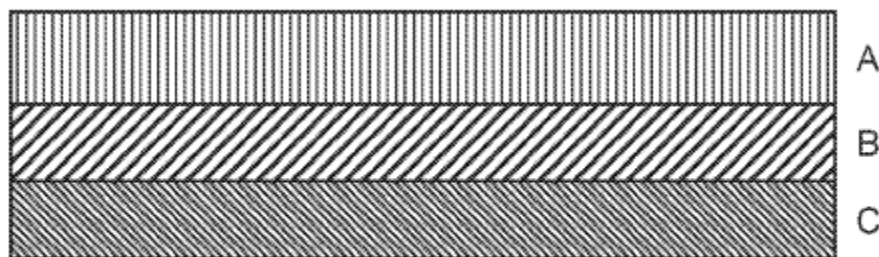


FIG. 1A

(Ex.1101, 3:41-42, Fig. 1A.)

Figure 1B depicts a cross-sectional view of a six-layer sheet with an ABC construction, where each of layers A, B, and C include multiple constituent layers:

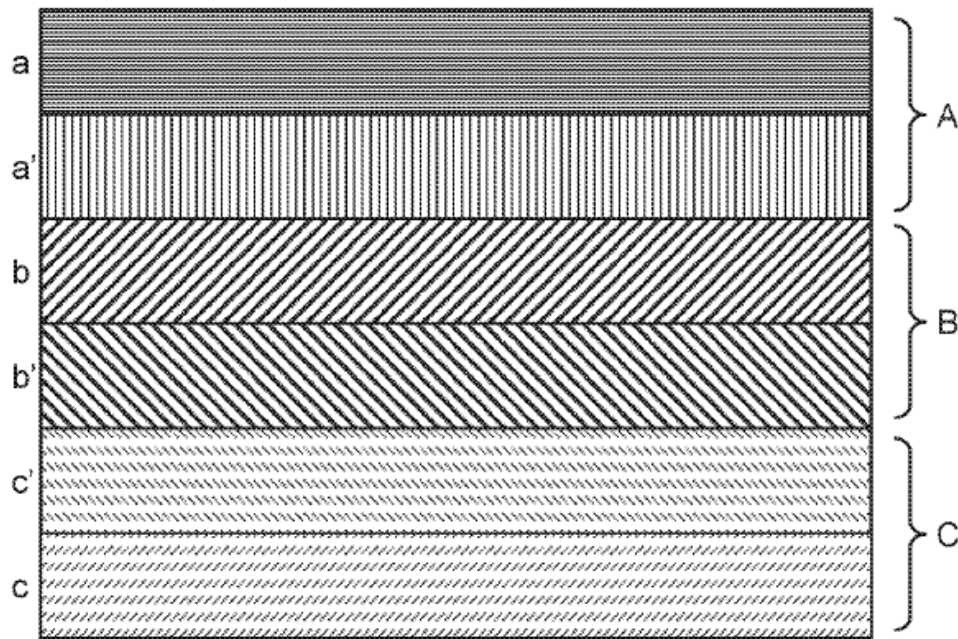


FIG. 1B

(Ex.1101, Fig. 1B, 3:47-55.)

In addition to a multilayer sheet with a layer AB C configuration, the '263 patent also discloses:

[A] polymeric sheet composition comprised of at least two rigid or hard outer layers A and C, at least two soft inner layers B and B' and at least a rigid or hard inner layer, D are provided. The A, C and D layers may be the same or different. The B and B' layers may be the same or different.

(*Id.*, 12:25-30.)

The disclosed “[m]ultilayer sheets may be prepared by a number of means including without limitation, hot or cold lamination, adhesive lamination, melt lamination, coextrusion multilayer extrusion or *other known methods*.”⁴ (Ex.1101, 15:17-20 (emphasis added).) The specification further explains that “[d]ental appliances may be constructed by thermoforming” the “dual shell” multilayer sheets over a model of one or more teeth. (*Id.*, 5:62-6:2.)

A. Claim Listing

Exhibit 1109 is a claim listing that enumerates each claim element.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSA”) as of December 18, 2019, (the effective date, as explained in Part VIII, *infra*) would have possessed a bachelor’s degree in mechanical, biomedical, or chemical engineering, or chemistry, materials science, or an equivalent science or engineering field and two years of experience in designing, manufacturing, and processing polymeric sheets, such as

⁴ All emphasis added, unless otherwise indicated.

thermoforming.⁵ Additional education could compensate for less practical experience, or vice versa. (Ex.1102, ¶17; *see generally* Ex.1102, ¶¶15-26.)

VII. CLAIM CONSTRUCTION

For this Petition only and with the exception of the terms addressed below, Petitioner applies Patent Owner’s interpretations where Patent Owner has adopted positions and/or statements in the district court and such interpretations may be required for the Board to evaluate the grounds presented. *See, e.g., Western Digital*

⁵ Although one aspect of the disclosed polymeric sheets is in the formation of dental appliances, the ’263 patent is not so limited: “The polymeric sheets are useful, *for example*, in a dental appliance” (Ex.1101, 1:21-24 (emphasis added); Ex.1102, ¶17, n.2.) Furthermore, all Challenged Claims except claim 18 are directed to “polymeric sheet compositions” without any recitation of a “dental appliance.” Accordingly, a POSA would not necessarily require specialized experience with “dental appliances.” The prior art herein involves standard thermoforming (*e.g.*, Ex.1117, 1:1-4, 6:177-181; Ex.1127, 6:60-64), which a POSA would readily understand how to perform in order to create a thermoformed dental appliance from a multilayer polymeric sheet. (Ex.1102, ¶17, n.2, ¶¶22-25; Ex.1101, 15:23-29 (“thermoforming may be performed using . . . *known thermoforming techniques*”) (emphasis added).)

Corp. v. SPEX Techs., Inc., IPR2018-00082, Paper 11 at 9-14 (P.T.A.B. April 25, 2018).

A. “layer A,” “layer B,” and “layer C”

The challenged claims recite “layers A and C” and “layer B.” There is no plain and ordinary meaning for “layer A,” “layer B,” or “layer C” within the art. (Ex.1102, ¶59.) Here, the specification provides a definition for “layer A,” “layer B,” or “layer C”: “Each layer A, B and C, may be a [*sic*] comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.” (Ex.1101, 3:48:51, Fig. 1B.) Petitioner proposes that definition be applied. (*See* Ex.1110, 13.) *See Thorner v. Sony Computer Enter. Am. LLC*, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012).

In response, Patent Owner also cited the specification’s definition and stated that, with respect to the “layers labeled layers A, B, and C,” “the specification explains that the layers ‘may be comprised of more than one layer.’” (Ex.1111, 3.) Accordingly, Patent Owner does not appear to dispute Petitioner’s construction that each of the recited layer A, layer B, and layer C “may be comprised of a single layer

or multiple layers and each layer may be comprised of one or more materials or a blend of materials,” as expressly set forth in the specification.⁶ (Ex.1102, ¶59.)

However, in IPR2022-01215, Patent Owner has asserted that the naked term “layer” should be construed according to the specification’s express definition of “[e]ach layer A, B and C.” (IPR2022-01215, Paper 6, 19-20.) This is incorrect. While the patent provides an express definition for each of “layer A, B and C,” as recited in the Challenged Claims, there is nothing in the specification that redefines the meaning of “layer” *per se* and there is no instance of any recitation of “layer” by

⁶ In opposing Patent Owner’s motion for a preliminary injunction, Petitioner additionally alleged that claims suffered from a “full scope” indefiniteness problem when applied to polymeric sheets wherein layers A, B, or C are *multiple* layers. (See Ex.1110, 13.) However, under Patent Owner’s interpretation against the accused five-layer material, Patent Owner contends that each of layers A, B, B', C, and D are satisfied by *single* layers. (See Ex.1116, ¶126.) Accordingly, the Board can determine whether the prior art Grounds asserted herein satisfy the Challenged Claims under Patent Owner’s *single* layer infringement theories for layers A, B, B', C, and D despite the indefiniteness that arises when layers A, B, and C are comprised of *multiple* layers. (Ex.1102, ¶¶59-60.)

itself within the Challenged Claims. Rather, every recitation of layer is only in the context of layer A, layer B, layer C, etc. This is in contrast to other patents related to the '263 patent, where the claims do recite inventions with “layer” or “layers” *per se* and do not recite “layers A and C” or “layer B.” (*See, e.g.*, Ex.1112 ('630 patent), claim 1 (“layers A and C” and “layer B”), claim 15 (“layers”)⁷; Ex.1102, ¶¶61-62.)

B. “layer D” and “layer B”

Independent claim 11 recites a polymeric sheet composition that further includes a “layer D” and a “layer B',” in addition to layers A, B, and C. (Ex.1101, claim 11.) The new matter within the '263 patent explains that “[t]he A, C and D layers may be the same or different” and “[t]he B and B' layers may be the same or different.” (*Id.*, 12:28-30.) Accordingly, “layer D” and “layer B” should be construed similar to layers A, B, and C—i.e., each of “layer D” and “layer B” individually “may be comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.” (Ex.1102, ¶65.)

⁷ In this claim, the term “layer(s)” has its plain and ordinary meaning within the art—i.e., “layer” is singular (i.e., one layer) and “layers” is plural (i.e., multiple layers). (Ex.1102, ¶62; *see* Ex.1112 (claim 15) (“more than two rigid layers, wherein at least one of the rigid layers . . .”).)

C. “inner layer B,” “inner layer B’,” and “inner layer D”

Solely for the purposes of this Petition, Petitioner adopts Patent Owner’s position that an “inner layer,” recited in conjunction with inner layer B, inner layer B’, and inner layer D, such that it “does not refer only to a core, middle, or innermost layer.” (Ex.1111, 2.)

VIII. THE EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS

The ’263 patent issued from U.S. App. No. 16/719,256, filed on December 18, 2019, as a continuation-in-part of the ’176 application, filed December 5, 2018, which was a continuation-in-part of application No. PCT/US2018/035384 (“PCT ’384 application”), filed on May 31, 2018. (*Id.*, 1:7-15.) The ’263 patent further claims the benefit of U.S. Provisional Application No. 62/512,786 (“’786 provisional” (Ex.1113)), filed May 31, 2017 and of U.S. Provisional Application No. 62/590,627 (“’627 provisional” (Ex.1114)), filed Nov. 26, 2017 (collectively, “the provisional applications”). (*Id.*)

Solely for this Petition, Petitioner presumes (without conceding) that the Challenged Claims have an effective filing date of May 31, 2018. However, Patent Owner cannot demonstrate entitlement to an earlier effective filing date to the provisional applications.

In order to receive the benefit of an earlier filed application, the earlier application must satisfy § 112(a) for the claimed subject matter. *Lockwood v.*

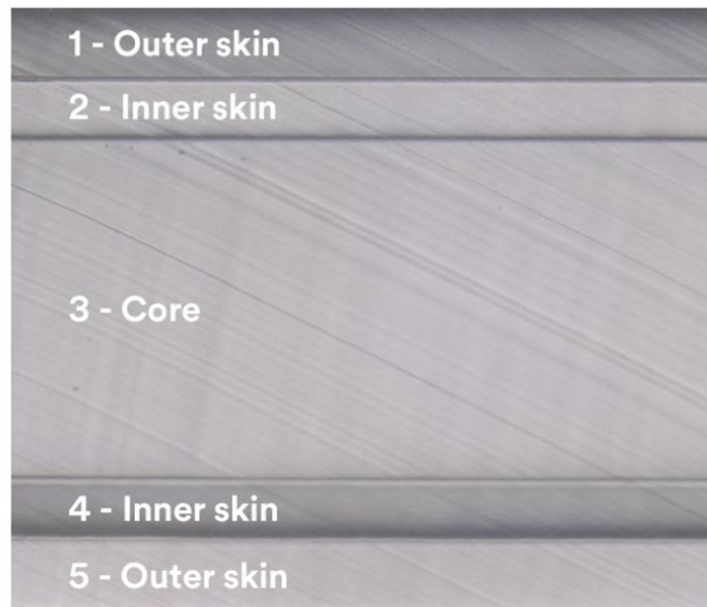
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American Airlines, Inc., 107 F.3d 1565, 1571-72 (Fed. Cir. 1997). Claim 1 recites “inner layer B” and claim 11 recites “inner layers B and B” as “having a hardness from about A60 to D85.” (Ex.1101.) The maximum hardness disclosed for any embodiments or teachings for a soft or elastic “inner layer” within the ’786 provisional or ’627 provisional applications is D75. (Ex.1102, ¶84.) Since the provisional applications fail to demonstrate the inventors were in possession of the full scope of the claimed hardness up to D75-D85, the Challenged Claims cannot have an earlier effective filing date based on either of the provisional applications. (*Id.*)

Additionally, the provisional applications have no disclosure of any multilayer sheets possessing “at least two rigid or hard outer layers A and C, at least two soft inner layers B and B’, and at least a rigid or hard inner layer, D” as recited in claim 11. (*Id.*) There is no mention of a “layer D” in the provisional applications. (*Id.*) Thus, a POSA would not find that the inventors were in possession of claim 11 or its dependents. (*Id.*)

IX. PATENT OWNER’S INFRINGEMENT POSITION

In the district court, Patent Owner has alleged that Petitioner’s five-layer material infringes claim 11. (Ex.1115, 8-9.) The five-layer construction of Petitioner’s accused product includes two inner and outer “skin” layers around a “core”:



(Ex.1102, ¶70.)

According to Patent Owner, the correspondence of the five-layers of the accused product to the recited layers A, B, B', C, and D of claim 11 is as follows:

“Outer skin” layers 1 and 5 correspond to the hard or rigid outer layers A and C, “Core” layer 3 corresponds to hard or rigid inner layer D and is shown as being the same material as layers “1” and “5”, and “Inner skin” layers 2 and 4 correspond to inner layers B and B'.

(Ex.1116, ¶¶125-126.)

Solely for this Petition, Petitioner applies Patent Owner’s application of layers A, B, B', C, and D in Grounds 4-5.

X. THE CHALLENGED CLAIMS ARE UNPATENTABLE

As detailed below, the Challenged Claims are obvious under Grounds 1-5.

A. Summary and Date Qualification of the Prior Art

1. Hinz [Ex.1117]

Hinz is an international patent application entitled “Method for Producing a Multilayer Dental Splint in a Deep-Drawing Device and Dental Splint,” published on April 22, 2010. (Ex.1117.) Hinz qualifies as prior art under § 102(a).

Hinz discloses “a method for producing a multilayer dental splint.” (*Id.*, 1:3-4.) Hinz discloses an embodiment for making a multilayer dental appliance from a pre-thermoformed hard-soft-hard multi-layered film:

Figure 3 shows . . . *a deep-drawing film 11 which has a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13 . . .*

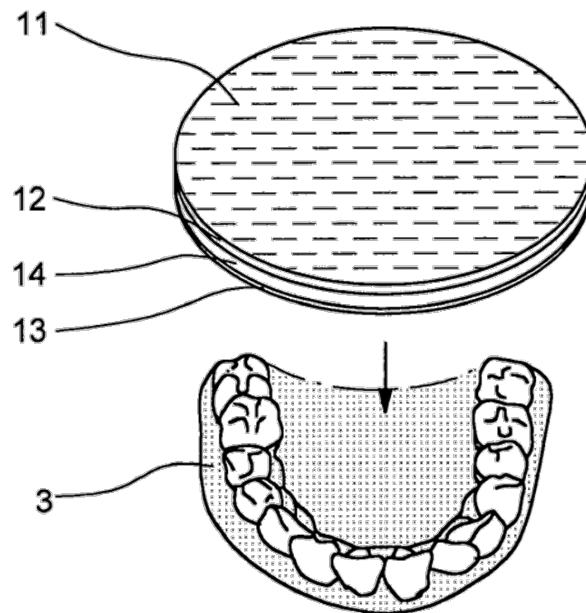


Fig. 3

(*Id.*, Fig. 3, 8:240-244 (emphasis added).)

Hinz discloses exemplary materials for the hard and soft layers of its hard-soft-hard multilayer dental splints. (*E.g.*, *id.*, 3:80-93; *see also* 8:240-244.) Hinz discloses “a hard layer made of a polyester plastic, preferably made of polycarbonate (PC) or polyethylene terephthalate (PET)” and “a soft layer made of a thermoplastic polyurethane (TPU).” (*Id.*, 3:80-90.) Hinz expressly discloses using the polymeric materials in “DURASOFT®” and “Imprelon ‘S’” from Scheu-Dental GmbH to create the disclosed hard-soft-hard multilayer dental splints. (*See id.*, 6:185-189, 7:206-207; *see also id.*, 6:177-7:217.) Hinz further discloses that “[t]he dental splint

according to the invention preferably has hard layers made of the same plastic material.” (*Id.*, 3:86-87.)

2. Durasoft (TPU/PC) Data Sheet [Ex.1119]

Durasoft (TPU/PC) Data Sheet is a publication entitled “Produktdatenblatt DURASOFT®,”⁸ which was publicly available as of August 8, 2016. (Ex.1119; Ex.1118, Page 1 (¶5), Pages 10-12 (“20160808”).) Durasoft (TPU/PC) Data Sheet qualifies as prior art under § 102(a)(1).

Durasoft (TPU/PC) consists of two layers: a hard layer of polycarbonate (“PC”) and a soft layer of thermoplastic polyurethane (“TPU”). It is expressly promoted for the “[m]anufacture of thermoformed dental splints.” (*Id.*) The hard “PC-Durasoft”⁹ layer has an elastic modulus of 2,400 MPa. (*Id.*) The soft “TPU-Durasoft”¹⁰ has an elastic modulus of 172 MPa, and hardness of A88 or D33. (*Id.*)

⁸ Translations are included with the exhibits containing the German-language datasheets.

⁹ “PC-Durasoft” refers to the polycarbonate (PC) material disclosed in Durasoft (TPU/PC) Data Sheet.

¹⁰ “TPU-Durasoft” refers to the thermoplastic polyurethane (TPU) material disclosed in Durasoft (TPU/PC) Data Sheet.

3. Durasoft (TPU/PETG) Data Sheet [Ex.1121]

Durasoft (TPU/PETG) Data Sheet is a publication entitled “Produktdatenblatt DURASOFT®,” which was publicly available as of August 8, 2016. (Ex.1121; Ex.1118, Page 1 (¶5), Pages 13-15 (“20160808”.) Durasoft (TPU/PETG) Data Sheet qualifies as prior art under § 102(a)(1).

Durasoft (TPU/PETG) Data Sheet discloses that Durasoft (TPU/PETG) consists of two layers: a hard PETG layer and a soft TPU layer, and is used in the “[m]anufacture of thermoformed dental splints.” (*Id.*) The hard “PETG-Durasoft”¹¹ layer has an elastic modulus of 2,200 MPa. (*Id.*) The soft thermoplastic polyurethane (TPU-Durasoft)¹² has a Shore A hardness of A86, and a Shore D hardness of D35. (*Id.*)

¹¹ “PETG-Durasoft” refers to the PETG material disclosed in Durasoft (TPU/PETG) Data Sheet.

¹² Although the Durasoft (TPU/PETG) Data Sheet does not disclose an elastic modulus value for the TPU material, a POSA would have recognized that that TPU material is essentially the same TPU material, as the TPU in the Durasoft (TPU/PC) Data Sheet, with essentially the same elastic modulus. (Ex.1102, ¶NN.) Therefore, Petitioner is applying the elastic modulus of 172 MPa for TPU-Durasoft.

4. Imprelon-S (Copolyester) Data Sheet [Ex.1123]

Imprelon-S (Copolyester) Data Sheet is a publication entitled “Produktdatenblatt IMPRELON® S pd,” which was publicly available at least as of August 9, 2016, as established by the Internet Archives. (Ex.1123; Ex.1118, Page 1 (¶5), Pages 19-21 (“20160809”.) Imprelon-S (Copolyester) Data Sheet qualifies as prior art under § 102(a)(1).

Imprelon-S (Copolyester) Data Sheet provides technical information regarding a copolyester material supplied by Scheu Dental used in the “[m]anufacture of thermoformed dental splints.” (*Id.*) “Copolyester-Imprelon”¹³ has an elastic modulus of 1,624 MPa. (*Id.*)

5. Sun [Ex.1124]

Sun is a patent application entitled “Method of Forming a Dental Product,” published on November 11, 2004. (Ex.1124.) Sun qualifies as prior art under § 102(a).

Sun discloses a “method of making dental night guards and splints” from sheets, including those with “flexible and rigid layers,” as well as their preferred

¹³ References hereinafter to “Copolyester-Imprelon” refers to the properties of the copolyester material disclosed in Imprelon-S (Copolyester) Data Sheet.

flexural modulus to ensure they are readily removable without discomfort. (*E.g.*, *id.*, [0002]-[0004], [0011]-[0012], [0029]-[0040].)

6. Kannan [Ex.1125]

Kannan is a chapter entitled “Thermoplastic Polyesters” in the Handbook of Thermoplastics, Second Edition, bearing a copyright of 2016. (Ex.1125.) The Library of Congress MARC record creation date in field 008 for Kannan is 160113, which reflects a January 13, 2016 date on (or shortly after) which, the work was first acquired and cataloged. (*See* Ex.1126, ¶¶37-41.) Kannan qualifies as prior art under § 102(a).

7. Li [Ex.1127]

Li is U.S. Patent 9,655,691, entitled “Multilayer Dental Appliances and Related Methods and Systems,” filed on May 14, 2012 and issued May 23, 2017. (Ex.1127.) Li qualifies as prior art under § 102(a).

Li discloses that “[i]n general, the structures, methods and systems of the present invention utilize a multilayer sheet for use in orthodontic appliances”—i.e., aligners. (*Id.*, 1:54-55.) “In one embodiment, the multilayer appliances can include a hard polymer layer of one type of material (e.g., a co-polyester), and two soft polymer layers of other types of material that can be the same or different (e.g., two soft polymer layers of thermoplastic polyurethane elastomer).” (*Id.*, 6:29-34.)

Figure 2 of Li “shows a multilayer structure according to the present invention. As shown, a multilayer sheet **20** can include a three layer structure: a hard polymer layer **24** and two soft polymer layers **22, 26**” (i.e., a “soft-hard-soft” layering configuration):

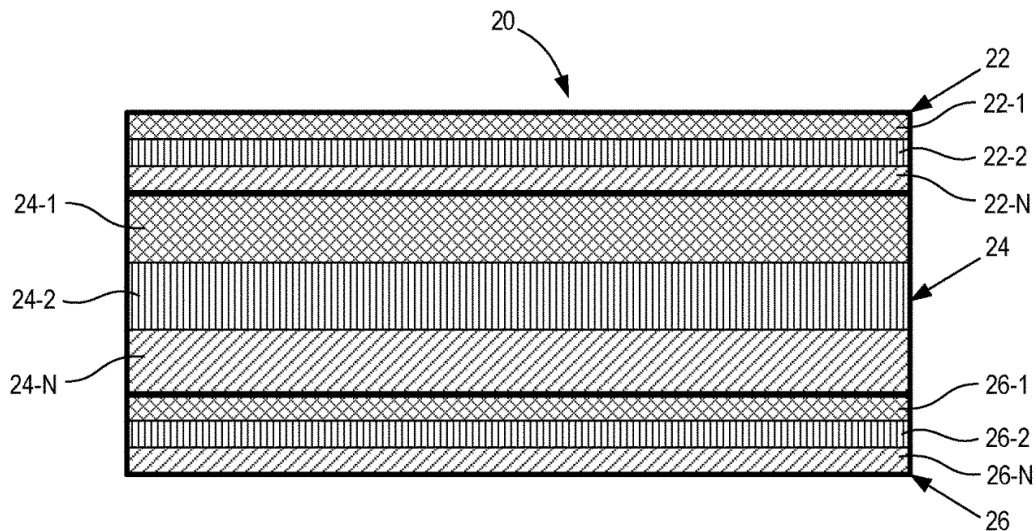


FIG. 2

(*Id.*, 5:12-15, Fig. 2; *see also* 5:46-49; 6:47-52.)

Figures 3 and 4 of Li depict a method of thermoforming a dental appliance from the disclosed multilayer sheets:

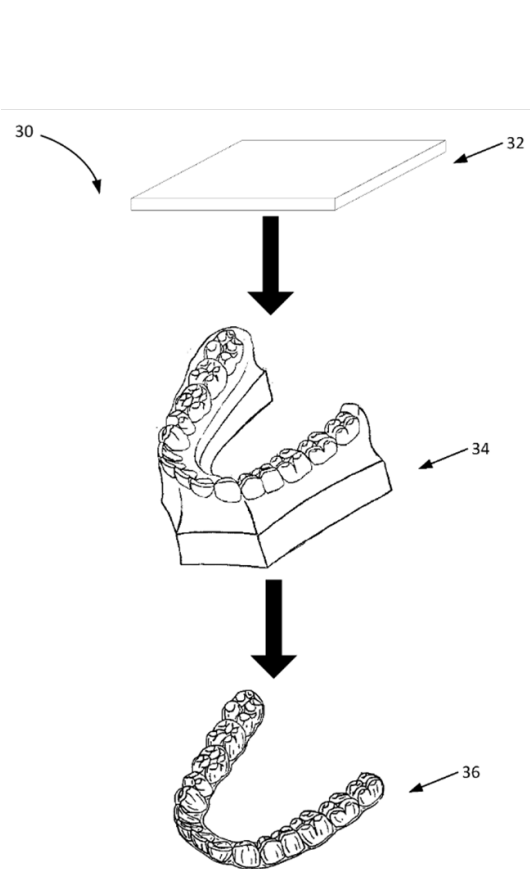


FIG. 3

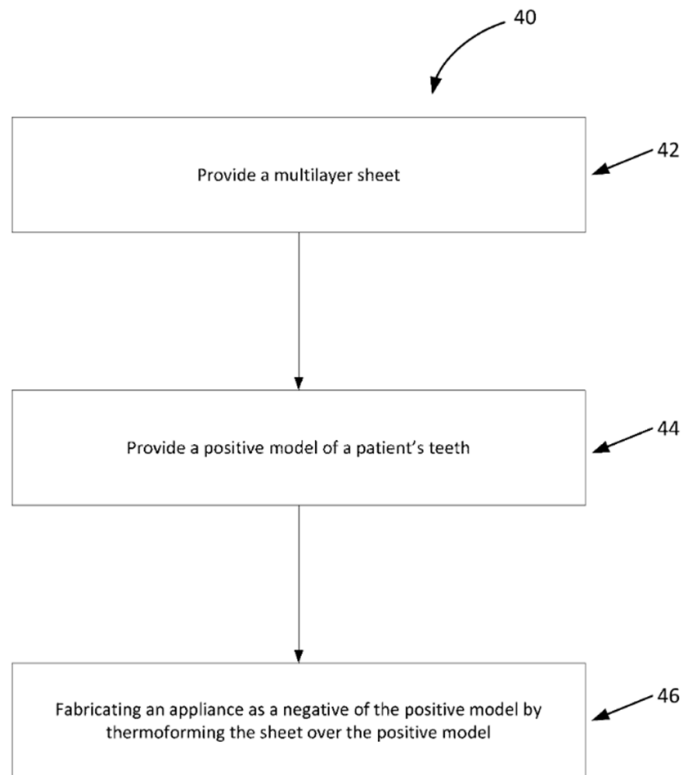


FIG. 4

(*Id.*, 7:4-20, 7:36-50, Figs. 3-4.)

Li discloses all aspects of the construction of the multilayer sheets for forming a dental appliance, including: (1) suitable polymeric materials and physical properties for the hard layer(s) (*Id.*, 5:34-67); (2) suitable polymeric materials and physical properties for the soft layers (*Id.*, 6:1-26); and (3) the thickness of the hard and soft layers, as well as the overall sheet thickness (*Id.*, 5:18-31).

8. Boronkay [Ex.1128]

Boronkay is an international patent application WO2017/007962, entitled "Fabrication of Attachment Templates and Multi-Material Aligners." (Ex.1128.)

Boronkay published on January 12, 2017, and qualifies as prior art under § 102(a).

Boronkay discloses “[s]ystems, methods, and devices for producing orthodontic appliances”—i.e., aligners. (Ex.1128, Abstract.) Figure 1A “illustrates an exemplary tooth positioning appliance or aligner 100”:

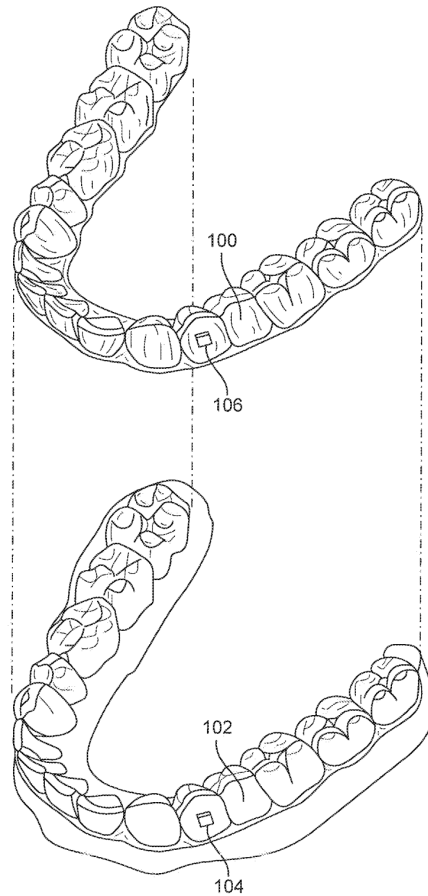


FIG. 1A

(*Id.*, [0088].)

Boronkay discloses multilayer aligners with hard and soft layers, including an embodiment with a soft-hard-soft configuration in FIG. 3C:

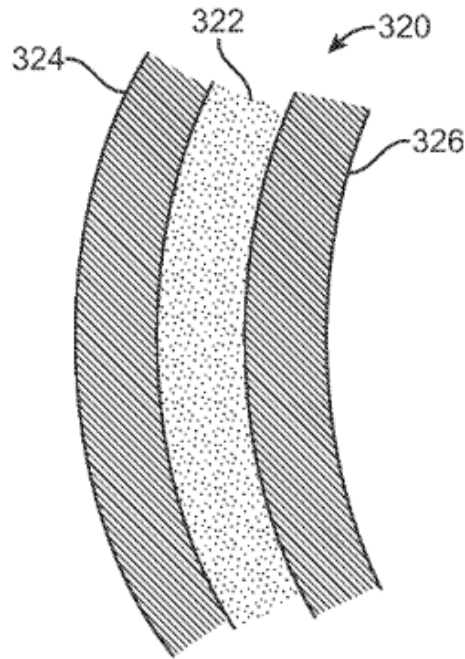


FIG. 3C

(*Id.*, [00108]¹⁴, Fig. 3C.)

Boronkay explains “[t]he orthodontic appliances provided herein can include other components in addition to a stiff outer shell and compliant inner structure,” and “these layers can perform various different functions.” (*Id.*, [00144]-[00145].) For instance, “a compliant, inner structure can be provided with a protective layer” and that such a “protective layer can be formed as a material layer or as a coating

¹⁴ Boronkay refers to “inner” as the layer of the dental aligner that is “tooth facing,” “outer” as the layer that is mouth facing, and “middle” the layer between them. (Ex.1128, [00108].)

deposited on the compliant inner structure.” (*Id.*, [00134].) This “innermost layer can be stiffer and/or harder than the inner structure, e.g., to protect the inner structure from abrasion, wear, staining, biological interactions, and the like.” (*Id.*, [00145].) Boronkay similarly discloses a stiff or hard protective “outermost layer” that serves “to protect the appliance, against abrasion, wear, staining, biological interactions (e.g., reduce plaque or biological growth), and the like.” (*Id.*, [00144].) Boronkay further teaches that the protective innermost/outermost layers should be thinner than the other layers in order to reduce their contributions “to the overall properties of the appliance.” (*Id.*, [00144], [00145].)

9. Chen [Ex.1129]

Chen is U.S. Patent 8,758,009, entitled “Restorative Dental Appliances,” and published on June 24, 2014. (Ex.1129.) Chen qualifies as prior art under § 102(a).

Chen discloses polymeric “aligner-type dental appliances for realigning teeth” that “may include a single or a plurality of polymeric material layers.” (*Id.*, 1:10-11, 3:45-46; *see also* 5:14-35.) The “dental appliance 100” comprising a polymeric concave trough 102 is illustrated in Figure 1:

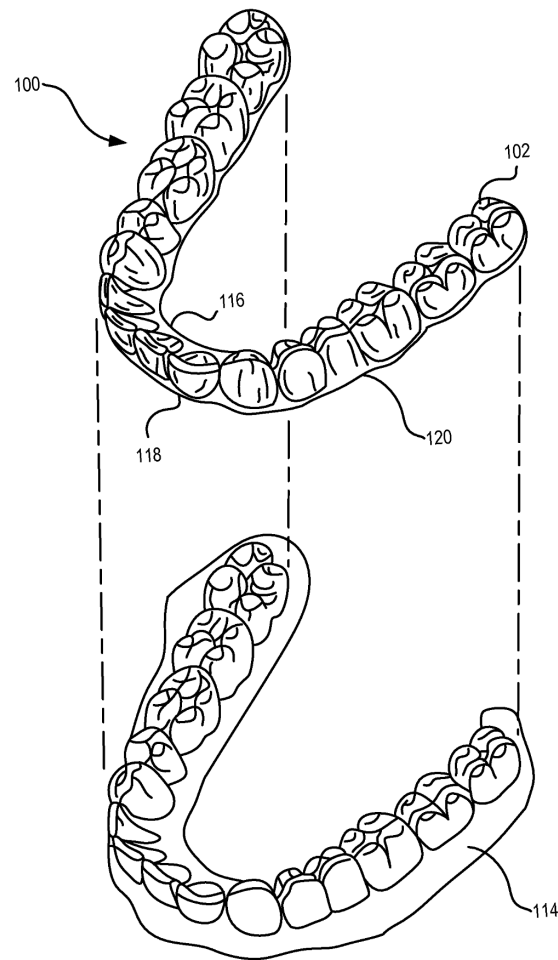


FIG. 1

(*Id.*, 2:33-41, Fig. 1.)

Chen teaches that “[c]ertain areas of the appliance will confer orthodontic forces onto the teeth” and, accordingly, that “[t]he concave trough **102** is made of a material that has a predetermined modulus.” (*Id.*, 2:50-53, 3:22-23.) “The modulus can be predetermined to match the compliance required to reposition the teeth,” and this is “preferably” a modulus range between “about 0.8 GPa to 1.5 GPa.” (*Id.*, 3:28-33.)

Chen further discloses that the layering geometry for the hard and soft layers, including two outer layers 134 and four or three inner layers 132:

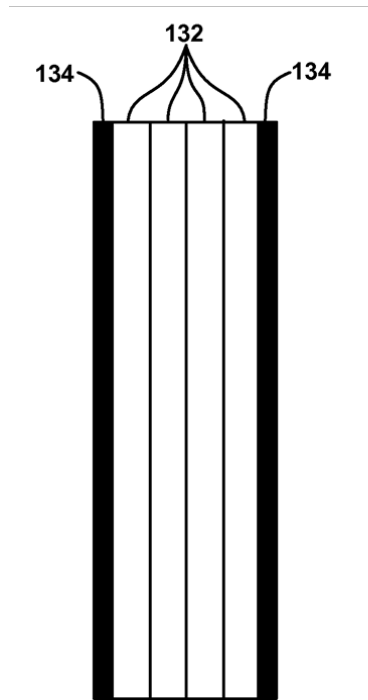


FIG. 4A

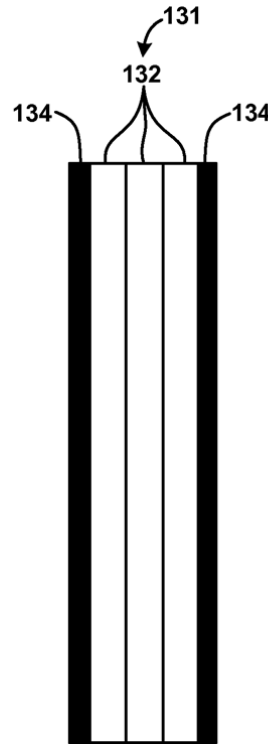


FIG. 4B

(*Id.*, 5:15-25, Figs. 4A, 4B.) Chen explains that “the layers may be formed in various orientations and configurations to suit the modulus and application requirements” and that “the layers may be formed by any process, such as thermoforming or similar process, such as co-extrusion, lamination, or any other process where layers are

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formed.” (*Id.*, 5:25-35.)

10. Stewart [Ex.1130]

Stewart is an international patent application (WO2013/130552) entitled “Dental Products and Procedures.” (Ex.1130.) Stewart published on September 6, 2013, and qualifies as prior art under § 102(a).

Stewart discloses appliances of polymeric “shells” made by thermoforming polymeric sheets that can “hav[e] two or more layers of different polymeric compositions.” (*Id.*, 2:10-12, 3:15-18, 12:26-30, 13:19-20, 15:9-12, 19:17-20.) Stewart teaches that “[i]n orthodontic procedures, the objective is to change the relative positions of two or more teeth” and for an “orthodontic appliance, it is desirable to use a polymeric sheet which, before being thermoformed . . . [has] a flexural modulus between 1000 and 3000 MPa.” (*Id.*, 1:12-13, 20:21-24.)

A. Ground 1: Obviousness of Claim 1 Based on Hinz in view of Durasoft (TPU/PC) Data Sheet, Durasoft (TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet

1. Motivation to Combine and Reasonable Expectation of Success

Hinz, Durasoft (TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet are each for the same specific application: construction of thermoformed dental splints. (Ex.1102, ¶118.) A POSA would have been motivated to construct pre-thermoformed multilayer hard-soft-hard films of Hinz using the polymeric materials disclosed in the Durasoft (TPU/PC) Data

Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S Data Sheet for thermoforming into Hinz's hard-soft-hard dental splints, based on the express disclosures within the references. (*Id.*) Specifically, a POSA would have been motivated to use TPU-Durasoft as the soft inner layer with two hard outer layers of either PC-Durasoft, PETG-Durasoft, or Copolyester-Imprelon in pre-thermoformed hard-soft-hard films to create Hinz's hard-soft-hard dental splints. (*Id.*)

Hinz discloses dental splints with a hard-soft-hard layer configuration. (*E.g.*, Ex.1117, 3:68-70 (“two hard outer layers and having a soft inner layer”).) A POSA would have been motivated to select the polymers and associated properties of the hard and soft polymeric materials of Durasoft and the hard Imprelon S polymer within Hinz's hard-soft-hard dental splints because Hinz expressly teaches their specific use within his splints. (Ex.1102, ¶119; Ex.1117, 7:206-207 (“a hard layer and a soft layer having the trade name DURASOFT® from Scheu-Dental GmbH.”), 6:185-187 (“IMPRELON® ‘S’ from Scheu-Dental GmbH can be used”).) As a consistent and reciprocal motivation, Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and Imprelon S (Copolyester) Data Sheet each disclose the use of the materials for the “[m]anufacture of thermoformed dental splints.” (*Id.*; Ex.1119; Ex. 1120; Ex.1123.)

A POSA would have recognized that the polymers in the Scheu-Dental materials are the same preferred polymers for the hard and soft layers taught by Hinz,

providing further motivation to use them to construct Hinz's hard-soft-hard dental splints. (Ex.1102, ¶120.) Thus, Hinz expressly discloses a preferred embodiment of the hard-soft-hard composite splint having a "soft inner layer" made from thermoplastic polyurethane (TPU), as well as the benefits obtained from selecting this soft material:

[A] deep-drawing film having a soft layer made of a thermoplastic polyurethane (TPU) . . . result[s] in a sufficiently high elasticity of the dental splint according to the invention, so that breakage of the dental splint during insertion and removal and while it is worn does not have to be a concern.

(Ex.1117, 3:89-93.) Accordingly, a POSA would have recognized and been motivated to use TPU-Durasoft as the soft inner TPU layer of Hinz's hard-soft-hard dental splints.¹⁵ (Ex.1102, ¶120.)

¹⁵ At least by 2016, a POSA would have understood that Scheu Dental had introduced a new version of Durasoft, which substituted a PETG polymer for the hard layer in lieu of the earlier PC polymer. (Ex.1102, ¶94; Ex.1121.)

Hinz further teaches that the “hard outer layers” can be made of “a polyester plastic, preferably a polycarbonate (PC) or a polyethylene terephthalate (PET),” and that these hard outer layers provide benefits to the hard-soft-hard splint:

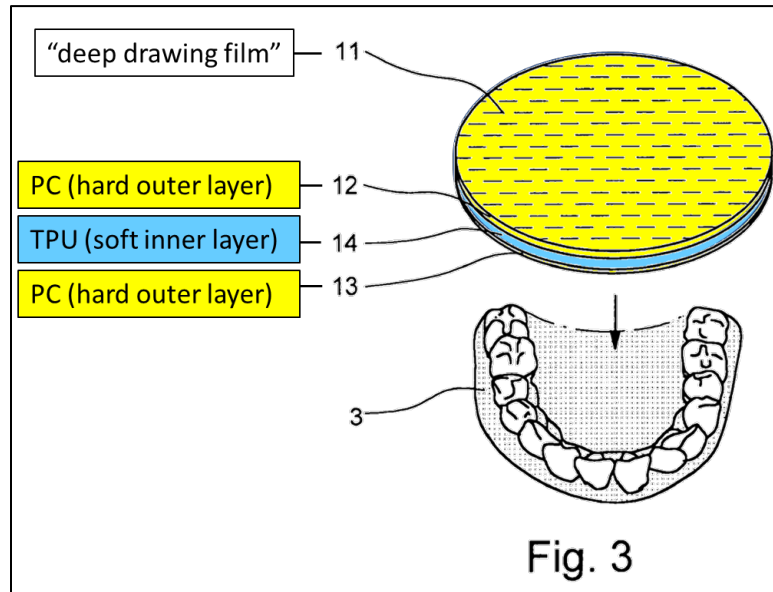
[A] deep-drawing film having a hard layer made of a polyester plastic, preferably made of polycarbonate (PC) or polyethylene terephthalate (PET), is selected to produce the dental splint. The external hard layers made of the polyester plastic in the layered composite are stable against discoloration and enable a crystal-clear appearance of the dental splint according to the invention. In addition, the hard layer is sufficiently break-resistant . . .

(Ex.1117, 3:80-86.)

Hinz also teaches that “[t]he dental splint according to the invention preferably has hard layers made of the same plastic material.” (*Id.*, 3:86-87.) Accordingly, a POSA would have been motivated to use either the PC-Durasoft, PETG-Durasoft, or Copolyester-Imprelon polymers as the two hard outer layers of Hinz’s hard-soft-hard dental splints. (Ex.1102, ¶122.)

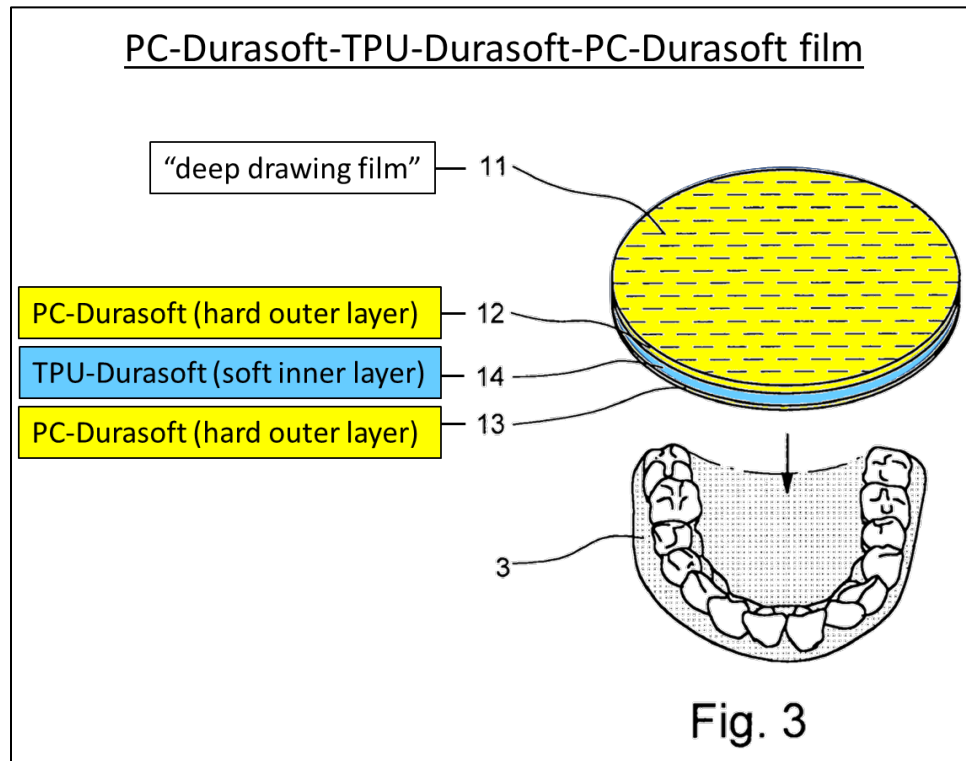
Hinz discloses making a hard-soft-hard dental splint using a pre-thermoformed multilayer hard-soft-hard film in Figure 3. (Ex.1117, 6:173-175, 7:240- Fig. 3.) In that embodiment, Hinz teaches the use of hard PC and soft TPU

polymers in a three-layer pre-thermoformed PC-TPU-PC (hard-soft-hard) film for creating a thermoformed three-layer hard-soft-hard dental splint:



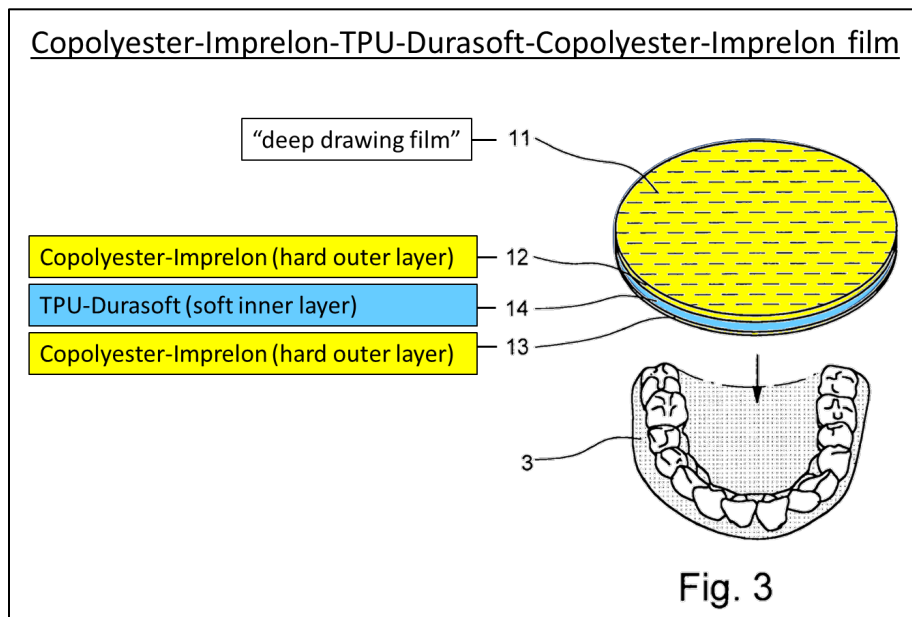
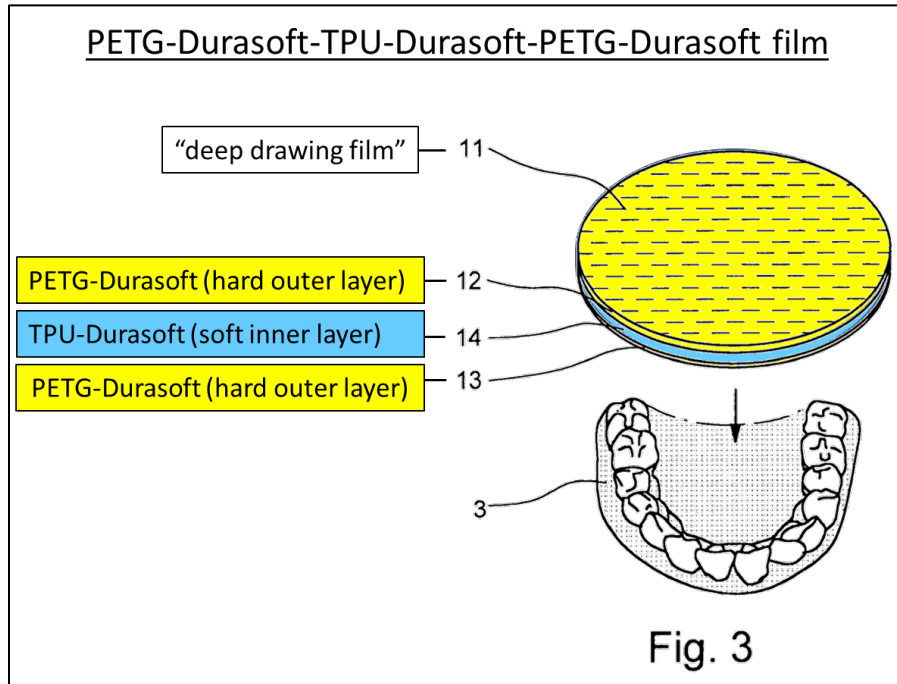
(Ex.1117, 8:240-244, Fig. 3 (annotated per Ex.1102, ¶123).)

A POSA would have recognized the suitability of the hard PC-Durasoft and soft TPU-Durasoft polymeric materials for the hard-soft-hard pre-thermoformed film of Hinz's Figure 3 embodiment because the embodiment expressly teaches a pre-thermoformed hard PC polymer for the outer layers and a soft TPU polymer for the inner layer. (Ex.1102 ¶124.) Thus, a POSA would have found it obvious to construct the following PC-Durasoft-TPU-Durasoft-PC-Durasoft film:



(*Id.*)

A POSA would also have understood that Hinz’s hard-soft-hard dental splints could be created according to Hinz Figure 3 using PETG-Durasoft or Copolyester-Imprelon polymers as the hard layers because they are disclosed by Hinz as alternative preferred polymers. (Ex.1102 ¶125; *e.g.*, Ex.1117, 3:80-81.) Thus, a POSA would also have found it obvious to construct pre-thermoformed hard-soft-hard PETG-Durasoft-TPU-Durasoft-PETG-Durasoft and/or Copolyester-Imprelon-TPU-Durasoft-Copolyester-Imprelon films, as follows:



(*Id.*)

A POSA would have found it routine and would have reasonably expected to be able to successfully construct pre-thermoformed three-layer hard-soft-hard films with TPU-Durasoft as the soft inner layer and two hard outer layers of either PC-

Durasoft, PETG-Durasoft, or Copolyester-Imprelon. (Ex.1102, ¶126.) First, Hinz discloses the Figure 3 embodiment of a pre-thermoformed film with a three-layer hard-soft-hard configuration. (Ex.1117, 8:240-244.) Hinz also discloses the use of TPU, polyester, PC, and PET polymers as preferred embodiments “of the invention,” and a POSA would have reasonably expected to be able to successfully utilize these preferred polymers within the embodiment of Figure 3. (*Id.*; Ex.1117, 3:80-93.)

Second, TPU, PC, PETG, and copolyesters were common, regularly used thermoplastic polymers for the formation of thermoformed multilayer dental appliances. (*E.g.*, Li, 5:34-46 , 6:27-34.) Indeed, the '263 patent admits that the prior art disclosed dental appliances made from “[e]xisting materials and products [] constructed from single layer materials, bi-layer materials, or tri-layer materials[.]” (Ex.1101, 1:31-33.) Selecting from amongst existing materials advertised for dental applications involves little inventive effort. (Ex.1102, ¶127.)

Third, the fact that Durasoft was already available as a two-layer “composite plate” of hard PC-Durasoft or PETG-Durasoft and soft TPU-Durasoft would have led a POSA to reasonably expect that the same hard PC-Durasoft and PETG materials could be readily formed onto both sides of the TPU-Durasoft to make a pre-thermoformed three-layer hard-soft-hard film. (Ex.1102, ¶128.) The prior art also disclosed multilayer plastic films with layers of copolyester bonded with TPU, further demonstrating a POSA’s reasonable expectation in successfully making a

pre-thermoformed Copolyester-Imprelon-TPU-Durasoft-Copolyester Imprelon film. (*Id.*)

Fourth, Hinz discloses that the films making up the multilayer dental splint “are ***bonded to one another*** by deep-drawing.” (Ex.1117, 2:61-3:73.) A POSA would have therefore understood that pre-thermoformed multilayer hard-soft-hard films with the TPU, PC, PETG, and copolyester materials of this Ground could be made by any number of different known methods utilizing the application of heat and/or pressure, for example, co-extrusion or lamination. (Ex.1102, ¶129.) The ’263 patent admits these are methods known to a POSA for making multilayer polymeric sheets. (Ex.1101, 15:17-20.)

A POSA would therefore have readily understood that TPU, PC, PETG, and Copolyester could be obtained or synthesized with the same properties as TPU-Durasoft, PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon and then used to construct the pre-thermoformed hard-soft-hard films taught by Hinz. (Ex.1102, ¶130.) Accordingly, a POSA would have had a reasonable expectation of success in utilizing TPU-Durasoft, PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon disclosed in the Scheu Dental datasheets to create the pre-thermoformed hard-soft-hard multilayer films taught by Hinz, and this obvious hard-soft-hard film satisfies all elements of claim 1. (*Id.*)

2. Independent Claim 1

Claim 1 is obvious over Hinz in view of Durasoft (TPU/PC) Data Sheet.

(a) Claim 1[pre]: “[a] polymeric sheet composition, comprising:”

If the preamble is limiting, it is disclosed by Hinz. (Ex.1102, ¶132.) Hinz discloses “a deep-drawing film 11 which has a three-layer structure” with a soft inner TPU layer in Figure 3. (Ex.1117, 8:240-244, Fig. 3.) A POSA would have recognized that Hinz embodiment Fig. 3 refers to a PC polymer for the hard outer layers, but would also recognize that these layers alternatively can be made of polyester or PET. (Ex.1102, ¶132.)

(b) Claim 1[a]: “at least two outer layers A and C and an elastomeric inner layer B”

1[a] is disclosed by Hinz’s hard-soft-hard pre-thermoformed film, and in combination with hard outer layers of either PC-Durasoft, PETG-Durasoft, or Copolyester-Imprelon and a soft inner layer of TPU-Durasoft. (Ex.1102, ¶132.) Hinz Figure 3 depicts a film with “a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Ex.1117, 8:240-243.) Hinz’s “two outer hard layers 12, 13 made of polycarbonate,” including specifically the obvious combination of Hinz using hard outer layers made of PC-Durasoft and, alternatively, PETG-Durasoft, or Copolyester-Imprelon, are “at least two outer layers A and C.”

(Ex.1102, ¶134.)

Hinz also discloses “an elastomeric inner layer B” in the form of “a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Ex.1117, 8:242-243.) Hinz describes this “internal soft layer” as providing a dental splint with “increased elasticity” caused by “the internal soft layer having higher elasticity.” (*Id.*, 3:73-76.) Hinz also refers to the polyurethane used for the “soft layer” as a “thermoplastic polyurethane (TPU),” and explains that use of this material “result[s] in a sufficiently high elasticity of the dental splint according to the invention....” (*Id.*, 3:89-91; *see also* 9:278, 10:323.) A POSA would have found it obvious that Hinz’s “soft layer 14 made of polyurethane” is referring to a soft, elastomeric polyurethane and therefore satisfies “an elastomeric inner layer B.” (Ex.1102, ¶135; Ex.1101, 5:20-21.)

A POSA also would have understood that TPU-Durasoft disclosed in Durasoft (TPU/PC) Data Sheet was a polyurethane elastomer. (Ex.1102, ¶136.) TPU-Durasoft has an elastic modulus of 172 MPa and a Shore hardness of A88 and D33. (Ex.1119.) A POSA would understand that the obvious use of TPU-Durasoft as the inner layer in the three-layer embodiment of Hinz is an “elastomeric inner layer B.” (*Id.*)

- (c) **Claim 1[b]: “wherein one or both of the outer layers A and C individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa”**

Hinz, in combination with each of the hard polymeric materials in the datasheets of this ground disclose 1[b]. (Ex.1102, ¶¶138.) A POSA would have known that PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon are thermoplastic polymers, because the datasheets indicate the materials are thermoformable. (*Id.*) PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon have a listed elastic modulus values of 2,400 MPa, 2,200 MPa, and 1,624 MPa, respectively, each of which falls within the claimed range of “about 1,000 MPa to 2,500 MPa” and, as isotropic materials, would have substantially the same flexural modulus. (*Id.*; Ex.1119; Ex.1121; Ex.1123.)

- (d) **Claim 1[c]: “and the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85”**

Hinz with TPU-Durasoft satisfies 1[c]. (Ex.1102, ¶141.) As in 1[a], a POSA would understand that Hinz’s preferred “soft inner layer” is made of polyurethane and the obvious use of TPU-Durasoft is an “elastomeric inner layer B.” TPU-Durasoft is identified as having a hardness of A88 and D33, which falls within the range of “a hardness from about A80 to D75.” (*Id.*)

Accordingly, Ground 1 renders claim 1 obvious.

B. Ground 2: Obviousness of Claims 2-4 Based on Ground 1 and Sun

Ground 2 relies on the same obvious hard-soft-hard films that render claim 1 obvious under Ground 1, and includes the teachings regarding the expressly disclosed flexural modulus values for the dental splint of Sun.

1. Motivation to Combine and Reasonable Expectation of Success

Like Hinz and the data sheets of Ground 1, Sun also “relates to method of making dental night guards and splints.” (Ex.1124, [0002], [0003].) A POSA would therefore have been motivated to look to the interrelated teachings of Hinz and Sun to understand the desirable mechanical properties for a dental splint, and would apply those interrelated teachings in the context of the obvious multilayer hard-soft-hard dental splints of Hinz constructed with the polymeric materials of the Scheu Dental data sheets of Ground 1. (Ex.1102, ¶144.) *See Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1003 (Fed. Cir. 2016) (a rationale to combine can arise from “interrelated teachings of multiple patents”) (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)).

Sun explains that “[t]he flexibility and softness of these dental night guards and dental splints enables them to be readily removable from a patient’s mouth without discomfort to the patient.” (Ex.1124, [0004].) Sun further discloses preferred maximum and minimum values for the flexural modulus of such dental splints: “a flexural modulus in order of increasing preference of less than [2,413],

[2,068], [1,723], [1,378] and [1,172 MPa]. . . at 23° C” and “a flexural modulus in order of increasing preference of at least [69]; [138]; or [345 MPa].” (Ex.1124, [0012]-[0013]; Ex.1102, ¶145.)

A POSA would have been motivated to combine Sun with the teachings of Hinz (per Ground 1), as both are directed to the interrelated construction of dental splints with “improved mechanical properties” that “may be inserted into and removed from patients easily.” (Ex.1102, ¶146; Ex.1117, 2:54-59; Ex.1124, [0004].) Although Sun teaches a different polymeric composition for forming a dental splint than the multilayer hard-soft-hard splints of Hinz, the final appliances remain the same—a thermoformed dental splint. (*Id.*) A POSA would therefore look to the teachings of the flexural modulus of the dental splints of Sun as guidance for achieving the mechanical properties of a dental splint that has “better insertion and removal behavior due to increased elasticity”. (*Id.*; Ex.1117, 3:74-76.)

A POSA would have reasonably anticipated success in forming the films and dental splints taught by Hinz to achieve the desired flexural modulus values of Sun with the specific multilayer configurations taught by Hinz in view of the Scheu Dental polymeric materials. (Ex.1102, ¶147.) As noted in Ground 1, Hinz expressly discloses hard polymer outer layers (PETG-Durasoft or Copolyester-Imprelon) and a soft elastomeric TPU-Durasoft from Scheu Dental, and Hinz further discloses preferred thicknesses for the layers within the hard-soft-hard films and dental splints.

(*Id.*) As set forth in Ground 1, a POSA would readily understand how to follow the teachings of Hinz to make multilayer hard-soft-hard films and dental splints with the TPU-Durasoft, PETG-Durasoft, and Copolyester-Imprelon polymers, and would have reasonably expected success in achieving the preferred flexural modulus values taught by Sun. (*Id.*)

2. Dependent Claim 2

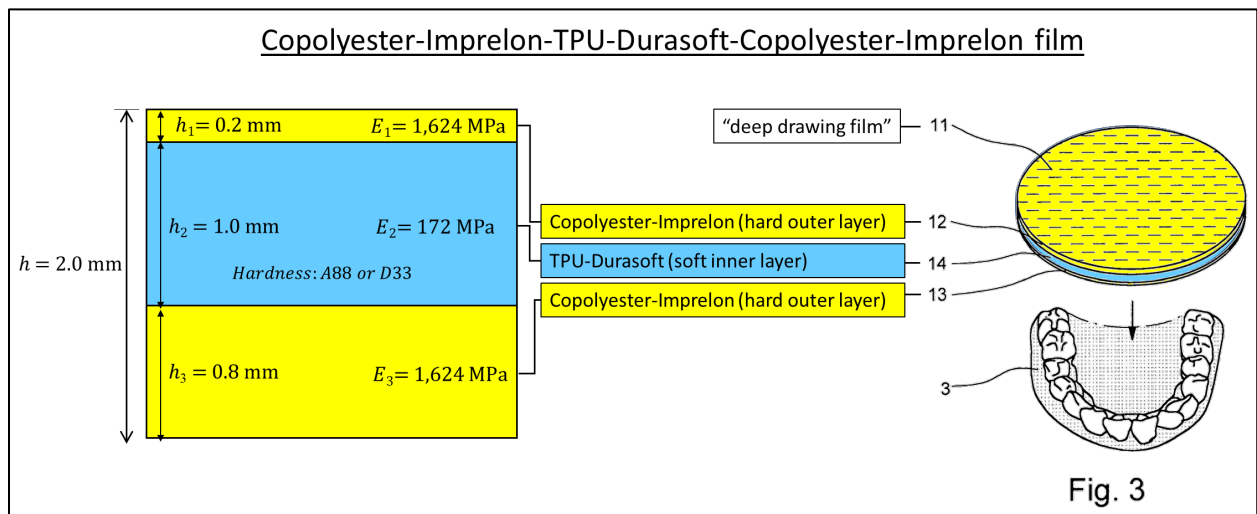
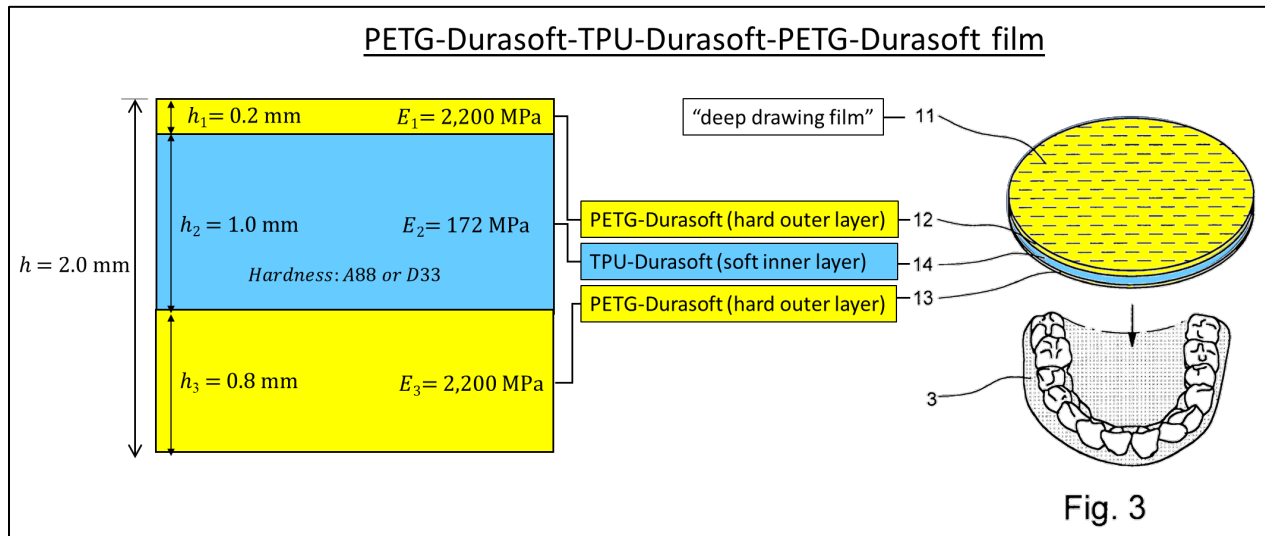
Claim 2 recites “[t]he polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa.” Claim 1 is obvious under Ground 1. The combination of Ground 1 with Sun under this Ground discloses and renders obvious claim 2. (Ex.1102, ¶148.)

Sun discloses a most-preferred *minimum* flexural modulus for a dental splint of 345 MPa. (Ex.1124, [0013]; Ex.1102, ¶149.) Sun also discloses a most-preferred *maximum* flexural modulus for a dental splint of 1,172 MPa, a second-most-preferred maximum flexural modulus for a dental splint of 1,378 MPa, and a third-most-preferred flexural modulus for a dental splint of 1,723 MPa. (Ex.1124, [0013]; Ex.1102, ¶149.) Thus, Sun discloses a most-preferred flexural modulus range of 345-1,172 MPa, a second-most-preferred range of 345-1,378 MPa, and a third-most-preferred range of 345-1,723 MPa. (Ex.1102, ¶149.) These preferred ranges have substantial overlap and render obvious the “flexural modulus of from 500 MPa to

1,500 MPa” limitation of claim 2. (*Id.*) *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art.”).

Hinz discloses a hard-soft-hard dental splint wherein the thickness of one outer hard layer is “in particular of less than 0.2 mm,” the soft layer has a thickness of “in particular of less than 1.0 mm[,]” and the other hard outer later has a thickness of “in particular of less than 0.8 mm.” (Ex.1117, 10:317-11:333 (claims 11-14).) Claims 11-14 of Hinz disclose a dental splint with a “three-layer structure” having two outer hard layers “made of a polyester plastic, preferably made of . . . polyethylene terephthalate (PET)” and an inner soft layer “made of a thermoplastic polyurethane (TPU),” which, in conjunction with Hinz’s teachings under Ground 1, would have directed a POSA to the selection of either the PETG-Durasoft or Copolyester-Imprelon for the two hard outer layers and TPU-Durasoft as the inner soft layer. (Ex.1102, ¶150) Hinz also discloses that “it is obvious that the layer thickness of the [pre-thermoformed] deep-drawing film is reduced upon deep drawing [thermoforming].” (*Id.*, 4:116-119.) A POSA would recognize that Hinz expressly discloses a pre-thermoformed film that includes an outer hard layer with a thickness of 0.2 mm, an inner soft layer with thickness of 1.0 mm, and an outer hard layer with a thickness of 0.8 mm, 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,”

respectively. (Ex.1102, ¶151.) These obvious constructions of a pre-thermoformed hard-soft-hard film according to Hinz, utilizing the expressly suggested PETG-Durasoft or Copolyester-Imprelon hard polymer layers and TPU-Durasoft soft inner layers for making a thermoformed dental splint, are depicted as follows:



(*Id.*)

The combined thickness for the hard-soft-hard “A, B and C layers” of the foregoing Hinz embodiments is 2.0 mm, satisfying claim 2’s combined thickness

limitation of “from 250 microns to 2,000 microns”. (Ex.1102, ¶152.) The calculated flexural modulus of the sheet with PETG-Durasoft hard outer layers is 1,439 MPa, inside Sun’s third-most-preferred range, and the sheet with Copolyester-Imprelon is 1,088 MPa, inside Sun’s most preferred range. (*Id.*) Accordingly, a POSA would have recognized that dental splints exhibiting the flexural modulus of claim 2 could be easily achieved through hard-soft-hard films of Hinz. (*Id.*)

Hinz also discloses preferred multilayer hard-soft-hard films wherein the hard layers “have a layer thickness . . . in particular of 0.2 to 0.5 mm” and “[t]he soft layer can have a layer thickness . . . in particular of 1.0 to 1.3 mm.” (Ex.1117, 4:112-114 *see also* Ex.1117, 9:285-10:294 (claims 5 and 6).) “It is obvious that all intermediate values of the above-mentioned intervals are disclosed, even if this is not described in detail.” (*Id.*, 4:114-117.) Thus, Hinz further teaches that the layer thickness for the hard-soft-hard films can be from 0.2-0.5 mm for the hard layers and 1.0-1.3 mm for the soft inner layer, resulting in films with combined thickness from 1.4-2.3 mm. (Ex.1102, ¶153.) The combined thickness of the layers taught by Hinz therefore render obvious claim 2’s “combined thickness of from 250 microns to 2,000 microns,” in addition to the above described embodiment of Hinz. (*Id.*) *In re Peterson*, 315 F.3d at 1329.

A POSA seeking to achieve the preferred flexural modulus values of Sun would have known that individual layer thickness and elastic modulus are the result-

effective variables for the overall flexural modulus of a multilayer film. (Ex.1102, ¶154.) Accordingly, a POSA would have known that optimizing the overall flexural modulus of Hinz's hard-soft hard films to achieve Sun's most-preferred flexural modulus range of 345-1,172 MPa or second-most-preferred flexural modulus range of 345-1,378 MPa, could be achieved by modifying the layer thickness within Hinz's thickness ranges and/or selecting polymeric materials with different elastic modulus values. (*Id.*) Accordingly, a person following Hinz's suggestion to utilize the Scheu-Dental materials (with their specific elastic modulus values) of Ground 1 would have known that the flexural modulus of the resulting hard-soft-hard films made from them could be optimized to achieve Sun's preferred flexural modulus values by modifying layer thickness. (*Id.*)

Furthermore, since a POSA would have recognized that the elastic modulus value of 2,200 MPa for PETG-Durasoft and 1,624 MPa for Copolyester-Imprelon are higher than the more preferred ranges for flexural modulus taught by Sun (e.g., 345-1,172 MPa (most-preferred) or 345-1,378 MPa (second-most-preferred)), a POSA would have recognized that relatively thinner layers of these hard materials and a relatively thicker layer of the soft inner layer would result in hard-soft-hard films with flexural modulus values leading to Sun's preferred disclosed values. (Ex.1102, ¶155.) That is, a POSA following Hinz's teaching that the hard layers "have a layer thickness . . . in particular of 0.2 to 0.5 mm" and "[t]he soft layer can

have a layer thickness . . . in particular of 1.0 to 1.3 mm,” would have recognized that selecting hard layers with 0.2 mm thickness and a soft layer of 1.3 mm thickness best optimizes the overall flexural modulus of the hard-soft-hard film according to the teachings of Sun. (*Id.*) Indeed, these layer thicknesses include in films with combined layer thickness of 1.7 mm and overall flexural modulus values of 1,293 MPa and 1,088 MPa when using hard layers of PETG-Durasoft or Copolyester-Imprelon, respectively, and fall within the most-preferred and second-most-preferred values for flexural modulus taught by Sun. (*Id.*) These obvious hard-soft-hard films also satisfy and render obvious the limitations of dependent claim 2.

3. Dependent Claim 3

Claim 3 recites: “The polymeric sheet composition of claim 2, wherein the outer layers A and C comprise one or more of a polyester, a co-polyester” Hinz discloses “a hard layer made of a polyester plastic, preferably made of . . . polyethylene terephthalate (PET).” (Ex.1117, 3:80-93.) As set forth above, the claimed “outer layers A and C” of Ground 2 are either PETG-Durasoft or Copolyester-Imprelon. PETG-Durasoft is identified as “polyethylene terephthalate glycol copolyester” and Copolyester-Imprelon is a copolyester, both of which satisfy claim 3. (Ex.1121; Ex.1123; Ex.1102, ¶157.)

4. Dependent Claim 4

Claim 4 recites: “The polymeric sheet composition of claim 2, wherein the inner layer B comprises one or more of a polyurethane elastomer” Hinz teaches “a soft layer made of a thermoplastic polyurethane (TPU)[,]” (Ex.1117, 3:89-90), and TPU-Durasoft is a thermoplastic polyurethane that a POSA would know is a “polyurethane elastomer.” (Ex.1102, ¶158.)

C. Ground 3: Obviousness of Claims 7 and 31 Based on Ground 2 further in view of Handbook of Thermoplastics

Ground 3 relies on Ground 2 further in view of Kannan.

5. Dependent Claim 7

Claim 7 recites: “[t]he polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a co-polyester having: (a) a dicarboxylic acid component and (b) a diol component, wherein the co-polyester exhibits a glass transition temperature (T_g) from 80° C to 150° C.”

The PETG-Durasoft outer layers A and C under Ground 2 are a “polyethylene terephthalate glycol copolyester.” (Ex.1121.) A POSA would have known that this PETG copolyester, as described in Kannan, is synthesized from monomers of terephthalic acid (TPA), which is a dicarboxylic acid component, and the diols cyclohexanedimethanol (CHDM) and ethylene glycol (EG). (Ex.1102, ¶161; Ex.1125, 333; *see also* Ex.1131, 538 (Table 20.1), 527.) A POSA would have found it obvious from the disclosure of Kannan that PETG has a glass transition

temperature of 81° C. (*Id.*; Ex.1125, 334 (Table 9.7); Ex.1132, 1096.) Thus, the obvious use of hard outer layers made of PETG-Durasoft within the hard-soft-hard films taught by Hinz satisfies and renders obvious claim 7.

6. Claim 31

Independent claim 31 is substantively identical to the combined limitations of challenged claim 7. (Ex.1102, ¶162.) Accordingly, for the same reasons discussed for claims 1, 2, and 7 above, Ground 3 also renders claim 31 obvious. (*Id.*)

D. Ground 4: Obviousness of Claim 11 Based on Li, Boronkay, and Chen

The combination of Li, Boronkay, and Chen discloses and renders obvious at least a five-layer polymeric sheet with a hard-soft-hard-soft-hard layering configuration that satisfies all elements of claims 11-14, 16, and 18.

1. Motivation to Combine

Li, Boronkay, and Chen are in the same field—multilayered polymeric dental aligners. (Ex.1102, ¶164; *see, e.g.*, Ex.1127, 1:6-8; Ex.1128, [0064], [00107], [00119]; Ex.1129, 3:45-52, 5:15-35.) They are each assigned to the same entity—Align Technologies—and each expressly refers to and/or incorporates by reference Align’s dental aligner developments. (*Id.*; *see, e.g.*, Li, 1:18-28, 4:8-15; Ex.1128, [0088]; Chen. 2:60-3:3.) Li, Boronkay, and Chen include overlapping co-inventors. (*Id.*) They each disclose the use of the combination of hard polymer layers and soft polymer layers within multilayer aligners. (*Id.*; *see, e.g.*, Li 5:12-6:59, Boronkay

[0098]-[0099], [00108], [00176]-[00177], Chen, 4:31-42, 5:51-53) Considering this substantial overlap, a POSA would have understood that Li, Boronkay, and Chen disclose interrelated teachings related to the creation of dental aligners that reasonably would have been combined in predictable ways as of the earliest effective filing date of the '263 patent. (*Id.*) *Unwired Planet*, 841 F.3d at 1003.

A POSA would have understood that Li, Boronkay, and Chen disclose various improvements for a multilayer polymeric dental aligner. (Ex.1102, ¶165.) Generally, aligners are plastic trays containing receptacles for a patient's teeth that are worn in sequence to move the teeth. (*E.g.*, Chen, 2:33-45.) The mismatch between the current position of a given tooth and the tray receptacle can cause a repositioning on the tooth that urges it on a path to a desired position. (*E.g.*, Chen, 2:50-53; Ex.1127, 1:36-41.) Considerations relevant to aligners accordingly can include, *inter alia*, the repositioning force generated by the tray materials. (*E.g.*, Li, 1:42-2:3, 3:5-19.)

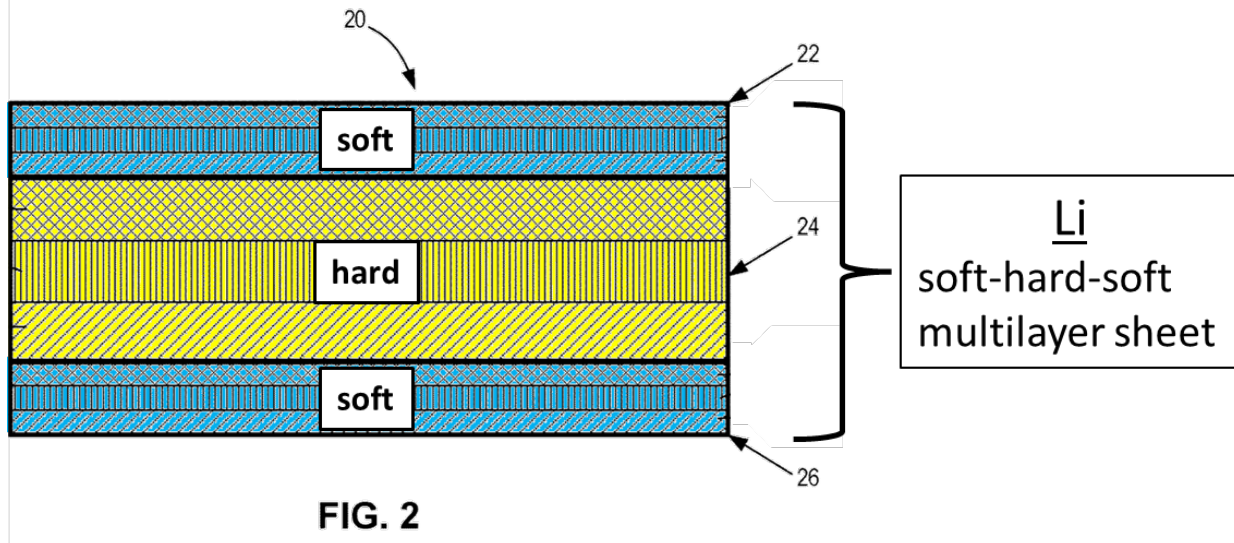
For instance, Chen discloses a dental aligner that may include a plurality of polymeric layers. (Ex.1129, 3:45-49, 5:63-64, 6:1-2.) Chen further discloses multilayer aligners with soft and hard layering geometries that include two hard outer layers and a variable number of inner layers, and explains that “[t]he layers may be formed in various orientations and configurations to suit the modulus and application requirements.” (Ex.1129, 5:29-31; *see also* Chen, 5:15-35, 6:2-4 (“The

inner and outer layers may have variable thickness . . . depending on the modulus requirements.”), 6:13-16.)

Chen further teaches that the dental aligner “is made of a material that has a predetermined modulus” and that “[t]he modulus can be predetermined to match the compliance required to reposition the teeth.” (Ex.1129, 3:2-31.) Chen teaches that a dental aligner should have a modulus of “*preferably about 0.8 GPa to 1.5 GPa.*” (Ex.1129, 3:31-33.) This equates to 800-1,500 MPa. (Ex.1102, ¶165.)

Li discloses a multilayer sheet with a hard-soft-hard configuration for making improved durability multilayer dental aligners. (Ex.1127, 5:1-11; *see also* Li, 3:5-19).) Li teaches additional benefits of the soft-hard-soft layering configuration, noting that “[t]he multilayer dental appliances of the present invention, among many aspects, provide, for example, improved material performance, stress relaxation properties and longer working range” and “reducing the need for midcourse corrections during treatment and the number of aligners used for a given treatment” (Ex.1127, 1:62-2:3.) A POSA would therefore have been motivated to explore Li’s disclosed soft-hard-soft multilayer sheet to achieve dental aligners with these benefits. (Ex.1102, ¶166.)

Li’s Figure 2 shows the beneficial soft-hard-soft multilayer sheet wherein the multilayer sheet 20 can include a three layer structure: a hard polymer layer 24 disposed between two soft polymer layers 22, 26:



(Ex.1127, 5:12-17, Fig 2 (annotated per Ex.1102, ¶167).) Li further discloses “a method of making a dental appliance for positioning a patient's teeth”—i.e., an “aligner”—that includes providing a multilayer sheet and thermoforming the sheet over a jaw model:

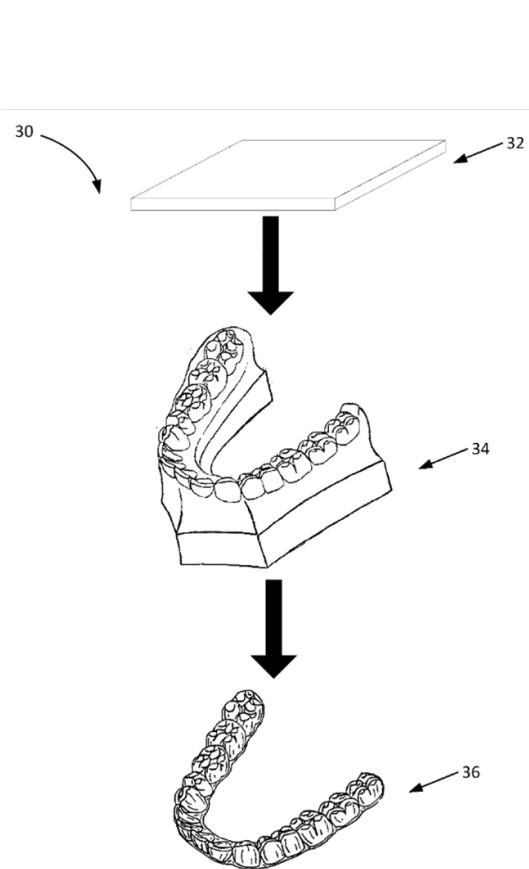


FIG. 3

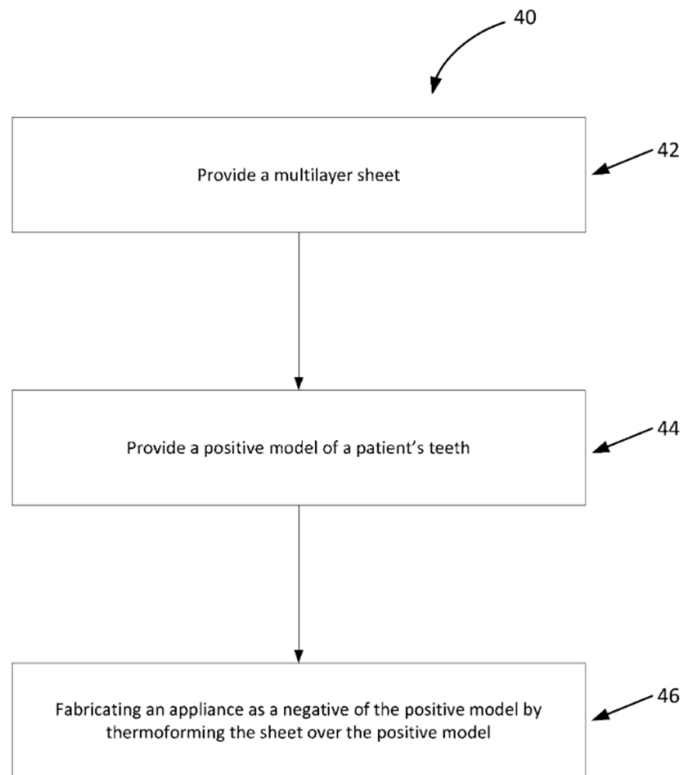


FIG. 4

(Ex.1127, 7:4-20, 7:36-50, Figs. 3-4.)

A POSA would have recognized from the interrelated teachings of Li and Chen that Li's soft-hard-soft multilayer sheet is a configuration with beneficial features for dental aligners (e.g., improved durability, mechanical properties, and material performance) and, according to Chen, that Li's soft-hard-soft sheet should "suit the modulus and application requirements" for a dental aligner. (Ex.1102, ¶169; Ex.1129, 5:29-31, 3:22-33.) A POSA would have followed Chen's teaching of the preferred predetermined modulus for a dental aligner, and would have been

motivated to construct Li's soft-hard-soft multilayer sheets such that they had a predetermined preferred modulus of about 800-1,500 MPa for repositioning a patient's teeth. (*Id.*)

Boronkay expressly teaches further improvement of the properties of a multilayer dental aligner by utilizing stiff/hard "innermost" and "outermost" layers that serve "to protect the appliance, against abrasion, wear, staining, biological interactions (e.g., reduce plaque or biological growth), and the like." (Ex.1128, [00144]-[00145]; *see also* Boronkay, [00135]; Ex.1102, ¶170.)

A POSA would have understood that the addition of Boronkay's hard protective coating layers outside Li's soft-hard-soft multilayer aligner would enhance and bolster the appliance's durability and wear resistance while adding the additional benefit of improved stain resistance because Boronkay teaches that such additional layers further serve "to protect the appliance, against abrasion, wear, staining, biological interactions . . ." (Ex.1102, ¶171; Ex.1128, [00144]-[00145]; *see also* Boronkay, [00135].)

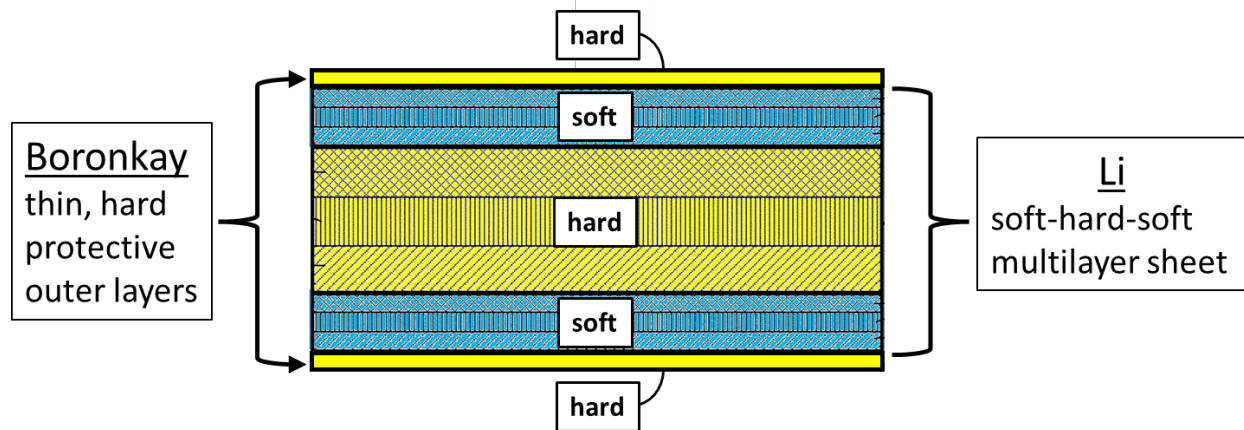
A POSA would not have been dissuaded from applying Boronkay's teaching of relatively thin hard protective layers on the outer sides of the multilayer aligners of Li. (Ex.1102, ¶172.) A POSA would have expected that the benefits of Boronkay's thin and hard protective layers would provide Li's multilayer aligners with enhanced resistance to abrasion, wear, staining, and biological interactions

without negating or substantially contributing to the “overall properties” of the multilayer aligner appliance taught by Li. (*Id.*; Ex.1128, [00144]-[00145].)

For instance, a POSA would understand that the “improved elastic properties” of Li’s multilayer aligners would remain even with the addition of Boronkay’s thin, hard protective layers since such an appliance would maintain the elasticity of Li’s soft polymeric layers. (*Id.*) Boronkay teaches that the protective or stain resistant layers should be “thinner” than the other layers “in order to reduce the contributions of the outermost/innermost layer to the overall properties of the appliance.” (Ex.1128, [00134], [00144], [00145].) A POSA would understand that Boronkay’s protective, stain-resistant layers should be relatively thin, so as to provide the stated benefits while only minimally changing the “overall properties of the appliance.” (Ex.1102, ¶173.) Plus, Boronkay teaches that “multiple protective layers may be used. For example, a stain resistant protective layer may be formed over a wear resistant protective layer.” (Ex.1128, [00138].) A POSA would therefore have understood that the protective layers can provide additional features to an aligner, such as stain resistance, without detracting from the orthodontic efficacy of the appliance. (Ex.1102, ¶¶172-173.)

Based on the foregoing, a POSA would have been motivated from the teaching of Boronkay to add thin, hard protective coating layers to the outer sides of Li’s soft-hard-soft multilayer sheets for making a thermoformed aligner, resulting in

the following overall hard-soft-hard-soft-hard configuration:



(Ex.1102, ¶174.)

2. Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in creating the hard-soft-hard-soft-hard multilayer polymeric sheet according to the combined disclosures and teachings of Li, Boronkay, and Chen. (Ex.1102, ¶¶176-179.)

A POSA would have reasonably expected success because Li discloses the formation of multilayer sheets with hard and soft layers, which is presumptively enabled. (Ex.1127, 5:13-18; 7:8-10.) *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). A POSA would have understood that Li and Boronkay disclose the same polymers for the hard layers (“a polyester, a copolyester, a polycarbonate”) and soft layers (polyurethane elastomer), such that selecting appropriate materials would be routine. (Ex.1102, ¶177; *compare* Li, 5:34-46 and 6:1-9 with Boronkay, [00176] and [00177].) A POSA would therefore have

reasonably expected to be able to successfully form a five layer hard-soft-hard-soft-hard multilayer sheet because Li already indicates that its hard and soft polymeric materials can be formed into multilayer sheets. (*Id.*)

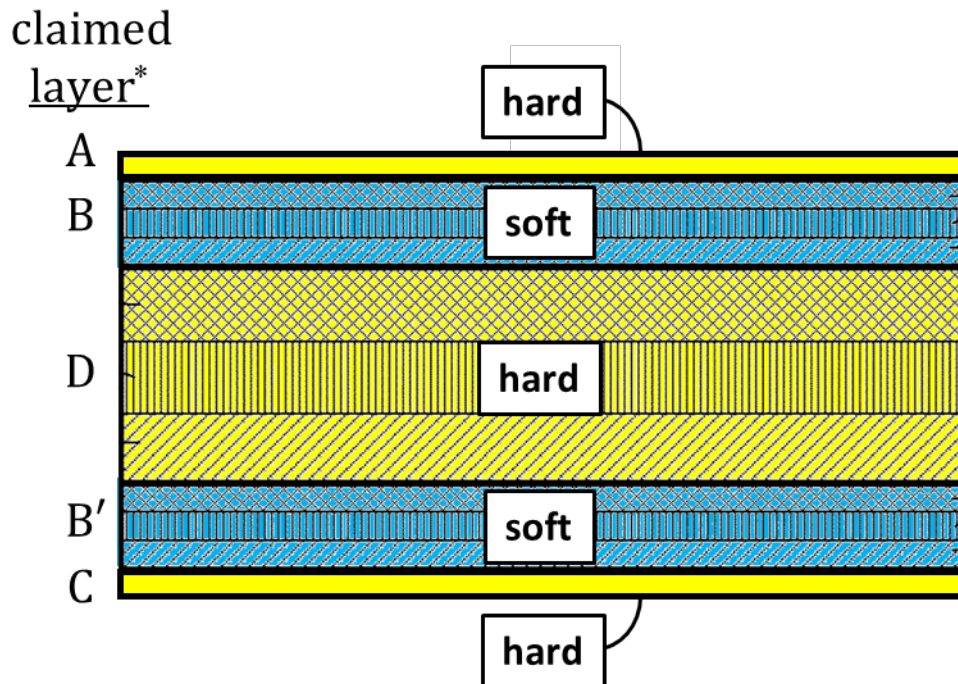
A POSA also would have recognized that Boronkay teaches that “[t]he protective layer can be formed as a material layer or as a coating deposited on the compliant inner structure,” further confirming a reasonable expectation of success. (Ex.1102, ¶178; Ex.1128, [00134].) Accordingly, POSA would have known that adding Boronkay’s suggested thin, hard outer layers to Li’s soft-hard-soft multilayer structure could be achieved using routine methods well known in the art such as, for example, co-extrusion, calendaring, or lamination processes. (*Id.*; *see also, e.g.*, Ex.1133, 64-65, 138; Ex.1134, 25:23-27.) The ’263 patent admits these are methods known to a POSA for making multilayer polymeric sheets. (Ex.1101, 15:15-19.)

A POSA would further have known that the modulus of a multilayer polymeric sheet, similar to the sheet’s flexural modulus, is a function of and can be calculated from the thickness and modulus of the individual layers that make up the polymeric sheet. (Ex.1102, ¶179.) Accordingly, a POSA would have understood that individual layer thickness and individual layer modulus are the result-effective variables of the overall modulus of a multilayer sheet. (*Id.*) A POSA would therefore have been able to optimize the individual layer thicknesses and select polymeric materials with suitable modulus according to the teachings of Li and

Boronkay to achieve configurations that result in hard-soft-hard-soft-hard polymeric sheet within Chen's preferred modulus of 800-1,500 MPa. (*Id.*)

1. Independent Claim 11

As explained in Section IX above and illustrated below, the five-layer hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay satisfies the layer stacking of claim 11 under Patent Owner's positions:



* per Patent Owner's infringement allegations

(Ex.1102, ¶180.) This obvious hard-soft-hard-soft-hard configuration for a multilayer sheet according to the disclosures of Li and Boronkay for layer thicknesses and material properties, designed to achieve the preferred 800-1,500 MPa modulus of Chen, satisfies all elements of claim 11. (*Id.*)

(a) Claim 11[pre]: “[a] polymeric sheet composition comprised of”

If limiting, the preamble is satisfied by the hard-soft-hard-soft-hard sheet taught by the combination of Li and Boronkay. As noted, Li discloses a three-layer soft-hard-soft polymeric sheet and Boronkay discloses the benefits of adding thin, hard outer polymeric layers to this sheet. (Ex.1102, ¶181.) This obvious hard-soft-hard-soft-hard sheet is a “polymeric sheet composition.” (*Id.*)

(b) Claim 11[a]: “at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D”

Under Patent Owner’s interpretation, the obvious hard-soft-hard-soft-hard sheet according to Li and Boronkay satisfies claim element 11[a]. (Ex.1102, ¶182.) Boronkay expressly discloses that the “stiffer and/or harder” protective or stain-resistant outer layers “can have a hardness greater than or equal to about 70 Shore D or about 90 Shore D.” (Ex.1128, [00144]-[00145].) A POSA would recognize that these thin, hard outer layers suggested by Boronkay are “two rigid or hard outer layers A and C.” (Ex.1102, ¶182.)

Li discloses a multilayer sheet with “a hard polymer layer disposed between two soft polymer layers.” (Ex.1127, 7:8-10.) A POSA would recognize that Li’s disclosed “soft polymer layers” are “two soft inner layers B and B” and Li’s “hard polymer layer” is “a rigid or hard inner layer, D” in the context of the hard-soft-hard-soft-hard sheet of this Ground. (Ex.1102, ¶183; Boronkay [00144]-[00145].)

- (c) **Claim 11[b]: “wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and”**

Li discloses that the inner “hard polymer layer,” which corresponds to rigid or hard layer D of claim 11, can have a tensile modulus “greater than about 150,000 psi” (i.e., greater than 1,034 MPa). (Ex.1102, ¶182; Ex.1127, 5:57-63.) While Li does not expressly disclose an upper limit on the modulus of the “hard polymer layer,” a POSA would recognize that there would be an upper limit on the modulus value of Li’s hard inner layer under this Ground imposed by Chen’s preferred 800-1,500 MPa modulus range for the overall sheet. (*Id.*)

In the broadest layer thicknesses disclosed, Li states that the “hard polymer layer can have a thickness in a range from about 400 μm to about 1100 μm ” and the “soft polymer layers can have a thickness in a range from about 25 μm to about 100 μm .” (Ex.1127, 5:21-27.) These thickness ranges teach that the inner “hard” layer of Li’s soft-hard-soft sheet is between about 67-96% of the overall sheet thickness. (Ex.1102, ¶186.) Since Li teaches that the majority of the thickness of the overall sheet is in the “hard” layer, a POSA would understand the modulus of the “hard” layer would be the dominant contributor to the sheet’s overall modulus and that it would contribute at least 67% (and up to 96%) to the overall modulus of Li’s soft-hard-soft sheet. (*Id.*) Consequently, a POSA would have recognized that to obtain

an overall sheet modulus that does not exceed 1,500 MPa—i.e., above Chen’s preferred modulus range of 800-1500 MPa—the maximum modulus of the inner hard layer for *any* combination of Li’s layer thicknesses within a hard-soft-hard-soft-hard multilayer sheet with Boronkay’s thin hard outer layers would necessarily have to be at least less than about 2,250 MPa (i.e., $2,250 \times 0.67 = 1,500$). (*Id.*)

Thus, a POSA would have understood that the obvious combination under this Ground requires Li’s inner “hard polymer layer” to have a modulus of between 1,034-2,250 MPa. (Ex.1102, ¶187.) This range falls entirely within and therefore satisfies the claimed “modulus of from about 1,000 MPa to 2,500 MPa” for rigid or hard layer D. *See In re Peterson*, 315 F.3d at 1329.

Boronkay discloses that the “stiffer and/or harder” protective outer layers, which correspond to hard layers A and C of claim 11 in Ground 3 herein, “can have a hardness greater than or equal to about 70 Shore D or about 90 Shore D.” (Ex.1128, [00144]-[00145].) The ’263 patent discloses that “Shore hardness and modulus are generally correlated and can be converted by approximation if only one value is known by methods described in the art.” (Ex.1101, 6:67-7:2.) Following this teaching, Shore hardness 70D and 90D correspond to converted modulus values of approximately 243 MPa and 2,812 MPa, respectively. (Ex.1102, ¶188.) Accordingly, a POSA would recognize that Boronkay’s teaching of thin, hard outer protective layers with a hardness greater than or equal to about 70D or 90D is

referring to a modulus in the range of approximately 243 MPa to 2,812 MPa, which overlaps the claimed “modulus of from about 1,000 MPa to 2,500 MPa” for rigid or hard layers A and C. (Ex.1102, ¶189.) *See In re Harris*, 409 F.3d at 1341.

Boronkay also teaches that the hard outer protective layers “can have a greater stiffness and/or hardness than the outer shell,” wherein the “outer shell” refers to a “stiff” layer “that generates the force and/or torque” on the teeth by the aligner. (*See* Boronkay, [00144]-[00145], [0008].) A POSA would have recognized that this teaching, under the hard-soft-hard-soft-hard sheet taught by the combination of Li and Boronkay, suggests that Boronkay’s hard protective outer layers should have “greater stiffness and/or hardness” than Li’s “hard” inner layer that generates the force to reposition the teeth. (Ex.1102, ¶190.)

Boronkay therefore teaches that the hard outer protective layers, when applied to the exterior of Li’s soft-hard-soft multilayer sheet, should have a stiffness and/or hardness at least greater than Li’s minimum of 1,034 MPa for the “inner” hard layer (such that the hard outer protective layers are stiffer/harder than Li’s inner hard layer). (Ex.1102, ¶191.) Accordingly, Boronkay’s further teaching in combination with Li would have led a POSA to a modulus for the hard outer protective layers at least greater than 1,034 MPa, which falls within an overall range from 1,034 MPa up to the 2,812 MPa value (of a material with hardness of 90D) that closely overlaps

with and renders obvious the rigid or hard layers A and C having “a modulus of from about 1,000 MPa to 2,500 MPa.” (*Id.*)

Additionally, both Li and Boronkay disclose the same materials for use as the rigid or hard layers, including a polyester, co-polyester, or polycarbonate. (Ex.1127, 5:34-46; Ex.1128, [00176].) Both Li and Boronkay disclose that their dental appliances can be made by thermoforming. (Ex.1127, 6:60-64, Figs. 3-4; Ex.1128, [00146], [00159].) A POSA would understand that the rigid or hard layers of the combination of Li and Boronkay to achieve Chen’s preferred modulus under Ground 4 would be thermoplastic polymers. (Ex.1102, ¶192.) Ground 4 therefore satisfies the “hard layers, A, C and D, individually comprise a thermoplastic polymer.”

(d) Claim 11[c]: “the soft inner layers B and B’ individually comprise an elastomeric material having a hardness from about A 60 to D 85”

Li discloses that “the soft polymer layers” can have “a hardness of about 60 A to about 85 D,” exactly as claimed. (Ex.1127, 6:18-21.) A POSA would recognize that Li’s disclosed “soft polymer layers” are “two soft inner layers B and B’” in the five-layer hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay in view of the preferred modulus of Chen. (Ex.1102, ¶194.)

Thus, claim 11 is obvious under Ground 4.

E. Ground 5: Obviousness of Claims 12-14, 16, and 18 Based on Ground 4 further in view of Stewart

Ground 5 relies on the same hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay of Ground 4, but adds Stewart’s preferred “flexural modulus” range of 1,000-3,000 MPa as a second property of the multilayer sheet to be optimized (along with Chen’s preferred “modulus”). (Ex.1102, ¶196.)

1. Motivation to Combine and Reasonable Expectation of Success

Stewart is in the same field as Li, Boronkay, and Chen—i.e., multilayer polymeric sheets for creating dental aligners. (*See* Stewart, 1:12-13; 3:15-18 (“this invention provides a sheet of polymeric composition for use in . . . thermoforming the sheet around a physical model of the teeth”); 13:19-20 (“[t]he sheet is a laminate having two or more layers of different polymeric compositions”).) Stewart discloses and incorporates by reference the same Align Technology patents as those cited and/or incorporated by reference in Li, Boronkay, and Chen. (*Compare* Stewart, 1:18-20 with Li, 1:18-28, 4:8-15; Ex.1128, [0088]; Chen. 2:60-3:3.) A POSA would therefore have been motivated to look to the interrelated teachings of Stewart for use within the combination of Li, Boronkay, and Chen, for additional desirable design considerations for a dental aligner. (Ex.1102, ¶197.)

Stewart discloses that for an “orthodontic appliance [i.e., a dental aligner], *it is desirable to use* a polymeric sheet which, before being thermoformed, is 0.5 to

0.8 mm thick and for the polymeric composition to have a *flexural modulus* between 1000-3000 MPa.” (Ex.1130, 20:21-24.) A POSA would therefore have been motivated to design a multilayer sheet for use in creating a dental aligner that satisfied Stewart’s expressly disclosed “desirable” flexural modulus of between 1000-3000 MPa. (Ex.1102, ¶198.)

Li teaches that both the hard and soft polymer layers of an appliance can have a variety of physical properties that can “improve treatment options.” (Ex.1127, 5:50-52, 6:13-14.) Li further explains that the physical properties of the materials such as tensile modulus (i.e., “modulus”) and flexural modulus, among others, “can each be specifically tailored for a particular application.” (Ex.1127, 5:52-56, 6:14-18.) While suggested in the context of the individual layers of a multilayer sheet, a POSA would have understood that Li’s teaching would equally apply to the overall multilayer sheet—i.e., tailoring both the modulus and the flexural modulus of the multilayer sheet could improve treatments options for dental aligners. (Ex.1102, ¶199.) Thus, a POSA would have been motivated to design multilayer sheets for use in dental aligners that simultaneously satisfied both Chen’s “preferabl[e]” modulus of 800-1,500 MPa and Stewart’s “desired” flexural modulus range of 1000-3000 MPa. (*Id.*)

As in Ground 4, a POSA would have reasonably expected to be able to successfully design a hard-soft-hard-soft-hard multilayer sheet according to the

teachings of Li and Boronkay to achieve Chen's preferred 800-1,500 MPa modulus. A POSA would further have reasonably expected success in designing such a multilayer sheet to also achieve Stewart's desired flexural modulus range of 1000-3000 MPa. (Ex.1102, ¶200.)

First, a POSA would have recognized that there is substantial overlap between Chen's preferred modulus range and Stewart's flexural modulus range. (Ex.1102, ¶201.) In district court, Patent Owner's expert stated that the "[f]lexural modulus is fundamentally equivalent to the elastic modulus of a material," but the two properties can "hold slightly different values." (Ex.1116, ¶30.) Patent Owner's expert referred to the foregoing statement in the context of his analysis of Petitioner's accused multilayer product, stating: "as I explained in section V.B, *the flexural modulus would be expected to be similar to the elastic modulus* and the two can be related using specific equations." (*Id.*, ¶109 ("the elastic *modulus of the composite sheet is calculated to be $E = 1247$ MPa, which is similar to the calculated flexural modulus*")).) A POSA therefore would have expected a multilayer sheet could be designed such that the modulus and flexural modulus properties are "similar" enough to have a reasonable expectation of success in achieving both Chen's preferred modulus and Stewart's desirable flexural modulus values. (Ex.1102, ¶201.)

Second, individual layer thickness and elastic modulus of each individual layer are the result-effective variables for both the overall modulus and overall flexural modulus of a multilayer film. (Ex.1102, ¶202.) Both the modulus and flexural modulus of a multilayer sheet can be calculated by different equations based on the thickness and modulus of each individual layer. (*Id.*; *see also* Ex. 1116, ¶38.) Accordingly, it would have been a matter of routine selection from within the express teachings of Li and Boronkay of appropriate individual layer thicknesses and materials with appropriate modulus properties for a POSA to design a hard-soft-hard-soft-hard multilayer sheet with both Chen’s preferred modulus (800-1,500 MPa) and Stewart’s desirable flexural modulus (1000-3000 MPa). (*Id.*)

2. Dependent Claim 12

Claim 12 recites: “The polymeric sheet composition of claim 11, wherein the polymeric sheet composition has a combined thickness of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa.” These limitations are satisfied by hard-soft-hard-soft-hard multilayer sheet of Ground 5. (Ex.1102, ¶¶203-208.)

(a) “a combined thickness of from 250 microns to 2,000 microns”

Li discloses that the “[m]ultilayer sheets used for making appliances having a hard polymer layer disposed between two soft polymer layers can range from a thickness of about 500 μm to about 1200 μm ” (Ex.1127, 5:27-31.) Adding the

thin hard protective outer layers taught by Boronkay to the outer sides of the multilayer sheets of Li to create a hard-soft-hard-soft-hard sheet would still fall well within claim 12's thickness range. (Ex.1102, ¶204.) Boronkay emphasizes that the outer protective layers should be thinner than the other layers of the appliance in order to reduce or minimize their contributions to the overall properties of the appliance. (*Id.*; Ex.1128, [00144]-[00145].) Li teaches that "the soft polymer layers can have a thickness in a range from about 25 μm to about 100 μm ." (Ex.1127, 5:24-26.) Thus, a POSA following Boronkay's teaching would recognize that the thin hard protective layers would at least have to be less than 25-100 μm such that the hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay would always satisfy the claimed 250-2,000 μm range. (Ex.1102, ¶204.)

(b) "a flexural modulus of from 500 MPa to 1,500 MPa"

Stewart discloses a "desirable" flexural modulus range for a polymeric sheet of 1000-3000 MPa, which overlaps with and satisfies the claimed range. (Ex.1102, ¶205.) *See E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018) ("overlap creates a presumption of obviousness").

Furthermore, a POSA would have been motivated to optimize the material properties of a multilayer sheet to satisfy both Chen's preferred modulus of 800-1500 MPa *and* Stewart's desirable flexural modulus of 1000-3000 MPa. (Ex.1102, ¶206.) As noted above in element 11[b], the combination of Li and Boronkay

teaches a hard-soft-hard-soft-hard multilayer sheet configured with a predominantly thick hard middle layer, relatively thin inner soft layers, and even thinner protective hard outer layers. A POSA would have understood that this configuration of a hard-soft-hard-soft-hard multilayer sheet has a configuration wherein the flexural modulus would be generally similar to the elastic modulus because it predominantly consists of a hard middle layer. (*Id.*; see Ex.1116, ¶109 (“the flexural modulus would be expected to be similar to the elastic modulus”).) A POSA would have recognized that optimizing the configuration of the obvious hard-soft-hard-soft-hard sheet according to Li and Boronkay to attain both Chen’s preferred modulus and Stewart’s desirable flexural modulus would essentially occur within or close to their similar overlapping values—i.e., from about 1,000-1500 MPa. (*Id.*) Consequently, a POSA would have been motivated to design sheets towards the lower end of Stewart’s stated desirable flexural modulus to ensure they would be able to satisfy both Chen’s preferred modulus and Stewart’s desired flexural modulus. (*Id.*) A POSA would therefore understand that the effective operative range of Stewart’s desired flexural modulus range under this Ground is essentially 1000-1,500 MPa, which closely overlaps with and satisfies the recited “flexural modulus of from 500 MPa to 1,500 MPa” of claim 12. (Ex.1102, ¶¶206-207.)

Accordingly, claim 12 is obvious under Ground 5.

3. Dependent Claim 13

Claim 13 recites: “The polymeric sheet composition of claim 12, wherein the rigid or hard layers, A, C and D individually comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane.” Both Li and Boronkay identify these exact same polymeric materials for use in “hard” or “rigid” layers of a multilayer appliance. (Ex.1102, ¶209; Ex.1127, 5:34-46 (“a co-polyester, a polycarbonate, a thermoplastic polyurethane”); Ex.1128, [00176].)

4. Dependent Claim 14

Claim 14 recites: “The polymeric sheet composition of claim 12, wherein the soft inner layers B and B' individually comprise one of more of a polyurethane elastomer.” Both Li and Boronkay expressly disclose the use of polyurethane elastomer as a suitable for the “soft” polymer layers of a multilayer sheet. (Ex.1127, 6:1-12, 8:12-14 (“thermoplastic polyurethane elastomer soft polymer layers.”), claim 1; Ex.1128, [00177]; *see* Ex.1102, ¶210.)

5. Dependent Claim 16

Claim 16 recites: “The polymeric sheet composition of claim 14, wherein the rigid or hard layers, A, C and D have a combined thickness of from 100 microns to about 750 microns.” As noted with respect to claim element 1[a] above, Li’s “hard polymer layer” corresponds to rigid or hard inner layer D and the claimed rigid or

hard layers A and C are satisfied by Boronkay's teaching of thin, hard outer protective layers on the outside of a multilayer appliance. (Ex.1102, ¶211.)

Li discloses that "the hard polymer layer can have a thickness in a range from about 400 μm to about 1100 μm . . . or about 550 μm to about 750 μm " and further discloses examples "having a hard polymer layer with thicknesses ranging from about 580 μm to about 715 μm ."¹⁶ (Ex.1127, 5:21-24; 8:7-10.) In turn, Boronkay emphasizes that the protective outer layers should be thinner than the other non-protective layers of the appliance, such that they would be thinner than the 25-100 μm "soft layers" disclosed by Li—i.e., less than 25-100 μm in thickness—to reduce their contributions to the appliance's overall properties. (Ex.1102, ¶212; Ex.1128, [00144]-[00145].)

Accordingly, the combined teachings of Li and Boronkay, disclose an inner hard layer D with a thickness of from about 400-1100 μm or about 550-750 μm and outer layers A and C that are thinner than 25-100 μm . (Ex.1102, ¶213.) The combined thickness of the rigid or hard layers, A, C and D under Ground 3 is

¹⁶ Consistent with Li, Boronkay discloses that "the stiff portion can have a thickness of about 0.5 mm, or within a range from about 0.2 mm to about 1 mm." (Ex.1128, [0096].)

therefore less than about 450 μm (thinnest) to less than about 1300 μm (thickest), which overlaps and thereby satisfies the claimed range of “from 100 microns to about 750 microns.” (*Id.*)

6. Dependent Claim 18

Claim 18 recites “A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.” In the district court, Patent Owner has taken the position that claim 18 can be met by any pre-thermoformed polymeric sheet that satisfies all limitations of claim 12 that is then thermoformed into a dental appliance. (*See* Ex.1135, 212:19-213:2.) As discussed above, the combination of Li and Boronkay teach a five-layer hard-soft-hard-soft-hard polymeric sheet that renders the claimed “polymeric sheet composition” of claim 12 obvious. Li discloses that such a multilayer sheet can be made into a dental appliance by thermoforming. (*E.g.*, Ex.1127, Fig. 4.; Ex.1102, ¶214.)

XI. SECONDARY CONSIDERATIONS

PO’s motion for a preliminary injunction only addressed claims 11, 12, and 18 of the ’263 patent and claims 1, 2, and 9 of the ’630 patent. (*See* Ex.1115, 8.) PO nevertheless made the general assertions that “the claimed inventions unexpectedly provide greatly improved properties over existing aligner materials. . . and have had great commercial success,” that PO’s commercial three-layer Zendura FLX product “surpasses the other aligner materials on the market, including Align’s multilayer

aligner,” and that “Zendura FLX has also been hugely successful.” (*See id.*, 11-12.)

However, PO only asserted that “Zendura™ FLX falls within the scope of claim 1 of the ’263 patent.” (Ex.1116, ¶55.) Accordingly, Petitioner is not aware of any secondary considerations for the challenged claims of the ’263 patent that rely on Zendura FLX with respect to independent claim 11. Indeed, PO’s 3-layer Zendura FLX product does not practice and therefore cannot support secondary considerations for challenged claims relying on claim 11 of the ’263 patent.

With respect to PO’s assertion regarding allegedly “greatly improved properties over *existing aligner materials*” for Zendura FLX, this assertion cannot support non-obviousness of claim 1. “It is well settled ‘that objective evidence or non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.’” *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (quoting *In re Tiffin*, 448 F.2d 791 (C.C.P.A. 1971)). Here, none of the challenged claims recite or are otherwise limited to “aligner materials.” The full scope of the claim 1 is extremely broad, including various types of materials, thicknesses, and properties of the constituent layers and overall sheet composition for which the singular (alleged) Zendura FLX embodiment is not remotely commensurate in scope. (*See* Ex.1102, ¶217.)

Moreover, because Grounds 1-3 disclose the multilayer sheets with the same configuration and polymeric materials as claim 1, any resulting properties of such

multilayer sheets would not be “unexpected.” (*See* Ex.1102, ¶218.) To the contrary, any properties of such sheets were either already disclosed by Hinz (and therefore not “unexpected”), not commensurate with the scope of the claims, and/or not supported by credible evidence. For instance, Hinz expressly discloses that its hard-soft-hard film constructs “have improved mechanical properties and are to be inserted into and removed from patients easily” and that it has “has increased breaking strength.” (Ex.1117, 2:54-3:78.) Hinz further discloses that the hard outer layers made of polyester “are stable against discoloration and enable a crystal-clear appearance.” (*Id.*, 3:82-83.) Thus, a POSA would understand that any assertion by Patent Owner that a hard-soft-hard multilayer film or dental appliance (e.g., splint) with improved properties, such as mechanical properties, tear strength, elasticity, easier insertion/removal, and stain resistance would not be “unexpected” because such improved features were already expressly disclosed by Hinz. (Ex.1102, ¶218.) *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013).

For objective indicia evidence to be accorded substantial weight, a nexus must exist “between the evidence and the merits of the claimed invention.” *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1330-31 (Fed. Cir. 2017) (citation omitted). “If commercial success is due to an element in the prior art, no nexus exists.” *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011). Here, Patent Owner’s allegation of non-obviousness based on commercial success is not

probative of validity because it fails to establish the required nexus and is not commensurate in scope with the claims. (Ex.1102, ¶220.) *See Novartis*, 853 F.3d at 1331.

Second, Patent Owner fails to show that the “merits of the invention” have driven any alleged “commercial success” of Zendura FLX. To the contrary, sales of Zendura FLX have arisen by cannibalizing sales of its previous Zendura A single layer material. (*See* Ex.1110, 9 (“doctors ‘tend to stick’ with one clear aligner provider and ‘not change brands.’”).) Patent Owner conceded aligner purchasing decisions has multiple factors beyond the material properties. (*See* Ex.1110, 3-4.) Accordingly, any presently known assertions by Patent Owner regarding commercial success lack the requisite evidence to be given any probative weight in support non-obviousness.

XII. CONCLUSION

Petitioner respectfully requests institution under Grounds 1-5.

Petition for *Inter Partes* Review of
U.S. Patent No. 10,870,263 B2

Dated: December 5, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this petition complies with the type-volume limits of 37 C.F.R. § 42.24(a)(1)(i) because it contains 13,636 words, according to the word-processing system used to prepare this petition, excluding the parts of this petition that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

DATED: December 5, 2022

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Sections 42.6 and 42.105, that a complete copy of the attached **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,870,263 B2**, including all exhibits (**Nos. 1101-1139**) and related documents, are being served via Federal Express on the 5th day of December, 2022, the same day as the filing of the above-identified document in the United States Patent and Trademark Office/Patent Trial and Appeal Board, upon the PO by serving the correspondence address of record with the USPTO as follows:

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And, via electronic mail upon counsel of record for the PO in the litigation pending before the U.S. District Court for the District of Delaware entitled *Bay Materials LLC. v. 3M Company*, Case No. 1:21-cv-01610 (D. Del.) as follows:

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