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Description: Petition to make special based on age/health

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PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION UNDER 37 CFR 1.102(c)(1)					
Application Information					
Application Number	TBA	Confirmation Number	TBA	Filing Date	2019-12-18
Attorney Docket Number (optional)	513043 (000550US)	Art Unit	TBA	Examiner	TBA
First Named Inventor	Ray F. Stewart				
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS				
Attention: Office of Petitions An application may be made special for advancement of examination upon filing of a petition showing that the applicant is 65 years of age, or more. No fee is required with such a petition. See 37 CFR 1.102(c)(1) and MPEP 708.02 (II). APPLICANT HEREBY PETITIONS TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION IN THIS APPLICATION UNDER 37 CFR 1.102(c)(1) and MPEP 708.02 (II) ON THE BASIS OF THE APPLICANT'S AGE. A grantable petition requires one of the following items: (1) Statement by one named inventor in the application that he/she is 65 years of age, or more; or (2) Certification by a registered attorney/agent having evidence such as a birth certificate, passport, driver's license, etc. showing one named inventor in the application is 65 years of age, or more.					
Name of inventor who is 65 years of age, or older					
Given Name	Middle Name	Family Name	Suffix		
Ray	F.	Stewart			
A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the format of the signature. Select (1) or (2): ☐ (1) I am an inventor in this application and I am 65 years of age, or more. ☒ (2) I am an attorney or agent registered to practice before the Patent and Trademark Office, and I certify that I am in possession of evidence, and will retain such in the application file record, showing that the inventor listed above is 65 years of age, or more.					
Signature	/Gerald T. Gray/		Date (YYYY-MM-DD)	2019-12-18	
Name	Gerald T. Gray		Registration Number	41797	

This collection of information is required by 37 CFR 1.102(c)(1). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) a petition to make special based on age for advancement of examination. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND COMPLETED FORMS TO THE CHIEF INFORMATION OFFICER. Submit completed forms electronically over EFS-Web, or mail to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Application Number	Herewith
Filing Date	Herewith
First Named Inventor	Ray F. Stewart et al.
Title	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	513043 (000550US)

SIGNATURE of Applicant or Patent Practitioner

Signature	/Gerald T. Gray/	Date (Optional)	
Name	Gerald T. Gray	Registration Number	41,797
Title (if Applicant is a juristic entity)	Attorney of Record		
Applicant Name (if Applicant is a juristic entity)	Bay Materials, LLC		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.



*Total of one forms are submitted.

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

- ☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 103606
- OR
- ☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☐ The address associated with the above-mentioned Customer Number

OR

☒ The address associated with Customer Number: 103606

OR

☐ Firm or Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Bay Materials, LLC

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature

Name

Title

Ray Stegall

Managing Member

Date (Optional)

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☒ Total of 1 forms are submitted.

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Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
First Named Inventor/Applicant Name:		Ray F. Stewart		
Filer:		Gerald Todd Gray./Christina Alton		
Attorney Docket Number:		513043 (000550US)		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	9	100	900
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	160	160

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				2780

Electronic Acknowledgement Receipt

EFS ID:	38075613
Application Number:	16719256
International Application Number:	
Confirmation Number:	7352
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
Filer:	Gerald Todd Gray./Christina Alton
Filer Authorized By:	Gerald Todd Gray.
Attorney Docket Number:	513043 (000550US)
Receipt Date:	18-DEC-2019
Filing Date:	
Time Stamp:	16:27:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$2780
RAM confirmation Number	E2019BHG27314444
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		513043_20191218_SPEC.pdf	276192	yes	39
			e4ddaac8116d62e0ac7bf31e58b93b299e9a84ab		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Abstract		39	39	
	Claims		34	38	
	Specification		1	33	
Warnings:					
Information:					
2	Drawings-only black and white line drawings	513043_20191218_DRAW.pdf	209531	no	4
			e7c3828d30005b895cba851f65a76b0ee7e9a740		
Warnings:					
Information:					
3	Application Data Sheet	513043_20191218_ADS.pdf	115046	no	9
			dd616d0275cdd18dab98e38ee4ac37fa012ce2a2		
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
4	Transmittal Letter	513043_20191218_TRA.pdf	126424	no	3
			910cb007191cd88140c810553b3c7951f8fbbae1		
Warnings:					
Information:					

5	Petition to make special based on Age/ Health	513043_20191218_PET.pdf	178230	no	2
			5373538022d0cb62a4565b186cc1478f3200c96		
Warnings:					
Information:					
6	Power of Attorney	513043_20191218_POA.pdf	819378	no	2
			7191fdb578c840008a4c69cd0e678433c4063353		
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	38062	no	2
			4529eb129dc9c2a5f0340a41e02c7cf39fffe25		
Warnings:					
Information:					
Total Files Size (in bytes):			1762863		
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ABSTRACT

Improved dental appliances and polymeric sheet compositions are disclosed. The polymeric sheet compositions are useful for making dental appliances having outer layers comprised of a material 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”), which exhibit improved flexibility and strength, and better stain and tear resistance than currently available materials and dental appliances.

WHAT IS CLAIMED IS:

1. A polymeric sheet composition, comprising:
at least two outer layers A and C and an elastomeric inner layer 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, and the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.
2. The 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
3. The polymeric sheet composition of claim 2, wherein the outer layers A and C comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such a polyvinyl chloride, and a fluoropolymer.
4. The polymeric sheet composition of claim 2, wherein the inner layer B comprises one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, and a fluoroelastomer.
5. The polymeric sheet composition of claim 3, wherein one or more of outer layers A and C comprise a microcrystalline polyamide having heat of fusion of less than 20 J/g and a light transmission of greater than 80%.

6. The polymeric sheet composition of claim 4, wherein the inner layer B comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

7. The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a co-polyester having a:

(a) a dicarboxylic acid component and

(b) a diol component, wherein the-copolyester exhibits a glass transition temperature (Tg) from 80°C to 150°C.

8. The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a polyurethane comprised of:

(a) a di-isocyanate, and

(b) a diol component comprising one or more of hexane diol and cyclohexane dimethanol wherein the polyurethane has a glass transition temperature Tg from about 85°C to about 150°C.

9. The polymeric sheet composition of claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having a compression set of less than 35%.

10. The polymeric sheet composition according to claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having an interlayer peel strength between the A and C layers and the B layer of greater than 50 N per 2.5 cm.

11. 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, 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 the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

12. 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.

13. 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, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic and/or isophthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic and/or isophthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such as polyvinyl chloride, and a fluoropolymer.

14. The polymeric sheet composition of claim 12, wherein the soft inner layers B and B' individually comprise one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, an anhydride functionalized styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, an acrylic elastomer and a fluoroelastomer.

15. The polymeric sheet composition of claim 14, wherein one or more of the soft inner layers B and B' comprise an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

16. The polymeric sheet composition of claim 14, wherein the rigid or hard layers, A, C and D have a combined thickness of from about 100 microns to about 750 microns.

17. The polymeric sheet composition of claim 14, wherein the soft layers, B and B' have a combined thickness of from about 150 microns to about 1,000 microns.

18. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.

19. A polymeric sheet composition, comprising:

three or more layers, A, A1, and B, wherein the outermost layers, A and A1 have different thicknesses from one another and individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa, and wherein the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

20. The polymeric sheet composition of claim 19, wherein the A, A1 and B layers of the polymeric sheet composition have a combined thickness of from about 500 microns to 2,000 microns.

21. The polymeric sheet composition of claim 20, wherein the outermost layer A1 has a thickness of from about 25 to about 250 microns.

22. The polymeric sheet composition of claim 20, wherein the ratio of the thickness of the outermost layer A1 to the thickness of the outermost layer A is from about 0.9 to about 0.2.

23. The polymeric sheet composition of claim 20, wherein the outermost layer A and outermost layer A1 are comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide and a polyolefin.

24. The dental appliance according to claim 20, wherein the outer layers A and A1 comprise the same material.

25. The dental appliance according to claim 20, wherein the outer layers A and A2 comprise different materials.

26. The polymeric sheet composition of claim 20, wherein the middle layer B is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane.

27. A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 20.

28. The dental appliance of claim 27, wherein the dental appliance exhibits improved tear resistance relative to the A, C or D layer alone.

29. The dental appliance of claim 27, wherein the dental appliance exhibits improved environmental stress resistance relative to the A, C or D layer alone.

DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. Application No. 16/211,176, filed December 5, 2018, which is a continuation-in-part application of International Application Serial No. PCT/US2018/035384, which has International filing date May 31, 2018, and further claims the benefit of U.S. Provisional Application No. 62/512,786, filed May 31, 2017 and of U.S. Provisional Application No. 62/590,627, filed November 26, 2017, each of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] Compositions in the form of polymeric sheets are disclosed. The polymeric sheets are useful, for example, in a dental appliance, and are constructed of layers that impart flexibility and strength and stain resistance to devices made from the sheets.

BACKGROUND

[0003] There is a need for improved orthodontic and dental appliances capable of facilitating orthodontic tooth movements, stabilizing tooth positions or protecting teeth from potentially damaging outside forces. Existing materials and products are constructed from single layer materials, bi-layer materials or tri-layer materials which have limited functionality and may suffer from performance deficiencies. Aligners are plastic shells which fit over teeth designed to apply translational or rotational forces to teeth. Their ability to accurately move teeth is limited by their effective modulus, elasticity and ability to resist creep and stress relaxation.

Additionally, they generally should be resistant to staining and environmental stress cracking.

[0004] Appliances for protection of teeth, for example, sports mouth guards, and dental splints have contradictory requirements. On the one hand, they should be capable of dissipating impact forces and on the other hand should be thin and not interfere with the natural occlusion of a person's teeth or impede speaking.

BRIEF SUMMARY

[0005] In one aspect, a composition comprised of at least two outer layers A and C and a middle layer B is provided. The A and C layers individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and a glass transition temperature and/or

melting point of from about 80°C to 180°C and the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to about 500 MPa and one or more of a glass transition temperature and/or melting point of from about 90°C to about 220°C.

[0006] In one embodiment, the A and C layers are comprised of one or more of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide or a polyolefin.

[0007] In another embodiment, the middle B layer is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane.

[0008] In yet another embodiment, the middle B layer material has a compression set of less than 35%, 30%, 25%, 20% or 10% after 22 hours at 25 °C.

[0009] In still another embodiment, the A and C layers have a lateral restoring force of less than 100 N (Newtons) per cm², 50 N per cm², 25 N per cm², or 10 N per cm², when displaced by 0.05 mm to 0.1 mm relative to each other.

[0010] In another embodiment, the interlayer peel strength between the A and C layers and the B layer is greater than 50 N per 2.5 cm.

[0011] In one embodiment, the combined thickness of the A, B and C layers is from about 250 microns to about 2,000 microns and the combined thickness of the A and C layers is from 25 microns to 750 microns, from 50 microns to 1000 microns, from 100 microns to 700 microns, from 150 microns to 650 microns, from 100 microns to 200 microns, from 200 microns to 600 microns, 100 microns, 125 microns, 150 microns, 175 microns, 200 microns, 225 microns, 250 microns, 275 microns, or 300 microns.

[0012] In still other embodiments, one or more of the A and C layers comprise a microcrystalline polyamide comprised of from 50 to 100 mole % of C6 to C14 aliphatic diacid moieties, and about 50 to 100 mole % of 4,4'-methylene-bis(cyclohexylamine) (CAS [1761-71-3]), having a glass transition of between about 100°C and 180°C, a heat of fusion of less than 20 J/g and a light transmission of greater than 80%.

[0013] In another embodiment, one or more of the A and C layers comprises a co-polyester comprised of: (a) a dicarboxylic acid component comprising 70 mole % to 100 mole % of terephthalic acid residues, and (b) a diol component comprising i) 0 to 95% ethylene glycol, ii) 5

mole % to 50 mole % of 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and iii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues, iii) 0 to 1% of a polyol having three or more hydroxyl groups, wherein the sum of the mole % of diol residues i) and ii) and iii) and iii) amounts to 100 mole % and the copolyester exhibits a glass transition temperature T_g from 80°C to 150°C.

[0014] In another embodiment, the middle B layer comprises an aromatic polyether polyurethane having a Shore hardness of from about A90 to D55, from about A85 to D60, or from about A80 to D65, and a compression set of less than 35%, wherein the interlayer peel strength between the A and C layers and the B layer is greater than 50 N per 2.5 cm.

[0015] In one embodiment, one or more of the A and C layers comprises a polyurethane comprised of (a) a di-isocyanate comprising 80 mole % to 100 mole % of methylene diphenyl diisocyanate residues and/or hydrogenated methylene diphenyl diisocyanate and (b) a diol component comprising i) 0 to 100 mole % hexamethylene diol and ii) 0 to 50 mole % 1,4-cyclohexanedimethanol, wherein the sum i) and ii) amounts to greater than 90 mole % and the polyurethane has a glass transition temperature T_g from about 85 °C to about 150 °C.

[0016] In another aspect, a dental appliance conformal to one or more teeth made from a composition or a polymeric sheet as described herein.

[0017] In one embodiment of the dental appliance the combined thickness of the A, B and C layers is from about 250 microns to about 2,000 microns and the combined thickness of the A and C layers is from 25 microns to 750 microns, from 50 microns to 1000 microns, from 100 microns to 700 microns, from 150 microns to 650 microns, from 100 microns to 200 microns, or from 200 microns to about 600 microns.

[0018] In another aspect, a reversibly deformable dental appliance comprised of a composition or a polymeric sheet material as described herein is provided, wherein the elastomeric middle layer and the outer layers can reversibly move relative to each other and have a lateral restoring force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm² when displaced by 0.05 mm to 0.1 mm relative to each other.

[0019] In one embodiment, the elastomeric middle layer comprises a polyurethane having a hardness from about A 80 to D 75, A 85 to D 65, or A 90 to D 55, e.g., A95, A90, A85, A80, A75, D50, D55, D60, D65 or D70.

[0020] In another aspect, a composition, polymeric sheet or dental appliance having environmental stress resistance comprised of at least two outer layers and an elastomeric inner layer, wherein one or more of the outer layers is a polyester or co-polyester having a modulus of from about 1,000 MPa to 2,500 MPa, and the inner layer comprises an elastomer having a modulus of from about 50 MPa to about 500 MPa, wherein the inter layer peel strength between at least one outer layer and the elastomer is greater than about 50 N /inch, is provided.

[0021] In another aspect, a reversibly deformable dental appliance is provided, wherein the thickness of the outer A layer is from about 175 microns to about 250 microns, about 100 microns to about 200 microns, e.g., 100 microns, 125 microns, 150 microns, 175 microns, 200 microns, 225 microns or 250 microns, the thickness of the outer C layer is from about 175 microns to about 250 microns, 100 microns to 200 microns, e.g., 100 microns, 125 microns, 150 microns, 175 microns, 200 microns, 225 microns or 250 microns, and the thickness of the middle B layer is from 300 to 500 microns, wherein the combined thickness of the A, B and C layers from 850 to 1,000 microns or from 600 to 800 microns.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIG. 1A is a schematic depiction of a cross sectional view of a three-layer sheet with a simple ABC construction. Layer A and layer C may be the same or different materials and each layer may be comprised of one or more materials, or blends or alloys. Layer B may be a single material, a blend of materials or alloys.

[0023] FIG. 1B is a schematic depiction of a cross sectional view of a multiple layer sheet. Each layer A, B and 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. Layer A may be comprised of more than one layer, for example, layer a and a', layer B may be comprised of more than one layer, for example, layer b and b', and layer C may be comprised of more than one layer, for example, layer c and c', as exemplified in FIG. 1B.

[0024] FIGS. 2A and 2B are schematic depictions of exemplary test samples for determining displacement (FIG. 2A) and lateral restoring force (translational movement; FIG. 2B), of a simple 3-layer sheet comprised of two rigid outer layers and an inner elastomeric layer, where A, B and C are individual layers of the sheet. In this example, layers A and C are reversibly translated relative to each other and layer B provides a restoring force. In one more specific

example, the A B C layers may each be about 250 microns thick, and layers A, B and C may be comprised of one or more materials and may each individually comprise one or more layers.

[0025] FIG. 3A is a graphic depiction of displacement/force curves for elastomers having different degrees of hardness. The graph demonstrates the restoring force (N) generated from translational movement of Layer A relative to Layer C, having a middle B layer with different hardness TPU elastomers, and that the hardness of the elastomer impacts displacement and restoring force. A harder thermoplastic urethane (TPU) will generate a greater restoring force, but may limit the amount of movement.

[0026] FIG. 3B is a graphic depiction of the restoring force (N) as a function of time (0 to 48 hours) for a given displacement between an A layer and a C layer having a middle B layer with different hardness TPU elastomers in the B layer. TPU 75A has a low compression set and shows the least initial force, but the force decays very little over time. TPU 75D has a high compression set, and while it shows a much higher initial restoring force, the force decays rapidly over time.

[0027] FIG. 4 is a graphic depiction of the retained force at 5% stress for different constructions exposed to 37 °C and water over a 48-hour time period.

[0028] It should be appreciated that the constructions and properties illustrated in FIGS. 1-4 are specific examples and not intended to limit the scope of constructions and testing that may be used. Other materials, constructions and sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments may contain additional layers including tie layers, pigments, optical additives or reinforcing agents and may be constructed in any manner known in the art such as flat sheet extrusion, coextrusion blown film, calendaring, laminating and adhesive bonding. The structures (or polymer sheets) and devices may in some embodiments be made by 3D printing or dip coating. One of ordinary skill in the art would recognize and appreciate many variations, modifications, and alternatives of the constructions.

[0029] The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. It will, however, be evident that various modifications and changes may be made thereunto without departing from the broader spirit and scope of the disclosure as set forth in the claims.

[0030] Other variations are within the spirit of the present disclosure. Thus, while the disclosed embodiments are susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and are described herein. It should be understood, however, that there is no intention to limit the disclosure to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions and equivalents falling within the spirit and scope of the disclosure, as defined in the appended claims.

DETAILED DESCRIPTION

[0031] Current orthodontic aligners have a very limited elastic range (typically 4% to 7%) and when deformed exhibit a rapid decay of recovery force. As a result, it may be necessary to change appliances frequently, increasing manufacturing cost, teeth may not move as desired, and the patient may experience discomfort from excessively high initial forces. Attempts to improve elastic range by providing a thin outer layer of elastomer (typically a polyurethane, as described for example in US 9,655,693 B2), can result in a tooth contact surface which is readily deformed, reducing accuracy of tooth movement, and may increase the propensity for unsightly staining by common foods, beverages or cigarettes. US Patent No. 6,524,101 describes dental appliances having regions with different elastic modulus and appliances having added stiffening elements. Non-staining polyurethanes used for fabricating dental appliances such as Zendura® A available from Bay Materials, LLC (Fremont, CA), have excellent properties but are hygroscopic, requiring rigorous drying prior to thermoforming, may initially be uncomfortable, are difficult to clean and may not be ideal for some applications.

[0032] Many other polyurethanes must also be dried prior to thermoforming, adding time and cost to the manufacturing process. Aromatic polyesters or co-polyesters may be used to form aligners; however, they exhibit poor chemical resistance and low impact and tear strength. Aligners constructed from stiff materials such as polyesters or rigid polyurethanes have a high modulus, for example greater than about 1,000 or 1,500 MPa, and when deformed can exert excessive forces on teeth causing discomfort and potential damage to tooth roots. Highly elastomeric polymers such as thermoplastic polyurethane elastomers (TPU), styrenic elastomers (such as SBS, SEBS, SIS for example) have low modulus (typically less than 100 or 200 MPa),

which may be insufficient for moving teeth and are readily stained making them of limited utility for producing aligners.

[0033] The present disclosure is based on the discovery that many of the deficiencies in prior art materials, and dental appliances constructed from them can be reduced or eliminated with a sheet or device having outer layers comprised of a material having a modulus of greater than about 1,000 MPA up to 2,500 MPA and an inner elastomeric layer or core comprised of elastomeric material or materials having a modulus of from about 50 MPa to 500 MPa, which can be non-staining, has a lower cost than rigid urethanes, exhibits improved elastic properties, and has surprisingly greater environmental stress cracking resistance.

[0034] A polymeric sheet or device may be comprised of more than two rigid layers, for example a third rigid layer may be disposed between two or more elastomeric layers. The multilayer construction provides a dual shell dental appliance which may be adapted to moving teeth, retaining teeth in an existing position, or protecting teeth from impact. As disclosed herein, the outer shell material that contacts the teeth may be substantially rigid to accurately mate with the teeth providing precise forces while maintaining the ability to exert a more nearly constant force over longer distances.

[0035] By selecting appropriate outer and inner material modulus and thickness, two or more substantially rigid shells may be reversibly displaced relative to each other to a greater extent than a rigid material of comparable thickness and shape providing a dental appliance that can apply desired forces to teeth with a greater range of movement while not creating excessive forces or exhibiting excessive stress relaxation when deformed. While not limiting the disclosure to specific constructions, a sheet or dental appliance may be referred to herein as a “dual shell” sheet or appliance. A “dual shell” sheet or appliance may comprise two or more shells or layers. The shells or layers may have the same or a different thickness. A series of dental appliances comprised of this “dual shell” construction may be used to move teeth in incremental stages wherein two or more appliances may be constructed of the same or different materials. Dental appliances may be constructed by thermoforming a dual shell material over a model of one or more teeth or may be constructed by sequentially thermoforming rigid and elastomeric precursor sheets or by sequentially dip coating a model with polymer solutions or polymer forming monomers or oligomers which may optionally cured or otherwise post

processed. The inventors have discovered that this unique construction can significantly reduce the amount of stress cracking that a shell or materials exhibits, thereby expanding the range of materials which can be used in the sheets or appliance.

DEFINITIONS

[0036] The use of the terms “a” and “an” and “the” and similar referents in the context of describing the disclosed embodiments (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. The term “connected” is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. The phrase “based on” should be understood to be open-ended, and not limiting in any way, and is intended to be interpreted or otherwise read as “based at least in part on,” where appropriate. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate embodiments of the disclosure and does not pose a limitation on the scope of the disclosure unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the disclosure.

[0037] The term "dental appliance" is used herein with reference to any device placed in or on the teeth of a subject. Dental appliances include but are not limited to orthodontic, prosthetic, retaining, snoring/airway, cosmetic, therapeutic, protective (e.g., mouth guards) and habit-modification devices.

[0038] The term "ASTM D638", is used herein with reference to the test for Plastics Tensile Strength.

[0039] The term "ASTM D1364", is used herein with reference to the test for inter layer peel strength.

[0040] The term "compression set" is used herein with reference to the permanent deformation of a material when a force is applied and removed. Unless specified otherwise, compression set is measured according to ASTM D 305-B at specified time and temperature, for example 22 hours at 23°C.

[0041] The term "flexural modulus" is used herein with reference to the rigidity of a material and/or resistance of the material to deformation in bending. The higher the flexural modulus of the material, the more resistant to bending it is. For an isotropic material the elastic modulus measured in any direction are the same.

[0042] The term "hardness" is used herein with reference to a Shore hardness scale, and unless otherwise stated is measured according to ASTM D 2240. A durometer measures the penetration of a metal foot or pin into the surface of a material. There are different durometer scales, but Shore A and Shore D are commonly used. Materials with higher durometer values will be harder compared to materials with a lower durometer value. 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.

[0043] The expressions "modulus," "Young's modulus" and "elastic modulus" are used herein with reference to the rigidity of a material and/or resistance of the material to stretching. The higher the modulus of the material, the more rigid. The flexural modulus and elastic modulus of a material may be the same or different. For isotropic materials such as A, B and C, flexural modulus and modulus (which may also be referred to as elastic modulus) are substantially the same and one or the other may be measured dependent upon the circumstances. For polymers, the mechanical properties including elastic modulus and other properties may be measured as proscribed by ASTM D 638. Flexural modulus may be measured by the test listed in ASTM D790), and uses units of force per area. Unless designated otherwise, "modulus" refers to elastic modulus.

[0044] The term "polymeric sheet" is used interchangeably herein with the term "plastic sheet".

[0045] The term "lateral restoring force" with respect to A and C layers of a polymeric sheet is used with reference to the force which may be exerted by one layer which has been translated relative to another layer which is fixed in position. If the A and C layers are caused to move

independently of each other they will subsequently return to their original positions if not restrained.

[0046] “Translational force” refers to the amount of force required to displace an A and C layer from their neutral position a given distance and is measured as Newtons per cm² (N /cm²) at a given displacement where the area (cm²) is calculated as the overlap area of the A and C layers. The measurement can be made by preparing a test sample of known overlap and displacing the A and C layers relative to each other a given distance, for example, by applying a force of 0.04 MPa/min using a mechanical force tester such as an Instron Materials Tester. The force measured at different displacements is recorded. The lateral translational force and the lateral restoring force will be the same for an elastic material.

[0047] FIG. 2A illustrates the test for determining displacement force. FIG. 2B illustrates the test for determining restoring force. The schematic of FIGS. 2A and 2B show a simple 3-layer sheet comprised of two rigid outer layers and an inner elastomeric layer, where layers A and C are reversibly translated relative to each other and layer B provides a restoring force. FIG. 3A demonstrates the force (N) to stretch and cause translational movement of Layer A relative to Layer C, having a middle elastomeric B layer wherein the hardness of the elastomer impacts displacement and restoring force. Example 2 and Table 4 show the lateral/translational restoring force for different B layers.

[0048] The term “shearing force,” as used herein means the translational force applied to two surfaces which are connected by an elastic material.

[0049] The term "shell" is used herein with reference to polymeric shells which fits over the teeth and are removably placeable over the teeth.

[0050] The term "stain resistant" is used herein with reference to a material designed to be resistant to being stained.

[0051] The term "thermoplastic polymer” is used herein with reference to a polymer is a polymer that becomes pliable or moldable above a specific temperature and solidifies upon cooling, provided that the heat and pressure do not chemically decompose the polymer.

[0052] The terms "tooth" and "teeth" include natural teeth, including natural teeth which have been modified by fillings or by crowns, implanted teeth, artificial teeth that are part of a bridge or

other fitting secured to one or more natural or implanted teeth, and artificial teeth that are part of a removable fitting.

[0053] In the following description, various embodiments are described. For purposes of explanation, specific configurations and details are described in order to provide a thorough understanding of the embodiments. However, it will also be apparent to those skilled in the art that the embodiments may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

EMBODIMENTS

[0054] In some embodiments (referred to herein as embodiment #1), a thermoformable polymeric sheet, is comprised of at least two outer layers A and C, and a middle layer B, wherein the A and C layers are individually comprised of a thermoplastic polymer having a modulus of greater than about 1,000 MPa, for example 1,000 MPa to 1,500 MPa; 1,100 MPa to 1,600 MPa; 1,200 MPa to 1,700 MPa; 1,300 MPa to 1,800 MPa; 1,400 MPa to 1,900 MPa; 1,500 MPa to 2,000 MPa; 1,100 MPa; 1,200 MPa; 1,300 MPa; 1,400 MPa; 1,500 MPa; 1,600 MPa; 1,700 MPa; 1,800 MPa; 1,900 MPa; 2000 MPa; or up to 2,500 MPa; and a glass transition temperature (T_g) and/or melting point from about 80 °C to 180 °C; 90 °C to 170 °C; 100 °C to 160 °C; 110 °C to 150 °C; 120 °C to 150 °C; 130 °C to 170 °C; 140 °C to 180 °C; 80 °C; 90 °C; 100 °C; 110 °C; 120 °C; 130 °C; 140 °C; 150 °C; 160 °C; 170 °C; or 180 °C.

[0055] In such embodiments, the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to about 500 MPa; 60 MPa to 470 MPa; 70 MPa to 440 MPa; 80 MPa to 400 MPa; 100 MPa to 350 MPa; 150 MPa to 300 MPa; 200 MPa to 400 MPa; 60 MPa, 70 MPa; 80 MPa, 90 MPa; 100 MPa; 110 MPa; 120 MPa; 130 MPa; 140 MPa; 150 MPa, 160 MPa; 170 MPa; 180 MPa; 190 MPa; 200 MPa, 250 MPa, 300 MPa, 350 MPa, 400 MPa, 450 MPa, or up to 500 MPa, and one or more of (a) a glass transition temperature, or (b) a melting point of from about 90°C to about 220°C; from 100°C to about 200°C; from 120°C to about 180°C; from 140°C to 220°C; or from 160°C to about 220°C. In some embodiments, the middle B layer is an elastomeric layer or shell, which may include one or more materials and one or more layers.

[0056] In embodiment #1, layers A and C may comprise a polyester or co-polyester, a polyurethane, a polyamide, a polyolefin, a (meth) acrylic polymer, a polycarbonate, a vinyl polymer such a polyvinyl chloride, or a fluoropolymer.

[0057] In embodiment #1, layer B may comprise a polyurethane elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a siloxane elastomer, a polyether elastomer a polyolefin elastomer, an olefin copolymer, an acrylic elastomer or a fluoroelastomer.

[0058] In embodiment #1, the B layer material has a 22 hours at 25 °C compression set of less than about 35%, 30%, 25%, 20%, 10%, less than 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%. In contradiction to the findings of US 9,655,693 B2 where an elastomer is used as an outer layer, we have found that a lower compression set rather than higher compression set is more effective.

[0059] In certain aspects of embodiment #1, the sheet has an overall thickness of from about 250 microns to about 2,000 microns.

[0060] In certain aspects of embodiment #1, the combined thickness of the A and C layers is from about 25 microns to about 1000 microns, 50 microns to 750 microns, 100 to 750 microns, 250 microns to 750 microns, or 250 microns to about 600 microns.

[0061] In certain aspects of embodiment #1, the thermoformable sheet has a flexural modulus of from about 100 MPa to about 2,000 MPa, from about 250 MPa to about 2,000 MPa, from about 500 MPa to 1,500 MPa, from about 750 MPa to about 2,000 MPa, or from about 750 microns to about 1,500 MPa.

[0062] In certain aspects of embodiment #1, the A and C layers have a Tg of between about 80°C and 150°C, and the B layer has a Tg or melting point of between about 180°C and 220°C and a heat of fusion of from about 5 Joules/g to about 20 Joules/g, or 5 Joules/g to 15 Joules/g.

[0063] In certain aspects of embodiment #1, the inter layer peel strength of an A layer is greater than about 50 N/inch, greater than about 60 N/inch, greater than about 70 N/inch.

[0064] In certain aspects of embodiment #1, the A and C layers each have a thickness of 25 microns to about 1000 microns, 50 microns to 750 microns, 100 to 750 microns, 125 to 300 microns, 250 microns to 750 microns, or 250 microns to about 600 microns and may have a combined thickness of about 250 microns to about 600 microns, 200 microns to 300 microns, or

150 microns to 250 microns, being comprised of a rigid co-polyester or polyurethane having a modulus of from 1000 MPa to 2,500 MPa with Tg of between 95°C and 150°C, the elastomeric B layer having a thickness of from about 200 microns to about 1000 microns or 200 to 500 microns e.g., 200 microns, 225 microns, 250 microns, 300 microns, 350 microns, 375 microns, 400 microns, 425 microns, 450 microns, 475 microns, 500 microns, 550 microns, 600 microns, 650 microns, 700 microns, 750 microns, 800 microns, 850 microns, 900 microns, 950 microns or 1,000 microns, is comprised of a polyether or polyester polyurethane having a hardness of from about D 35 to about D 65, e.g., D35, D40, D45, D50, D55, D60, or D65, and a 22 hours at 25 °C compression set of less than about 35%, 30%, 25%, 20% 10%, less than 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%, and an A layer that has an inter layer peel strength of greater than about 50 N/inch, greater than about 60 N/inch or greater than about 70 N/inch, wherein the polymer sheet has flexural modulus of from about 750 MPa to about 1,500 MPa; from about 100 MPa to about 2,000 MPa; from about 250 MPa to about 2,000 MPa; from about 500 MPa to 1,500 MPa; or from about 750 MPa to about 2,000 MPa.

[0065] In some aspects of embodiment #1 thin layers of additional polymers (tie layers) may be present to improve the adhesion of polymer layers that are not naturally adhesive to each other for example a layer of maleic anhydride grafted polypropylene may be used to increase the adhesion between a polypropylene A layer and polyester or polyamide B layer.

[0066] In some embodiments (referred to herein as embodiment #2), the A and C layers of the sheet or device can reversibly move relative to each other (for example translationally) from about 0.05 mm to about 0.1mm with a force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm².

[0067] In some aspects of embodiment #2, the A and C layers of the sheet or device have a total thickness of from about 500 microns to 1,000 microns and can reversibly move relative to each other by a distance 0.05mm to 0.1mm with a force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm².

[0068] In some aspects of embodiment #2, the B layer material has a 22 hours at 25 °C compression set of less than about 35%, 30%, 25%, 20% 10%, less than 35%, 34%, 33%,

32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%.

[0069] In some embodiments (referred to herein as embodiment #3), one or more of the A and C layers comprises a microcrystalline polyamide comprised of from 50 to 100, 50 to 90, 50 to 80, 50 to 70, 60 to 90, 60 to 80, or 70 to 90 mole % of C6 to C14 aliphatic diacid moieties, and about 50 to 100, 50 to 90, 50 to 80, 50 to 70, 60 to 90, 60 to 80, or 70 to 90 mole % of 4,4'-methylene-bis(cyclohexylamine) (CAS [1761-71-3]), having a glass transition temperature of between about 100 °C and 180 °C, a heat of fusion of less than 20 J/g, e.g., 5 Joules/g to about 20 Joules/g, or 5 Joules/g to 15 Joules/g. See, e.g., DE Application No. 43 10 970 (embodiment 3). In some aspects of embodiments #3, the combined thickness of the A and C layers is less than about 500 microns, less than about 400 microns, less than about 300 microns.

[0070] In some embodiments (referred to herein as embodiment #4), a dental appliance conformal to one or more teeth comprises at least two outer layers A and C, and a middle layer B wherein the A and C layers, are individually comprised of a thermoplastic polymer having a modulus of greater than about greater than 1,000 MPA, for example 1,000 MPA to 1,500 MPA; 1,100 MPA to 1,600 MPA; 1,200 MPA to 1,700 MPA; 1,300 MPA to 1,800 MPA; 1,400 MPA to 1,900 MPA; 1,500 MPA to 2,000 MPA; 1,100 MPA; 1,200 MPA; 1,300 MPA; 1,400 MPA; 1,500 MPA; 1,600 MPA; 1,700 MPA; 1,800 MPA, 1,900 MPA; 2000 MPA; up to 2,500 MPA, in certain aspects greater than 1,500 MPa, and a glass transition temperature and/or melting point from about 80 °C to 180 °C; 90 °C to 170 °C; 100 °C to 160 °C; 110 °C to 150 °C; 120 °C to 150 °C; 130 °C to 170 °C; 140 °C to 180 °C; 80 °C; 90 °C; 100 °C; 110 °C; 120 °C; 130 °C; 140 °C; 150 °C; 160 °C; 170 °C: or 180 °C, in certain aspects 80 to 150 °C or 95 to 150 °C. In such embodiments, the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to 500 MPa; 70 MPa to 450 MPa; 80 MPa to 400 MPa; 100 MPa to 350 MPa; 150 MPa to 300 MPa; 200 MPa to 400 MPa; 60 MPa, 70 MPa; 80 MPa, 90 MPa; 100 MPa; 110 MPa; 120 MPa; 130 MPa; 140 MPa; 150 MPa, 160 MPa; 170 MPa; 180 MPa; 190 MPa; 200 MPa, up to 250 MPa, and one or more of a glass transition temperature or melting point of from about 90 °C to about 220 °C.

[0071] In some aspects of embodiment #4 the A and C layers have a combined thickness of about 25 microns to about 600 microns, e.g., 100 microns, 125 microns, 150 microns, 175

microns, 200 microns, 225 microns, 250 microns, 300 microns, 350 microns, 400 microns, 450 microns, 500 microns, 550 microns or 600 microns, being comprised of a rigid co-polyester or polyurethane having a modulus of greater than 1,000 MPa, for example 1,000 MPa to 1,500 MPa; 1,100 MPa to 1,600 MPa; 1,200 MPa to 1,700 MPa; 1,300 MPa to 1,800 MPa; 1,400 MPa to 1,900 MPa; 1,500 MPa to 2,000 MPa; 1,100 MPa; 1,200 MPa; 1,300 MPa; 1,400 MPa; 1,500 MPa; 1,600 MPa; 1,700 MPa; 1,800 MPa, 1,900 MPa; 2000 MPa; or up to 2,500 MPa with a Tg of from 80 °C to 180 °C; 90 °C to 170 °C; 100 °C to 160 °C; 110 °C to 150 °C; 120 °C to 150 °C; 130 °C to 170 °C; 140 °C to 180 °C; 80 °C; 90 °C; 100 °C; 110 °C; 120 °C; 130 °C; 140 °C; 150 °C; 160 °C; 170 °C; or 180 °C, e.g., 80 to 150 °C or 95 to 150 °C.

[0072] In some aspects of embodiment #4, the elastomeric B layer has a thickness of from about 200 microns to about 1,000 microns, e.g., 100 microns, 125 microns, 150 microns, 175 microns, 200 microns, 225 microns, 250 microns, 300 microns, 350 microns, 375 microns, 400 microns, 425 microns, 450 microns, 475 microns, 500 microns, 550 microns, 600 microns, 650 microns, 700 microns, 750 microns, 800 microns, 850 microns, 900 microns, 950 microns or 1,000 microns, is comprised of a polyether or polyester polyurethane having a hardness of from about D35 to about D65, e.g., D35, D40, D45, D50, D55, D60, or D65, and a 22 hour at 25 °C compression set of less than about 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%, and an A layer with an inter layer peel strength of greater than about 50 N/inch, greater than about 55 N/inch, greater than about 60 N, greater than about 70 N, wherein the polymeric sheet has flexural modulus of from about 100 MPa to about 2,000 MPa, from about 250 MPa to about 2,000 MPa, from about 500 MPa to 1,500 MPa, from about 750 MPa to about 2,000 MPa, e.g., from about 750 microns to about 1,500 MPa.

[0073] In some aspects of embodiment #4, the A and C layers have a lateral restoring force of 0.05 mm to 0.1mm with a force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm².

[0074] In some embodiments (referred to herein as embodiment #5), a dental appliance is formed by thermoforming a multilayer sheet over a model of teeth wherein thermoforming is performed at a temperature that is at least greater than the glass transition temperature and/or

melting point of the outer layers and less than the upper glass transition temperature and/or melting point of at least an inner layer elastomer material.

[0075] In one embodiment of embodiment #5, a dental appliance is prepared by thermoforming a multilayer sheet having least an A and C layer having a Tg from about 80 °C to 180 °C; 90 °C to 170 °C; 100 °C to 160 °C; 110 °C to 150 °C; 120 °C to 150 °C; 130 °C to 170 °C; 140 °C to 180 °C; 80 °C; 90 °C; 100 °C; 110 °C; 120 °C; 130 °C; 140 °C; 150 °C; 160 °C; 170 °C; or 180 °C, and the B layer has a glass transition temperature and/or melting point from about 90 °C and 220 °C, e.g., 180 °C to 220 °C and a heat of fusion of from about 5 J/g to about 20 J/g, e.g., about 5 J/g to about 20 Joules/g, or 5 Joules/g to 15 Joules/g.

[0076] In one aspect of embodiment #5 the A and C layers comprise a copolyester or polyurethane having a Tg from about 90 °C to about 120 °C, the B layer is comprised of a polyurethane having a modulus of from about 50 MPa to 500 MPa and a glass transition temperature and/or melting point of from about 170 °C to about 220 °C and thermoforming is performed at a temperature between about 150 °C and 200 °C.

[0077] It should be understood that elements of two or more embodiments may be combined.

[0078] In some embodiments, the thermoformable polymeric sheet, is comprised of at least two outer layers A and C, and a middle layer B, wherein one or more of the A and C layers comprise a microcrystalline polyamide comprised of from 50 to 100 mole % of C6 to C14 aliphatic diacid moieties, and about 50 to 100 mole % of 4,4'-methylene-bis(cyclohexylamine) (CAS [1761-71-3]), having a glass transition of between about 100 °C and 180 °C, a heat of fusion of less than 20 J/g and a light transmission of greater than 80%.

[0079] In some embodiments, the thermoformable polymeric sheet, is comprised of at least two outer layers A and C, and a middle layer B, wherein one or more of the A and C layers comprises, a co-polyester comprised of a dicarboxylic acid component comprising 70 mole % to 100 mole % of terephthalic acid residues, and a diol component comprising, (i) 0 to 95% ethylene glycol, (ii) 5 mole % to 50 mole % of 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and (ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues, and (iii) 0 to 1% of a polyol having three or more hydroxyl groups, wherein the sum of the mole % of diol residues (i) and (ii) and (iii) amounts to 100 mole % and the copolyester exhibits a glass transition temperature Tg from 80 °C to 150 °C. In some aspects of this embodiment, the thermoformable

polymeric sheet includes a middle B layer which comprises an aromatic polyether polyurethane having a Shore hardness of from about A90 to D55 and a compression set of less than 35%, wherein the interlayer peel strength between the A and C layers and the B layer is greater than 50 N per 2.5 cm.

[0080] In some embodiments, a dental appliance conformal to one or more teeth is made from the microcrystalline polyamide or the co-polyester described above.

[0081] In one embodiment, 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.

[0082] In some embodiments, 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.

[0083] In some embodiments, the rigid or hard layers, A, C and D individually comprise a thermoplastic polymer with a glass transition temperature and/or melting point of from about 80 °C to 180 °C.

[0084] In some embodiments, the rigid or hard layers, A, C and D comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester comprising terephthalic acid and/or isophthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester comprising terephthalic acid and/or isophthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, polypropylene or a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such a polyvinyl chloride, and a fluoropolymer.

[0085] In some embodiments, the inner layers B and B' individually comprise one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, an anhydride functionalized styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester

polyurethane, a siloxane elastomer, a polyether elastomer, an olefin copolymer, an acrylic elastomer and a fluoroelastomer.

[0086] In some embodiments, the inner layers B and B' comprise a polymeric material with a hardness of from about A 60 to D 85, from about A 70 to D 75, from about A 80 to D 65, or from about D40 to D70.

[0087] In some embodiments, the inner layers B and B' comprise a polymeric material with a glass transition temperature and/or melting point of from about 90 °C to 220 °C

[0088] In some embodiments, the inner layers B and B' comprise a polymeric material with a modulus of from about 50 MPa to 500 MPa.

[0089] In some embodiments, the sheet has an overall thickness of from about 250 microns to about 2,000 microns, from about 300 microns to about 1900 microns, from about 400 microns to about 1750 microns or from about 500 microns to about 1500 microns.

[0090] In some embodiments, the rigid or hard layers, A, C and D have a combined thickness of from about 100 microns to about 750 microns, from about 150 microns to about 600 microns, or from about 200 microns to about 500 microns.

[0091] In some embodiments, the rigid or hard layers, A and C have a combined thickness of from about 50 microns to about 250 microns, from about 40 microns to about 150 microns, or from about 25 microns to about 50 microns.

[0092] In some embodiments, the soft layers, B and B' have a combined thickness of from about 200 microns to about 1,000 microns, from about 250 microns to about 900 microns, from about 150 microns to about 750 microns.

[0093] In some embodiments, a dental appliance conformal to one or more teeth is made from a polymeric sheet composition comprising at least layers, A, B, B', C and D, as described herein. In some embodiments, the order of these layers may be different.

[0094] In some embodiments, the dental appliance has a combined thickness of from about 250 microns to 2,000 microns and a flexural modulus of from about 500 MPa to 1,500 MPa.

[0095] In some embodiments, the dental appliance is adapted to sequentially position teeth.

[0096] In some embodiments, the dental appliance exhibits improved tear resistance relative to the A, C, or D layer alone.

[0097] In some embodiments, the dental appliance exhibits improved environmental stress resistance relative to the A, C or D layer alone.

[0098] If one hard outer layer is thinner than another hard outer layer, thermoforming the thinner hard layer against a model can provide improved contact and conformity to the model increasing comfort, fit, and mechanical force coupling.

[0099] In some embodiments, a tooth contacting hard layer on the inside of an appliance has a thickness that is less than another hard layer.

[00100] In some embodiments, the thickness of the tooth contacting hard layer can be less than about 250 microns or as thin as about 50 microns.

[00101] In one embodiment, a polymeric sheet composition is comprised of three or more layers wherein one outermost hard layer (A1) has a different thickness, than another outermost hard layer (A). In some embodiments, one outermost hard layer (A1) is thinner than another outermost hard layer (A).

[00102] In some embodiments, outermost hard layer (A1) has a thickness of from about 25 to about 250 microns, or from about 25 to about 150 microns, or from about 25 to about 100 microns.

[00103] In some embodiments, the ratio of the thickness of an outermost hard layer (A1) to a thickness of a second outermost hard layer (A) is less than about 0.9, 0.85, 0.8, 0.75, 0.7, 0.6, 0.5, 0.35, 0.25, 0.15, e.g., from about 0.9 to about 0.2, from about 0.8 to about 0.3, from about 0.5 to about 0.15.

[00104] In some embodiments, the thickness of a polymeric sheet composition comprising an outermost hard layer (A), an inner soft layer B, and an outermost hard layer (A1) is from about 500 microns to about 2,000 microns, or from about 625 microns to about 1,000 microns. In some aspects of this embodiment, the ratio of the thickness of an outermost hard layer (A1) to a thickness of a second outermost hard layer (A) is from about from about 0.9 to about 0.2, from about 0.8 to about 0.3, or from about 0.75 to about 0.25.

[00105] Table 9. Exemplary Thickness of Layers.

	Thickness (microns)				Ratio
	Total	A	B	A1	A1:A
Symmetric 1	750	250	250	250	1.00
Symmetric 2	624	187	250	187	1.00
Non-symmetric 1	750	250	375	125	0.50

Non-symmetric 2	750	375	250	125	0.33
Non-symmetric 3	750	400	250	100	0.25
Non-symmetric 4	750	425	250	75	0.18
Non-symmetric 5	875	350	425	100	0.29
Non-symmetric 6	1000	375	525	100	0.27

[00106] In some embodiments, the flexural modulus of a polymeric sheet composition comprising an outermost hard layer (A), inner soft layer B, and outermost hard layer (A1) is from about 100 MPa to about 2,000 MPa, from about 250 MPa to about 2,000 MPa, from about 500 MPa to 1,500 MPa, from about 750 MPa to about 2,000 MPa, or from about 750 microns to about 1,500 MPa.

[00107] In some embodiments, the flexural modulus of an outermost hard layer (A) and outermost hard layer (A1) is from about 1000 MPa to 2,500 MPa, from about 1,000 MPa to about 1,500 MPa; from about 1,100 MPa to about 1,600 MPa; from about 1,200 MPa to about 1,700 MPa; from about 1,300 MPa to about 1,800 MPa; from about 1,400 MPa to about 1,900 MPa; from about 1,500 MPa to about 2,000 MPa; about 1,100 MPa; about 1,200 MPa; about 1,300 MPa; about 1,400 MPa; about 1,500 MPa; about 1,600 MPa; about 1,700 MPa; about 1,800 MPa, about 1,900 MPa; about 2000 MPa; or up to 2,500 MPa. The flexural modulus of the outermost hard layer (A) and outermost hard layer (A1) may be the same or different.

[00108] In some embodiments, the Shore hardness of an inner soft layer B, is from about A 60 to about D 85, from about A 65 to about D 80, from about A 70 to about D 75, from about A 85 to about D 70, or from about A 90 to about D 65; or from about D 35 to about D 65.

[00109] In some embodiments, the glass transition temperature or melting point of an outermost hard layer (A) and outermost hard layer (A1) is from about 80 °C to 180 °C; 90 °C to 170 °C; 100 °C to 160 °C; 110 °C to 150 °C; 120 °C to 150 °C; 130 °C to 170 °C; 140 °C to 180 °C; 80 °C; 90 °C; 100 °C; 110 °C; 120 °C; 130 °C; 140 °C; 150 °C; 160 °C; 170 °C; or 180 °C; 95 °C to 150 °C.

[00110]

In some embodiments, the glass transition temperature or melting point of an inner soft layer B is from about 90°C to about 220 °C; from 100 °C to about 200 °C; from 120 °C to about 180 °C; from 140 °C to 220 °C; or from 160 °C to about 220 °C

[00111] In some embodiments, the compression set of an inner soft layer B is less than about 35%, 30%, 25%, 20% or 10%, less than 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10% after 22 hours at 25 °C.

[00112] In some embodiments, outermost hard layer (A) and outermost hard layer (A1) are comprised of one or more of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide or a polyolefin. In some embodiments, the outermost hard layer (A) and outermost hard layer (A1) comprise the same material. In some embodiments, the outermost hard layer (A) and outermost hard layer (A1) comprise different materials.

[00113] In some embodiments, a middle B layer is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane.

Construction Methods

[00114] Multilayer 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. Sheets may be fully prepared before forming into an orthodontic appliance, or an appliance may be produced using a sequence of individual thermoforming steps to create multiple layers.

[00115] Thermoforming of sheets to produce test samples or dental appliances may be performed using a “Biostar” pressure former available from Great Lakes Orthodontics using procedures commonly used in the industry. Alternatively, thermoforming may be performed using a roll fed thermoformer, a vacuum former or other known thermoforming techniques. Thermoforming may be conducted using different conditions, forms or models to vary draw ratio and part thickness. Multilayer appliances may be fabricated through one or more 3D printing processes or by sequential dip coating, spray coating, powder coating or similar processes known for producing films, sheets and 3D structures.

[00116] Sheet temperature during thermoforming can be measured using an infrared thermometer or a surface thermocouple.

Utility

[00117] The sheets and materials described herein have utility as thermoformable materials having superior dimensional stability, impact cushioning, and restorative forces. The sheets may be converted into a number of types of oral appliances, for example for moving teeth, for use as a sports mouth guard with improved impact resistance and for use as an orthodontic retainer. Improved properties of the materials and appliances described herein relative to currently available materials and appliances include but are not limited to greater flexibility resulting in improved end user comfort, improved tooth movement results, greater stain and stress cracking resistance and excellent cosmetics all of which promote more consistent wear by the subjects.

Test Methods

[00118] Tensile properties were measured using an Instron Universal Materials Tester. The procedures of ASTM D638 were employed unless otherwise noted. Color and transparency were measured using a BYK Gardner Spin colorimeter.

[00119] Impact resistance was measured using a Gardner impact tester. Tear strength was measure using an Materials Tester at a rate of 250 mm per minute.

[00120] Stress relaxation of samples at 37 °C in water were measured by the method described in US Patent No. 8,716,425 B2.

[00121] Resistance to staining was measured by exposing test articles to a staining medium such as mustard or coffee for 24 hours at 37 °C and measuring color on a white color tile before and after exposure.

[00122] Translational recovery force was measured by constructing a three-layer structure (or polymer sheet) as shown in FIGS. 1 and 2. Samples were displaced from 0 to 0.5 mm and the force reported in N/cm².

[00123] Inter layer peel strength is measured at a rate of 50 mm/min and may be reported as Newtons (N) per inch or per 2.54 cm (N). Details may be found in test method ASTM D3164.

[00124] Thermal testing to determine glass transition temperatures, melting, and freezing points were measured using a differential scanning calorimeter at a heating and cooling rate of 10°C per minute unless indicated otherwise.

[00125] Resistance to environmental stress cracking may be determined by fixturing a sheet sample around a cylindrical mandrel to induce a specified strain on the outer surface, for example 3% or 5%, and exposing the samples to a specified environment for a specified time, for example a saliva mimic solution, mouth rinse or other solution of interest. The response can be measured semi quantitatively by visual observation of type and number of cracks, or quantitatively by subsequently measuring a mechanical property such as tear strength.

Materials and Methods.

[00126] Materials of construction. A large number of commercially available materials can be utilized in producing the sheets and appliances described herein. Table 1 provides a listing of exemplary materials for use in the A or C component. Table 2 provides a listing of exemplary materials for use in the B component. Similar or related materials can be obtained from other manufacturers or produced by known methods.

Table 1. Exemplary Materials Useful as Primary Components of A or C Materials

Trade Name	Supplier	Chemical Composition	Tg or Tm	Modulus Range	Hardness Range
Tritan MX 710, MX 810, MP 100 MP 200	Eastman Chemical	Co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol.	Tg 100 to 120°C	1,000 to 1,500 MPa	R 100 to 115
Eastar 6763	Eastman Chemical	Co-polyester of terephthalic acid, ethylene glycol and diethylene glycol	Tg 80°C	2,000 to 2,100 MPa	R106
Isoplast 2530	Lubrizol	Aromatic polyurethane based on MDI and hexanediol	Tg 85 - 95°C	1,900 MPa	R 121
Isoplast 2531	Lubrizol	Aromatic polyurethane with aliphatic diols	Tg 95 – 110°C	2,100 MPa	R 121
Polypropylene co-polymer	Generic	Co-polymer of propylene, ethylene and C4 to C8 alpha olefin	Tm 135 to 160°C	1,000 to 1,500 MPa	D 55-65
Trogamide CX7323	Evonik	Cycloaliphatic polyamide	Tg 140°C Tm 250°C	1,400 MPa	D 81

Table 2. Exemplary Materials Useful as Primary Components of B Materials

Trade Name	Supplier	Chemical Composition	Tg or Tm °C	Compression set 22 Hr. @ 23 °C	Modulus * MPa	Hardness Range
Elastollan 1195A	BASF	Aromatic polyether polyurethane	Tm 180 – 200	30%	52	95 A
Texin RxT 50D	Covestro	Aromatic polyether polyurethane	Tm 180 – 200	20%	151	50 D
Elastollan 1185 A	BASF	Aromatic polyether polyurethane	Tm 180 – 200	14%	57	85 A
Texin 985	Covestro	Aromatic polyether polyurethane	Tm 180 – 200	17%	60	85 A
Pebax Clear 300	Arkema	Polyether polyamide	TM 160	< 20%	183	53 D
Kraton FG 1901	Kraton Polymers	Maleated SEBS	Tg 90 - 100	15%	25	71 A
Noito	Mitsui Chemical	Propylene – ethylene microcrystalline elastomer	Tm Est 120 C	20%	30	75 A
Vestamide E or ME	Evonik	Polytetramethylene ether polyamide block polymer	Tm Est. 170 to 220 C	25 to 40%	50 to 500	D40 to D70

* Modulus from vendor literature or estimated based on Shore hardness

[00127] Additional suitable materials for the A, B or C layers can include compatible or incompatible blends, for example blends of two or more co-polyesters, blends of polypropylene and polyethylene and ethylene propylene elastomers, fluoropolymers, such as polyvinylidene fluoride or its co-polymers, styrene acrylonitrile resins, acrylonitrile styrene butadiene resins (ABS), polyurethanes containing polycarbonate soft blocks, siloxane soft blocks, silicone elastomers such as Geniomer TM, a siloxane urea co-polymer, and cyclic olefin co-polymers and cyclic olefin elastomers.

EXAMPLES

[00128] The disclosure is further illustrated by the following examples. The examples are provided for illustrative purposes only. They are not to be construed as limiting the scope or content of the disclosure in any way.

EXAMPLE 1

[00129] A series of monolayer and multilayer sheets of nominal total thickness 0.76 mm were prepared as shown in Table 3. Test samples 1-4 were prepared by compression molding and heat laminating individual films or by extrusion lamination. Examples of prior art materials, P1, P2 and P3, were prepared by compression molding films and optionally heat laminating them.

[00130] Press lamination was conducted at 200 to 220 °C, extrusion lamination was done using a polyurethane melt temperature of 210 to 240 °C, and coextrusion was done with a polyester melt temperature of 240 °C to 260 °C, and a polyurethane melt temperature of 210 to 240 °C. Conditions of time, temperature and pressure were varied to maximize structure (polymer sheet) quality, thickness and adhesion.

[00131] Mechanical properties, optical properties, stress relaxation and shape recovery were measured to compare the suitability of resulting structures (polymer sheets).

Table 3. Monolayer and Multilayer Sheets

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

* Polyester A is a copolyester marketed by Eastman Chemical (Eastar 6763). Polyester B is cycloaliphatic copolyester marketed by Eastman Chemical under the tradename Tritan

1 - 5% strain / 37°C/ water

2 - Mustard/ 24hr / 22°C

[00132] Prior art material P1 is a commercial thermoformable aligner material supplied by Bay Materials, LLC, Fremont Ca. Prior art material P2 is a polyester having a glass transition temperature of about 90°C manufactured by Eastman Chemical sold under the trade name Eastar 6763. Prior art material P3 is described in US 9,655,693 B2. Test samples 1-4 are multilayer laminates (as described herein), demonstrating improved stress relaxation properties, increased tear strength and excellent stain resistance.

[00133] Compared to the prior art materials, test samples 1-4 exhibited a number of unexpected properties. Comparing test samples 1-4 and prior art materials P1 and P2, it can be seen that test samples 1-4 exhibit substantially lower initial forces in the stress relaxation test

(believed to translate to greater user comfort), but surprisingly, maintain the forces for a longer time. This is in contradiction to the teachings of US 9,655,693 B2, which teaches that an outer layer of elastomer is required to protect the inner hard layer.. The ability of multilayer sheets to maintain appropriate force levels for long time periods under demanding conditions can readily be seen in FIG. 4. Samples A and B in Figure 4 are monolayer sheets while samples 1 and 2 are multilayer sheets as described in Table 3.

[00134] Tear strength is an important property of dental appliances. Materials with low tear strength have low durability and may crack at locations where stress is concentrated. Comparing the tear strength of prior art materials P1, P2 and P3, with test samples 1-4 show that such multilayer structures (or polymer sheets) with an elastomeric B layer have significantly greater tear strength than comparable monolayer structures or prior art multilayer structured.

[00135] To further investigate the effect of construction on tear strength, another laminate (#5) was prepared with 0.25 mm A and C layers comprised of Eastar 6763, a copolyester available from Eastman Chemical having a Tg of 86°C and a 0.2 mm B layer of Shore 50 D urethane elastomer to give a total thickness of 0.7 mm. Tear strength of this sample was compared to prior art materials P1, P2 and P3. Sample #5 exhibited a tear strength of 120 N, more than 200% of the value of prior art material P3, while having similar ratios of polyurethane and polyester.

EXAMPLE 2 (Measurement of Translational Force)

[00136] A three-layer sheet was prepared as described in Example 1 for test material 2. A strip of the sheet 2.54 cm x 1 cm was bonded between two strips of rigid polyester 2.54 cm wide to create 0.5 cm overlap (“multilayer sample A2”). A control test sample was prepared using the same size and thickness of polyester A (prior art) between two strips of rigid polyester. The displacement / force response was measured at a rate of 0.04 MPa/min and results are reported in Table 4. The multilayer construction allows the two outer layers (or the two shells) of an appliance to accommodate greater elastic movement with appropriate forces than the prior art constructions.

Table 4. Controlled Elastic Movement of Multilayer Material

Displacement (mm)	Force (N)/cm ²		
	Polyester A	95 A	50 D
0	0	0	0
0.1	43	8	12
0.25	106	20	31
0.5	249	50	71

[00137] Orthodontic devices were made using the materials and methods described herein and compared to devices of the same shape and thickness made from Zendura A and Essix Plus. The disclosed devices were substantially more elastic and more comfortable to wear. Because the inner and outer shells can deform independently from each other, they can accommodate a greater offset between the actual teeth and the appliance without causing undue discomfort to the patient and exert a near constant force for long time periods to accurately move teeth.

EXAMPLE 3

[00138] A clarified polypropylene film designated BFI 257 supplied by Blue Ridge Films (Petersburg, Virginia), with a thickness of 0.25 mm was laminated to both sides of 0.25mm thick film prepared from Kraton GF (maleated SEBS, available from Kraton Polymers) in a hot press at 180 F, cooled and cut into a 125 mm circle. The modulus of the polypropylene is reported at 1,100 MPa. The SEBS elastomer has a reported hardness of 71 A and a modulus of 25 MPa. The multilayer film exhibited low staining and was thermoformable over a dental model to produce a retainer with excellent elastic recovery properties.

EXAMPLE 4

[00139] The durability of sheet materials in the presence mouthwash was investigated since it is known that dental appliances may be readily damaged by alcohols and /or surfactants. Test sheets with a thickness of 0.75 mm were prepared 2.54 cm wide X 12 cm length. Prior art materials P1, P2 and P3, and multilayer sheet (test material) #2 were wrapped on a mandrel of sufficient diameter to produce a strain of 5%. The samples were immersed in mouth rinse and maintained at 37 °C. This environment is known to promote environmental stress cracking and to induce set causing the materials to be in a hoop shape instead of flat. After 24 hours, the

samples were rinsed with deionized water and the amount of recovery was measured immediately and again after 24 and 48 hours at ambient temperature. Subsequently, the samples were viewed under a microscope to determine the amount of stress cracking on the side which was under extension. A sample which returned to completely flat is scored to have 100% recovery. Stress cracking was rated from 1 to 5, with 5 being no visible cracking and 1 being severe cracking. Shape recovery for the samples is given in Table 5. The multilayer sheet (#2) recovered more rapidly and more completely than prior art materials P1, P2 and P3.

Table 5. Shape Recovery of Samples

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

EXAMPLE 5

[00140] Three laminates were prepared as in Example 1, sample 2 and designated as samples #6, #7 and #8. Sample #6 was extrusion laminated using untreated polyester film at a roll temperature of 40 °C, sample #7 was extrusion laminated using corona treated polyester film at a roll temperature of 60 °C and sample #8 was extrusion laminated using corona treated film at a roll temperature of 80 °C. Corona treatment is commonly used to activate film surfaces to increase their polarity. A control sample of polyester A was designated sample #9. The mechanical properties and environmental stress cracking resistance of the three samples are given in Table 6.

Table 6. Effect of Inter Layer Peel Strength on ESC Resistance of A Layer

Property	#6	#7	#8	#9
Modulus (Mpa)	1,490	1,572	1,589	2,700
Elongation at Yield (%)	6.1	5.8	6.1	6.2
Elongation at Break (%)	124	131	129	131
Inter Layer Peel Strength (N/inch)	35	53	137	NA
Tear Strength	55	117	179	48
ESCR / Mouthrinse / 37 °C	1	2.5	4	1

[00141] The dramatic improvement in environmental resistance observed for samples #7 and #8 compared to samples #6 and #9 are unanticipated and unexpected. In each case the material exposed to the environment is chemically identical and under equal amounts of stress. While not wishing to be bound by theory we hypothesize that some concentrated strain induced stress present in the outer polyester layer may be transferred to the elastomeric material and the force transfer is more efficient in the materials having higher interlayer bond strength. However, we are not aware of any precedent for this result.

[00142] It is well known that thermoplastic non-crystalline co-polyesters (PETGs and PCTGs) have poor environmental stress cracking resistance and are prone to rapid degradation when used as dental appliances. US Patent 9,655,691 teaches that covering both sides of such a co-polyester with a thermoplastic polyurethane elastomer having a hardness of from about 60A to about 85D surprisingly increased the durability of dental aligners made from such materials (described as a “hard polymer layer disposed between two soft polymer layers”). Presumably the outer material provides a physical and/or chemical protective layer. A disadvantage of such materials is that the polyurethane elastomers and other elastomers have poor staining resistance, and the disclosed multilayer structure has poor tear resistance.

[00143] The inventors have unexpectedly discovered that the stress cracking resistance of amorphous polyester films, sheets, or thermoformed parts prepared therefrom can be dramatically improved by bonding an elastomeric material such as a polyurethane between two layers of the polyester. The resulting structure, having a soft polymer layer disposed between two hard polymer layers, has excellent chemical resistance, high transparency, and excellent stain resistance. Additionally, the tear resistance of the multilayer structure is greater than either the polyester or the elastomer alone. The inventors have also discovered that the improved properties require a high bond strength between the layers and that a material with poorly bonded layers has inferior cracking resistance and inferior tear strength.

[00144] It is known in the art that rigid polyurethane sheets by themselves have very good stress cracking resistance. Unexpectedly, we observed that a three layer ABA structure which has rigid polyurethane A (outer) layers and an elastomeric B (inner) layer with excellent adhesion had WORSE environmental stress cracking resistance than the rigid polyurethane alone, the opposite effect to that observed with a polyester outer layer.

EXAMPLE 6

[00145] Testing was conducted to investigate the effect of thermal treatment and thermoforming conditions on the performance of devices made from the sheets. Three sheets (2A, 2B and 2C) of test material 2 (three-layer, polyester, polyurethane, polyester), were dried at 60 °C under vacuum for 12 hours. The samples were put in moisture barrier bags and subjected to the thermal treatment and thermoforming conditions shown in Table 7. Sample 2A was maintained at 22 °C and samples 2B and 2C were annealed at 100 °C for 24 hours. The samples were then thermoformed to produce flat sheet using different thermoforming temperatures. Samples 2A and 2B were thermoformed at a temperature below the high end of the melting range of the polyurethane while 2C was thermoformed at a temperature above the melting range of the polyurethane.

Table 7. Effect of Thermal Treatment/Thermoforming Conditions on Retained Stress

	Sample Treatment and Performance		
Sample / Treatment	#2A	#2B	#2C
Temperature	22 °C	100 °C	100 °C
Time	24 hrs.	24 hrs.	24 hrs.
T _m (°C)	160-190	170 - 195	170 - 195
J/g	6.8	12.4	12.6
Thermoforming temperature	180	180	200
T _m	160-190 °C	160 - 210	160 - 200
J/g	6.3	8.3	6.4
Retained Stress 24 hr.	51%	72%	47%

[00146] Test samples were cut from thermoformed samples, analyzed by DSC and subjected to stress relaxation testing at 37 °C in water. DSC showed that the melting point and heat of fusion of the samples were increased by annealing at 100 °C and that the thermoforming reduced the amount of heat of fusion and melting range. However, the sample thermoformed below the upper melting range of the polyurethane retained more crystallinity and performed better in the stress relaxation test. The conditions for sample 2B in Table 7 were used to fabricate a dental appliance.

EXAMPLE 7

[00147] Additional compositions can be made by selection of suitable layer materials having differences in modulus and elasticity as shown in Table 8.

Table 8. Exemplary Multilayer Sheet Materials

	Sample #6		Sample #7		Sample #8	
Layers	Material	Thickness	Material	Thickness	Material	Thickness
A	Trogamide CX 7323	0.125 mm	Trogamide CX 7323 / Polyamide 614 Blend 90:10	0.2 mm	Altuglas Luctor CR 13	0.125 mm
A'					Altuglas SG10	0.125 mm
B	Pebax Clear 300	0.5 mm	Pellethane 2373 55D	0.3 mm	Kurarity LA4285	0.25 mm
B'						
C'	Trogamide CX 7323	0.125 mm	Trogamide CX 7323 / Polyamide 614 Blend 90:10	0.2 mm	Altuglas SG10	0.125 mm
C					Altuglas Luctor CR 13	0.125 mm

Altuglas SG10 is a transparent impact modified polymethyl methacrylate sold by Arkema

Altuglas Luctor CR13 is a transparent impact modified polymethyl methacrylate sold by Arkema

Kurarity LA4285 is an acrylic ABA block co-polymer of methyl methacrylate and butyl methacrylate

EXAMPLE 8

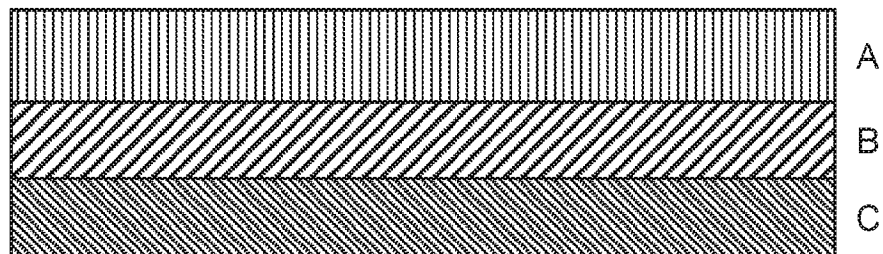
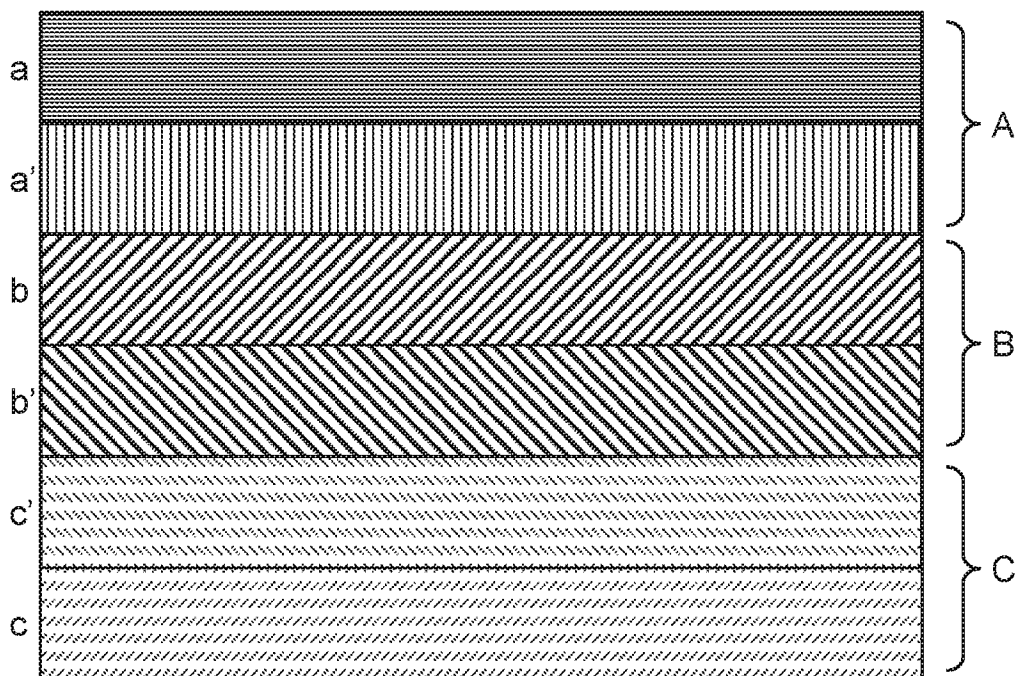
[00148] A 2mm thick sheet was prepared by laminating two outer films of polypropylene homopolymer 0.250 mm thick (Blue Ridge Films BFI 3270, modulus 1,200 MPa) and an inner layer of 1.50 mm thick ethylene propylene microcrystalline elastomer (Noito PN 2070, Mitsui Chemical) modulus 150 MPa. The sheet was cut into a disc 125 mm in diameter and thermoformed over a model of the maxillary teeth of an individual and trimmed to make a highly impact resistant sports mouth guard. Surprisingly, the mouth guard provides better impact protection and comfort than a standard device fabricated from 4 mm thick ethylene vinyl acetate copolymer marketed by Dreve under the Tradename Drufosoft.

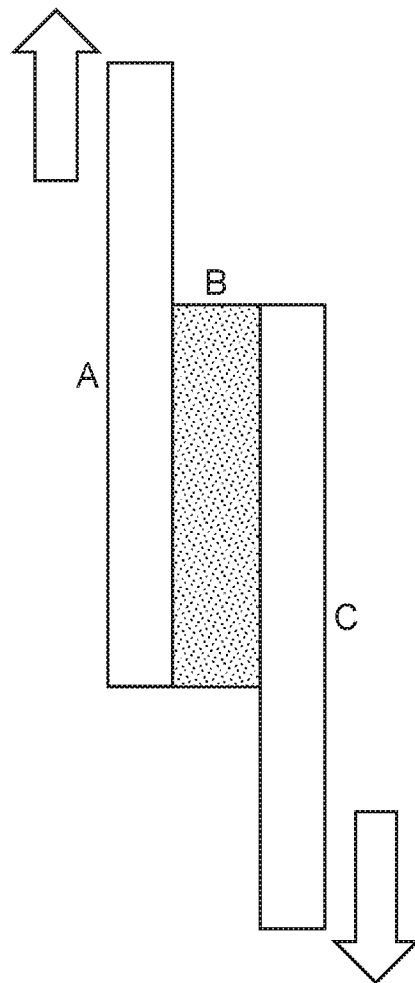
EXAMPLE 9

[00149] An aligner was made by thermoforming a three-layer sheet over a model of teeth. Two outer layers were comprised of a rigid polyurethane having a Tg of about 120 °C and an

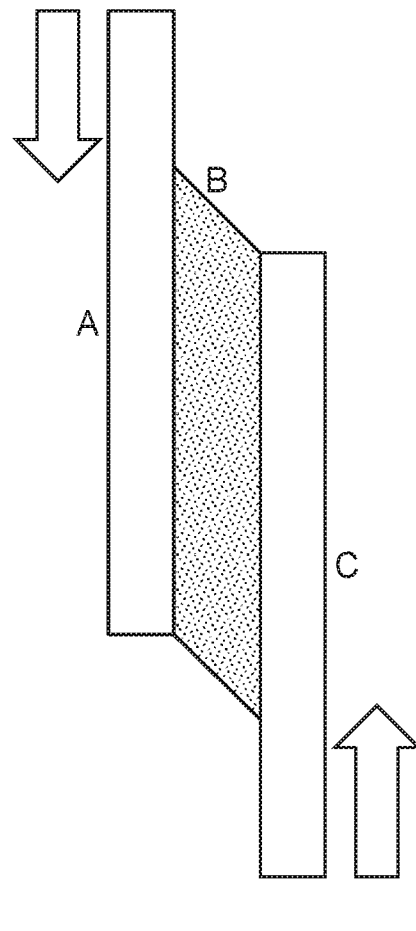
inner B layer comprised of a Shore A 85 aromatic polyether polyurethane having a hard block melting point of 160 to 195 °C and heat of fusion of 8 J/gram. The appliance was annealed at 100 °C for 24 hours which is below the Tg of the outer layer. No deformation was observed. Testing demonstrated that this appliance was more elastic and exhibited less creep under load than the before annealing at 100 °C. The improvement is thought to be due to improvement in the microstructure of the polyurethane elastomer.

[00150] In a second test a comparison was made between a multilayer device and a single layer device where in each case Zendura A materials was used as the A/C material or as the A/B/C material respectively. The devices were annealed at 90 °C for 24 hours. It was observed that the monolayer device extensively deformed while the multilayer maintained its shape. It is hypothesized that in the multilayer device the elastomer maintains a stabilizing force on the more rigid material during annealing to prevent undesired dimensional changes.

**FIG. 1A****FIG. 1B**



Displacement Force

FIG. 2A

Restoring Force

FIG. 2B

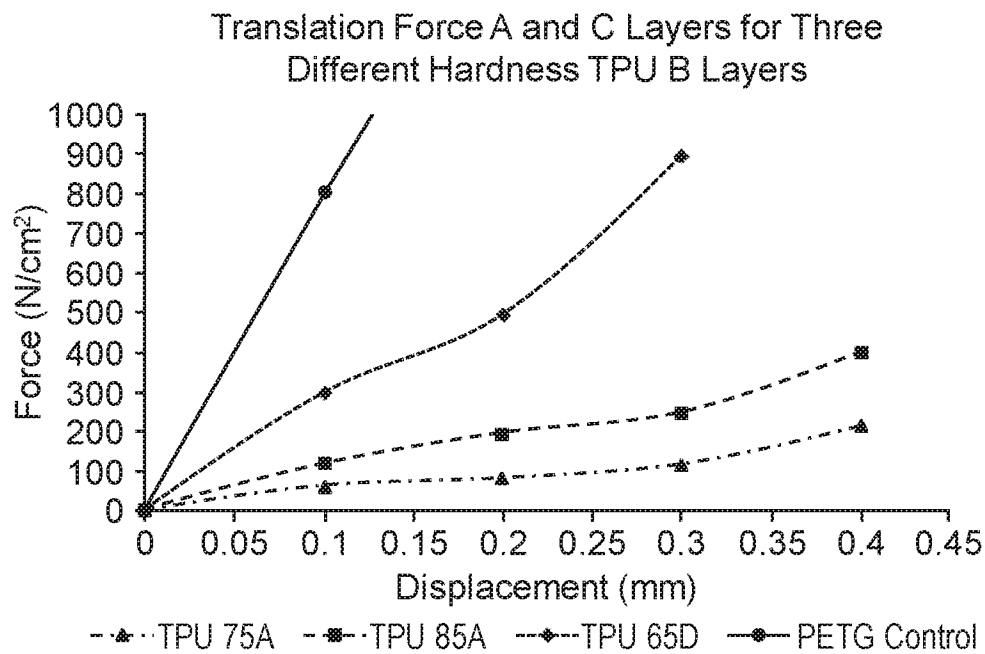


FIG. 3A

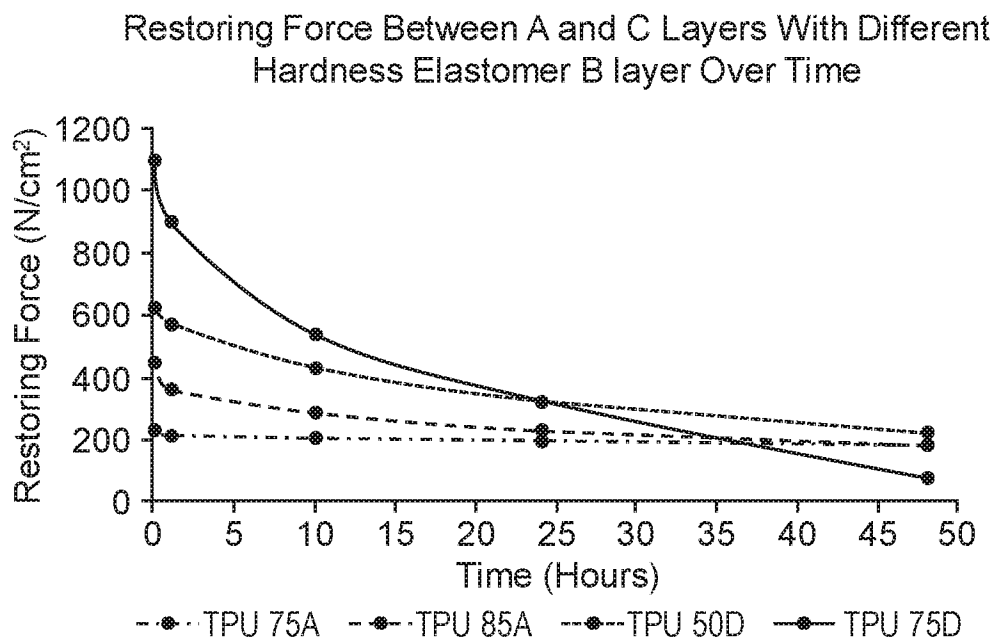
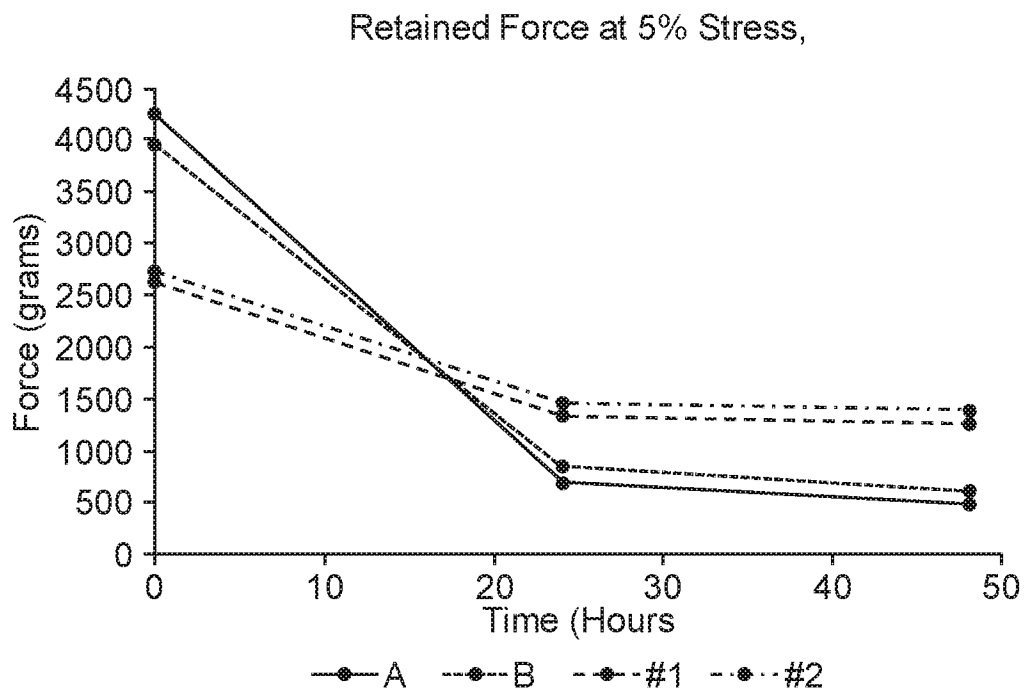


FIG. 3B

**FIG. 4**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Inventor 1					Remove	
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Prefix	Given Name	Middle Name	Family Name	Suffix		
	Ray	F.	Stewart			
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Mailing Address of Inventor:						
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Address 2						
City	Redwood City	State/Province	CA			
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
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Application Information:

Title of the Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
Attorney Docket Number	513043 (000550US)	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	103606		

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

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This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation in part of	16211176	2018-12-05
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16211176	Continuation in part of	PCT/US2018/035384	2018-05-31
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2018/035384	Claims benefit of provisional	62590627	2017-11-26
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2018/035384	Claims benefit of provisional	62512786	2017-05-31

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Application Number	Country ¹	Filing Date (YYYY-MM-DD)	Remove	Access Code ¹ (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. ☐ NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.	
--	--

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

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1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

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☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

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NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant 1			
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
Clear			
☐ Assignee		☐ Legal Representative under 35 U.S.C. 117	
		☐ Joint Inventor	
☒ Person to whom the inventor is obligated to assign.		☐ Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor:			
If the Applicant is an Organization check here. ☒			
Organization Name	Bay Materials, LLC		
Mailing Address Information For Applicant:			
Address 1	48450 Lakeview Blvd.		
Address 2			
City	Fremont	State/Province	CA
Country	US	Postal Code	94538
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			

Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

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Signature:

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See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Gerald T. Gray/		Date (YYYY-MM-DD)	2019-12-18
First Name	Gerald T.	Last Name	Gray	Registration Number
41797				

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	513043 (000550US)
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>		Attorney Docket No. 513043 (000550US)	
		Client Reference No. DD4105P/US05	
		First Inventor	Ray F. Stewart et al.
		Title	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
APPLICATION ELEMENTS		Commissioner for Patents ADDRESS TO: P.O. Box 1450 Alexandria, VA 22313-1450	
1. ☒ Utility Patent Application Transmittal Form 2. ☐ Applicant asserts small entity status (37 CFR 1.27) 3. ☐ Applicant certifies micro entity status (37 CFR 1.29 – Form PTO/SB/15A or B must be submitted) 4. ☒ Specification (including claims and abstract) [Total Pages 39] 5. ☒ Drawings [Total Sheets 4] 6. ☐ Inventor Declaration(s) [Total Pages] a. ☐ Newly executed b. ☐ Copy from prior application 7. ☒ Application Data Sheet. See 37 CFR 1.76 8. ☐ CD-ROM or CD-R (Large Table or Computer Program (Appendix)) 9. Nucleotide and/or Amino Acid Sequence Submission a. ☐ Computer Readable Form (CRF) b. Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper Copy c. ☐ Statement verifying identity of above copies		ACCOMPANYING APPLICATION PARTS 10. ☐ Applicant requests early publication (include publication fee under 37 CFR 1.18(d)) 11. ☐ 37 CFR 3.73(c) Statement (when there is an Assignee) 12. ☒ Power of Attorney 13. ☐ English Translation Document (if applicable) 14. ☐ Information Disclosure Statement (IDS) ☐ Form PTO-1449 ☐ Copies of References (except for U.S. patents and applications) 15. ☐ Preliminary Amendment 16. ☐ Return Receipt Postcard (should be specifically itemized) 17. ☐ Certified Copy of Priority Document(s) 18. ☐ Nonpublication Request Under 35 USC 122(b)(2)(B)(i) (Form PTO/SB/35 or its equivalent must be submitted with this application) 19. ☒ Other: Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	

APPLICATION FEES						
BASIC FILING FEE						\$300
UTILITY SEARCH FEE						\$660
UTILITY EXAMINATION FEE						\$760
CLAIM FEE	NUMBER FILED			NUMBER EXTRA	RATE	
TOTAL	29	MINUS	20	= 9	x \$100 =	\$900
INDEPENDENT	3	MINUS	3	= 0	x \$460 =	\$0
☐	FIRST PRESENTATION OF MULTIPLY DEPENDENT CLAIM					+ \$820 = \$0
☐	Application Size Fee – If the specification, claims, abstract, drawings, and preliminary amendment exceed 100 sheets of paper, enter number of sheets here: - If application is filed in paper form, enter this number in Total Sheets below. - If application is filed via EFS-Web, multiply this number by 0.75 and enter result in Total Sheets below.					
Total Sheets =		– 100 =		÷ 50 =	(round up to a whole number)	x 400 = \$0
☐	Early Publication Fee					\$0
☒	Processing Fee for Late Filing of Inventor Declarations					\$160
SUBTOTAL (of all items above)						\$2780
☐	Small Entity Status – Fees Above Are Reduced by ½					(\$0)
☐	Small Entity Status – BASIC FILING FEE is reduced by an additional \$75 if EFS filing					(\$0)
☐	Micro Entity Status – Fees Above Are Reduced by ¾					(\$0)

TOTAL AMOUNT TO BE CHARGED TO DEPOSIT ACCOUNT	\$2780
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UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No. 513043 (000550US)

20. ☒ Please charge Deposit Account No. 12-1216 in the amount indicated above.
21. The Commissioner is hereby authorized to credit overpayments or charge any additional fees of the following types to Deposit Account No. 12-1216:
- a. ☒ Fees required under 37 CFR 1.16.
 - b. ☒ Fees required under 37 CFR 1.17.
22. ☒ The Commissioner is hereby generally authorized under 37 CFR 1.136(a)(3) to treat any future reply in this or any related application filed pursuant to 37 CFR 1.53 requiring an extension of time as incorporating a request therefor, and the Commissioner is hereby specifically authorized to charge Deposit Account No. 12-1216 for any fee that may be due in connection with such a request for an extension of time.

CORRESPONDENCE ADDRESS☒ Customer No. **103606**

Name	Gerald T. Gray, Reg. No. 41,747
Signature	/Gerald T. Gray/
Contact Information	Telephone: 925-482-0100 Facsimile: 925-482-0110
Date	December 18, 2019

Telephone: 925-482-0100
Facsimile: 925-482-0110



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)

CONFIRMATION NO. 7352

INFORMAL NOTICE



103606
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083

Date Mailed: 01/24/2020

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Ray F. Stewart
John Lahlouh

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/tgebre/

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 16/719,256				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	660			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760			
TOTAL CLAIMS (37 CFR 1.16(j))	29 minus 20 =	*				x 100 =	900			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 460 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL	2620			
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x =			x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =			x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x =			x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =			x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
16/719,256	12/18/2019	1737	2780	513043 (000550US)	29	3

CONFIRMATION NO. 7352

FILING RECEIPT

103606
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083



Date Mailed: 01/24/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Ray F. Stewart, Redwood City, CA;
John Lahlouh, San Jose, CA;

Applicant(s)

Bay Materials, LLC, Fremont, CA

Power of Attorney: The patent practitioners associated with Customer Number 103606

Domestic Priority data as claimed by applicant

This application is a CIP of 16/211,176 12/05/2018 PAT 10549511
which is a CIP of PCT/US2018/035384 05/31/2018
which claims benefit of 62/590,627 11/26/2017
and claims benefit of 62/512,786 05/31/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 01/23/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/719,256**

Projected Publication Date: 04/30/2020

Non-Publication Request: No

Early Publication Request: No
Title

DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

Preliminary Class

430

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352
103606 7590 01/24/2020 LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083			EXAMINER	
			ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			01/24/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chgpatent@leydig.com



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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In re Application of :
Stewart, Ray, F. :
Application No. 16/719,256 :
Deposited: December 18, 2019 : **DECISION ON PETITION**
For: DUAL SHELL DENTAL :
APPLIANCE AND MATERIAL :
CONSTRUCTIONS :

This is a decision on the petition under 37 CFR 1.102(c)(1), filed December 18, 2019, to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section II.

There is no indication that the petition is signed by a registered patent attorney or patent agent of record. However, in accordance with 37 CFR 1.34, the signature of Gerald T. Gray appearing on the correspondence shall constitute a representation to the United States Patent and Trademark Office that he/she is authorized to represent the particular party in whose behalf he/she acts.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c)(1) and MPEP § 708.02, Section II: Applicant's Age must be accompanied by evidence showing that at least one of the applicants is 65 years of age, or more, such as a birth certificate or a statement by applicant. No fee is required

The instant petition includes a statement from registered practitioner Gerald T. Gary declaring that he/she is in possession of such evidence that shows the applicant, is 65 years of age or older. Accordingly, the above-identified application has been accorded "special" status.

The application is being forwarded to the Office of Patent Application Processing (OPAP) for action on the merits commensurate with this decision.

Telephone inquiries concerning this decision should be directed to LaShawn Marks at 571-272-7141. All other inquiries concerning either the examination or status of the application should be directed to the Office of Patent Application Processing (OPAP).

/JOANNE L BURKE/
Lead Paralegal Specialist, OPET

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 16/719,256

Confirmation No. 7352

Inventor(s): Ray F. Stewart et al.

Filed: December 18, 2019

TC/AU: Unassigned

Examiner: Unassigned

Docket No.: 513043 (000550US)

Customer No.: 103606

SUBMISSION OF DECLARATIONS

Applicant submits herewith the executed Declarations of inventors in the above-identified patent application.

Since the \$160.00 fee for submission of a late Declaration has already been charged to Deposit Account No. 12-1216, Applicant does not believe that any additional fees are due. However, if it is determined that a fee is due, the Commissioner is authorized to charge Deposit Account No. 12-1216.

/Gerald T. Gray/



Gerald T. Gray, Reg. No. 41,797
Telephone: 312-616-5600
Facsimile: 312-616-5700

Date: February 4, 2020

[Revised Jan. 12, 2018]

Electronic Acknowledgement Receipt

EFS ID:	38486063
Application Number:	16719256
International Application Number:	
Confirmation Number:	7352
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
Filer:	Gerald Todd Gray./Christina Alton
Filer Authorized By:	Gerald Todd Gray.
Attorney Docket Number:	513043 (000550US)
Receipt Date:	04-FEB-2020
Filing Date:	18-DEC-2019
Time Stamp:	12:57:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	513043_20200204_DECS.pdf	1394356	no	2
			efd3809ef06fd6809054c18f03d89f7a22862345		

Warnings:

Information:					
2	Transmittal Letter	513043_20200204_Decs_TRA.pdf	72156	no	1
			005734757282f371440823d2724d39acfe22e952		
Warnings:					
Information:					
Total Files Size (in bytes):			1466512		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**Title of
Invention**DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS**

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

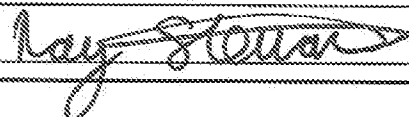
☒United States application or PCT international application number 16/719,256filed on December 18, 2019

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001
by fine or imprisonment of not more than five (5) years, or both.**WARNING:**

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: Ray F. StewartDate (Optional): 01-29-2020Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)Title of
Invention**DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS**

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 16/719,256filed on December 18, 2019

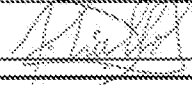
The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: John LahfouhDate (Optional): 01-29-2020* Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352
103606 7590 02/20/2020 LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083			EXAMINER FERGUSON, LAWRENCE D	
			ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			02/20/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chgpatent@leydig.com

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, 19-23 and 26, drawn to a polymeric sheet, classified in class B32B 7/12.
 - II. Claims 18, 24-25 and 27-29, drawn to a dental appliance, classified in class A61C 7/08.
2. Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as packaging, a cleaning sheet or touch screen display and the inventions are deemed patentably distinct because there is nothing of record to show them to be obvious variants.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. A telephone call was made to Gerald Gray on February 5, 2020, to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Ferguson whose telephone number is 571-272-1522. The examiner can normally be reached on Monday through Friday 9:00 AM – 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Vineis, can be reached on 571-270-1547. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/LAWRENCE D FERGUSON/
Examiner, Art Unit 1781

<i>Index of Claims</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM			DATE							
Final	Original	02/14/2020								
	1	÷								
	2	÷								
	3	÷								
	4	÷								
	5	÷								
	6	÷								
	7	÷								
	8	÷								
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	28	÷								
	29	÷								

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 16/719,256

Confirmation No. 7352

Inventor(s): Ray F. Stewart et al.

Filing or 371(c) Date: December 18, 2019

TC/AU: 1781

Examiner: Lawrence D. Ferguson

Docket No. 513043 (000550US)

Customer No. 103606

RESPONSE TO OFFICE ACTION

In reply to the Office action dated February 20, 2020, please enter the following amendments and consider the following remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Original) A polymeric sheet composition, comprising:
at least two outer layers A and C and an elastomeric inner layer 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, and the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.
2. (Original) The 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
3. (Original) The polymeric sheet composition of claim 2, wherein the outer layers A and C comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such a polyvinyl chloride, and a fluoropolymer.
4. (Original) The polymeric sheet composition of claim 2, wherein the inner layer B comprises one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, and a fluoroelastomer.

5. (Original) The polymeric sheet composition of claim 3, wherein one or more of outer layers A and C comprise a microcrystalline polyamide having heat of fusion of less than 20 J/g and a light transmission of greater than 80%.

6. (Original) The polymeric sheet composition of claim 4, wherein the inner layer B comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

7. (Original) The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a co-polyester having a:

- (a) a dicarboxylic acid component and
- (b) a diol component, wherein the-copolyester exhibits a glass transition temperature (T_g) from 80°C to 150°C.

8. (Original) The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a polyurethane comprised of:

- (a) a di-isocyanate, and
- (b) a diol component comprising one or more of hexane diol and cyclohexane dimethanol wherein the polyurethane has a glass transition temperature T_g from about 85°C to about 150°C.

9. (Original) The polymeric sheet composition of claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having a compression set of less than 35%.

10. (Original) The polymeric sheet composition according to claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having an interlayer peel strength between the A and C layers and the B layer of greater than 50 N per 2.5 cm.

11. (Original) 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, 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 the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

12. (Original) 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.

13. (Original) 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, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic and/or isophthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic and/or isophthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such as polyvinyl chloride, and a fluoropolymer.

14. (Original) The polymeric sheet composition of claim 12, wherein the soft inner layers B and B' individually comprise one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, an anhydride functionalized styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, an acrylic elastomer and a fluoroelastomer.

15. (Original) The polymeric sheet composition of claim 14, wherein one or more of the soft inner layers B and B' comprise an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

16. (Original) The polymeric sheet composition of claim 14, wherein the rigid or hard layers, A, C and D have a combined thickness of from about 100 microns to about 750 microns.

17. (Original) The polymeric sheet composition of claim 14, wherein the soft layers, B and B' have a combined thickness of from about 150 microns to about 1,000 microns.

18. (Withdrawn) A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.

19. (Original) A polymeric sheet composition, comprising:
three or more layers, A, A1, and B, wherein the outermost layers, A and A1 have different thicknesses from one another and individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa, and wherein the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

20. (Original) The polymeric sheet composition of claim 19, wherein the A, A1 and B layers of the polymeric sheet composition have a combined thickness of from about 500 microns to 2,000 microns.

21. (Original) The polymeric sheet composition of claim 20, wherein the outermost layer A1 has a thickness of from about 25 to about 250 microns.

22. (Original) The polymeric sheet composition of claim 20, wherein the ratio of the thickness of the outermost layer A1 to the thickness of the outermost layer A is from about 0.9 to about 0.2.

23. (Original) The polymeric sheet composition of claim 20, wherein the outermost layer A and outermost layer A1 are comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide and a polyolefin.

24. (Currently Amended) The ~~dental appliance~~ polymeric sheet composition according to claim 20, wherein the outer layers A and A1 comprise the same material.

25. (Currently Amended) The dental appliance polymeric sheet composition according to claim 20, wherein the outer layers A and A2 comprise different materials.

26. (Original) The polymeric sheet composition of claim 20, wherein the middle layer B is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane.

27. (Withdrawn) A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 20.

28. (Withdrawn) The dental appliance of claim 27, wherein the dental appliance exhibits improved tear resistance relative to the A, C or D layer alone.

29. (Withdrawn) The dental appliance of claim 27, wherein the dental appliance exhibits improved environmental stress resistance relative to the A, C or D layer alone.

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-29 are pending. Claims 24 and 25 have been amended. Claims 18 and 27-29 are hereby withdrawn. No new matter is added hereby. Therefore, upon entry of this amendment, which is respectfully requested, claims 1-29 will remain pending, with claims 18 and 27-29 being withdrawn.

Favorable reconsideration is requested for the reasons presented below.

Restriction Requirement

The claims were subjected to a restriction requirement. Specifically, the claims were restricted to the following two claims groups:

Group I, claims 1-17, 19-23 and 26, drawn to a polymeric sheet, classified in class B32B 7/12.

Group II, claims 18, 24-25 and 27-29, drawn to a dental appliance, classified in class A61C 7/08.

Applicant hereby elects Group I, without traverse, specifically claims 1-17, 19-23 and 26 for prosecution on the merits. Claims 24 and 25 have been amended to recite a polymeric sheet composition depending from claim 20, and are requested to be considered within Group I. Claims 18 and 27-29 are hereby withdrawn.

CONCLUSION

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.



/Gerald T. Gray/
Gerald T. Gray, Reg. No. 41,797
Telephone: 312-616-5600
Facsimile: 312-616-5700

Date: March 6, 2020

USPTO TRANSMITTAL

PATENT

Attorney Docket No. 513043 (000550US)
Client Reference No. DD4105P/US05

Application No. 16/719,256
Confirmation No. 7352

Transmitted herewith is a reply to office action in the subject application.

- ☐ Petition for an extension of time for the period noted below, as well as for any additional period necessary to render the present submission timely. Please charge Deposit Account No. 12-1216 for the appropriate petition fee.
- ☐ Other:
- ☐ Please charge Deposit Account No. 12-1216 in the total amount indicated below.

TIME EXTENSION PETITION FEE			none		\$0	
subtract time extension fee previously paid			none		(\$0)	
CLAIM FEE	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	EXTRA CLAIMS PRESENT	RATE	ADDITIONAL CLAIM FEE
TOTAL	29	MINUS	29	= 0	x \$100 =	\$0
INDEPENDENT	3	MINUS	3	= 0	x \$460 =	\$0
☐	FIRST PRESENTATION OF MULTIPLY DEPENDENT CLAIM				+ \$820 =	\$0
SUBTOTAL (of all items above)						\$0
☐	Small entity status is claimed for this application under 37 CFR 1.27. Fees above are reduced by ½.					(\$0)
☐	Micro entity status is claimed for this application under 37 CFR 1.27. Fees above are reduced by ¾.					(\$0)
OTHER FEES AS DESCRIBED:						\$0
TOTAL AMOUNT TO BE CHARGED TO DEPOSIT ACCOUNT						\$0

- ☒ The Commissioner is hereby authorized to charge any deficiencies in the following fees associated with this communication or credit any overpayment to Deposit Account No. 12-1216.
- ☒ Any filing fees under 37 CFR 1.16 and/or 1.492 for the presentation of extra claims.
- ☒ Any patent application processing fees under 37 CFR 1.17.



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797
Telephone: 312-616-5600
Facsimile: 312-616-5700

Date: March 6, 2020

Electronic Acknowledgement Receipt

EFS ID:	38796607
Application Number:	16719256
International Application Number:	
Confirmation Number:	7352
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
Filer:	Gerald Todd Gray./Christina Alton
Filer Authorized By:	Gerald Todd Gray.
Attorney Docket Number:	513043 (000550US)
Receipt Date:	06-MAR-2020
Filing Date:	18-DEC-2019
Time Stamp:	16:57:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		513043_20200306_RRR.pdf	186300	yes	8
			3fbc894dc91d3be9aa29e0d668c574b04c0b66b1		

Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Response to Election / Restriction Filed			1	1	
Claims			2	6	
Applicant Arguments/Remarks Made in an Amendment			7	8	
Warnings:					
Information:					
2	Transmittal Letter	513043_20200306_RR_TRA.pdf	82388	no	1
			11574791097bad1332534d7ea6d4780104dd16a8		
Warnings:					
Information:					
Total Files Size (in bytes):			268688		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/719,256		Filing Date 12/18/2019		☐ To be Mailed				
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO												
APPLICATION AS FILED - PART I												
		(Column 1)	(Column 2)									
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)					
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A	N/A		N/A							
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A	N/A		N/A							
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A	N/A		N/A							
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *		x \$100 =								
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *		x \$460 =								
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))												
* If the difference in column 1 is less than zero, enter "0" in column 2.					TOTAL							
APPLICATION AS AMENDED - PART II												
		(Column 1)		(Column 2)	(Column 3)							
AMENDMENT	03/06/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)				
	Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0	x \$100 =		0				
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$460 =		0				
	☐ Application Size Fee (37 CFR 1.16(s))											
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
						TOTAL ADD'L FEE		0				
		(Column 1)		(Column 2)	(Column 3)							
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)				
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =						
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =						
	☐ Application Size Fee (37 CFR 1.16(s))											
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
						TOTAL ADD'L FEE						
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						SLIE						
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/SONYA M WILLIAMS/						
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".												
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.												

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352
103606 7590 03/17/2020 LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083			EXAMINER FERGUSON, LAWRENCE D	
			ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			03/17/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chgpatent@leydig.com

Office Action Summary	Application No. 16/719,256	Applicant(s) Stewart et al.	
	Examiner LAWRENCE D FERGUSON	Art Unit 1781	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/6/20.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-29 is/are pending in the application.
5a) Of the above claim(s) 18,25 and 27-29 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-4, 11-14, 16-24 and 26 is/are rejected.
- 8) ☒ Claim(s) 5-10 and 15 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 12/18/19 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Response to Election

1. Applicant's election without traverse of claims 1-17, 19-23 and 26 in the reply filed on March 6, 2020, is acknowledged.

Claims 18, 25 and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is deemed proper and is therefore made **FINAL**.

Claim Rejections – 35 USC § 103(a)

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 11-14, 16-17, 19-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabert et al. (U.S. 5,318,737).

Trabert discloses a thermoplastic resin composition comprising a polymeric core layer (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). Trabert discloses the core layer and outer layer comprise a resin which is made from the same monomer(s) used to prepare the composition, which includes polyvinyl chloride (column 5, lines 9-38). The elastomeric intermediate layer can comprise copolyomers of acrylate (polyacrylic acid) (column 8, lines 1-22). Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; however, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness, as in claims 1 and 3-4.

Concerning claim 2, Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Concerning claims 11 and 13-14, Trabert discloses a thermoplastic resin composition comprising a polymeric core layer (outer layer), an elastomeric

intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). Trabert discloses the core layer and outer layer comprise a resin which is made from the same monomer(s) used to prepare the composition, which includes polyvinyl chloride (column 5, lines 9-38). The elastomeric intermediate layer can comprise copolymers of acrylate (polyacrylic acid) (column 8, lines 1-22). Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; however, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness.

Although Trabert does not explicitly disclose additional outer and inner layers, it would have been obvious to one of ordinary skill in the art to duplicate the layers of Trabert, since it has been held that mere duplication of parts or layers has no patentable significance unless a new and unexpected result is produced *In re Harza*, 274 F.2d 669, 124 USPO 378 (CCPA 1960).

Concerning claim 12, Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725

F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Concerning claims 16-17, Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Concerning claims 19-24 and 26, Trabert discloses a thermoplastic resin composition comprising a polymeric core layer (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). Trabert discloses the core layer and outer layer comprise a resin which is made from the same monomer(s) used to prepare the composition, which includes polyvinyl chloride (column 5, lines 9-38). The elastomeric intermediate layer can comprise copolymers of acrylate (polyacrylic acid) (column 8, lines 1-22). Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; however, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness.

Although Trabert does not explicitly disclose additional outer and inner layers, it would have been obvious to one of ordinary skill in the art to duplicate the layers of Trabert, since it has been held that mere duplication of parts or layers has no patentable significance unless a new and unexpected result is produced *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Claim Objections

4. Claims 5-10, 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The closest prior art does not teach or suggest the recited polymeric sheet composition further including where one or more of the outer layers A and C comprise a microcrystalline polyamide having heat of fusion of less than 20J/g and a light transmission of greater than 80%. The closest prior art does not teach or suggest the recited polymeric sheet composition further including where the inner layer comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

The prior art does not teach motivation or suggestion for modification to make the invention as instantly claimed.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Ferguson whose telephone number is 571-272-1522. The examiner can normally be reached on Monday through Friday 9:00 AM – 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Vineis, can be reached on 571-270-1547. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1781

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/LAWRENCE D FERGUSON/
Examiner, Art Unit 1781

Notice of References Cited	Application/Control No. 16/719,256		Applicant(s)/Patent Under Reexamination Stewart et al.	
	Examiner LAWRENCE D FERGUSON		Art Unit 1781	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-5318737-A	06-1994	Trabert; Loren D.	C08L51/06	264/173.16
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

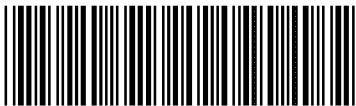
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	02/14/2020	03/12/2020							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	O							
	6	÷	O							
	7	÷	O							
	8	÷	O							
	9	÷	O							
	10	÷	O							
	11	÷	✓							
	12	÷	✓							
	13	÷	✓							
	14	÷	✓							
	15	÷	O							
	16	÷	✓							
	17	÷	✓							
	18	÷	N							
	19	÷	✓							
	20	÷	✓							
	21	÷	✓							
	22	÷	✓							
	23	÷	✓							
	24	÷	✓							
	25	÷	N							
	26	÷	✓							
	27	÷	N							
	28	÷	N							
	29	÷	N							

Search Notes 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

CPC - Searched*		
Symbol	Date	Examiner
B32B 7/02	03/12/2020	/LF/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
East Search	03/12/2020	/LF/
CPC Search	03/12/2020	/LF/
NPL Search	03/12/2020	/LF/
Inventor Search	03/12/2020	/LF/
Assignee Search	03/12/2020	/LF/

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	9	(Bay with Materials).as.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S2	127	(Ray with Stewart).in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S3	21	(John with Lahlouh).in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S4	2	S2 and dual with shell	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:11
S5	7	S2 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:11
S6	4	S3 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:12
S7	3	dual with shell with dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:30
S8	2015	outer with layers same flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:31
S9	1887	S8 and (core or inner or intermediate or center or central) near3 layer	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:49
S10	1264	S8 and (core or inner or intermediate or center or central) near3 layer with hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S11	0	S8 and (core or inner or intermediate or center or central) near3 layer with hardness with "D 85"	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S12	1	S8 and (core or inner or intermediate or center or central) near3 layer with hardness with "A 60"	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S13	50169	polymeric with sheet	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S14	297	S13 and elastomeric with (inner or intermediate or core) near3 (sheet layer)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S15	3	S13 and elastomeric with (inner or intermediate or core) near3 (sheet layer) same hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S16	3	S15 and modulus	US-PGPUB; USPAT;	OR	ON	2020/03/12 13:53

			USOCR			
S17	2	S15 and flexural same modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:53
S18	178	S14 and outer near3 layers	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:54
S19	2	S14 and outer near3 layers same flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:54
S20	1	"5318737".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:32
S21	1	"5318737".pn. and intermediate	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:33
S22	1	"5318737".pn. and (laminat\$4 or extrusion or coextrusion or extruding or thermoform\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:52
S23	1	"5318737".pn. and thick\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:54
S24	1	"5318737".pn. and total with thick\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:54

EAST Search History (Interference)

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3/12/2020 9:41:42 PM

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BIB DATA SHEET

CONFIRMATION NO. 7352

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.	
16/719,256	12/18/2019	428	1781	513043 (000550US)	
APPLICANTS Bay Materials, LLC, Fremont, CA INVENTORS Ray F. Stewart, Redwood City, CA; John Lahlouh, San Jose, CA; ** CONTINUING DATA ***** This application is a CIP of 16/211,176 12/05/2018 PAT 10549511 which is a CIP of PCT/US2018/035384 05/31/2018 which claims benefit of 62/590,627 11/26/2017 and claims benefit of 62/512,786 05/31/2017 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 01/23/2020					
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and /LAWRENCE D FERGUSON/ Acknowledged Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY CA	SHEETS DRAWINGS 4	TOTAL CLAIMS 29	INDEPENDENT CLAIMS 3
ADDRESS LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083 UNITED STATES					
TITLE DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS					
FILING FEE RECEIVED 2780	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:				
☐ All Fees					
☐ 1.16 Fees (Filing)					
☐ 1.17 Fees (Processing Ext. of time)					
☐ 1.18 Fees (Issue)					
☐ Other _____					
☐ Credit					

Substitute for Form 1449A/B/PTO				Patent Application No.	16/719,256
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Confirmation No.	7352
				Attorney Docket No.	513043 (000550US)
				Client Reference No.	DD4105P/US05
Sheet	1	of	2		

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	1	6,390,812	B1	Chishti et al.	05/21/2002	
	2	6,454,565	B2	Phan et al.	09/24/2002	
	3	6,497,574	B1	Miller	12/24/2002	
	4	6,524,101	B1	Phan et al.	02/25/2003	
	5	6,572,372	B1	Phan et al.	06/03/2003	
	6	6,746,757	B1	Takagi et al.	06/08/2004	
	7	6,964,564	B2	Phan et al.	11/15/2005	
	8	7,121,825	B2	Chishti et al.	10/17/2006	
	9	7,210,926	B2	Tadros et al.	05/01/2007	
	10	8,235,713	B2	Phan et al.	08/07/2012	
	11	8,337,199	B2	Wen	12/25/2012	
	12	8,765,031	B2	Li et al.	07/01/2014	
	13	8,858,226	B2	Phan et al.	10/14/2014	
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	18	2006/0078841	A1	DeSimone et al.	04/13/2006	
	19	2008/0248438	A1	DeSimone et al.	10/09/2008	
	20	2011/0020761	A1	Kalili	01/27/2011	
	21	2015/0004553	A1	Li et al.	01/01/2015	
	22	2015/0140300	A1	Pudleiner et al.	05/21/2015	
	23	2015/0366637	A1	Kopelman et al.	12/24/2015	
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	25	2017/0007361	A1	Borankay et al.	01/12/2017	
	26	2017/0007362	A1	Chen et al.	01/12/2017	
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	35	2006/0078841	A1	DeSimone et al.	04/13/2006	
	36	2009/0130624	A1	Sun et al.	05/21/2009	
	37	2011/0039223	A1	Li et al.	02/17/2011	
	38	2011/0207087	A1	Jones et al.	08/25/2011	

Examiner Signature		Date Considered	
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* If the reference is not in English, then at least one of the following is provided: (a) an English translation in whole or in part or (b) a concise statement of relevance in the form of, for example, an English language counterpart, an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office.

Substitute for Form 1449A/B/PTO				Patent Application No.	16/719,256
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Confirmation No.	7352
				Attorney Docket No.	513043 (000550US)
				Client Reference No.	DD4105P/US05
Sheet	2	of	2		

FOREIGN PATENT DOCUMENTS							
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation *
		Office	Application or Patent Number	Kind Code			
	39	WO	2006/009745	A1	Dentsply. Int., Inc.	01/26/2006	
	40	WO	2010/074789	A1	Dow Global Tech., Inc.	07/01/2010	
	41	DE	2020013001392	U1	Scheu Dental GmbH	04/09/2013	(a)
	42	WO	2013/171124	A1	Bayer Material Science AG	11/21/2013	

OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation *
	43	International Search Report and Written Opinion from International Patent Application No. PCT/US2018/035384, 14 pages, August 22, 2018.	
	44	Campo, E. Alfredo, "Mechanical Properties of Polymeric Materials." Selection of Polymeric Materials: Plastics Design Library, 2008, 4 pages.	
	45	Bayer Product Information sheet for TEXIN® 990R, Pages 1-4, November 2002, Pittsburgh, PA.	
	46	Barner-Kowollik et al., 2016, "Polymer Interfaces: Synthetic Strategies Enabling Functionality, Adaptivity, and Spatial Control", Macromolecules, 2016, 49, 14, 5001-5016.	
	47	Desmopan (TPU) Product Range-Reference Data, Bayer Material Science, 2004-09.	
	48	Mid-West Innovators: Durometer, http://www.midwestinnovators.com/material-properties/durometer.html , 02/24/2020.	
	49	Thermoplastic-Polyurethane Elastomers (TPU), Technical Information, The Chemical Company BASF, 28 pages.	
	50	Barner-Kowollik et al., Macromolecules, Polymer Interfaces, Perspective pubs.acs.org/Macromolecules .	

Examiner Signature		Date Considered	
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* If the reference is not in English, then at least one of the following is provided: (a) an English translation in whole or in part or (b) a concise statement of relevance in the form of, for example, an English language counterpart, an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 16/719,256

Confirmation No. 7352

Attorney Docket No. 513043 (000550US)

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR 1.97 and 1.98, the documents listed on the accompanying Form PTO-1449, Substitute Form PTO-1449, and/or USPTO Form SB/08 (hereinafter, individually or collectively referred to as "Form") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the documents in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the documents be entered into the record of the present application and that the Examiner initial the appropriate area on the accompanying Form, thereby indicating the Examiner's consideration of each of the documents.

The submission of the documents listed on the Form is for the purpose of providing a complete record and is not a concession that the documents listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any document submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the documents is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any document is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☐ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- ☐ Note: This submission includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), such that no reduction in patent term adjustment is warranted by the filing of this Information Disclosure Statement.
- ☒ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

- ☐ the Statement under 37 CFR 1.97(e) (see “Statement under 37 CFR 1.97(e)” below).
- ☐ Note: This submission includes the Statement under 37 CFR 1.704(d) (see “Statement under 37 CFR 1.704(d)” below), such that no reduction in patent term adjustment is warranted by the filing of this Information Disclosure Statement.

– or –

- ☒ the fee set forth in 37 CFR 1.17(p) (see “Fees” below).
- ☐ **on or after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see “Statement under 37 CFR 1.97(e)” below), and the fee set forth in 37 CFR 1.17(p) (see “Fees” below).
- ☐ Note: This submission includes the Statement under 37 CFR 1.704(d) (see “Statement under 37 CFR 1.704(d)” below), such that no reduction in patent term adjustment is warranted by the filing of this Information Disclosure Statement.

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Citation to Other Patent Applications

- ☐ The following U.S. patent applications are hereby brought to the attention of the Examiner. The U.S. patent applications claim subject matter that may be considered by the Examiner to be similar to the subject matter claimed in the above-identified patent application. Accordingly, these U.S. patent applications and/or the prosecution pertaining thereto may include information considered to be material to the prosecution of the above-identified patent application. Since the Examiner has electronic access to the prosecution histories of these U.S. patent applications, copies of prosecution materials therefrom are not provided herewith, but will be promptly provided if the Examiner so desires and requests same.

U.S. APPLICATIONS		STATUS (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Never Issued: Abandoned/Expired
1.				
2.				
3.				

Copies of the Documents

- ☒ Copies of any U.S. patents and published patent applications that are listed on the accompanying Form are not enclosed herewith. Copies of any other documents identified on the accompanying Form are enclosed herewith.
- ☒ For each document not in the English language, at least one of the following is provided: (a) an English translation in whole or in part or (b) a concise statement of relevance in the form of, for example, an English language counterpart, an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office.
- ☒ The documents listed on the accompanying Form were previously identified in the parent application(s) of the present application, and copies of the documents were furnished at that time. Accordingly, additional copies of the documents are not submitted herewith, so as not to burden the file with duplicate copies of documents. The Examiner is respectfully requested to carefully review the documents in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the documents were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING OR 371(c) DATE	Patented	Pending	Abandoned
1. 16/211,176	Dec. 5, 2018	X		

2.				
3.				

Fee Calculation

- ☐ **No fee** is owed by the applicant(s).
- ☒ IDS Fee (37 CFR 1.17(p)) \$240.00
- ☐ Applicant(s) assert(s) small entity status. Therefore, the fee shown above is reduced by 50%, and the resulting fee is shown below.
- ☐ Applicant(s) certifies/certify micro entity status. Therefore, the fee shown above is reduced by 75%, and the resulting fee is shown below. Note: Form PTO/SB15A or B must either be enclosed or have been submitted previously
- ☒ **Total Fee Due** **\$240.00**

Fee Payment

- ☒ Charge the indicated **Total Fee Due** to Deposit Account No. 12-1216.
- ☒ Charge any additional fees owed in connection with this communication to Deposit Account No. 12-1216.
- ☒ Credit any refund to Account No. 12-1216.



/Gerald T. Gray/

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Date: March 17, 2020



Espacenet

Bibliographic data: DE202013001392 (U1) — 2013-04-09

Dentalschiene mit äußerer TPU-Schicht
Dental splint with outer TPU layer

Inventor(s):

Applicant(s): SCHEU DENTAL GMBH [DE] ± (SCHEU-DENTAL GMBH)

Classification: - international: A61C7/00; B32B27/40; B32B33/00
- cooperative: A61C7/08 (EP); B32B27/08 (EP); B32B27/36 (EP);
B32B27/365 (EP); B32B27/40 (EP); B32B33/00
(EP); B32B7/02 (EP); B32B2250/24 (EP);
B32B2274/00 (EP); B32B2307/402 (EP);
B32B2307/412 (EP); B32B2307/536 (EP);
B32B2375/00 (EP)

Application number: DE20132001392U 20130214

Priority number(s): DE20132001392U 20130214

Abstract of DE202013001392 (U1)

Dentalschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund (1), wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, dadurch gekennzeichnet, dass eine thermoplastische Polyurethan (TPU) -Folie oder -Platte (2) auf die zu den Zähnen eines Benutzers der Dentalschiene gerichtete Seite des Schichtverbundes (1) auflaminiert ist.

Notice

This translation is machine-generated. It cannot be guaranteed that it is intelligible, accurate, complete, reliable or fit for specific purposes. Critical decisions, such as commercially relevant or financial decisions, should not be based on machine-translation output.

ABSTRACT DE202013001392

Dental rail of thermoplastic elastomer, consisting of a layer composite (1), wherein at least two layers (11, 12) have different hardnesses, characterized in that a thermoplastic polyurethane (TPU) film or sheet (2) on the teeth of a User of the dental rail directed side of the laminate (1) is laminated.

Dentalschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund (1), wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, dadurch gekennzeichnet, dass eine thermoplastische Polyurethan (TPU)-Folie oder -Platte (2) auf die zu den Zähnen eines Benutzers der Dentalschiene gerichtete Seite des Schichtverbundes (1) auflaminiert ist.

(19)



Deutsches
Patent- und Markenamt



(10) **DE 20 2013 001 392 U1** 2013.05.29

(12)

Gebrauchsmusterschrift

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(51) Int Cl.: **A61C 7/00 (2013.01)**

B32B 27/40 (2013.01)

B32B 33/00 (2013.01)

(73) Name und Wohnsitz des Inhabers:
Scheu-Dental GmbH, 58642, Iserlohn, DE

(74) Name und Wohnsitz des Vertreters:
**Schneiders & Behrendt Rechts- und
Patentanwälte, 44787, Bochum, DE**

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Bezeichnung: **Dentalschiene mit äußerer TPU-Schicht**

(57) Hauptanspruch: Dentalschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund (1), wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, dadurch gekennzeichnet, dass eine thermoplastische Polyurethan (TPU)-Folie oder -Platte (2) auf die zu den Zähnen eines Benutzers der Dentalschiene gerichtete Seite des Schichtverbundes (1) auflaminiert ist.



Beschreibung

[0001] Die Erfindung betrifft eine Dentialschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund, wobei mindestens zwei Schichten unterschiedliche Härten aufweisen.

[0002] Dentialschienen der genannten Art sind beispielsweise aus der deutschen Offenlegungsschrift DE 10 2008 061 325 A1 bekannt. Diese Offenlegungsschrift beschreibt eine mehrschichtige Dentialschiene mit zwei äußeren harten Segmenten und einem in der Mitte liegenden weichen Segment. Zudem wird ein Verfahren zur Herstellung der mehrschichtigen Dentialschiene offenbart. Tiefziehverfahren sind allgemein bekannt zur Herstellung von mehrschichtigen Dentialschienen. Dazu werden Tiefziehfolien, bestehend aus thermoplastischen Elastomeren, in Tiefziehgeräten erwärmt, über ein Gipsmodell tiefgezogen und anschließend nachbearbeitet.

[0003] Eine Färbung der Tiefziehfolien kann nach dem Stand der Technik dadurch erzielt werden, dass die thermoplastische Elastomermasse mit Farbpigmenten vermischt wird.

[0004] Die vorbekannten Dentialschienen haben den Vorteil, dass sich ihre mechanischen Eigenschaften durch eine gezielte Auswahl von unterschiedlichen Materialien für die Verbundschichten einstellen lassen. Durch die harte Oberfläche erhöht sich die Verschleißbeständigkeit. Damit ist ein längerer Einsatz der Dentialschiene möglich.

[0005] Dentialschienen der genannten Art haben jedoch den Nachteil, dass der Schichtverbund nach mehrfachem Gebrauch an Farbechtheit verliert. Dies geschieht insbesondere an Stellen, an denen die Tiefziehfolie mit den Zähnen des Benutzers der Dentialschiene in Kontakt kommt.

[0006] Es ist Aufgabe der Erfindung, eine Dentialschiene der genannten Art bereitzustellen, die eine günstige Herstellung ermöglicht. Insbesondere soll eine individuelle Färbung günstig möglich sein. Nach mehrfacher Anwendung der Dentialschiene sollten Verfärbungen vermieden werden.

[0007] Zur Lösung dieser Aufgabe schlägt die Erfindung vor, dass eine thermoplastische Polyurethan (TPU)-Folie oder -Platte auf die zu den Zähnen des Benutzers der Dentialschiene gerichtete Seite des Schichtverbundes auflaminiert ist.

[0008] Die TPU-Folie oder -Platte ermöglicht ein vollflächiges Anschmiegen der Dentialschiene an die Zähne. Da Dentialschienen zu kieferorthopädischen Zwecken häufig über Nacht getragen werden, ist ein Softeffekt wünschenswert. Die Dentialschiene soll hierbei keinen intraoralen Störkörper darstellen. Zur

Anwendung bei sportlichen Aktivitäten weist die weiche TPU-Folie oder -Platte ein gutes Dämpfungsverhalten auf. Neben dem reduzierten Risiko der Zahnbeschädigung wird die Wahrscheinlichkeit reduziert, dass sich die Dentialschiene aufgrund der Nachgiebigkeit der weichen TPU-Folie oder -Platte bei Stoßbelastungen vom Gebiss löst.

[0009] Eine positive Ausgestaltung der Erfindung sieht vor, dass die TPU-Folie oder -Platte eine oder mehrere Schichten aufweist. Dies ermöglicht eine Optimierung des Dämpfungsverhaltens und der Anschmiegsamkeit der gesamten Dentialschiene.

[0010] Eine besonders vorteilhafte Optimierung des Dämpfungsverhaltens und der Anschmiegsamkeit lässt sich dadurch einstellen, dass die Schichten der TPU-Folie oder -Platte unterschiedliche Härten aufweisen. Die Folge ist ein steuerbarer Härteverlauf innerhalb der TPU-Folie oder -Platte.

[0011] Als vorteilhafte Ausführungsform der Erfindung hat sich erwiesen, dass die zu der Dentialschiene gerichtete Schicht der TPU-Folie oder -Platte eine Härte aufweist, die gleich oder höher ist als die Härte der weichen Schicht des Schichtverbundes. Im Falle einer Färbung des Schichtverbundes wird ein Übergang der Farbpigmente aufgrund der mindestens gleich harten Schicht verhindert. Diese dient als Barriere. Mithin handelt sich um eine Möglichkeit, um die Farbechtheit der Dentialschiene beizubehalten.

[0012] Eine weitere Ausgestaltungsvariante der Erfindung sieht vor, dass die von der Dentialschiene abgewandte Schicht der TPU-Folie oder -Platte eine Härte aufweist, die gleich oder niedriger ist als die Härte der weichen Schicht des Schichtverbundes. Dabei handelt es sich um die Schicht, die im Gebrauchszustand der Dentialschiene direkt mit den Zähnen in Kontakt kommt. Dies ermöglicht ein noch weiches und anschmiegsames Kontaktverhalten mit den Zähnen, wodurch sich der Tragekomfort erhöht.

[0013] Durch eine mindestens teilweise Färbung der auflaminierten TPU-Folie oder -Platte lässt sich eine Ent- oder Verfärbung des Schichtverbundes kaschieren. Dabei sollte die Färbung der TPU-Folie oder -Platte möglichst dem Farbton des Schichtverbundes entsprechen. Durch die mindestens teilweise Färbung der auflaminierten TPU-Folie oder -Platte wird die optische Wahrnehmung der Gebrauchsspuren aufgrund der Farbgleichheit reduziert.

[0014] Der Einsatz einer farbigen auflaminierten TPU-Folie hat den Vorteil, dass individuell farbige hart/weiche Dentialschienen herstellbar sind, ohne dass das Grundmaterial in diversen Einfärbungen vorliegen muss. Das Grundmaterial kann z. B. stets transparent sein.

[0015] Wenn beabsichtigt ist, die Farbechtheit des Schichtverbundes beizubehalten, reicht der Einsatz von transparenten TPU-Folien oder -Platten aus. Dies reduziert die Herstellungskosten für Dental-schienen. Eine Voraussetzung für den sinnvollen Ein-satz von transparenten TPU-Folien oder -Platten be-steht darin, dass die zum Schichtverbund gerichte-te Schicht der TPU-Folie oder -Platte eine Härte auf-weist, die gleich oder höher ist als die Härte der wei-cheren Schicht des Schichtverbundes.

[0016] Die Erfindung sieht bevorzugt vor, dass die TPU-Folie oder -Platte eine Stärke von 0,1–0,5 mm aufweist. Es hat sich herausgestellt, dass TPU-Foli-en oder -Platten mit vorgenannter Stärke besonders gute Eigenschaften hinsichtlich der Anschmiegsam-keit aufweisen. Dabei gehen die Eigenschaften des Schichtverbundes positiv in die Eigenschaften der TPU-Folie oder -Platte ein.

[0017] Eine besonders bevorzugte Ausführungsform sieht vor, dass die weichere Schicht des Schicht-verbundes thermoplastisches Polyurethan (TPU) und die härtere Schicht Polyethylenterephthalatglycol (PETG), Polycarbonat (PC) oder ein thermoplasti-sches Elastomer mit ähnlichen Eigenschaften auf-weist. Die weichere Schicht ermöglicht einen Softef-fekt auf die Zähne. Die härtere Schicht stabilisiert die gesamte Dental-schiene. Die vorgenannten Materiali-en sind preiswert und gut durch Tiefziehen verarbeit-bar.

[0018] Es hat sich herausgestellt, dass Schichtver-bunde besonders gute mechanische Eigenschaften aufweisen, wenn die weichere Schicht eine Härte im Bereich von Shore A 85 bis Shore A 90 aufweist.

[0019] Zudem sollte die härtere Schicht eine Härte im Bereich von Shore D 75 bis Shore D 90 aufwei-sen. Durch die vorgenannten Werte lässt sich ein be-sonders komfortables Tragegefühl erreichen, bei ei-ner gleichzeitig vollflächigen Anschmiegung der Den-talschiene an die Zähne.

[0020] Die Schichten des Schichtverbundes sind be-vorzugt miteinander sowie mit der TPU-Folie oder -Platte mittels eines Heizpressverfahrens verbunden. Dabei erfolgt eine vorkonfektionierte Laminierung in einem kontinuierlichen oder diskontinuierlichen Heiz-pressverfahren. Hier sind alle dem Fachmann be-kannten kontinuierlichen Laminier- bzw. Heizpress-verfahren anwendbar.

[0021] Schließlich sieht die Erfindung einen Schicht-verbund aus thermoplastischem Elastomer vor, bei dem mindestens zwei Schichten unterschiedliche Härten aufweisen. Dabei weist der Schichtverbund eine auflaminierte TPU-Folie oder -platte auf, die mit einer Isolierfolie verbunden ist. Es hat sich als beson-ders vorteilhaft herausgestellt, wenn zwischen dem

Gipsmodell und der TPU-Folie oder -Platte eine Iso-lierschicht tiefgezogen wird. Eine derartige Isolier-schicht verhindert Gipsanhaftungen an der Dental-schiene und erleichtert zudem das Abformen. Ein weiteres bedeutendes Merkmal liegt darin, dass es aufgrund der Isolierschicht nicht zu scharfen Abfor-mungen des Gipsmodells kommt. Die Dental-schiene sitzt somit im Allgemeinen besser auf den Zähnen des Benutzers.

[0022] Die vorgenannte Isolierfolie ist bevorzugt ei-ne Hart-Polyethylen(HDPE)-Folie. Isolierfolien aus HDPE haben gegenüber anderen Materialien die vorteilhafte Eigenschaft, dass HDPE hinsichtlich der Passgenauigkeit besonders hochwertige Dental-schienen tiefziehen lässt. Damit erhöht sich der Tra-gekomfort und letztlich die Zufriedenheit des Benut-zers.

[0023] Im Weiteren wird die Erfindung anhand von Ausführungsbeispielen erläutert. Es zeigen:

[0024] Fig. 1: Schnittdarstellung des gefärbten Schichtverbundes der Dental-schiene mit auflaminier-ter, gefärbter TPU-Folie;

[0025] Fig. 2: Schnittdarstellung des gefärbten Schichtverbundes der Dental-schiene mit auflaminier-ter, zweischichtiger TPU-Folie.

[0026] Fig. 1 zeigt einen gefärbten Schichtverbund 1, wobei eine harte Schicht 12 aus PETG und eine weiche Schicht 11 aus TPU besteht. Eine auflamini-erte TPU-Folie 2 weist den gleichen Farbton wie der Schichtverbund 1 auf. Sollte sich der Schichtverbund verfärben, wird diese Verfärbung durch die Färbung der TPU-Folie 2 kaschiert.

[0027] Fig. 2 zeigt den gefärbten Schichtverbund 1, bestehend aus der harten Schicht 12 aus PETG und der weichen Schicht 11 aus TPU. Auf die wei-che Schicht 11 wird eine dünne TPU-Folie 2 auflami-niert. Diese ist in zwei Schichten unterteilt. Die zum Schichtverbund gerichtete Schicht 21 wird auf die weiche Schicht 11 auflaminiert. Dabei handelt es sich um eine harte und transparente Schicht. Dies ver-hindert das Austreten von Farbpigmenten aus dem Schichtverbund 1. Die nächste Schicht bildet die von dem Schichtverbund abgewandte Schicht 22. Dabei handelt es sich um eine weiche TPU-Schicht. Diese ermöglicht ein vollflächiges Anschmiegen der Den-talschiene an die Zähne.

[0028] Es ist auch möglich, dass das zum Schicht-verbund gerichtete Element 21 nicht transparent son-dern ebenfalls gefärbt ist. Dadurch wird eine Farbpig-mentbarriere gebildet.

ZITATE ENTHALTEN IN DER BESCHREIBUNG

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Zitierte Patentliteratur

- DE 102008061325 A1 [0002]

Schutzansprüche

1. Dentschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund (1), wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, **dadurch gekennzeichnet**, dass eine thermoplastische Polyurethan (TPU)-Folie oder -Platte (2) auf die zu den Zähnen eines Benutzers der Dentschiene gerichtete Seite des Schichtverbundes (1) auflaminiert ist.

2. Dentschiene nach Anspruch 1, dadurch gekennzeichnet, dass die TPU-Folie oder -Platte (2) eine oder mehrere Schichten (21, 22) aufweist.

3. Dentschiene nach Anspruch 2, dadurch gekennzeichnet, dass die Schichten (21, 22) der TPU-Folie oder -Platte (2) unterschiedliche Härten aufweisen.

4. Dentschiene nach Anspruch 2 oder 3, dadurch gekennzeichnet, dass die zum Schichtverbund (1) gerichtete Schicht (21) der TPU-Folie oder -Platte (2) eine Härte aufweist, die gleich oder höher ist als die Härte der weichen Schicht (11) des Schichtverbundes (1).

5. Dentschiene nach Anspruch 3 bis 5, dadurch gekennzeichnet, dass die von dem Schichtverbund (1) abgewandte Schicht (22) der TPU-Folie oder -Platte (2) eine Härte aufweist, die gleich oder niedriger ist als die Härte der weichen Schicht (11) des Schichtverbundes (1).

6. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die TPU-Folie oder -Platte (2) mindestens teilweise gefärbt ist.

7. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die TPU-Folie oder -Platte (2) mindestens teilweise transparent ist.

8. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die TPU-Folie oder -Platte (2) eine Stärke von 0,1 bis 0,5 mm aufweist.

9. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die weiche Schicht (11) thermoplastisches Polyurethan (TPU) und die härtere Schicht (12) Polyethylenterephthalatglycol (PETG), Polycarbonat (PC) oder ein thermoplastisches Elastomer mit ähnlichen Eigenschaften aufweist.

10. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die weiche Schicht (11) eine Härte von Shore A 85 bis Shore A 90 aufweist.

11. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die härtere Schicht (12) eine Härte von Shore D 75 bis Shore D 90 aufweist.

12. Dentschiene nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, dass die Schichten (11, 12) des Schichtverbundes (1) miteinander sowie mit der TPU-Folie oder -platte (2) mittels eines Heizpressverfahrens verbunden sind.

13. Schichtverbund aus thermoplastischem Elastomer, wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, dadurch gekennzeichnet, dass der Schichtverbund (1) eine auflaminierte TPU-Folie oder -platte (2) aufweist, die mit einer Isolierfolie verbunden ist.

14. Schichtverbund nach Anspruch 13, dadurch gekennzeichnet, dass die Isolierfolie Hart-Polyethylen (HDPE) oder ein Material mit ähnlichen Eigenschaften aufweist.

Es folgt ein Blatt Zeichnungen

Anhängende Zeichnungen

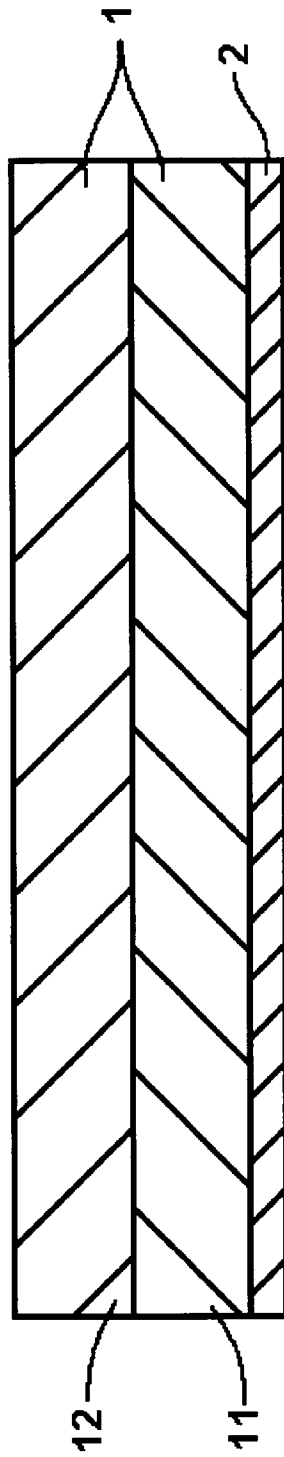


Fig. 1

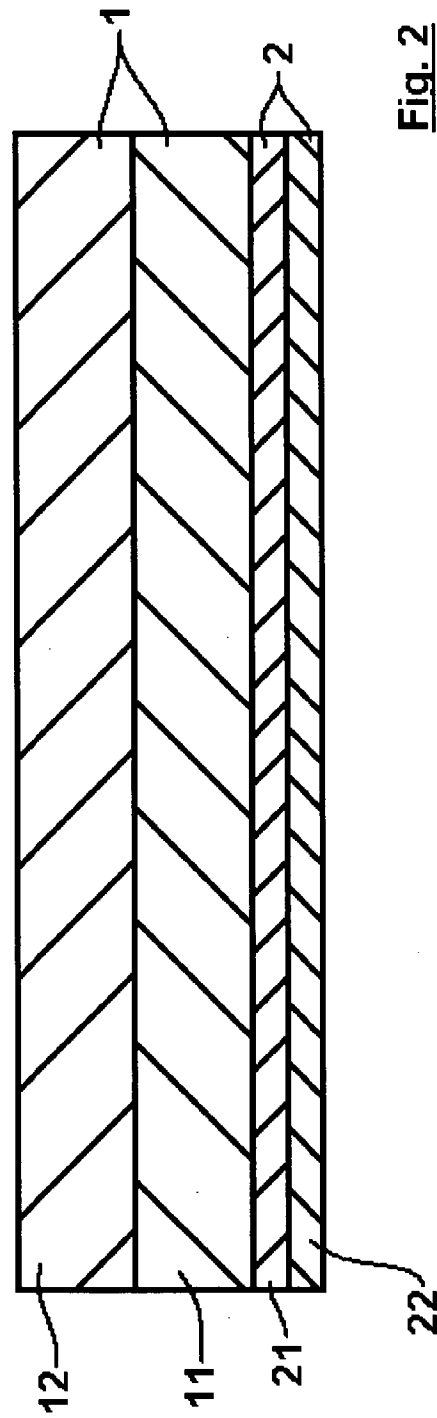


Fig. 2



Espacenet

Bibliographic data: DE202013001392 (U1) — 2013-04-09

Dentalschiene mit äußerer TPU-Schicht
Dental splint with outer TPU layer

Inventor(s):

Applicant(s): SCHEU DENTAL GMBH [DE] ± (SCHEU-DENTAL GMBH)

Classification: - international: A61C7/00; B32B27/40; B32B33/00
- cooperative: A61C7/08 (EP); B32B27/08 (EP); B32B27/36 (EP);
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Application number: DE20132001392U 20130214

Priority number(s): DE20132001392U 20130214

Abstract of DE202013001392 (U1)

Dentalschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund (1), wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, dadurch gekennzeichnet, dass eine thermoplastische Polyurethan (TPU) -Folie oder -Platte (2) auf die zu den Zähnen eines Benutzers der Dentalschiene gerichtete Seite des Schichtverbundes (1) auflaminiert ist.

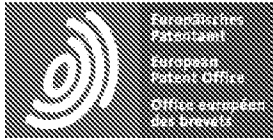
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ABSTRACT DE202013001392

Dental rail of thermoplastic elastomer, consisting of a layer composite (1), wherein at least two layers (11, 12) have different hardnesses, characterized in that a thermoplastic polyurethane (TPU) film or sheet (2) on the teeth of a User of the dental rail directed side of the laminate (1) is laminated.

Dentalschiene aus thermoplastischem Elastomer, bestehend aus einem Schichtverbund (1), wobei mindestens zwei Schichten (11, 12) unterschiedliche Härten aufweisen, dadurch gekennzeichnet, dass eine thermoplastische Polyurethan (TPU)-Folie oder -Platte (2) auf die zu den Zähnen eines Benutzers der Dentalschiene gerichtete Seite des Schichtverbundes (1) auflaminiert ist.



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DESCRIPTION DE202013001392

[0001]

The invention relates to a dental splint made of thermoplastic elastomer, consisting of a layer composite, wherein at least two layers have different hardnesses.

[0002]

Dental splints of the type mentioned are known for example from German patent application DE 10 2008 061 325 A1. This publication describes a multilayer dental splint having two outer hard segments and a central soft segment. In addition, a method for producing the multilayer dental splint is disclosed. Deep-drawing processes are generally known for the production of multilayer dental splints. For this thermoforming films, consisting of thermoplastic elastomers, heated in thermoforming equipment, deep drawn on a gypsum model and then reworked.

[0003]

A coloring of thermoforming films can be achieved according to the prior art, that the thermoplastic elastomer composition is mixed with color pigments.

[0004]

The previously known dental splints have the advantage that their mechanical properties can be

adjusted by a specific selection of different materials for the composite layers.

The hard surface increases the wear resistance. For a longer use of the dental rail is possible.

[0005]

However, dental splints of the type mentioned have the disadvantage that the layer composite loses its color fastness after repeated use. This happens in particular at places where the thermoforming foil comes into contact with the teeth of the user of the dental rail.

[0006]

It is an object of the invention to provide a dental rail of the type mentioned, which allows a favorable production. In particular, an individual coloring should be cheap. After multiple use of the dental splint discoloration should be avoided.

[0007]

In order to achieve this object, the invention proposes that a thermoplastic polyurethane (TPU) film or sheet is laminated onto the side of the laminar composite facing the teeth of the user of the dental rail.

[0008]

The TPU foil or plate allows a full-surface nestling of the dental splint to the teeth.

Since dental splints are often worn overnight for orthodontic purposes, a soft effect is desirable. The dental splint should not represent an intraoral obstruction. For use in sports activities, the soft TPU film or plate has a good damping behavior. In addition to the reduced risk of tooth damage, the likelihood of the dental splint detaching from the dentition due to the compliance of the soft TPU foil or plate under shock loading is reduced.

[0009]

A positive embodiment of the invention provides that the TPU film or plate has one or more layers. This allows an optimization of the damping behavior and the conformability of the entire dental rail.

[0010]

A particularly advantageous optimization of the damping behavior and the conformability can be adjusted by the fact that the layers of the TPU film or plate have different hardnesses. The result is a controllable hardness curve within the TPU foil or plate.

[0011]

As an advantageous embodiment of the invention, it has been found that the layer of the TPU foil or plate directed towards the dental splint has a hardness which is equal to or higher than the hardness of the softer layer of the layer composite. In the case of a coloring of the layer composite, a transition of the color pigments due to the at least the same hard layer is prevented. This serves as a barrier. Thus, there is a possibility to maintain the color fastness of the dental splint.

[0012]

A further embodiment variant of the invention provides that the layer of the TPU foil or plate remote from the dental rail has a hardness which is equal to or lower than the hardness of the softer layer of the layer composite. This is the layer that comes into direct contact with the teeth during use of the dental splint. This allows for even softer and more supple contact with the teeth, which increases the wearing comfort.

[0013]

By at least partial coloring of the laminated TPU film or sheet, a dis- or discoloration of the layer

composite can be concealed. The coloring of the TPU foil or plate should correspond as far as possible to the color tone of the layer composite. The at least partial coloring of the laminated TPU foil or plate reduces the visual perception of the traces of use due to the color uniformity.

[0014]

The use of a colored laminated TPU film has the advantage that individually colored hard / soft dental splints can be produced without the base material having to be present in various colorations. The base material can z. B. always be transparent.

[0015]

If it is intended to maintain the color fastness of the laminate, the use of transparent TPU films or plates is sufficient. This reduces the manufacturing costs for dental rails. A prerequisite for the sensible use of transparent TPU films or plates is that the layer composite of the layer of TPU film or plate has a hardness that is equal to or higher than the hardness of the softer layer of the composite layer.

[0016]

The invention preferably provides that the TPU foil or plate has a thickness of 0.1-0.5 mm. It has been found that TPU films or plates with the aforementioned thickness have particularly good properties with regard to conformability. The properties of the layered composite have a positive effect on the properties of the TPU film or sheet.

[0017]

A particularly preferred embodiment provides that the softer layer of the laminate has thermoplastic polyurethane (TPU) and the harder layer polyethylene terephthalate glycol (PETG), polycarbonate (PC) or a thermoplastic elastomer having similar properties. The softer layer allows a soft effect on the teeth. The harder layer stabilizes the entire dental splint. The aforementioned materials are inexpensive and well processable by deep drawing.

[0018]

It has been found that laminates have particularly good mechanical properties when the softer layer has a hardness in the range of Shore A 85 to Shore A 90.

[0019]

In addition, the harder layer should have a hardness in the range of Shore D 75 to Shore D 90.

Due to the above values, a particularly comfortable wearing feeling can be achieved with a simultaneous full-surface fitting of the dental splint to the teeth.

[0020]

The layers of the layer composite are preferably connected to one another and to the TPU film or sheet by means of a heat press process. In this case, a prefabricated lamination takes place in a continuous or discontinuous Heizpressverfahren. Here are all known in the art continuous laminating or Hot pressing process applicable.

[0021]

Finally, the invention provides a layer composite of thermoplastic elastomer in which at least two layers have different hardnesses. In this case, the layer composite on a laminated TPU film or plate, which is connected to an insulating film. It has been found to be particularly advantageous if an insulating layer is deep-drawn between the plaster model and the TPU film or sheet. Such an insulating layer prevents plaster adhering to the dental rail and also facilitates the molding. Another important feature is that it does not come too sharp impressions of the plaster model due to the insulating layer. The dental splint thus generally sits better on the user's teeth.

[0022]

The aforementioned insulating film is preferably a hard polyethylene (HDPE) film. Insulation films

made of HDPE have the advantageous property, compared to other materials, that HDPE can deep-draw particularly high-quality dental slides with regard to the accuracy of fit. This increases the wearing comfort and ultimately the satisfaction of the user.

[0023]

Furthermore, the invention will be explained with reference to exemplary embodiments. Show it:

[0024]

1 shows a sectional view of the colored layer composite of the dental splint with laminated TPU foil laminated on;

[0025]

Fig. 2: sectional view of the colored layer composite of the dental splint with laminated, two-layered TPU film.

[0026]

Fig. 1 shows a colored layer composite 1, wherein a hard layer 12 made of PETG and a soft layer 11 consists of TPU.

A laminated TPU film 2 has the same color as the layer composite 1.

If the layer composite discolours, this discoloration is masked by the color of the TPU film 2.

[0027]

Fig. 2 shows the colored layer composite 1, consisting of the hard layer 12 of PETG and the soft layer 11 of TPU. On the soft layer 11, a thin TPU film 2 is laminated. This is divided into two layers. The composite layer 21 is laminated onto the soft layer 11. It is a hard and transparent layer. This prevents the escape of color pigments from the layer composite 1. The next layer forms

the layer 22 facing away from the layer composite. This is a soft TPU layer. This allows a full-surface nestling of the dental rail to the teeth.

[0028]

It is also possible that the element 21 directed to the layer composite is not transparent but also colored. This forms a color pigment barrier.

QUOTES INCLUDE IN THE DESCRIPTION

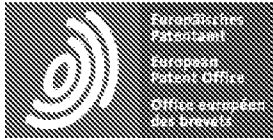
[0029]

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Cited patent literature

[0030]

DE 102008061325 A1



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CLAIMS DE202013001392

1.

Dental rail of thermoplastic elastomer, consisting of a layer composite (1), wherein at least two layers (11, 12) have different hardnesses, characterized in that a thermoplastic polyurethane (TPU) film or sheet (2) on the teeth of a User of the dental rail directed side of the laminate (1) is laminated.

2.

Dental splint according to claim 1, characterized in that the TPU foil or plate (2) has one or more layers (21, 22).

3.

Dental splint according to claim 2, characterized in that the layers (21, 22) of the TPU foil or plate (2) have different hardnesses.

4.

Dental splint according to claim 2 or 3, characterized in that the layer (21) of the TPU foil or plate (2) directed towards the layer composite (1) has a hardness which is equal to or higher than the hardness of the softer layer (11). of the layer composite (1).

5.

Dental splint according to claim 3 to 5, characterized in that the layer (22) of the TPU foil or plate

(2) facing away from the layer composite (1) has a hardness which is equal to or lower than the hardness of the softer layer (11) of the layer composite (1).

6.

Dental rail according to one of the preceding claims, characterized in that the TPU film or plate (2) is at least partially colored.

7.

Dental splint according to one of the preceding claims, characterized in that the TPU foil or plate (2) is at least partially transparent.

8.

Dental splint according to one of the preceding claims, characterized in that the TPU foil or plate (2) has a thickness of 0.1 to 0.5 mm.

9.

Dental splint according to one of the preceding claims, characterized in that the softer layer (11) comprises thermoplastic polyurethane (TPU) and the harder layer (12) polyethylene terephthalate glycol (PETG), polycarbonate (PC) or a thermoplastic elastomer having similar properties.

10.

Dental rail according to one of the preceding claims, characterized in that the softer layer (11) has a hardness of Shore A 85 to Shore A 90.

11.

Dental rail according to one of the preceding claims, characterized in that the harder layer (12) has a hardness of Shore D 75 to Shore D 90.

12.

Dental rail according to one of the preceding claims, characterized in that the layers (11, 12) of the layer composite (1) are connected to one another and to the TPU film or sheet (2) by means of a heat-pressing process.

13.

Layer composite of thermoplastic elastomer, wherein at least two layers (11, 12) have different hardnesses, characterized in that the layer composite (1) has a laminated TPU film or plate (2), which is connected to an insulating film.

14.

Laminate according to claim 13, characterized in that the insulating film hard polyethylene (HDPE) or a material having similar properties.

Electronic Patent Application Fee Transmittal				
Application Number:		16719256		
Filing Date:		18-Dec-2019		
Title of Invention:		DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
First Named Inventor/Applicant Name:		Ray F. Stewart		
Filer:		Gerald Todd Gray./Christina Alton		
Attorney Docket Number:		513043 (000550US)		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
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Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
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First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
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New International Application Filed with the USPTO as a Receiving Office

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(54) Title: MULTI-LAYER FILM WITH IMPROVED MODULUS PROPERTIES

(57) Abstract: The invention relates to a multi-layer, preferably co-extruded, plastic film with improved modulus properties, which is suitable, in particular, for producing three-dimensionally shaped articles.



WO 2013/171124 A1

MULTI-LAYER FILM WITH IMPROVED MODULUS PROPERTIES**FIELD OF THE INVENTION**

The invention relates to a multi-layer, preferably co-extruded, plastic film with improved modulus properties, which is suitable, in particular, for producing
5 three-dimensionally formed products e.g. by a thermo-forming process.

BACKGROUND OF THE INVENTION

For several applications, in particular medical applications, it is of major interest that three-dimensionally formed articles, which have been obtained by forming a plastic film, are stable in its three-dimensional form in presence of a
10 wet or humidity environment. Additionally, great demands are made of the plastic films, particularly with respect to the tensile modulus thereof, since the formed articles have to exert sufficient tension during the time of its use.

In the past, single-layer films, for example, consisting of a variety of thermoplastic materials have been employed for applications in wet or humidity
15 environment, which, however, have the disadvantage that despite a high tensile modulus prior to the start of the use this tensile modulus falls off greatly during the period of its use, so that frequently the desired success of the use is not obtained as planned and a reworking of the three-dimensionally formed article becomes necessary. Such a reworking is very costly.

20 In order to avoid this disadvantage, a demand has therefore existed for plastic films for the production three-dimensionally shaped products, with which the distinct drop in the tensile modulus during the period of the use in wet environment can be diminished.

SUMMARY OF THE INVENTION

25 The object that underlay the present invention accordingly consisted in providing suitable plastic films for the production of three-dimensionally shaped products, with which the distinct drop in the tensile modulus during the period of the its use can be diminished.

Surprisingly, it has been found that a multi-layer, preferably three-layer, plastic film containing a core layer comprising a polycarbonate or copolycarbonate and/or a polyester or copolyester between two layers comprising a thermoplastic polyurethane and/or a polyester or copolyester with special properties eliminates the disadvantages listed above.

DETAILED DESCRIPTION OF THE INVENTION

The subject-matter of the present invention is therefore a multi-layer plastic film, characterised in that

- it has a core layer A containing at least one polycarbonate or copolycarbonate and/or a polyester or copolyester having a glass transition temperature T_g from 80 °C to 200°C, preferably from 80 °C to 170 °C, more preferably from 80°C to 150 °C
- and this core layer is located between two outer layers B containing at least one thermoplastic polyurethane and/or polyester or copolyester exhibiting a hardness from 45 Shore D to 85 Shore D.

Glass transition temperatures T_g are determined by means of differential scanning calorimetry (DSC) according to standard DIN EN 61006 at a heating-rate of 20 K/min with definition of T_g as the midpoint temperature (tangent method).

Preferably according to the present invention the core layer A comprises at least one polyester or copolyester, wherein the inherent viscosity of the polyester or copolyester amounts to 0.50 dL/g to 1.20 dL/g and the polyester or copolyester exhibits a glass transition temperature T_g from 80 °C to 150 °C.

The inherent viscosity is determined in 60/40 (wt/wt) phenol/tetrachloroethane at a concentration of 0.5 g/100 ml at 25°C.

Preferably according to the present invention the two outer layers B comprise at least one thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D.

5 In a preferred embodiment of the present invention the multi-layer plastic film

- has a core layer A containing at least one polyester or copolyester having an inherent viscosity from 0.50 dL/g to 1.20 dL/g and a glass transition temperature T_g from 80°C to 150 °C
- and this core layer A is located between two outer layers B containing at least one thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D.

Suitable and preferred polyester or copolyester for the core layer A are poly- or copolycondensates of terephthalic acid or naphthalene dicarboxylic acid, such as, for example and preferably, poly- or copolyethylene terephthalate (PET or 15 CoPET), glycol-modified PET (PETG) or poly- or copolybutylenc terephthalate (PBT or CoPBT), poly- or copolyethylene naphthalate (PEN or CoPEN).

Suitable and preferred polycarbonates or copolycarbonates for the core layer A are in particular polycarbonates or copolycarbonates with average molecular weights M_w of from 500 to 100,000, preferably from 10,000 to 80,000, 20 particularly preferably from 15,000 to 40,000.

Additionally, blends containing at least one such polycarbonate or copolycarbonate are suitable and preferred for the core layer A. Blends of the abovementioned polycarbonates or copolycarbonates with at least one poly- or copolycondensate of terephthalic acid, in particular at least one such poly- or 25 copolycondensate of terephthalic acid with average molecular weights M_w of from 10,000 to 200,000, preferably from 26,000 to 120,000, are furthermore also suitable and preferred. In particularly preferred embodiments of the invention, the blend is a blend of polycarbonate or copolycarbonate with poly- or

copolybutylene terephthalate. Such a blend of polycarbonate or copolycarbonate with poly- or copolybutylene terephthalate can preferably be one with 1 to 90 wt.% of polycarbonate or copolycarbonate and 99 to 10 wt.% of poly- or copolybutylene terephthalate, preferably with 1 to 90 wt.% of polycarbonate and 99 to 10 wt.% of polybutylene terephthalate, the contents adding up to 100 wt.%. Such a blend of polycarbonate or copolycarbonate with poly- or copolybutylene terephthalate can particularly preferably be one with 20 to 85 wt.% of polycarbonate or copolycarbonate and 80 to 15 wt.% of poly- or copolybutylene terephthalate, preferably with 20 to 85 wt.% of polycarbonate and 80 to 15 wt.% of polybutylene terephthalate, the contents adding up to 100 wt.%. Such a blend of polycarbonate or copolycarbonate with poly- or copolybutylene terephthalate can very particularly preferably be one with 35 to 80 wt.% of polycarbonate or copolycarbonate and 65 to 20 wt.% of poly- or copolybutylene terephthalate, preferably with 35 to 80 wt.% of polycarbonate and 65 to 20 wt.% of polybutylene terephthalate, the contents adding up to 100 wt.%.

In preferred embodiments, particularly suitable polycarbonates or copolycarbonates are aromatic polycarbonates or copolycarbonates.

The polycarbonates or copolycarbonates can be linear or branched in a known manner.

The preparation of these polycarbonates can be carried out in a known manner from diphenols, carbonic acid derivatives, optionally chain terminators and optionally branching agents. Details of the preparation of polycarbonates have been laid down in many patent specifications for about 40 years. Reference may be made here by way of example merely to Schnell, "Chemistry and Physics of Polycarbonates", Polymer Reviews, volume 9, Interscience Publishers, New York, London, Sydney 1964, to D. Freitag, U. Grigo, P. R. Müller, H. Nouvertne', BAYER AG, "Polycarbonates" in Encyclopedia of Polymer Science and Engineering, volume 11, second edition, 1988, pages 648-718 and finally to Dres. U. Grigo, K. Kirchner and P. R. Müller "Polycarbonate" in Becker/Braun,

Kunststoff-Handbuch, volume 3/1, Polycarbonate, Polyacetale, Polyester, Celluloseester, Carl Hanser Verlag Munich, Vienna 1992, pages 117-299.

Suitable diphenols can be, for example, dihydroxyaryl compounds of the general formula)III)

5 HO-Z-OH (III)

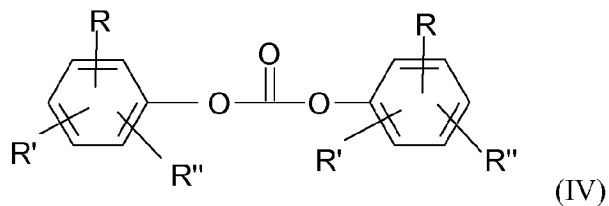
wherein Z is an aromatic radical having 6 to 34 C atoms, which can contain one or more optionally substituted aromatic nuclei and aliphatic or cycloaliphatic radicals or alkylaryls or hetero atoms as bridge members.

10 Particularly preferred dihydroxyaryl compounds are resorcinol, 4,4'-dihydroxydiphenyl, bis-(4-hydroxyphenyl)-diphenyl-methane, 1,1-bis-(4-hydroxyphenyl)-1-phenyl-ethane, bis-(4-hydroxyphenyl)-1-(1-naphthyl)-ethane, bis-(4-hydroxyphenyl)-1-(2-naphthyl)-ethane, 2,2-bis-(4-hydroxyphenyl)-propane, 2,2-bis(3,5-dimethyl-4-hydroxyphenyl)-propane, 1,1-bis-(4-hydroxyphenyl)-
15 cyclohexane, 1,1-bis-(3,5-dimethyl-4-hydroxyphenyl)-cyclohexane, 1,1-bis-(4-hydroxyphenyl)-3,3,5-trimethyl-cyclohexane, 1,1'-bis-(4-hydroxyphenyl)-3-diisopropyl-benzene and 1,1'-bis-(4-hydroxyphenyl)-4-diisopropyl-benzene.

Very particularly preferred dihydroxyaryl compounds are 4,4'-dihydroxydiphenyl, 2,2-bis-(4-hydroxyphenyl)-propane and bis-(4-
20 hydroxyphenyl)-3,3,5-trimethyl-cyclohexane.

A very particularly preferred copolycarbonate can be prepared using 1,1-bis-(4-hydroxyphenyl)-3,3,5-trimethyl-cyclohexane and 2,2-bis-(4-hydroxyphenyl)-propane.

Suitable carbonic acid derivatives can be, for example, phosgene or diaryl
25 carbonates of the general formula (IV)



wherein

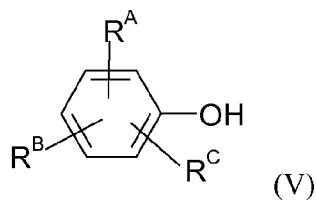
R, R' and R'' independently of each another are identical or different and represent hydrogen, linear or branched C₁-C₃₄-alkyl, C₇-C₃₄-alkylaryl or C₆-C₃₄-aryl, and R can furthermore also denote -COO-R''', wherein R''' represents hydrogen, linear or branched C₁-C₃₄-alkyl, C₇-C₃₄-alkylaryl or C₆-C₃₄-aryl.

Particularly preferred diaryl compounds are diphenyl carbonate, 4-tert-butylphenyl phenyl carbonate, di-(4-tert-butylphenyl) carbonate, biphenyl-4-yl phenyl carbonate, di-(biphenyl-4-yl) carbonate, 4-(1-methyl-1-phenylethyl)-phenyl phenyl carbonate, di-[4-(1-methyl-1-phenylethyl)-phenyl] carbonate and di-(methyl salicylate) carbonate.

Diphenyl carbonate is very particularly preferred.

Either one diaryl carbonate or different diaryl carbonates can be used

One or more monohydroxyaryl compound(s) which has/have not been used for the preparation of the diaryl carbonate(s) used can additionally be employed, for example, as chain terminators to control or vary the end groups. These can be those of the general formula (V)



wherein

R^A represents linear or branched C₁-C₃₄-alkyl, C₇-C₃₄-alkylaryl, C₆-C₃₄-aryl or -COO-R^D, wherein R^D represents hydrogen, linear or branched C₁-C₃₄-alkyl, C₇-C₃₄-alkylaryl or C₆-C₃₄-aryl, and

5 R^B, R^C independently of each other are identical or different and represent hydrogen, linear or branched C₁-C₃₄-alkyl, C₇-C₃₄-alkylaryl or C₆-C₃₄-aryl.

4-tert-Butylphenol, 4-iso-octylphenol and 3-pentadecylphenol are preferred.

Suitable branching agents can be compounds with three and more functional groups, preferably those with three or more hydroxyl groups.

10 Preferred branching agents are 3,3-bis-(3-methyl-4-hydroxyphenyl)-2-oxo-2,3-dihydroindole and 1,1,1-tris-(4-hydroxyphenyl)-ethane.

For the core layer A poly- or copolyalkylene terephthalates or poly- or copolyalkylene naphthalates are suitable in preferred embodiments of the invention as poly- or copolycondensates of terephthalic acid or naphthalene dicarboxylic acid. Suitable poly- or copolyalkylene terephthalates or poly- or
15 copolyalkylene naphthalates are for example reaction products of aromatic dicarboxylic acids or reactive derivatives thereof (for example dimethyl esters or anhydrides) and aliphatic, cycloaliphatic or araliphatic diols and mixtures of these reaction products.

As used herein, the term "terephthalic acid" is intended to include
20 terephthalic acid itself and residues thereof as well as any derivative of terephthalic acid, including its associated acid halides, esters, half-esters, salts, half-salts, anhydrides, mixed anhydrides, or mixtures thereof or residues thereof useful in a reaction process with a diol to make polyester. In one embodiment, the esters are chosen from at least one of the following: methyl, ethyl, propyl,
25 isopropyl, and phenyl esters. In one embodiment, terephthalic acid may be used as the starting material. In another embodiment, dimethyl terephthalate may be used as the starting material. In another embodiment, mixtures of terephthalic acid and

dimethyl terephthalate may be used as the starting material and/or as an intermediate material.

As used herein, the term "naphthalene dicarboxylic acid" is intended to include naphthalene dicarboxylic acid itself and residues thereof as well as any derivative of naphthalene dicarboxylic acid, including its associated acid halides, esters, half-esters, salts, half-salts, anhydrides, mixed anhydrides, or mixtures thereof or residues thereof useful in a reaction process with a diol to make polyester. In one embodiment, the esters are chosen from at least one of the following: methyl, ethyl, propyl, isopropyl, and phenyl esters. In one embodiment, naphthalene dicarboxylic acid may be used as the starting material. In another embodiment, the dimethylester of naphthalene dicarboxylic acid may be used as the starting material. In another embodiment, mixtures of terephthalic acid and the dimethylester of naphthalene dicarboxylic acid may be used as the starting material and/or as an intermediate material.

In addition to terephthalic acid or naphthalene dicarboxylic acid, the dicarboxylic acid component of the poly- or copolyester useful in the invention can optionally comprises up to 30 mole %, preferably up to 20 mole %, more preferably up to 10 mole %, most preferably up to 5 mole % of one or more modifying aromatic dicarboxylic acids. In one preferred embodiment the dicarboxylic acid component of the poly- or copolyester useful in the invention comprise up to 1 mole % of one or more modifying aromatic dicarboxylic acids. Yet in another preferred embodiment the dicarboxylic acid component of the poly- or copolyester useful in the invention comprises 0 mole % modifying aromatic dicarboxylic acids. Thus, if present, it is contemplated that the amount of one or more modifying aromatic dicarboxylic acids can range from any of these preceding endpoint values including, for example, from 0.01 to 30 mole %, preferably from 0.01 to 20 mole %, more preferably from 0.01 to 10 mole %, most preferably from 0.01 to 5 mole % and in a preferred embodiment from 0.01 to 1 mole. In one embodiment, modifying aromatic dicarboxylic acids that may be used in the present invention include but are not limited to those having up to 20 carbon atoms, preferably having 8 to 14 carbon atoms, and which can be linear,

para-oriented, or symmetrical. Examples of modifying aromatic dicarboxylic acids which may be used in this invention include, but are not limited to, phthalic acid, isophthalic acid, 4,4'-biphenyldicarboxylic acid, 1,4-, 1,5-, 2,6-, 2,7-naphthalenedicarboxylic acid (in case of poly- or copolyalkylene terephthalates),
5 terephthalic acid (in case of poly- or copolyalkylene naphthalates) and trans-4,4'-stilbenedicarboxylic acid, and esters thereof.

The carboxylic acid component of the copolyesters useful in the invention can optionally be further modified with up to 10 mole %, such as up to 5 mole % or preferably up to 1 mole % of one or more aliphatic dicarboxylic acids
10 containing 2 to 16 carbon atoms, such as, for example, malonic, succinic, glutaric, adipic, pimelic, suberic, azelaic, sebacic, cyclohexane diacetic and dodecanedioic dicarboxylic acids. Yet another embodiment contains 0 mole % modifying aliphatic dicarboxylic acids. Thus, if present, it is contemplated that the amount of one or more modifying aliphatic dicarboxylic acids can range from any of these
15 preceding endpoint values including, for example, from 0.01 to 10 mole % and preferably from 0.1 to 10 mole %.

Preferred poly- or copolyalkylene terephthalates or poly- or copolyalkylene naphthalates contain at least 70 mole %, preferably at least 80 mole % ethylene glycol, butanediol-1,4, 2,2,4,4-tetramethyl-1,3-cyclobutanediol
20 and/or 1,4-cyclohexanedimethanol residues, relative to the diol component.

The preferred poly- or copolyalkylene terephthalates or poly- or copolyalkylene naphthalates can contain in addition to ethylene glycol, butanediol-1,4, 2,2,4,4-tetramethyl-1,3-cyclobutanediol and/or 1,4-cyclohexanedimethanol residues up to 30 mole %, preferably up to 20 mole % of
25 other aliphatic diols having 3 to 12 C atoms or cycloaliphatic diols having 6 to 21 C atoms, for example radicals of propanediol-1,3, 2-ethylpropanediol-1,3, neopentyl glycol, pentanediol-1,5, hexanediol-1,6, cyclohexane dimethanol-1,4, 3-methylpentanediol-2,4, 2-methylpentanediol-2,4, 2,2,4-trimethylpentanediol-1,3 and 2-ethylhexanediol-1,6, 2,2-diethylpropanediol-1,3, hexanediol-2,5, 1,4-di-
30 ([beta]-hydroxyethoxy)-benzene, 2,2-bis-(4-hydroxycyclohexyl)propane, 2,4-

dihydroxy-1,1,3,3-tetramethylcyclobutane, 2,2-bis-(3-[beta]-hydroxyethoxyphenyl)propane and 2,2-bis-(4-hydroxypropoxyphenyl)propane (cf. DE-OS 24 07 674, 24 07 776, 27 15 932).

5 The poly- or copolyesters of the invention can comprise from 0 to 10 mole %, for example, from 0.01 to 5 mole % based on the total mole percentages of either the diol or diacid residues, respectively, of one or more residues of a branching monomer, also referred to herein as a branching agent, having 3 or more carboxyl substituents, hydroxyl substituents, or a combination thereof. In certain embodiments, the branching monomer or agent may be added prior to and/or during and/or after the polymerization of the poly- or copolyester. The poly- or copolyester(s) useful in the invention can thus be linear or branched. In preferred embodiments the poly- or copolyester(s) useful in the invention are linear and thus do not contain such branching agent.

15 Examples of branching monomers, if present, include, but are not limited to, multifunctional acids or multifunctional alcohols such as trimellitic acid, trimellitic anhydride, pyromellitic dianhydride, trimethylolpropane, glycerol, pentaerythritol, citric acid, tartaric acid, 3-hydroxyglutaric acid and the like. In one embodiment, the branching monomer residues can comprise 0.1 to 0.7 mole percent of one or more residues chosen from at least one of the following:

20 trimellitic anhydride, pyromellitic dianhydride, glycerol, sorbitol, 1,2,6-hexanetriol, pentaerythritol, trimethylolethane, and/or trimesic acid. The branching monomer may be added to the copolyester reaction mixture or blended with the copolyester in the form of a concentrate as described, for example, in U.S. Patent Nos. 5,654,347 and 5,696,176.

25 Preferred poly- or copolyalkylene terephthalates or poly- or copolyalkylene naphthalates contain at least 70 mole %, preferably 80 mole % terephthalic acid or naphthalene dicarboxylic acid residues, relative to the dicarboxylic acid component, and at least 70 mole %, preferably at least 80 mole % ethylene glycol, butanediol-1,4, 2,2,4,4-tetramethyl-1,3-cyclobutanediol and/or

30 1,4-cyclohexanedimethanol residues, relative to the diol component.

In one particularly preferred embodiment the core layer A comprises at least one copolyester produced solely from terephthalic acid and reactive derivatives thereof (for example dialkyl esters thereof) and ethylene glycol and/or butanediol-1,4.

5 In another particularly preferred embodiment the core layer A comprises at least one blend of polycarbonate or copolycarbonate with poly- or copolybutylene terephthalate with 1 to 90 wt.% of polycarbonate or copolycarbonate and 99 to 10 wt.% of poly- or copolybutylene terephthalate, preferably with 35 to 80 wt.% of polycarbonate and 65 to 20 wt.% of polybutylene terephthalate, the contents
10 adding up to 100 wt.%.

In another particularly preferred embodiment of the present invention the core layer A comprises at least one copolyester that exhibits residues from

(a) a dicarboxylic acid component comprising

- i) 70 mole % to 100 mole % terephthalic acid residues,
- 15 ii) 0 mole % to 30 mole % aromatic dicarboxylic acid residues with up to 20 carbon atoms, and
- iii) 0 mole % to 10 mole % aliphatic dicarboxylic acid residues with up to 16 carbon atoms, and

(b) a diol component comprising

- 20 i) 5 mole % to 50 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and
- ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,

wherein the sum of the mole % of residues i) – iii) of the dicarboxylic acid
25 component amounts to 100 mole % and the sum of the mole % of residues i) and ii) of the diol component amounts to 100 mole %.

The two outer layers B preferably comprise at least one thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D.

Particularly preferably such at least one thermoplastic polyurethane is obtainable from

- 5 a) one or more linear polyether diols with mean molecular weights from 500 g/mol to 10,000 g/mol, preferably 500 g/mol to 6000 g/mol, and, on average, in each instance at least 1.8 and at most 3.0, preferably 1.8 to 2.2, Tserevitinov-active hydrogen atoms
- b) one or more organic diisocyanates,
- 10 c) one or more diol chain-extenders with molecular weights from 60 g/mol to 500 g/mol and with, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms

in the presence of

- d) optionally, one or more catalysts
- 15 with addition of

- e) optionally, auxiliary substances and additives,

wherein the molar ratio of the NCO groups in b) to the groups in a) and c) that are reactive towards isocyanate amounts to 0.85:1 to 1.2:1, preferably 0.9:1 to 1.1:1.

20 In a particularly preferred embodiment of the present application the multi-layer plastic film is characterised in that

- it has a core layer A containing at least one copolyester that exhibits residues from

(a) a dicarboxylic acid component comprising

- i) 70 mole % to 100 mole % terephthalic acid residues,

- ii) 0 mole % to 30 mole % aromatic dicarboxylic acid residues with up to 20 carbon atoms, and
 - iii) 0 mole % to 10 mole % aliphatic dicarboxylic acid residues with up to 16 carbon atoms, and
- 5 (b) a diol component comprising
- i) 5 mole % to 50 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and
 - ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,
- 10 wherein the sum of the mole % of residues i) – iii) of the dicarboxylic acid component amounts to 100 mole % and the sum of the mole % of residues i) and ii) of the diol component amounts to 100 mole %
- and wherein the inherent viscosity of the copolyester amounts to 0.50 dL/g to 1.20 dL/g and the copolyester exhibits a glass transition temperature T_g
- 15 from 80 °C to 150 °C,
- and this core layer is located between two outer layers B containing at least one thermoplastic polyurethane, the thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D and being obtainable from
- a) one or more linear polyether diols with mean molecular weights
 - 20 from 500 g/mol to 10,000 g/mol, preferably 500 g/mol to 6000 g/mol, and, on average, in each instance at least 1.8 and at most 3.0, preferably 1.8 to 2.2, Tserevitinov-active hydrogen atoms
 - b) one or more organic diisocyanates,
 - c) one or more diol chain-extenders with molecular weights from
 - 25 60 g/mol to 500 g/mol and with, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms

in the presence of

d) optionally, one or more catalysts

with addition of

e) optionally, auxiliary substances and additives,

- 5 wherein the molar ratio of the NCO groups in b) to the groups in a) and c) that are reactive towards isocyanate amounts to 0.85:1 to 1.2:1, preferably 0.9:1 to 1.1:1.

The film according to the invention surprisingly exhibits a distinctly smaller drop in the tensile modulus under wet or humidity conditions. Moreover,
10 the three-dimensional shaped articles made from such a film according to the invention are stable in its three-dimensional shape under such conditions.

Thermoplastic polyurethanes (TPU) are mostly constructed from linear polyols (macrodiols) such as polyester diols, polyether diols or polycarbonate diols, organic diisocyanates and short-chain, mostly difunctional, alcohols (chain-
15 extenders). They may be produced continuously or discontinuously. The most well-known production processes are the belt process (GB-A 1,057,018) and the extruder process (DE-A 1 964 834).

The thermoplastic polyurethanes preferably employed in accordance with the invention are reaction products formed from the aforementioned

- 20 a) polyether diols
b) organic diisocyanates
c) chain-extenders.

By way of diisocyanates b), use may be made of aromatic, aliphatic, araliphatic, heterocyclic and cycloaliphatic diisocyanates or mixtures of these
25 diisocyanates (cf. HOUBEN-WEYL "Methoden der organischen Chemie",

Volume E20 "Makromolekulare Stoffe", Georg Thieme Verlag, Stuttgart, New York 1987, pp 1587-1593 or "Justus Liebigs Annalen der Chemie", 562, pages 75 to 136).

In detail, let the following be mentioned in exemplary manner: aliphatic
5 diisocyanates, such as hexamethylene diisocyanate, cycloaliphatic diisocyanates, such as isophorone diisocyanate, 1,4-cyclohexane diisocyanate, 1-methyl-2,4-cyclohexane diisocyanate and 1-methyl-2,6-cyclohexane diisocyanate and also the corresponding isomer mixtures, 4,4'-dicyclohexylmethane diisocyanate, 2,4'-dicyclohexylmethane diisocyanate and 2,2'-dicyclohexylmethane diisocyanate and
10 also the corresponding isomer mixtures, aromatic diisocyanates, such as 2,4-toluylene diisocyanate, mixtures consisting of 2,4-toluylene diisocyanate and 2,6-toluylene diisocyanate, 4,4'-diphenylmethane diisocyanate, 2,4'-diphenylmethane - diisocyanate and 2,2'-diphenylmethane diisocyanate, mixtures consisting of 2,4'-diphenylmethane diisocyanate and 4,4'-diphenylmethane diisocyanate, urethane-
15 modified liquid 4,4'-diphenylmethane diisocyanates and 2,4'-diphenylmethane - diisocyanates, 4,4'-diisocyanatodiphenylethane-(1,2) and 1,5-naphthylene diisocyanate. Use is preferentially made of 1,6-hexamethylene diisocyanate, isophorone diisocyanate, dicyclohexylmethane-4,4'-diisocyanate, diphenylmethane-diisocyanate isomer mixtures with a content of 4,4'-
20 diphenylmethane diisocyanate of more than 96 wt.% and, in particular, 4,4'-diphenylmethane diisocyanate and 1,5-naphthylene diisocyanate. The stated diisocyanates may find application individually or in the form of mixtures with one another. They may also be used together with up to 15 wt.% (calculated with respect to the total quantity of diisocyanate) of a polyisocyanate, for example
25 triphenylmethane-4,4',4''-triisocyanate or polyphenyl-polymethylene polyisocyanates.

In the case of the organic diisocyanate(s) b) it is preferably a question of one or more isocyanate(s) selected from the group containing 4,4'-diphenylmethane diisocyanate, isophorone diisocyanate, dicyclohexylmethane-4,4'-diisocyanate and 1,6-hexamethylene diisocyanate.
30

Tserevitinov-active polyether diols a) are those with, on average, at least 1.8 to at most 3.0, preferably 1.8 to 2.2, Tserevitinov-active hydrogen atoms.

Designated as Tserevitinov-active hydrogen atoms are all hydrogen atoms bonded to N, O or S that yield methane by conversion with methylmagnesium halide in accordance with a process discovered by Tserevitinov. The determination takes place after the Tserevitinov reaction, whereby methylmagnesium iodide is converted with the compound to be investigated and reacts with acid hydrogen to form a magnesium salt and the corresponding hydrocarbon. The methane arising is determined by gas-volumetric analysis.

Suitable such polyether diols can be produced by one or more alkylene oxides with 2 to 4 carbon atoms in the alkylene residue being converted with a starter molecule that contains two active hydrogen atoms in bonded form. By way of alkylene oxides, let the following be mentioned, for example: ethylene oxide, 1,2-propylene oxide, epichlorohydrin, 1,2-butylene oxide and 2,3-butylene oxide. The alkylene oxides may be used individually, alternately in succession or as mixtures. By way of starter molecules there enter into consideration, for example: water, amino alcohols, such as N-alkyldiethanolamines, for example N-methyldiethanolamine, and diols such as ethylene glycol, 1,3-propylene glycol, 1,4-butanediol and 1,6-hexanediol. Optionally, mixtures of starter molecules may also be employed. Suitable polyether diols are furthermore the hydroxyl-group-containing polymerisation products of tetrahydrofuran and/or of 1,3-propylene glycol. Trifunctional polyethers in proportions from 0 wt.% to 30 wt.%, relative to the bifunctional polyethers, may also be employed, but at most in such quantity that a product arises that is still thermoplastically workable.

The polyether diols preferentially possess number-average molecular weights M_n from 500 g/mol to 8000 g/mol, particularly preferably 500 g/mol to 6000 g/mol. They may find application both individually and in the form of mixtures with one another.

The number-average molecular weights M_n can be determined with end-group determination, such as determination of hydroxyl numbers according to ASTM D 4274.

5 Tserevitinov-active chain-extendors c) are so-called chain-extension agents and possess, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms and have a number-average molecular weight from 60 g/mol to 500 g/mol. Such agents are understood to be – besides compounds exhibiting amino groups, thiol groups or carboxyl groups – those with two to three, preferably two, hydroxyl groups. Hydroxyl compounds with two to three, preferably two, hydroxyl groups are
10 particularly preferred as chain-extendors.

Employed by way of chain-extension agents are, for example and preferably, diols or diamines with a molecular weight from 60 g/mol to 500 g/mol, preferentially aliphatic diols with 2 to 14 carbon atoms, such as, for example, ethanediol, 1,2-propanediol, 1,3-propanediol, 1,4-butanediol, 2,3-butanediol, 1,5-
15 pentanediol, 1,6-hexanediol, diethylene glycol and dipropylene glycol. Also suitable, however, are diesters of terephthalic acid with glycols with 2 to 4 carbon atoms, for example terephthalic acid-bis-ethylene glycol or terephthalic acid-bis-1,4-butanediol, hydroxyalkylene ethers of hydroquinone, for example 1,4-di(β -hydroxyethyl)hydroquinone, ethoxylated bisphenols, for example 1,4-di(β -
20 hydroxyethyl)bisphenol A, (cyclo)aliphatic diamines, such as isophoronediamine, ethylenediamine, 1,2-propylenediamine, 1,3-propylenediamine, N-methylpropylene-1,3-diamine, N,N'-dimethylethylenediamine, and aromatic diamines, such as 2,4-toluylenediamine, 2,6-toluylenediamine, 3,5-diethyl-2,4-toluylenediamine or 3,5-diethyl-2,6-toluylenediamine or primary mono-, di-,
25 tri- or tetraalkyl-substituted 4,4'-diaminodiphenylmethanes. Particularly preferably, use is made of 1,2-ethylene glycol, 1,2-propanediol, 1,3-propanediol, 1,4-butanediol, 1,6-hexanediol, 1,4-di(β -hydroxyethyl)hydroquinone or 1,4-di(β -hydroxyethyl)bisphenol A by way of chain-extendors. Mixtures of the
aforementioned chain-extendors may also be employed. In addition, relatively
30 small quantities of triols may also be added.

The number-average molecular weights M_n can be determined with end-group determination, such as determination of hydroxyl numbers according to ASTM D 4274.

In the case of the diol chain-extender(s) c) it is preferably a question of one or more selected from the group containing 1,4-butanediol, 1,3-propanediol, 1,2-propanediol, 1,2-ethylene glycol, 1,6 hexanediol, 1,4-di(β -hydroxyethyl)hydroquinone and 1,4-di(β -hydroxyethyl)bisphenol A.

Reactive groups towards isocyanate in a) and c) are in particular Tserevitinov-active hydrogen atoms containing groups.

The relative quantities of compounds a) and c) are preferably so chosen that the ratio of the sum of the isocyanate groups in b) to the sum of the Tserevitinov-active hydrogen atoms in a) and c) amounts to 0.85:1 to 1.2:1, particularly preferably 0.9:1 to 1.1:1.

The thermoplastic polyurethanes employed in accordance with the invention may optionally contain catalysts d). Suitable catalysts are the tertiary amines that are known and conventional in accordance with the state of the art, such as, for example, triethylamine, dimethylcyclohexylamine, N-methylmorpholine, N,N'-dimethylpiperazine, 2-(dimethylaminoethoxy)ethanol, diazabicyclo[2,2,2]octane and similar and also, in particular, organic metallic compounds such as titanate acid esters, iron compounds or tin compounds, such as tin diacetate, tin dioctoate, tin dilaurate, or the dialkyltin salts of aliphatic carboxylic acids, such as dibutyltin diacetate or dibutyltin dilaurate or similar. Preferred catalysts are organic metallic compounds, in particular titanate acid esters, iron compounds and tin compounds. The total quantity of catalysts in the thermoplastic polyurethanes amounts, as a rule, to about 0 wt.% to 5 wt.%, preferably 0 wt.% to 2 wt.%, relative to the total weight of the TPU.

The thermoplastic polyurethanes (TPU) employed in accordance with the invention may optionally contain, by way of auxiliary substances and additives e), 0 wt.% up to at most 20 wt.%, preferably 0 wt.% to 10 wt.%, relative to the total

weight of the TPU, of the conventional auxiliary substances and additives.
Typical auxiliary substances and additives are pigments, dyestuffs, flame
retardants, stabilisers against the influences of ageing and weathering, plasticisers,
slip additives, mould-release agents, chain terminators, substances acting
5 fungistatically and bacteriostatically and also fillers and mixtures thereof.

By way of such additives, inter alia compounds that are monofunctional in
relation to isocyanates may preferably be employed in proportions up to 2 wt.%,
relative to the total weight of the thermoplastic polyurethane, as so-called chain
terminators or mould-release aids. Suitable are, for example, monoamines such as
10 butylamine and dibutylamine, octylamine, stearylamine, N-methylstearylamine,
pyrrolidine, piperidine or cyclohexylamine, monoalcohols such as butanol, 2-
ethylhexanol, octanol, dodecanol, stearyl alcohol, the various amyl alcohols,
cyclohexanol and ethylene glycol monomethyl ether.

Examples of further additives are slip additives, such as fatty-acid esters,
15 the metallic soaps thereof, fatty-acid amides, fatty-acid ester amides and silicone
compounds, anti-blocking agents, inhibitors, stabilisers against hydrolysis, light,
heat and discoloration, flame retardants, dyestuffs, pigments, inorganic and/or
organic fillers, for example polycarbonates, and also plasticisers and reinforcing
agents. Reinforcing agents are, in particular, fibrous reinforcing substances such
20 as, for example, inorganic fibres, which are produced in accordance with the state
of the art and which may also have been subjected to a sizing material. Further
particulars concerning the stated auxiliary substances and additives can be
gathered from the specialist literature, for example from the monograph by J.H.
Saunders and K.C. Frisch entitled "High Polymers", Volume XVI, Polyurethanes:
25 Chemistry and Technology, Parts 1 and 2, Interscience Publishers 1962 and 1964,
from the *Taschenbuch der Kunststoff-Additive* by R.Gächter u. H.Müller (Hanser
Verlag Munich 1990) or from DE-A 29 01 774.

The thermoplastic polyurethanes employed in accordance with the
invention preferably exhibit a hardness from 50 Shore D to 80 Shore D.
30 The Shore hardness is determined in accordance with DIN EN ISO 868.

The thermoplastic polyurethanes employed in accordance with the invention can be produced continuously in the so-called extruder process, for example in a multiple-shaft extruder, or in the so-called belt process. The metering of the TPU components a), b) and c) can be undertaken simultaneously, i.e. in the one-shot process, or in succession, i.e. by means of a prepolymer process. The prepolymer process is particularly preferred. In this connection the prepolymer may be produced both by charging in batches and continuously in a part of the extruder or in a separate upstream prepolymer unit, for example in a static-mixer reactor, for example a Sulzer mixer.

10 The preferred polyester or copolyester, in particular copolyester employed in accordance with the invention preferably exhibits a glass transition temperature T_g from 85 °C to 130 °C, particularly preferably from 90 °C to 120 °C.

The polyester or copolyester, in particular copolyester employed in accordance with the invention preferably exhibits an inherent viscosity from 0.50 dL/g to 0.80 dL/g.

Preferred copolyesters used in the present invention typically can be prepared by the reaction of terephthalic acid and optionally one or more additional difunctional carboxylic acids and/or multifunctional carboxylic acids – hereinafter referred to as dicarboxylic acid component - with at least the two difunctional hydroxyl compounds 2,2,4,4-tetramethyl-1,3-cyclobutanediol and 1,4-cyclohexanedimethanol and optionally additional difunctional hydroxyl compounds and/or multifunctional hydroxyl compounds – hereinafter referred to as diol component. Typically the dicarboxylic acid component can be one or more dicarboxylic acid(s) and the diol compound can be two or more dihydric alcohols/glycols. The dicarboxylic acids and alcohols/glycols preferably react in substantially equal proportions and are incorporated into the copolyester polymer as their corresponding residues. The copolyesters used according to the present invention, therefore, can contain substantially equal molar proportions of acid residues and diol residues.

The term "residue", as used herein, means any organic structure incorporated into a polymer through a polycondensation and/or an esterification reaction from the corresponding monomer.

5 The dicarboxylic acid residues may be derived from a dicarboxylic acid monomer or its associated acid halides, esters, salts, anhydrides, or mixtures thereof. As used herein, therefore, the term "dicarboxylic acid" is intended to include dicarboxylic acids and any derivative of a dicarboxylic acid, including its associated acid halides, esters, half-esters, salts, half-salts, anhydrides, mixed anhydrides, or mixtures thereof, useful in a reaction process with a diol to make
10 (co)polyester.

The dicarboxylic acid component in the particularly preferred embodiment comprises 70 to 100 mole % of terephthalic acid residues, preferably 80 to 100 mole % of terephthalic acid residues, more preferably 90 to 100 mole % of terephthalic acid residues, most preferably 95 to 100 mole % of terephthalic acid
15 residues. In a particularly preferred embodiment the dicarboxylic acid component comprises 98 to 100 mole % of terephthalic acid residues. In another particularly preferred embodiment the dicarboxylic acid component comprises 100 mole % of terephthalic acid residues.

The total mole % of the dicarboxylic acid component is 100 mole %.

20 Esters and/or salts of the modifying dicarboxylic acids may be used instead of the dicarboxylic acids. Suitable examples of dicarboxylic acid esters include, but are not limited to, the dimethyl, diethyl, dipropyl, diisopropyl, dibutyl, and diphenyl esters. In one embodiment, the esters are chosen from at least one of the following: methyl, ethyl, propyl, isopropyl, and phenyl esters.

25 The ratio of 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues and 1,4-cyclohexanedimethanol residues from the diol component of the copolyester preferably amounts to 10 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues to 65 mole % to 90 mole % 1,4-cyclohexanedimethanol residues, particularly preferably 15 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-

cyclobutanediol residues to 65 mole % to 85 mole % 1,4-cyclohexanedimethanol residues, quite particularly preferably 15 mole % to 30 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues to 70 mole % to 85 mole % 1,4-cyclohexanedimethanol residues, whereby the sum of the mole % of these two
5 components of the diol component amounts to 100 mole %.

The diol component of the copolyester(s) in the particularly preferred embodiment can contain 25 mole % or less of one or more modifying diols which are not 2,2,4,4-tetramethyl-1,3-cyclobutanediol or 1,4-cyclohexanedimethanol. In one embodiment, the copolyesters useful in the invention may contain 15 mole %
10 or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention can contain 10 mole % or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention can contain 5 mole % or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention can contain 3 mole % or less of one or more
15 modifying diols. In another embodiment, the copolyesters useful in the invention can contain 0 mole % modifying diols. Certain embodiments can also contain 0.01 or more mole %, such as 0.1 or more mole %, 1 or more mole %, 5 or more mole %, or 10 or more mole % of one or more modifying diols. Thus, if present, it is contemplated that the amount of one or more modifying diols can range from any
20 of these preceding endpoint values including, for example, from 0.01 to 15 mole % and preferably from 0.1 to 10 mole %.

Modifying diols useful in the copolyester(s) useful in the invention refer to diols other than 2,2,4,4-tetramethyl-1,3-cyclobutanediol and 1,4-cyclohexanedimethanol and may contain 2 to 16 carbon atoms. Examples of
25 suitable modifying diols include, but are not limited to, ethylene glycol, 1,2-propanediol, 1,3-propanediol, neopentyl glycol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, p-xylene glycol or mixtures thereof. Preferred modifying diols, if present, are ethylene glycol, 1,3-propanediol and/or 1,4-butanediol.

Each of the diols 2,2,4,4-tetramethyl-1,3-cyclobutanediol or 1,4-cyclohexanedimethanol may be cis, trans, or a mixture thereof.
30

For the desired copolyester, the molar ratio of cis/trans 2,2,4,4-tetramethyl-1,3-cyclobutanediol can vary from the pure form of each or mixtures thereof. In certain embodiments, the molar percentages for cis and/or trans 2,2,4,4-tetramethyl-1,3-cyclobutanediol are greater than 50 mole % cis and less than 50 mole % trans; or greater than 55 mole % cis and less than 45 mole % trans; or 30 to 70 mole % cis and 70 to 30 mole % trans; or 40 to 60 mole % cis and 60 to 40 mole % trans; wherein the total sum of the mole percentages for cis- and trans-2,2,4,4-tetramethyl-1,3-cyclobutanediol is equal to 100 mole %.

For the desired copolyester, the molar ratio of 1,4-cyclohexanedimethanol can vary from the pure form of each or mixtures thereof. By using a mixture of cis and trans the molar ratio of cis/trans 1,4-cyclohexanedimethanol can vary within the range of 50/50 to 0/100, for example, between 40/60 to 20/80.

The poly- or copolyester useful in the invention can be made by processes known from the literature such as, for example, by processes in homogeneous solution, by transesterification processes in the melt, and by two phase interfacial processes. Suitable methods include, but are not limited to, the steps of reacting one or more dicarboxylic acids with one or more diols at a temperature of 100°C to 315°C at a pressure of 0.13 mbar to 1011 mbar (0.1 to 760 mm Hg) for a time sufficient to form a polyester. See U.S. Patent No. 3,772,405 or Kunststoffs-Handbuch, Vol. VIII, p. 695 ff, Karl-Hanser-Verlag, Munich 1973 for methods of producing (co)polyesters.

Suitable polycarbonates or copolycarbonates useful in the invention are commercially available, for example under the trademark Makrolon® from Bayer MaterialScience AG. Suitable polyesters or copolyesters useful in the invention are also commercially available, for example under the trademark Skygreen from SK Chemical or Tritan™ from Eastman Chemical Company. Suitable thermoplastic polyurethanes useful in the invention are also commercially available, e.g. from Bayer MaterialScience AG.

The plastic film according to the invention preferably exhibits a total thickness from 300 μm to 2000 μm , particularly preferably from 400 μm to 1500 μm , quite particularly preferably from 500 μm to 1200 μm .

5 In the case of the plastic film according to the invention, in a preferred embodiment it is a question of a three-layer film consisting of the core layer A between the two outer layers B.

This preferred embodiment of the plastic film according to the invention displays an excellent adhesion between the core layer A, particularly preferred the copolyester core layer A, and the outer layers B, particularly preferred the TPU
10 outer layers B. Good adhesion between these layers is particularly advantageous and necessary, since a delamination of the plastic film during its use in a wet or humidity environment is undesirable. Moreover, after the production of three-dimensional shaped articles e.g. by means of thermoforming of the film according to the invention and trimming on the cut edges, the articles have to be ground.
15 Also in the course of this grinding process a delamination of the individual layers is undesirable.

The adhesive force between the core layer A and the outer layers B preferably amounts to more than 0.3 N/mm, preferably more than 0.5 N/mm. Adhesive force can be determined in accordance with ASTM D 903 98.

20 The core layer A of the plastic film according to the invention preferably exhibits a layer thickness from 250 μm to 1600 μm , particularly preferably from 350 μm to 1400 μm , quite particularly preferably from 400 μm to 1000 μm . The outer layers B of the plastic film according to the invention preferably exhibit in each instance a layer thickness from 25 μm to 500 μm , particularly preferably
25 from 30 μm to 300 μm , quite particularly preferably from 50 μm to 200 μm .

For some application e.g. for medical applications it is, inter alia, also desirable that the film for the production of the shaped articles is as inconspicuous as possible during the course of usage. Therefore it is furthermore advantageous

if the plastic film is as transparent as possible. This requirement is likewise satisfied by the film according to the invention.

The plastic film according to the invention preferably exhibits a transmission of visible light within the wavelength range from 380 nm to 780 nm of more than 70 %, particularly preferably of more than 80 %. The transmission can be determined in accordance with ASTM D 1003 – for example, with an Ultra Scan XE produced by Hunter Associates Laboratory Inc.

The plastic film according to the invention can be produced by means of co-extrusion or double lamination. Production by means of co-extrusion is preferred.

The production of multi-layer plastic films by means of co-extrusion is known to a person skilled in the art. In this connection, for the respective plastic layers the respective plastics, for example and preferably in the form of granular materials, are fused in a compounding extruder and are extruded into a film via a nozzle.

In the course of the double lamination, firstly two films are produced for the two outer layers B, preferentially by means of extrusion, and the core layer A is produced by running the melt in between these two plastic films.

By reason of their outstanding properties – such as, for example, slight drop in the tensile modulus, stability in its three-dimensional shape and good transparency – the plastic films according to the invention are particularly well suited for the purpose of producing three-dimensionally shaped articles. For the purpose of producing such 3D-shaped articles, shaping into the appropriate shape is effected by means of thermoforming from the plastic films according to the invention, and the latter is subsequently cut and polished.

Therefore, a further object of the present invention is a three-dimensionally shaped article obtained from the multi-layered film according to the present invention, in particular by means of thermoforming.

The plastic films according to the invention are particularly well suited for the purpose of producing three-dimensionally shaped articles, in particular for use in medical applications, such as for orthopaedic devices, e.g. orthopaedic supports, dental devices, e.g. dental splints or retainers, or splints, e.g. for
5 stabilizing sprained joints or fractures. Additionally the plastic films according to the invention are particularly well suited for the purpose of producing three-dimensionally shaped articles for non-medical applications, such as photovoltaic or (underfloor) heating applications. Moreover, the plastic films according to the invention could particularly be well suited for bullet-proof glass laminates.

10 The following Examples serve for exemplary elucidation of the invention and are not to be interpreted as limitation.

EXAMPLES

Feed materials

ISOPLAST 2530: commercial aromatic transparent thermoplastic polyurethane for medical applications with a Shore hardness of 82 D according to
5 DIN EN ISO 868 (Lubrizol Corp.)

DESMOPAN DP 9365 D: commercial aromatic transparent thermoplastic polyether polyurethane with a Shore hardness of 65 D according to DIN EN ISO 868 (Bayer MaterialScience AG)

Copolyester I: Copolycondensate of terephthalic acid consisting of
10 48.4 wt.% terephthalic acid, 11.9 wt.% (23 mole % relative to the diol component) 2,2,4,4-tetramethyl-1,3-cyclobutanediol and 39.7 wt.% (77 mole % relative to the diol component) cyclohexanedimethanol, with an inherent viscosity of 0.72 dl/g (measured in a 1:1 mixture consisting of phenol and tetrachloroethane at 25 °C) (Eastman Chemical), Glass transition temperature 110°C (determined by DSC)

Copolyester II: Copolycondensate of terephthalic acid consisting of
15 48.3 wt.% terephthalic acid, 11.7 wt.% (23 mole % relative to the diol component) 2,2,4,4-tetramethyl-1,3-cyclobutanediol and 40.0 wt.% (77 mole % relative to the diol component) cyclohexanedimethanol, with an inherent viscosity of 0.63 dl/g (measured in a 1:1 mixture consisting of phenol and tetrachloroethane at 25 °C),
20 Glass transition temperature 105°C (determined by DSC)

TEXIN 970U: commercial aromatic transparent thermoplastic polyether polyurethane with a Shore hardness of 70 D according to DIN EN ISO 868 (Bayer MaterialScience AG)

MAKROLON 3108: commercial high viscous amorphous, thermoplastic
25 Bisphenol A-Polycarbonat with a Melt Volume Rate (MVR) of 6 g/10min according to ISO 1133 at 300°C and 1,2 kg from Bayer MaterialScience AG; Glass transition temperature 149°C (determined by DSC)

HYTREL 7246: is a commercial high modulus thermoplastic polyester elastomer grade with nominal Shore hardness according to DIN EN ISO 868 of 72 D from Dupont Company, Wilmington

POCAN B 1600: is a commercial thermoplastic butylene terephthalate
5 with a Melt Volume Rate (MVR) of 14 g/10min according to ISO 1133 at 260°C and 2,16 kg from Lanxess AG

Production of the layered structures according to the invention:

Production of extruded films

- The film extrusion line that is used for producing the co-extruded film(s)
10 comprises:
- an extruder with a screw of 60 mm diameter (D) and with a length of 33 D.
The screw exhibits a degassing zone;
 - a melt pump;
 - a crosshead;
 - 15 ▪ a flat sheet die with a width of 450 mm;
 - a three-roll calender with horizontal roller arrangement, the third roller being capable of swivelling about +/- 45° in relation to the horizontal;
 - a roller conveyor;
 - thickness measurement
 - 20 ▪ a device for bilateral application of protective film;
 - a take-off device;
 - a winding machine.

The granular material was conveyed out of the dryer into the feed hopper of the extruder. In the plasticising system constituted by the cylinder/screw of the extruder the melting and conveying of the material took place. From the flat sheet die the melt arrived at the calender. On the calender (consisting of three rolls) the definitive shaping and cooling of the film took place. For the purpose of texturing the surfaces of the film, in this connection two polished chromium rollers (for gloss/gloss surfaces) were employed. Subsequently the film was transported through a take-off, the protective film is applied on both sides, then the winding-up of the film took place.

10 **Example 1 (not according to the invention)**

With the film extrusion line described above, with a temperature of the main extruder from 240 °C to 260 °C a monolayer film consisting of Copolyester I with a thickness of 760 µm was produced.

Example 2 (not according to the invention)

15 With the same film extrusion line as in Example 1, with a temperature of the main extruder from 220 °C to 240 °C a monolayer film consisting of ISOPLAST 2530 with a thickness of 750 µm was produced.

Example 3 (according to the invention)

Co-extrusion of film

20 The film extrusion line that is used consists of

- an extruder with a screw of 105 mm diameter (D) and with a length of 41xD. The screw exhibits a degassing zone;
- a co-extruder for applying the top layer with a screw of length 25 D and with a diameter of 35 mm
- 25 ▪ a crosshead;

- a special co-extrusion film die with a width of 1500 mm;
 - a three-roll calender with horizontal roller arrangement, the third roller being capable of swivelling about $\pm 45^\circ$ in relation to the horizontal;
 - a roller conveyor;
- 5
- a device for application of protective film on both surfaces;
 - a take-off device;
 - winding machine .

The granular material of the base material was supplied to the feed hopper of the main extruder. In the respective plasticising system constituted by

10 cylinder/screw the melting and conveying of the respective material took place. Both material melts were brought together in the co-extrusion nozzle. From the nozzle the melt arrived at the calender. On the roll calender the definitive shaping and cooling of the material take place. For the purpose of structuring the surfaces of the film, in this connection two polished chromium rollers (for gloss/gloss

15 surfaces) were employed. Subsequently the film was transported through a take-off, the protective film is applied on both sides, then the winding-up of the film took place.

With this film extrusion line , with a temperature of the main extruder from 220 °C to 240 °C and with a temperature of the co-extruder from 228 °C to 260 °C

20 three-layer films according to the invention with two smooth, glossy sides with a layer thickness of 800 μm were extruded, the copolyester core layer being 650 μm thick and the thermoplastic polyurethane layer on each side being in each instance 75 μm thick.

Example 4 (according to the invention):

In the film extrusion line as in Example 3, instead of Copolyester I the more readily flowing Copolyester II was employed for the purpose of producing the three-layer films.

- 5 From this, with a temperature of the main extruder from 220 °C to 235 °C and with a temperature of the co-extruder from 227 °C to 260 °C three-layer films according to the invention with two smooth, shiny sides with a layer thickness of 800 µm were extruded, the copolyester core layer being 650 µm thick and the thermoplastic polyurethane layer on each side being in each instance 75 µm thick.

10 **Example 5 (according to the invention):**

In the same film extrusion line as in Example 3, a film according to the invention with one glossy surface and one matt surface was extruded.

- In this connection, for the purpose of structuring the two surfaces of the film a polished chromium roller and a structured silicone-rubber roller were
15 employed. Rubber rollers that are used for the structuring of the surface of the film are described in DE 32 28 002 (or in the equivalent US 4,368,240) held by Nauta Roll Corporation.

- With a temperature of the main extruder from 220 °C to 235 °C and with a temperature of the co-extruder from 227 °C to 260 °C three-layer films according
20 to the invention with a smooth, glossy side and with a matt side with a layer thickness of 800 µm were extruded, the copolyester core layer being 650 µm thick and the thermoplastic polyurethane layer on each side being in each instance 75 µm thick.

Example 6 (according to the invention):

- 25 In the film extrusion line as in Example 3, instead of Copolyester I the blend of 60% by weight MAKROLON 3108 and 40% by weight POCAN B 1600 for the main extruder and TEXIN 970U for the co extruder were employed for the

purpose of producing the three-layer films. The TEXIN 970U forms the outer layers, the MAKROLON/POCAN blend the core layer.

From this, with a temperature of the main extruder from 260 °C to 270 °C and with a temperature of the co-extruder from 210 °C to 230 °C three-layer films according to the invention with two smooth, shiny sides with a layer thickness of 750 µm were extruded, the copolyester core layer being 550 µm thick and the thermoplastic polyurethane layer on each side being in each instance 100 µm thick.

Example 7 (according to the invention):

10 In the film extrusion line as in Example 3, instead of Copolyester I the blend of 60% by weight MAKROLON 3108 and 40% by weight POCAN B 1600 for the main extruder and HYTREL 7246 for the co extruder were employed for the purpose of producing the three-layer films. The HYTREL 7246 forms the outer layers, the MAKROLON/POCAN blend the core layer.

15 From this, with a temperature of the main extruder from 260 °C to 270 °C and with a temperature of the co-extruder from 227 °C to 245 °C three-layer films according to the invention with two smooth, shiny sides with a layer thickness of 750 µm were extruded, the copolyester core layer being 550 µm thick and the thermoplastic polyester elastomer layer on each side being in each instance 100 µm thick.

Example 8 (according to the invention):

25 In the film extrusion line as in Example 3, instead of Copolyester I the blend of 60% by weight MAKROLON 3108 and 40% by weight POCAN B 1600 for the main extruder and ISOPLAST 2530 for the co extruder were employed for the purpose of producing the three-layer films. The ISOPLAST 2530 forms the outer layers, the MAKROLON/POCAN blend the core layer.

From this, with a temperature of the main extruder from 260 °C to 270 °C and with a temperature of the co-extruder from 210 °C to 240 °C three-layer films

according to the invention with two smooth, shiny sides with a layer thickness of 750 μm were extruded, the copolyester core layer being 550 μm thick and the thermoplastic polyurethane layer on each side being in each instance 100 μm thick.

5 **Example 9:**

Method for determining the peel strength of the thermoplastic polyurethane (TPU) layer on the copolyester layer of examples 3 to 5

Preparation of the specimens:

- 10 1. Die-cut specimens to 4 inch L x 0.76 inch W (10 mm L x 19.3mm W): Die dimension can vary depending on availability (W: 0.75 ~ 1 inch, L: minimum 4 inch).
2. Mark on the side of the TPU layer being tested. Flip the sample to the other side. Scratch a line by a sharp cutter at 7mm from one edge of the specimen.
- 15 3. Gently bend the specimen along the cut line while having the tested TPU layer intact.
4. Gently start peeling the TPU layer by pulling the small cut portion away from the cut line.
- 20 5. Continue peeling until the peel TPU layer is 13 mm in length. Make sure the TPU layer is peeled uniformly across the whole specimen width.
6. Cut the other end of the specimen to make the total adhered area be 62 mm in length.

Example 10:

25 Determination of the peel strength

Method:

The determination of the peel strength was carried out following the model of ASTM D 903 98. The specimens, which were prepared in accordance with the method in Example 6, were stored at 50 % relative humidity and 23 °C and subsequently tested under these conditions. The separation rate amounted to 305 mm/min. From the calibration curves the mean value between 5 mm and 25 mm was evaluated.

The determination has been carried out at three different positions of the specimen. The following show the calculated average results.

For for the bottom layer an average load per unit width of 0.76 N/mm for example 3, 0.79 N/mm for example 4 and 0.97 N/mm for example 5 was measured. For for the top layer an average load per unit width of 1.13 N/mm for example 3, 0.60 N/mm for example 4 and 1.10 N/mm for example 5 was measured. The results show that the films according to the invention exhibit an excellent adhesion between the copolyester core layer and the TPU outer layers.

For the three-layered films according to example 6 to 8 the peel strength between the outer layers and the core layer were so high that no separation without damage of the outer layer was possible, so that also these films according to the invention exhibit an excellent adhesion between the core layer and the outer layers.

Example 11

Method for determination of tensile strenght

The measure of tensile strength was carried out following the model of ASTM D 638. The tensile tests were carried out on a tensile testing machine of the type ZwickZ020/148385. Use was made of tensile test specimens of type 4. For the purpose of evaluation, the mean value of 5 measurements was drawn upon. The specimens were stored at > 48 hours at 50 % relative humidity and 23 °C and subsequently tested under these conditions. The speed of testing

amounted to 12.7 mm/min, in the course of the determination of Young's modulus (elastic modulus or modulus of elasticity), 1 mm/min.

The determination has been carried out at three different positions of the specimen. The following table show the calculated average results.

5 Results:

Example	average yield stress (N/mm ²)	average yield strain (%)	average tensile strength (N/mm ²)	average elongation at break (%)	average tensile modulus (N/mm ²)
3	36.0	6.6	54.7	168.7	1233.0
4	36.3	6.3	53.5	171.6	1246.0
5	35.7	6.3	56.6	183.4	1249.0
6	32.4	4.3	40.4	128.8	1069
7	34.9	4.2	58.4	193.4	1202
8	39.6	4.2	56.4	180.2	1157

The results show that the films according to the invention exhibit an excellent tensile strength and an outstanding tensile modulus.

Example 12:

10 Method for determining the stress relaxation

The stress relaxation has been determined according to a modification of ASTM D790:

- sample dimensions: 51 mm (length) X 21.5 mm (width) X ~0.8mm (thickness)
- water soaking of the samples at defined temperature (25 °C or 50°C) before measurement of stress relaxation
- three-point bending with 5% strain
- support span: 16 mm

Results:

Water Temperature (°C)	Materials	Initial load (N) (t = 0 hour)	Remaining Load (N) (t = 24 hours)	% Remaining Load
25 °C	Example 2 (not according to the invention))	45.8	17.7	39
	Example 3 (according to the invention)	25.7	18.3	71
	Example 6 (according to the invention)	45	26,9	60
	Example 7 (according to the invention)	35,5	21,4	60
	Example 8 (according to the invention)	51,1	24	47
50 °C	Example 2 (not according to the invention))	39.6	2.05	5
	Example 3 (according to the invention)	20.7	4.5	22
	Example 6 (according to the invention)	32,9	11	33
	Example 7 (according to the invention)	27,4	11,2	41
	Example 8 (according to the invention)	39,7	6,5	16

In this connection the values for initial load represent the measured values at the time prior to storage, i.e. at time $t = 0$, and the values for remaining load represent the measured values at the time after 24 h of storage.

- 5 The results show that at both storage temperatures the three-layer films according to the invention exhibited a higher remaining load after 24 h storage than the TPU single-layer film from Example 2. In particular for examples 3 and 7 it is the more surprising that - although at both storage temperatures the three-

layer film according to the invention exhibited a distinctly lower initial load at the time prior to storage - the force that it was still able to exert after storage after 24 h fell to a considerably slighter extent.

5 Only the samples consisting of the three-layer films according to the invention exhibit a small drop in the tensile modulus during the storage in the wet environment. In addition, the films according to the invention display an outstanding adhesion between the core layers and the other layers.

10 Although the invention has been described in detail in the foregoing for the purpose of illustration, it is to be understood that such detail is solely for that purpose and that variations can be made therein by those skilled in the art without departing from the spirit and scope of the invention except as it may be limited by the claims.

WHAT IS CLAIMED IS:

1. Multi-layer plastic film, characterised in that
 - it has a core layer A containing at least one polycarbonate or copolycarbonate and/or a polyester or copolyester having a glass transition temperature T_g from 80 °C to 200°C,
 - and this core layer A is located between two outer layers B containing at least one thermoplastic polyurethane and/or polyester or copolyester exhibiting a hardness from 45 Shore D to 85 Shore D.
2. Multi-layer plastic film according to claim 1, characterised in that it has a core layer A containing at least one polyester or copolyester having an inherent viscosity from 0.50 dL/g to 1.20 dL/g and a glass transition temperature T_g from 80 °C to 200°C.
3. Multi-layer plastic film according to claim 1 or 2, characterised in that the two outer layers B containing at least one thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D.
4. Multi-layer plastic film according to at least one of Claims 1 to 3, characterised in that
 - it has a core layer A containing at least one copolyester that exhibits residues from
 - (a) a dicarboxylic acid component comprising
 - i) 70 mole % to 100 mole % terephthalic acid residues,
 - ii) 0 mole % to 30 mole % aromatic dicarboxylic acid residues with up to 20 carbon atoms, and
 - iii) 0 mole % to 10 mole % aliphatic dicarboxylic acid residues with up to 16 carbon atoms, and

(b) a diol component comprising

- i) 5 mole % to 50 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and
- ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol

5 residues,

wherein the sum of the mole % of residues i) – iii) of the dicarboxylic acid component amounts to 100 mole % and the sum of the mole % of residues i) and ii) of the diol component amounts to 100 mole %

10 and wherein the inherent viscosity of the copolyester amounts to 0.50 dL/g to 1.20 dL/g and the copolyester exhibits a glass transition temperature T_g from 80 °C to 150 °C,

- and this core layer is located between two outer layers B containing at least one thermoplastic polyurethane, the thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D and being
15 obtainable from

a) one or more linear polyether diols with mean molecular weights from 500 g/mol to 10,000 g/mol, preferably 500 g/mol to 6000 g/mol, and, on average, in each instance at least 1.8 and at most 3.0, preferably 1.8 to 2.2, Tserevitinov-active hydrogen atoms

20 b) one or more organic diisocyanates,

c) one or more diol chain-extenders with molecular weights from 60 g/mol to 500 g/mol and with, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms

in the presence of

25 d) optionally, one or more catalysts

with addition of

e) optionally, auxiliary substances and additives,

wherein the molar ratio of the NCO groups in b) to the groups in a) and c)
that are reactive towards isocyanate amounts to 0.85:1 to 1.2:1, preferably
5 0.9:1 to 1.1:1.

5. Multi-layer plastic film according to at least one of Claims 1 to 4,
characterised in that the thermoplastic polyurethane exhibits a hardness
from 50 Shore D to 80 Shore D.
6. Multi-layer plastic film according to Claim 4 or 5, characterised in that the
10 polyether diols a) used for producing the thermoplastic polyurethane are
selected from one or more polyether diols of the group based on 1,4-
butanediol units and/or 1,3-propylene glycol units.
7. Multi-layer plastic film according to at least one of Claims 4 to 6,
characterised in that the organic diisocyanate b) used for producing the
15 thermoplastic polyurethane is selected from one or more isocyanates of the
group containing 4,4'-diphenylmethane diisocyanate, isophorone
diisocyanate, dicyclohexylmethane-4,4'-diisocyanate or 1,6-hexamethylene
diisocyanate.
8. Multi-layer plastic film according to at least one of Claims 4 to 7,
20 characterised in that the diol chain-extender c) used for producing of the
thermoplastic polyurethane is selected from one or more chain-extenders of
the group containing 1,4-butanediol, 1,3-propanediol, 1,2-propanediol, 1,2-
ethylene glycol, 1,6-hexanediol, 1,4-di(β -hydroxyethyl)hydroquinone or
1,4-di(β -hydroxyethyl)bisphenol A.
- 25 9. Multi-layer plastic film according to at least one of Claims 4 to 8,
characterised in that the thermoplastic polyurethane was produced in the
prepolymer process.

10. Multi-layer plastic film according to at least one of Claims 4 to 9,
characterised in that the diol component of the copolyester comprises
10 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues
and 65 mole % to 90 mole % 1,4-cyclohexanedimethanol residues,
5 preferably 15 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol
residues and 65 mole % to 85 mole % 1,4-cyclohexanedimethanol residues,
particularly preferably 15 mole % to 30 mole % 2,2,4,4-tetramethyl-1,3-
cyclobutanediol residues and 70 mole % to 85 mole % 1,4-
cyclohexanedimethanol residues, the sum of the mole % of these two
10 components of the diol component amounting to 100 mole %.
11. Multi-layer plastic film according to at least one of Claims 4 to 10,
characterised in that the residues from the dicarboxylic acid component of
the polyester include 95 mole % to 100 mole % terephthalic acid residues.
12. Multi-layer plastic film according to at least one of Claims 1 to 11,
15 characterised in that the film has been co-extruded.
13. Multi-layer plastic film according to at least one of Claims 1 to 12,
characterised in that it has a total thickness from 300 μm to 2000 μm ,
preferably from 400 μm to 1500 μm , particularly preferably from 500 μm to
1200 μm .
- 20 14. Multi-layer plastic film according to at least one of Claims 1 to 13,
characterised in that the core layer A has a layer thickness from 250 μm to
1600 μm , preferably from 350 μm to 1400 μm , particularly preferably from
400 μm to 1000 μm .
- 25 15. Multi-layer plastic film according to at least one of Claims 1 to 14,
characterised in that the outer layers B each have a layer thickness from
25 μm to 500 μm , preferably from 30 μm to 300 μm , particularly preferably
from 50 μm to 200 μm .

16. Multi-layer plastic film according to at least one of Claims 2 to 15,
characterised in that the poly- or copolyester exhibits an inherent viscosity
from 0.50 dL/g to 0.80 dL/g.
17. Multi-layer plastic film according to at least one of Claims 1 to 16,
5 characterised in that the poly- or copolyester exhibits a glass transition
temperature T_g from 85 °C to 130 °C, preferably from 90 °C to 120 °C.
18. Three-dimensionally shaped article obtained by three-dimensionally
forming the multi-layer plastic film according to at least one of Claims 1 to
17.

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2013/059701

A. CLASSIFICATION OF SUBJECT MATTER

INV. C08J5/18 C08L67/02 C08L69/00 C08L75/08 B32B27/36
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C08J C08L B32B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/146670 A1 (CHIN ALBERT [US] ET AL) 29 July 2004 (2004-07-29) examples 14-17 -----	1,2, 12-18
A	DE 10 2010 009230 A1 (GIESECKE & DEVRIENT GMBH [DE]) 25 August 2011 (2011-08-25) -----	1-18
A	DE 10 2004 014023 A1 (KRD COATINGS GMBH [DE]) 20 October 2005 (2005-10-20) -----	1-18



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

19 June 2013

Date of mailing of the international search report

28/06/2013

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Lohner, Pierre

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2013/059701

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004146670 A1	29-07-2004	CA 2514487 A1	19-08-2004
		EP 1587569 A1	26-10-2005
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		DE 102004014023 A1	20-10-2005
		EP 1577084 A1	21-09-2005



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)

CONFIRMATION NO. 7352

PUBLICATION NOTICE



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103606
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083

Title:DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

Publication No.US-2020-0130333-A1

Publication Date:04/30/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

USPTO TRANSMITTAL

PATENT

Attorney Docket No. 513043 (000550US)
Client Reference No. DD4105P/US05

Application No. 16/719,256
Confirmation No. 7352

Transmitted herewith is a reply to office action in the subject application.

- ☐ Petition for an extension of time for the period noted below, as well as for any additional period necessary to render the present submission timely. Please charge Deposit Account No. 12-1216 for the appropriate petition fee.
- ☐ Other:
- ☒ Please charge Deposit Account No. 12-1216 in the total amount indicated below.

TIME EXTENSION PETITION FEE			none			\$0
subtract time extension fee previously paid			none			(\$0)
CLAIM FEE	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	EXTRA CLAIMS PRESENT	RATE	ADDITIONAL CLAIM FEE
TOTAL	34	MINUS	29	= 5	x \$100 =	\$500
INDEPENDENT	8	MINUS	3	= 5	x \$460 =	\$2,300
☐	FIRST PRESENTATION OF MULTIPLY DEPENDENT CLAIM				+ \$820 =	\$0
SUBTOTAL (of all items above)						\$2,800
☐	Small entity status is claimed for this application under 37 CFR 1.27. Fees above are reduced by ½.					(\$0)
☐	Micro entity status is claimed for this application under 37 CFR 1.27. Fees above are reduced by ¾.					(\$0)
OTHER FEES AS DESCRIBED:						\$0
TOTAL AMOUNT TO BE CHARGED TO DEPOSIT ACCOUNT						\$2,800

- ☒ The Commissioner is hereby authorized to charge any deficiencies in the following fees associated with this communication or credit any overpayment to Deposit Account No. 12-1216.
- ☒ Any filing fees under 37 CFR 1.16 and/or 1.492 for the presentation of extra claims.
- ☒ Any patent application processing fees under 37 CFR 1.17.



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797
Telephone: 312-616-5600
Facsimile: 312-616-5700

Date: June 12, 2020

Electronic Patent Application Fee Transmittal				
Application Number:		16719256		
Filing Date:		18-Dec-2019		
Title of Invention:		DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
First Named Inventor/Applicant Name:		Ray F. Stewart		
Filer:		Gerald Todd Gray./Christina Alton		
Attorney Docket Number:		513043 (000550US)		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	5	100	500
INDEPENDENT CLAIMS IN EXCESS OF 3	1201	5	460	2300
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				2800

Electronic Acknowledgement Receipt

EFS ID:	39705389
Application Number:	16719256
International Application Number:	
Confirmation Number:	7352
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
Filer:	Gerald Todd Gray./Christina Alton
Filer Authorized By:	Gerald Todd Gray.
Attorney Docket Number:	513043 (000550US)
Receipt Date:	12-JUN-2020
Filing Date:	18-DEC-2019
Time Stamp:	14:19:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$2800
RAM confirmation Number	E20206BE19395695
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	513043_20200612_ROA.pdf	506388	no	12
			c5ec6b8b6b9067a1998ccba25f16d2494f53f2a		
Warnings:					
Information:					
2	Transmittal Letter	513043_20200612_TRA.pdf	83413	no	1
			0f28263ff10e913b684940e1e63b4164ffa79ccb		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32027	no	2
			72cc2c27f6a84ca5282bd176e2b6a330cadcc98d1		
Warnings:					
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Total Files Size (in bytes):			621828		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	:	Confirmation No.: 7352
STEWART and LAHLOUH	:	
	:	Art Unit: 1781
Application No.: 16/719,256	:	
	:	Examiner: FERGUSON, Lawrence D.
Filed: December 18, 2019	:	
	:	
For: DUAL SHELL DENTAL APPLIANCE AND	:	
MATERIAL CONSTRUCTIONS	::	

Mail Stop – **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AND AMENDMENT UNDER 37 C.F.R. §1.111

Dear Commissioner:

This paper is filed in response to the Non-Final Office Action mailed March 17, 2020 in the above-identified application. This paper is fully responsive to that Office Action. Reconsideration and allowance are respectfully requested in view of the amendments and remarks below.

Amendments to the **CLAIMS** begin in the listing of claims on **page 2** of this paper.

REMARKS begin on **page 7** of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Original) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer 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, and the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.
2. (Currently Amended) The 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.
3. (Original) The polymeric sheet composition of claim 2, wherein the outer layers A and C comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such a polyvinyl chloride, and a fluoropolymer.
4. (Original) The polymeric sheet composition of claim 2, wherein the inner layer B comprises one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, and a fluoroelastomer.
5. (Original) The polymeric sheet composition of claim 3, wherein one or more of outer layers A and C comprise a microcrystalline polyamide having heat of fusion of less than 20 J/g and a light transmission of greater than 80%.
6. (Original) The polymeric sheet composition of claim 4, wherein the inner layer B comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.
7. (Original) The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a co-polyester having a:
 - (a) a dicarboxylic acid component and
 - (b) a diol component, wherein the-copolyester exhibits a glass transition temperature (Tg) from 80°C to 150°C.

8. (Original) The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a polyurethane comprised of:

(a) a di-isocyanate, and

(b) a diol component comprising one or more of hexane diol and cyclohexane dimethanol

wherein the polyurethane has a glass transition temperature T_g from about 85°C to about 150°C.

9. (Original) The polymeric sheet composition of claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having a compression set of less than 35%.

10. (Original) The polymeric sheet composition according to claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having an interlayer peel strength between the A and C layers and the B layer of greater than 50 N per 2.5 cm.

11. (Original) 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, 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 the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

12. (Original) 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.

13. (Currently amended) 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, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic and/or isophthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic and/or isophthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such as a polyvinyl chloride, and a fluoropolymer.

14. (Original) The polymeric sheet composition of claim 12, wherein the soft inner layers B and B' individually comprise one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, an anhydride functionalized styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, an acrylic elastomer and a fluoroelastomer.

15. (Original) The polymeric sheet composition of claim 14, wherein one or more of the soft inner layers B and B' comprise an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

16. (Original) The polymeric sheet composition of claim 14, wherein the rigid or hard layers, A, C and D have a combined thickness of from about 100 microns to about 750 microns.

17. (Original) The polymeric sheet composition of claim 14, wherein the soft layers, B and B' have a combined thickness of from about 150 microns to about 1,000 microns.

18. (Withdrawn) A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.

19. (Original) A polymeric sheet composition, comprising:

three or more layers, A, A1, and B, wherein the outermost layers, A and A1 have different thicknesses from one another and individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa, and wherein the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

20. (Original) The polymeric sheet composition of claim 19, wherein the A, A1 and B layers of the polymeric sheet composition have a combined thickness of from about 500 microns to 2,000 microns.

21. (Original) The polymeric sheet composition of claim 20, wherein the outermost layer A1 has a thickness of from about 25 to about 250 microns.

22. (Original) The polymeric sheet composition of claim 20, wherein the ratio of the thickness of the outermost layer A1 to the thickness of the outermost layer A is from about 0.9 to about 0.2.

23. (Original) The polymeric sheet composition of claim 20, wherein the outermost layer A and outermost layer A1 are comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, and a polyolefin.

24. (Previously presented) The polymeric sheet composition according to claim 20, wherein the outer layers A and A1 comprise the same material.

25. (Withdrawn) The polymeric sheet composition according to claim 20, wherein the outer layers A and A2 comprise different materials.

26. (Original) The polymeric sheet composition of claim 20, wherein the middle layer B is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane.

27. (Withdrawn) A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 20.

28. (Withdrawn) The dental appliance of claim 27, wherein the dental appliance exhibits improved tear resistance relative to the A, C or D layer alone.

29. (Withdrawn) The dental appliance of claim 27, wherein the dental appliance exhibits improved environmental stress resistance relative to the A, C or D layer alone.

30. (New) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) the inner layer B comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

31. (New) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) one or more of the A and C layers comprises a co-polyester having a:

(c) a dicarboxylic acid component and

(d) a diol component, wherein the-copolyester exhibits a glass transition temperature (T_g) from 80°C to 150°C.

32. (New) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) one or more of the A and C layers comprises a polyurethane comprised of:

(c) a di-isocyanate, and

(d) a diol component comprising one or more of hexane diol and cyclohexane dimethanol wherein the polyurethane has a glass transition temperature T_g from about 85°C to about 150°C.

33. (New) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) the inner layer B comprises an aromatic polyether polyurethane having a compression set of less than 35%.

34. (New) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) the inner layer B comprises an aromatic polyether polyurethane having an interlayer peel strength between the A and C layers and the B layer of greater than 50 N per 2.5 cm.

REMARKS

I. STATUS OF THE CLAIMS

Claims 1-29 were pending in the present application.

Claims 18, 25 and 27-29 were previously withdrawn as directed to a non-elected invention.

Claims 2 and 13 have been amended to correct obvious typographical errors. No new matter is added.

Claims 30-34 are new.

With entry of the present amendment, claims 1-17, 19-23, 26, and 30-34 are under consideration and subject to substantive examination on the merits.

The new claims submitted herewith do not introduce new matter.

II. OBJECTIONS TO THE CLAIMS

Claims 5-10 and 15 are objected to as being dependent upon a rejected base claim. The Examiner states that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In order to expedite prosecution on the merits, and manage costs consistent with the recommendation from the Examiner, claims 6-10 have been rewritten in independent form and are presented as claims 30-34. Applicant respectfully submits that new claims 30-34 are in condition for allowance.

III. REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-4, 11-14, 16-17, 19-24 and 26 stand rejected as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,318,737 ("Trabert et al.").

Applicant respectfully traverses the rejections of Claims 1-4, 11-14, 16-17, 19-24 and 26, as unpatentable under 35 U.S.C. 103 over Trabert et al. (the '737 patent).

Trabert et al. discloses acrylic resin capstocks (surfacing materials) for coating structural plastics (e.g., ABS), and methods of making a plastic composite sheet of the capstock (made from an acrylic polymer and an acrylate-based impact modifier resin in the form of discrete multi-layered polymeric particles) and a structural plastic (See, e.g., Abstract, and Col. 4, lines 27-33).

The Office Action states that the Trabert et al. discloses a thermoplastic resin composition comprising a polymeric core (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). The Office Action further states that the core layer and outer layer comprise a resin which is made from the same monomer(s) used to prepare the claimed composition, which includes polyvinyl chloride (column 5, lines 9-38) and that the elastomeric intermediate layer can comprise copolyomers of acrylate (polyacrylic acid) (column 8, lines 1-22). The Office Action acknowledges

that Trabert et al. does not teach the flexural modulus of the outer layers or the hardness of the intermediate layer, but states that substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties.

Applicants respectfully disagree. Trabert et al. discloses a thermoplastic resin composition made from an acrylic polymer and polymeric particles (an acrylate-based impact modifier resin) comprising a polymeric core (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer. The thermoplastic resin composition of Trabert et al. (the “capstock”) comprises particles that have a polymeric core (outer layer), an elastomeric intermediate layer, and a relatively hard polymeric outer layer. The reference to high flexural modulus in Trabert et al. relates to a capstock/structural plastics composition. A diagram illustrating the materials disclosed by Trabert et al. is provide in Section (F), below.

(A) The Claimed Invention

Independent claims 1, 11 and 19 recite polymeric sheet compositions, where the polymeric sheet compositions have at least three layers, including a rigid or hard outer layer comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa, and an inner elastomeric layer comprising an elastomeric material having a hardness from about A 60 to D 85.

(B) The Prior Art - Trabert et al.

Trabert et al. discloses acrylic resin capstocks (surfacing materials) for coating structural plastics in the form of a thin protective layer applied to the surface of the structural plastic (e.g., ABS), and methods of making a plastic composite of a capstock (comprising an impact modifier resin) and a structural plastic, by standard lamination or feedblock coextrusion (See, e.g., Abstract, Col. 4, lines 27-33, and Example 2). The impact modifier resin used to make the capstock comprises multi-layered polymeric particles composed of (1) a non-elastomeric polymeric core (outer layer); (2) an intermediate layer comprising an elastomeric polymer; and (3) a relatively hard polymeric outer layer (See, e.g., Col. 5, lines 9-17).

The impact modifier resin of Trabert et al. comprises 3-layer core shell particles having a dimension of 250 to 350 nm incorporated into an acrylic resin. Trabert et al. does not disclose a layered polymeric sheet composition wherein one or both of outer layers comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa. Importantly, Trabert et al. does not disclose a layered polymeric sheet composition having an inner layer comprising an elastomeric material of any kind, let alone an elastomeric material having a hardness from about A 60 to D 85.

Trabert et al. states that the use of an impact modifier resin of this type (core shell particles dispersed in a thermoplastic resin) is a capstock which is capable of being formed into products which have a high flexural modulus and high Izod impact strength. (column 5, lines 23-27). Trabert does not teach the flexural modulus of the impact modified resin (capstock), which is used to coat a sheet of a structural plastic, for example, ABS sheet, PVC, modified styrene polymers, polycarbonate, and polycarbonate-ABS blends, nor does Trabert et al. teach the flexural modulus of

the outer layer(s) of an article made from the impact modified resin (capstock) and structural plastic.

(C) The Claimed Invention is Distinguishable from Trabert et al.

The Examiner rejected claims 1–4, 11-14, 16-17, 19-24 and 26 as allegedly obvious over Trabert et al. Applicant disagrees and offers rebuttal.

None of the impact modifier particles, the impact modified resin (capstock), or the articles comprising an impact modified capstock and a structural plastic, disclosed by Trabert et al. teach or suggest a polymeric sheet composition having at least three layers, including a rigid or hard outer layer comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa, and an inner layer comprising an elastomeric material of any kind, let alone an elastomeric material having a hardness from about A 60 to D 85, as presently claimed.

Indeed, Trabert states that the impact modified capstock is used with “structural plastics, for example, ABS sheet, PVC, modified styrene polymers, polycarbonate, and polycarbonate-ABS blends”, all of which are known to be rigid materials, which are the opposite of elastomers.

(D) Properties of Materials in Trabert et al. cannot be Extrapolated

The Office Action states that although Trabert et al. does not explicitly teach the flexural modulus of the outer layers or the hardness of the inner layer; substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties, the properties of the materials described in Trabert et al. are expected to have substantially identical properties as the materials described in the presently pending claims (flexural modulus of the outer layers or the hardness of the inner layer). Trabert et al. teaches capstocks made from impact modifier resins, comprising multi-layered polymeric particles, dispersed in an acrylate-based thermoplastic resin, and articles comprising a composite of the capstock impact modified resin and a hard plastic such as ABS.

Trabert et al. is silent with regard to layers of the capstock and the articles. The only reference to layers is with respect to the particles of the impact modifier resin used to make the capstock. Thus, the properties of the claimed polymeric sheet compositions having at least three layers, with a rigid or hard outer layer comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa, and an inner layer comprising an elastomeric material having a hardness from about A 60 to D 85, are not taught, suggested or predicted by the disclosure of Trabert et al.

More specifically, with respect to claims 11 and 13-14, the Office Action states that in Trabert et al., the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate intermediate layer) and process conditions (coextrusion) which are substantially identical to those disclosed by applicants, and that therefore the claimed polymeric sheet composition would be expected to meet the claimed flexural modulus and hardness. Similarly, with respect to claims 19-24 and 26, the Office Action states that Trabert et al. discloses the core layer and outer layer comprise a resin

which is made from the same monomer(s) used to prepare the claimed polymer sheet composition and that although Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties and would be expected to meet the claimed flexural modulus and hardness.

One of skill in the art will appreciate that the properties of the claimed polymeric sheet compositions are not predictable based on the composition of the 3-layer core shell particles disclosed by Trabert et al. for incorporation into an acrylic resin to make a capstock. Trabert et al. discloses impact modified capstock used to coat “structural plastics, for example, ABS sheet, PVC, modified styrene polymers, polycarbonate, and polycarbonate-ABS blends”, all of which are known to be rigid materials. Only the impact modifier resin particles described by Trabert et al. found in the capstock have an elastomeric inner layer, the articles do not. Accordingly, neither the articles disclosed by Trabert et al., nor the components of such articles teach, suggest, or predict the claimed polymeric sheet composition having an inner layer comprising an elastomeric material. Trabert et al. teaches rigid materials coated with a protective capstock, which have no elastomeric inner layer, let alone an elastomeric inner layer material having a hardness from about A 60 to D 85, as presently claimed. In addition, the only use of the term “high flexural modulus” in Trabert et al. (column 5, lines 23-27) is with reference to an article that is the composite of a capstock and a structural plastic which does not teach, suggest or predict the claimed polymeric sheet composition having a rigid or hard outer layer comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa.

A finding of obviousness under 35 U.S.C. § 103 requires that the Examiner provide prior art that collectively teaches or suggests each limitation of the claim. MPEP § 2143. If a claim limitation is not met by the prior art reference or other appropriate evidence, a rejection is inappropriate. To support a rejection under obviousness, some teaching, suggestion, or motivation in the prior art is required that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. In making a rejection under 35 U.S.C. § 103, the Examiner must articulate a finding that there was some teaching, suggestion, or motivation to modify or combine the reference teachings, and further, a finding that there would have been a reasonable expectation of success to make the modification. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. MPEP § 2143.

Applicant respectfully submits that Trabert et al. does not rise to the level of evidence required to support an obviousness rejection of the pending claims, and respectfully requests that the rejection of claims 1, 3-4, 11, 13-14, 19-24 and 26 be reconsidered and withdrawn.

(E) Material Thickness by Itself is Not Predictive of Other Polymer Characteristics.

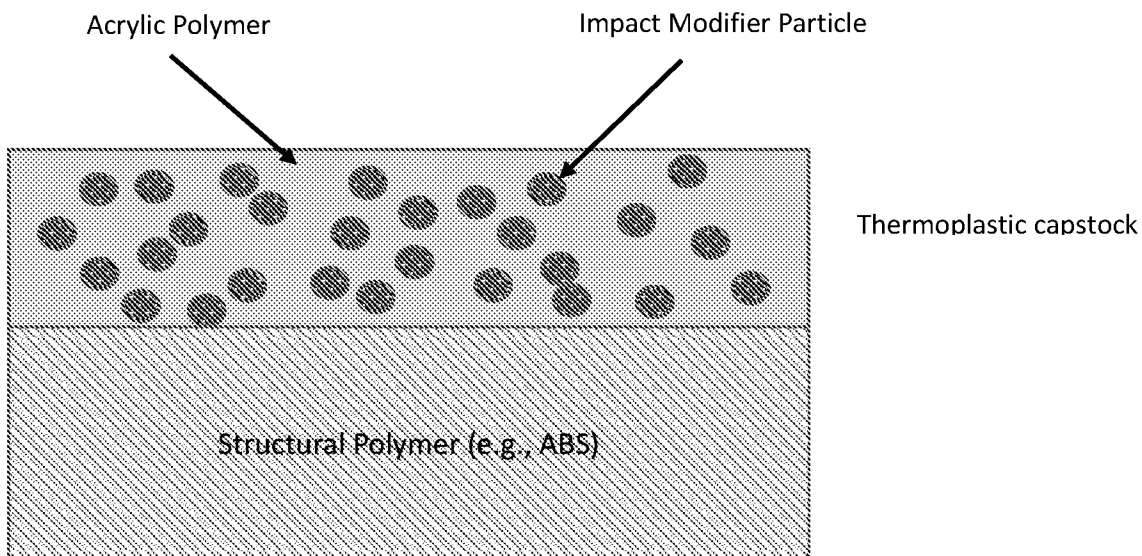
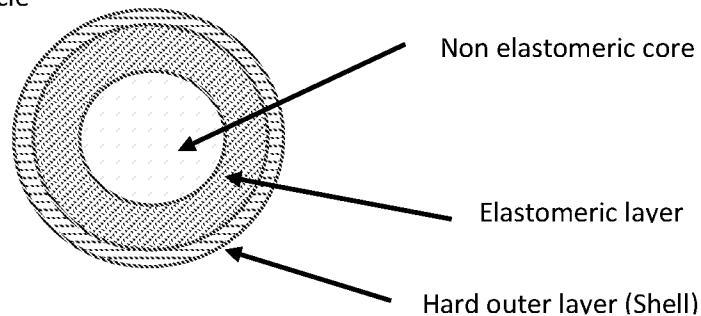
In addition, the Office Action also states that concerning claim 2, 12, 16 and 17, Trabert et al. does not explicitly disclose the thickness of the layers as claimed; however thickness modifications

involve a mere change in the size of a component and a change in size is generally recognized as being within the level of ordinary skill in the art.

For the reasons stated above, the Examiner's reliance on Trabert et al. to support a rejection of the independent claims under 35 USC § 103 is defective because Trabert et al. does not teach, suggest or predict each of the elements recited in independent claims 1 and 11. As a result, Applicant asserts that claims 1 and 11 were nonobvious at the time the invention was made for the reasons provided above. If an independent claim is nonobvious, it follows that any claim that depends from that independent claim is also nonobvious. For this reason, it follows that claims 2, 12, 16 and 17 are also nonobvious. Applicant respectfully requests that the rejection of claims 2, 12, 16 and 17 be reconsidered and withdrawn.

(F) Diagram of Materials Disclosed by Trabert et al.

Impact Modifier Particle



CONCLUSION

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.



/Gerald T. Gray/

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Date: June 12, 2020

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/719,256		Filing Date 12/18/2019		☐ To be Mailed	
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO									
APPLICATION AS FILED - PART I									
		(Column 1)	(Column 2)						
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A	N/A		N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A	N/A		N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A	N/A		N/A				
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *		x \$100 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *		x \$460 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.					TOTAL				
APPLICATION AS AMENDED - PART II									
		(Column 1)		(Column 2)	(Column 3)				
AMENDMENT	06/12/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 34	Minus	** 29	= 5	x \$100 =		500	
	Independent (37 CFR 1.16(h))	* 8	Minus	*** 3	= 5	x \$460 =		2300	
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		2800	
		(Column 1)		(Column 2)	(Column 3)				
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/SHAREILL A COLES/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352
103606 7590 07/07/2020 LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083			EXAMINER FERGUSON, LAWRENCE D	
			ART UNIT 1781	PAPER NUMBER
			NOTIFICATION DATE 07/07/2020	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chgpatent@leydig.com

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment filed June 12, 2020. Claims 2 and 13 have been amended and claims 30-34 have been added, rendering claims 1-34, with claims 18, 25 and 27-29 withdrawn as a non-elected invention.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections – 35 USC § 103(a)

3. Claims 1-4, 11-14, 16-17, 19-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabert et al. (U.S. 5,318,737).

Trabert discloses a thermoplastic resin composition comprising a polymeric core layer (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). Trabert discloses the core layer and outer layer comprise a resin which is made from

the same monomer(s) used to prepare the composition, which includes polyvinyl chloride (column 5, lines 9-38). The elastomeric intermediate layer can comprise copolymers of acrylate (polyacrylic acid) (column 8, lines 1-22). Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; however, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness, as in claims 1 and 3-4.

Concerning claim 2, Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Concerning claims 11 and 13-14, Trabert discloses a thermoplastic resin composition comprising a polymeric core layer (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). Trabert discloses the core layer and outer layer comprise a resin which is made from the same monomer(s) used to prepare the composition, which includes polyvinyl chloride (column 5, lines 9-38). The

elastomeric intermediate layer can comprise copolyomers of acrylate (polyacrylic acid) (column 8, lines 1-22). Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; however, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness. Although Trabert does not explicitly disclose additional outer and inner layers, it would have been obvious to one of ordinary skill in the art to duplicate the layers of Trabert, since it has been held that mere duplication of parts or layers has no patentable significance unless a new and unexpected result is produced *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Concerning claim 12, Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Concerning claims 16-17, Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level

of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Concerning claims 19-24 and 26, Trabert discloses a thermoplastic resin composition comprising a polymeric core layer (outer layer), an elastomeric intermediate layer and a relatively hard polymeric outer layer, where the composition has a high flexural modulus (column 5, lines 9-38). Trabert discloses the core layer and outer layer comprise a resin which is made from the same monomer(s) used to prepare the composition, which includes polyvinyl chloride (column 5, lines 9-38). The elastomeric intermediate layer can comprise copolyomers of acrylate (polyacrylic acid) (column 8, lines 1-22). Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; however, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness. Although Trabert does not explicitly disclose additional outer and inner layers, it would have been obvious to one of ordinary skill in the art to duplicate the layers of Trabert, since it has been held that mere duplication of parts or layers has no patentable significance unless a new and unexpected result is produced *In re Harza*, 274 F.2d 669, 124 USPO 378 (CCPA 1960).

Trabert does not explicitly disclose the thickness of the combined layers; however thickness modifications involve a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art and therefore obvious. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) See MPEP 2144.04.

Claim Objections

4. Claims 5-10 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The closest prior art does not teach or suggest the recited polymeric sheet composition further including where one or more of the outer layers A and C comprise a microcrystalline polyamide having heat of fusion of less than 20J/g and a light transmission of greater than 80%. The closest prior art does not teach or suggest the recited polymeric sheet composition further including where the inner layer comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

The prior art does not teach motivation or suggestion for modification to make the invention as instantly claimed.

Allowable Claims

5. Claims 30-34 have are allowed. The prior art of record does not teach or suggest the recited polymeric sheet composition further including an anhydrided functionalized styrenic elastomer having a hardness of from about A60 to D50.

The prior art of record does not teach or suggest the recited polymeric sheet composition further including a diol component where a copolyester exhibits a glass transition temperature from 80C to 150C.

The prior art of record does not teach or suggest the recited polymeric sheet composition further including an aromatic polyether polyurethane having a compression set of less than 35%.

The prior art of record does not teach or suggest the recited polymeric sheet composition further including an interlayer peel strength between the A and C layers and the B layer of greater than 50N per 2.5cm.

The prior art does not teach motivation or suggestion for modification to make the invention as instantly claimed.

Response to Arguments

6. Applicant's arguments of the rejection made under 35 U.S.C. 103(a) as being unpatentable over Trabert et al. (U.S. 5,318,737) has been considered; however, are

unpersuasive. Applicant argues Trabert does not disclose the flexural modulus or hardness, as in instant claim 1. In response to Applicant's argument, although Trabert does not appear to explicitly teach the flexural modulus of the outer layers or the hardness of the intermediate layer; substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties. In the present case the polymeric sheet composition is carried out using material (polyvinyl chloride outer layer and acrylate (polyacrylic acid) intermediate layer and process conditions (coextrusion) which are substantially identical to those disclosed by applicants. Therefore the polymeric sheet composition discussed above would be expected to meet the claimed flexural modulus and hardness.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Ferguson whose telephone number is 571-272-1522. The examiner can normally be reached on Monday through Friday 9:00 AM – 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Vineis, can be reached on 571-270-1547. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

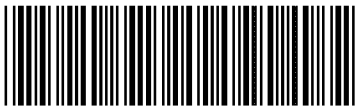
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/LAWRENCE D FERGUSON/
Examiner, Art Unit 1781

<i>Index of Claims</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant					☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE								
Final	Original	02/14/2020	03/12/2020	07/01/2020						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	✓						
	4	÷	✓	✓						
	5	÷	○	○						
	6	÷	○	○						
	7	÷	○	○						
	8	÷	○	○						
	9	÷	○	○						
	10	÷	○	○						
	11	÷	✓	✓						
	12	÷	✓	✓						
	13	÷	✓	✓						
	14	÷	✓	✓						
	15	÷	○	○						
	16	÷	✓	✓						
	17	÷	✓	✓						
	18	÷	N	N						
	19	÷	✓	✓						
	20	÷	✓	✓						
	21	÷	✓	✓						
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	24	÷	✓	✓						
	25	÷	N	N						
	26	÷	✓	✓						
	27	÷	N	N						
	28	÷	N	N						
	29	÷	N	N						
	30			=						
	31			=						
	32			=						
	33			=						
	34			=						

<i>Search Notes</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

CPC - Searched*		
Symbol	Date	Examiner
B32B 7/02	03/12/2020	/LF/
Updated Search	07/01/2020	/LF/

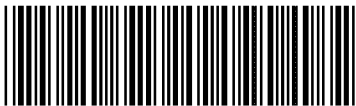
CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
East Search	03/12/2020	/LF/
CPC Search	03/12/2020	/LF/
NPL Search	03/12/2020	/LF/
Inventor Search	03/12/2020	/LF/
Assignee Search	03/12/2020	/LF/
Updated Search	07/01/2020	/LF/

/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	
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<i>Search Notes</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	9	(Bay with Materials).as.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S2	127	(Ray with Stewart).in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S3	21	(John with Lahlouh).in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S4	2	S2 and dual with shell	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:11
S5	7	S2 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:11
S6	4	S3 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:12
S7	3	dual with shell with dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:30
S8	2,015	outer with layers same flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:31
S9	1,887	S8 and (core or inner or intermediate or center or central) near3 layer	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:49
S10	1,264	S8 and (core or inner or intermediate or center or central) near3 layer with hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50

S11	0	S8 and (core or inner or intermediate or center or central) near3 layer with hardness with "D 85"	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S12	1	S8 and (core or inner or intermediate or center or central) near3 layer with hardness with "A 60"	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S13	50,169	polymeric with sheet	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S14	297	S13 and elastomeric with (inner or intermediate or core) near3 (sheet layer)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S15	3	S13 and elastomeric with (inner or intermediate or core) near3 (sheet layer) same hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S16	3	S15 and modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:53
S17	2	S15 and flexural same modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:53
S18	178	S14 and outer near3 layers	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:54
S19	2	S14 and outer near3 layers same flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:54
S20	1	"5318737".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:32
S21	1	"5318737".pn. and intermediate	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:33
S22	1	"5318737".pn. and (laminat\$4 or extrusion or coextrusion or extruding or thermoform\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:52

S23	1	"5318737".pn. and thick\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:54
S24	1	"5318737".pn. and total with thick\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:54
S25	1	16/719256	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S26	44,220	((A61C7/08 OR B32B2250/24 OR B32B2307/536 OR B32B2307/546 OR B32B2535/00 OR B32B27/08 OR B32B27/302 OR B32B27/32 OR B32B27/36 OR B32B27/40).CPC.)	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S27	36	S26 and dual with shell	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S28	1,958	S26 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S29	12	S27 and S28	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S30	727	S28 and elastomer\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S31	49	S30 and flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:22
S32	41	S31 and hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:22
S33	14	S32 and "D" with "85"	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:22

EAST Search History (Interference)

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7/1/2020 9:22:49 PM

C:\Users\lferguson\Documents\EAST\Workspaces\16719256.wsp

Atty Docket No.: 513043 (000550US) (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	:	Confirmation No.: 7352
STEWART and LAHLOUH	:	
	:	Art Unit: 1781
Application No.: 16/719,256	:	
	:	Examiner: FERGUSON, Lawrence D.
Filed: December 18, 2019	:	
	:	
For: DUAL SHELL DENTAL APPLIANCE AND	:	
MATERIAL CONSTRUCTIONS	::	

Mail Stop AF

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Applicant Interview Summary

A telephonic interview took place on August 19, 2020 with Examiner Lawrence Ferguson, the inventor, Dr. Ray Stewart of Bay Materials LLC, in-house counsel for Bay Materials LLC, Linda R. Judge (Reg. No. 42,702), and the Attorney of record for the Applicant, Gerald Gray (Reg No. 41,797) in attendance.

An agenda for the Interview which included a diagram showing certain technical features of the pending claims and a diagram of the disclosure of Trabert et al. (US Patent Number 5,318,737), was submitted to Examiner Ferguson on August 18, 2020.

During the Interview, Dr. Stewart reviewed technical features of the claimed invention and the disclosure of Trabert et al. Dr. Stewart explained how the current claims differ from Trabert et al. The discussion focused on the diagrams which show the differences between the 3-layer particles of Trabert et al. and the polymeric sheet compositions of claim 1 and claim 2.

Agreement was reached with respect to the lack of obviousness of the pending claims over Trabert et al.

Applicant agreed to submit a response to the final Office Action by the 2 month deadline of September 7, 2020, so the prosecution can move forward.

Respectfully submitted,



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797

Telephone: 312-616-5600

Facsimile: 312-616-5700

Date: August 21, 2020

USPTO TRANSMITTAL

PATENT

Attorney Docket No. 513043 (000550US)
Client Reference No. DD4105P/US05

Application No. 16/719,256
Confirmation No. 7352

Transmitted herewith is a reply to office action in the subject application.

- ☐ Petition for an extension of time for the period noted below, as well as for any additional period necessary to render the present submission timely. Please charge Deposit Account No. 12-1216 for the appropriate petition fee.
- ☒ Other: Applicant Interview Summary
- ☐ Please charge Deposit Account No. 12-1216 in the total amount indicated below.

TIME EXTENSION PETITION FEE			none			\$0
subtract time extension fee previously paid			none			(\$0)
CLAIM FEE	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	EXTRA CLAIMS PRESENT	RATE	ADDITIONAL CLAIM FEE
TOTAL	34	MINUS	34	= 0	x \$100 =	\$0
INDEPENDENT	8	MINUS	8	= 0	x \$460 =	\$0
☐	FIRST PRESENTATION OF MULTIPLY DEPENDENT CLAIM				+ \$820 =	\$0
SUBTOTAL (of all items above)						\$0
☐	Small entity status is claimed for this application under 37 CFR 1.27. Fees above are reduced by ½.					(\$0)
☐	Micro entity status is claimed for this application under 37 CFR 1.27. Fees above are reduced by ¾.					(\$0)
OTHER FEES AS DESCRIBED:						\$0
TOTAL AMOUNT TO BE CHARGED TO DEPOSIT ACCOUNT						\$0

- ☒ The Commissioner is hereby authorized to charge any deficiencies in the following fees associated with this communication or credit any overpayment to Deposit Account No. 12-1216.
- ☒ Any filing fees under 37 CFR 1.16 and/or 1.492 for the presentation of extra claims.
- ☒ Any patent application processing fees under 37 CFR 1.17.



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797
Telephone: 312-616-5600
Facsimile: 312-616-5700

Date: August 21, 2020

Electronic Acknowledgement Receipt

EFS ID:	40354623
Application Number:	16719256
International Application Number:	
Confirmation Number:	7352
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
Filer:	Gerald Todd Gray./Christina Alton
Filer Authorized By:	Gerald Todd Gray.
Attorney Docket Number:	513043 (000550US)
Receipt Date:	21-AUG-2020
Filing Date:	18-DEC-2019
Time Stamp:	17:22:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response After Final Action	513043_20200821_RFOA.pdf	340465	no	9
			707f970baab951ac1141efbdd694e4adc5e53100		

Warnings:

Information:					
2	Applicant summary of interview with examiner	513043_20200821_IS.pdf	85673	no	2
			5ee49d96b314cf1dbb064b426559d60e54620d49		
Warnings:					
Information:					
3	Transmittal Letter	513043_20200821_TRA.pdf	80883	no	1
			a5429e9ccc620064e62f647a6dd61b1da8eb7c30		
Warnings:					
Information:					
Total Files Size (in bytes):			507021		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Atty Docket No.: 513043 (000550US) (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

STEWART and LAHLOUH

Application No.: 16/719,256

Filed: December 18, 2019

For: DUAL SHELL DENTAL APPLIANCE AND
MATERIAL CONSTRUCTIONS

: Confirmation No.: 7352

:

: Art Unit: 1781

:

: Examiner: FERGUSON, Lawrence D.

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Mail Stop AF

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Commissioner:

This paper is filed in response to the Final Office Action mailed July 7, 2020 in the above-identified application. An Applicant Interview Summary of the telephonic interview which took place on August 19, 2020 is submitted herewith. This paper is fully responsive to the Final Office Action. Reconsideration and allowance are respectfully requested in view of the amendments and remarks below.

LISTING OF CLAIMS begins on **page 2** of this paper.

REMARKS begin on **page 6** of this paper.

LISTING OF CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Original) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer 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, and the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

2. (Previously Presented) The 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.

3. (Original) The polymeric sheet composition of claim 2, wherein the outer layers A and C comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such a polyvinyl chloride, and a fluoropolymer.

4. (Original) The polymeric sheet composition of claim 2, wherein the inner layer B comprises one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, and a fluoroelastomer.

5. (Original) The polymeric sheet composition of claim 3, wherein one or more of outer layers A and C comprise a microcrystalline polyamide having heat of fusion of less than 20 J/g and a light transmission of greater than 80%.

6. (Original) The polymeric sheet composition of claim 4, wherein the inner layer B comprises an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

7. (Original) The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a co-polyester having a:

(a) a dicarboxylic acid component and

(b) a diol component, wherein the-copolyester exhibits a glass transition temperature (T_g) from 80°C to 150°C.

8. (Original) The polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a polyurethane comprised of:

(a) a di-isocyanate, and

(b) a diol component comprising one or more of hexane diol and cyclohexane dimethanol

wherein the polyurethane has a glass transition temperature T_g from about 85°C to about 150°C.

9. (Original) The polymeric sheet composition of claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having a compression set of less than 35%.

10. (Original) The polymeric sheet composition according to claim 2, wherein the inner layer B comprises an aromatic polyether polyurethane having an interlayer peel strength between the A and C layers and the B layer of greater than 50 N per 2.5 cm.

11. (Original) 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, 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 the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

12. (Original) 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.

13. (Previously presented) 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, a polyamide, a polyolefin, a microcrystalline polyamide, a co-polyester of terephthalic and/or isophthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol, a co-polyester of terephthalic and/or isophthalic acid, ethylene glycol and diethylene glycol, an aromatic polyurethane based on MDI and hexanediol, an aromatic polyurethane with aliphatic diols, a co-polymer of propylene, ethylene and C4 to C8 alpha olefin, a cycloaliphatic polyamide, a (meth) acrylic polymer, a vinyl polymer such as a polyvinyl chloride, and a fluoropolymer.

14. (Original) The polymeric sheet composition of claim 12, wherein the soft inner layers B and B' individually comprise one or more of a polyurethane elastomer, an aromatic polyether polyurethane, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, an anhydride functionalized styrenic elastomer, a polyamide elastomer, a polyether polyamide (polypropylene oxide-based or polytetramethylene oxide-based), a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether, a polyester polyurethane, a siloxane elastomer, a polyether elastomer, a polyolefin elastomer, an olefin copolymer, an acrylic elastomer and a fluoroelastomer.

15. (Original) The polymeric sheet composition of claim 14, wherein one or more of the soft inner layers B and B' comprise an anhydride functionalized styrenic elastomer having a hardness of from about A60 to D50.

16. (Original) The polymeric sheet composition of claim 14, wherein the rigid or hard layers, A, C and D have a combined thickness of from about 100 microns to about 750 microns.

17. (Original) The polymeric sheet composition of claim 14, wherein the soft layers, B and B' have a combined thickness of from about 150 microns to about 1,000 microns.

18. (Withdrawn) A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.

19. (Original) A polymeric sheet composition, comprising:

three or more layers, A, A1, and B, wherein the outermost layers, A and A1 have different thicknesses from one another and individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa, and wherein the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

20. (Original) The polymeric sheet composition of claim 19, wherein the A, A1 and B layers of the polymeric sheet composition have a combined thickness of from about 500 microns to 2,000 microns.

21. (Original) The polymeric sheet composition of claim 20, wherein the outermost layer A1 has a thickness of from about 25 to about 250 microns.

22. (Original) The polymeric sheet composition of claim 20, wherein the ratio of the thickness of the outermost layer A1 to the thickness of the outermost layer A is from about 0.9 to about 0.2.

23. (Original) The polymeric sheet composition of claim 20, wherein the outermost layer A and outermost layer A1 are comprised of one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide, and a polyolefin.

24. (Previously presented) The polymeric sheet composition according to claim 20, wherein the outer layers A and A1 comprise the same material.

25. (Withdrawn) The polymeric sheet composition according to claim 20, wherein the outer layers A and A2 comprise different materials.

26. (Original) The polymeric sheet composition of claim 20, wherein the middle layer B is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer, an acrylic elastomer, an aromatic or aliphatic polyether and a polyester polyurethane.

27. (Withdrawn) A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 20.

28. (Withdrawn) The dental appliance of claim 27, wherein the dental appliance exhibits improved tear resistance relative to the A, C or D layer alone.

29. (Withdrawn) The dental appliance of claim 27, wherein the dental appliance exhibits improved environmental stress resistance relative to the A, C or D layer alone.

30. (Previously Presented) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) the inner layer B comprises an anhydride functionalized styrenic elastomer

having a hardness of from about A60 to D50.

31. (Previously presented) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) one or more of the A and C layers comprises a co-polyester having a:

(c) a dicarboxylic acid component and

(d) a diol component, wherein the-copolyester exhibits a glass transition temperature (T_g) from 80°C to 150°C.

32. (Previously presented) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) one or more of the A and C layers comprises a polyurethane comprised of:

(c) a di-isocyanate, and

(d) a diol component comprising one or more of hexane diol and cyclohexane dimethanol

wherein the polyurethane has a glass transition temperature T_g from about 85°C to about 150°C.

33. (Previously presented) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) the inner layer B comprises an aromatic polyether polyurethane having a compression set of less than 35%.

34. (Previously presented) A polymeric sheet composition, comprising:

at least two outer layers A and C and an elastomeric inner layer B, wherein (i) 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, (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85, (iii) 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, and (iv) the inner layer B comprises an aromatic polyether polyurethane having an interlayer peel strength between the A and C layers and the B layer of greater than 50 N per 2.5 cm.

REMARKS

Applicant would like to thank the Examiner for the courtesy extended during the August 19, 2020 telephonic interview.

I. STATUS OF THE CLAIMS

Claims 1-34 are pending in the present application.

Claims 18, 25 and 27-29 were previously withdrawn as directed to a non-elected invention.

Claims 30-34 are allowed.

Claims 5-10 and 15 are objected to as being dependent upon a rejected base claim. The Examiner states that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

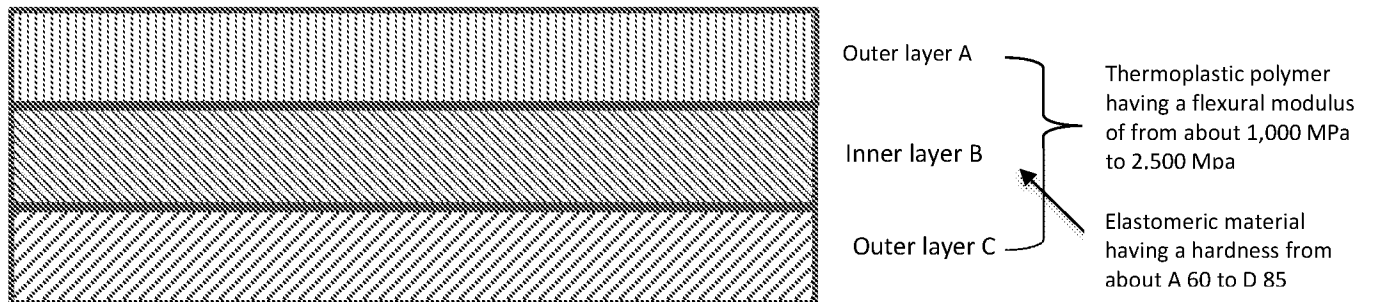
Claims 1-4, 11-14, 1-17, 19-24 and 26 stand rejected.

With entry of the present amendment, claims 1-17, 19-23, 26, and 30-34 are under consideration and subject to substantive examination on the merits.

II. THE CLAIMED INVENTION

As illustrated in the diagram below, independent claims 1, 11 and 19 recite polymeric sheet compositions, where the polymeric sheet compositions have at least three layers, including a rigid or hard outer layer comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa, and an inner elastomeric layer comprising an elastomeric material having a hardness from about A 60 to D 85.

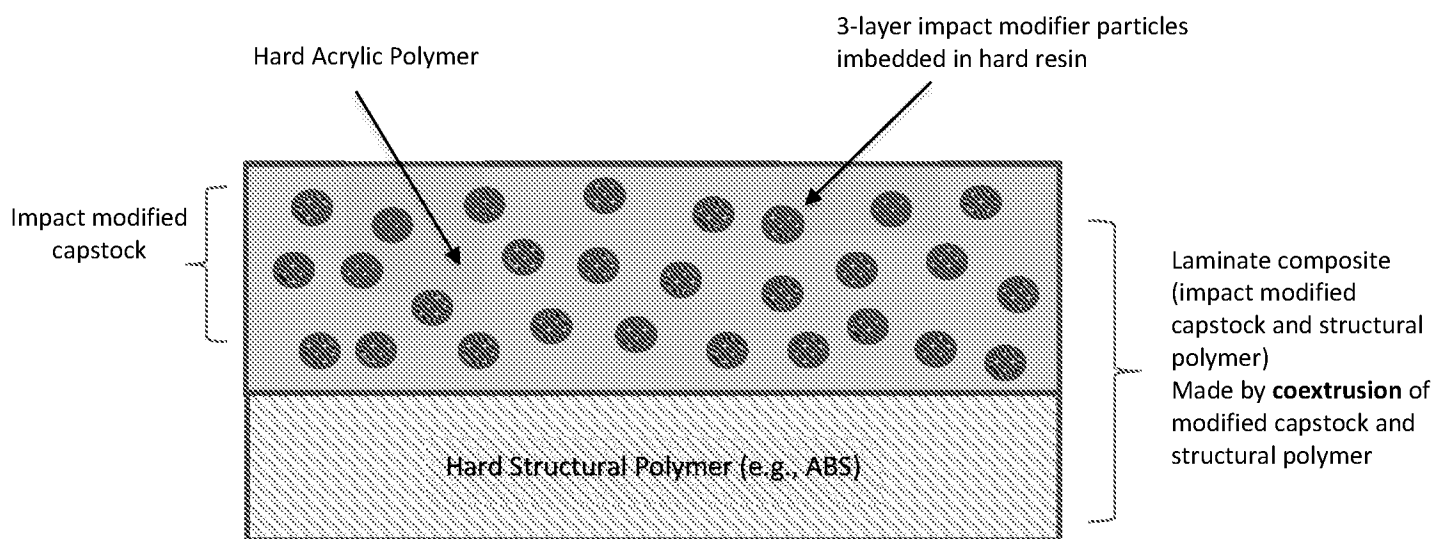
Example Polymeric Sheet Composition with ABC Construction



Three layer sheet (250 to 2,000 microns) may be made by coextrusion or lamination

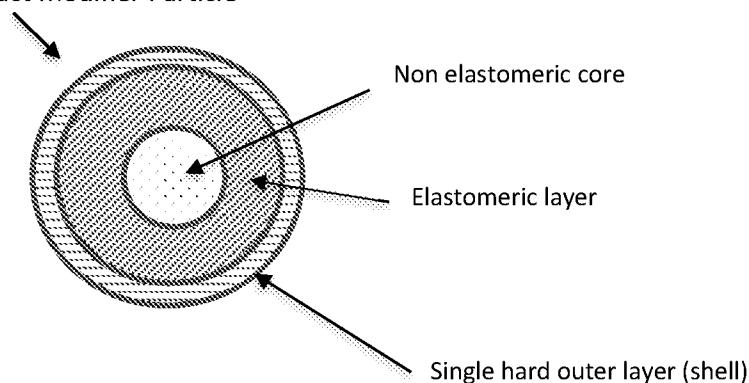
III. THE PRIOR ART - TRABERT et al.

- Trabert et al. discloses acrylic resin capstocks for coating structural plastics and methods of making a composite of an acrylic resin capstock and a structural plastic e.g., ABS (as illustrated in the first diagram below), by standard lamination or feedblock coextrusion (Abstract, Col. 4, lines 27-33, and Example 2).
- The capstock is a methyl methacrylate resin comprising 3-layer polymeric particles less than 1 micron in diameter, as illustrated in the second diagram below. (See, e.g., Col. 5, lines 9-17.)
- The 3-layer particles are not made by lamination or feedblock coextrusion. The 3-layer polymeric particles of Trabert et al. are made by a three-stage, sequential addition of the components for each layer of the 3-layer particles by the procedure described in US 3,793,402, which is emulsion polymerization. The particles are then mixed with a methyl methacrylate copolymer (the acrylic polymer) by manual agitation in an extruder. This results in an impact modifier resin which has 3-layer particles dispersed in an acrylic polymer.



Impact modifier particles are tiny (< 1 micron) spheres made by sequential emulsion polymerization of monomers in water followed by spray drying then compounded into thermoplastic polymer

Sub-micron 3-layer Impact Modifier Particle



IV. REJECTIONS UNDER 35 U.S.C. § 103

Claims 1–4, 11-14, 16-17, 19-24 and 26 stand rejected as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,318,737 (“Trabert et al.”).

Applicant respectfully traverses the rejection of Claims 1–4, 11-14, 16-17, 19-24 and 26, as unpatentable under 35 U.S.C. 103 over Trabert et al.

As illustrated in the diagrams above, the elements of the claims are not suggested or predicted by Trabert for at least the following reasons:

- Trabert discloses particles having a single outer layer. The claims are directed to sheets having at least two outer layers. The inner core of Trabert particles would not be considered an “outer layer” as required by the claims.
- Trabert discloses impact modified acrylic resin capstocks which comprise 3-layer polymeric particles less than 1 micron in diameter dispersed in an acrylic polymer.
- The claimed polymeric sheet composition has a thickness of from 250 microns to 2,000 microns (see, e.g., claim 2).
- The 3-layer particles of Trabert are not made by lamination or feedblock coextrusion. Standard lamination and feedblock coextrusion is disclosed in Trabert only with reference to composites of an impact modified capstock and a structural polymer. See, e.g., Col. 1, lines 13-15; Col. 1, lines 54-58; Col. 5, lines 48-58.

The Office Action states that although Trabert et al. does not explicitly teach the flexural modulus of the outer layers or the hardness of the inner layer, substantially identical materials treated in a substantially identical manner are expected to have substantially identical properties as the materials described in the presently pending claims (flexural modulus of the outer layers or the hardness of the inner layer).

The 3-layer particles of Trabert et al. do not teach, suggest or predict properties of the claimed polymeric sheet compositions having at least 2 outer layers as required by claim 1.

Regarding claim 2, as noted above, and indicated in the diagram of Trabert’s 3-layer polymeric particles, the particles are tiny (< 1 micron; dimension of 250 to 350 nm) and the small size is required for them to function as impact modifiers when suspended in a polymeric polymer. In contrast, the polymeric sheet composition has a thickness of from 250 microns to 2,000 microns.

It follows that the properties of materials disclosed in Trabert et al. cannot be extrapolated to render obvious the claimed polymeric sheet compositions having at least three layers, with two rigid or hard outer layers comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa, and an inner layer comprising an elastomeric material having a hardness from about A 60 to D 85.

One of skill in the art will appreciate that none of the impact modifier particles, the impact modified resin (capstock), or the articles comprising an impact modified capstock and a structural plastic, disclosed by Trabert et al. teach or suggest a polymeric sheet composition having at least three layers, including two rigid or hard outer layers of any kind.

A finding of obviousness under 35 U.S.C. § 103 requires that the Examiner provide prior art that collectively teaches or suggests each limitation of the claim. MPEP § 2143. If a claim limitation is not met by the prior art reference or other appropriate evidence, a rejection is inappropriate. To support a rejection under obviousness, some teaching, suggestion, or motivation in the prior art is required that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. In making a rejection under 35 U.S.C. § 103, the Examiner must articulate a finding that there was some teaching, suggestion, or motivation to modify or combine the reference teachings, and further, a finding that there would have been a reasonable expectation of success to make the modification. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. MPEP § 2143.

Applicant respectfully submits that Trabert et al. does not rise to the level of evidence required to support an obviousness rejection and that the independent claims were nonobvious at the time the invention was made for the reasons provided above. If an independent claim is nonobvious, it follows that any claim that depends from that independent claim is also nonobvious. For this reason, Applicant respectfully requests that the rejection of claims 1, 3-4, 11, 13-14, 19-24 and 26 be reconsidered and withdrawn.

Applicant respectfully submits that the patent application is in condition for allowance.



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797

Telephone: 312-616-5600

Facsimile: 312-616-5700

Date: August 21, 2020

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/719,256		Filing Date 12/18/2019		☐ To be Mailed	
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO									
APPLICATION AS FILED - PART I									
		(Column 1)	(Column 2)						
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A	N/A		N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A	N/A		N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A	N/A		N/A				
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *		x \$100 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *		x \$460 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.					TOTAL				
APPLICATION AS AMENDED - PART II									
		(Column 1)		(Column 2)	(Column 3)				
AMENDMENT	08/21/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 34	Minus	** 34	= 0	x \$100 =		0	
	Independent (37 CFR 1.16(h))	* 8	Minus	*** 8	= 0	x \$460 =		0	
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		0	
		(Column 1)		(Column 2)	(Column 3)				
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/BRENDA MURPHY/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352
103606 7590 08/25/2020 LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083			EXAMINER FERGUSON, LAWRENCE D	
			ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			08/25/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chgpatent@leydig.com

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiners responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicants correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,-
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicants record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiners version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, Interview Record OK on the paper recording the substance of the interview along with the date and the examiners initials.

Applicant Initiated Interview Request Form

Application No.: 16/719,256

First Named Applicant: Ray F. Stewart

Examiner: Lawrence D. Ferguson

Art Unit: 1781

Status of Application: Pending

Tentative Participants:

(1) Gerald T. Gray

(2) Ray F. Stewart

(3) Linda Judge, Esq.

(4)

Proposed Date of Interview: August 19, 2020

Proposed Time: 3:00 (OAM OPM)

Type of Interview Requested:(1) ☒ Telephonic(2) ☐ Personal(3) ☐ Video ConferenceExhibit To Be Shown or Demonstrated: ☒ YES☐ NO

If yes, provide brief description: Visualizations of Trabert's technology and Claimed composition, attached

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 103	1-4	Trabert	☐	☐	☐
(2)			☐	☐	☐
(3)			☐	☐	☐
(4)			☐	☐	☐

☐ Continuation Sheet Attached☐ Proposed Amendment or Arguments Attached

Brief Description of Arguments to be Presented:

An interview was conducted on the above-identified application on

NOTE: This form should be completed and filed by applicant in advance of the interview (see MPEP § 713.01). If this form is signed by a registered practitioner not of record, the Office will accept this as an indication that he or she is authorized to conduct an interview on behalf of the principal (37 CFR 1.32(a)(3)) pursuant to 37 CFR 1.34. This is not a power of attorney to any above named practitioner. See the Instruction Sheet for this form, which is incorporated by reference. By signing this form, applicant or practitioner is certifying that he or she has read the Instruction Sheet. After the interview is conducted, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible. This application will not be delayed from issue because of applicant's failure to submit a written record of this interview.

/Gerald T. Gray/

Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Gerald T. Gray

Typed/Printed Name of Applicant or Representative

(925) 482-0100

Applicant's/Applicant's Representative's Telephone Number

41,797

Registration Number, if applicable

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 24 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

STEWART and LAHLOUH

Application No.: 16/719,256

Filed: December 18, 2019

For: DUAL SHELL DENTAL APPLIANCE AND
MATERIAL CONSTRUCTIONS

: Confirmation No.: 7352

: Art Unit: 1781

: Examiner: FERGUSON, Lawrence D.

Mail Stop AF

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

EXAMINER INTERVIEW - WEDNESDAY, AUGUST 19, 2020.

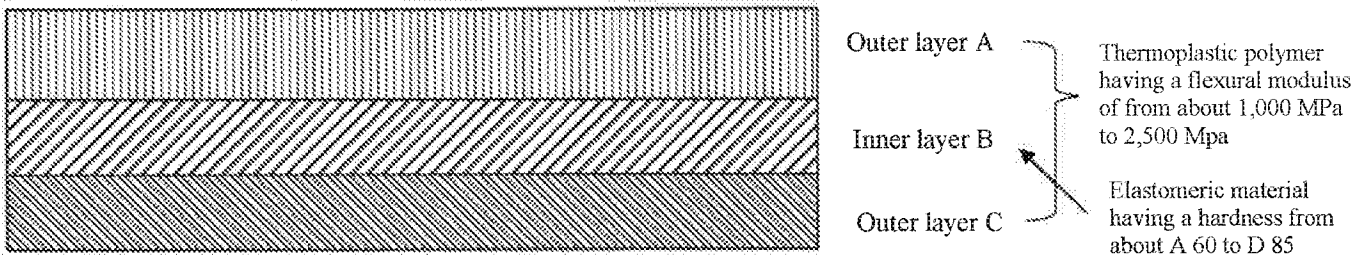
Gerald Gray (attorney of record) will introduce Dr. Ray Stewart (Inventor and General Manager, Bay Materials LLC) and Linda Judge Esq., (in-house counsel for Bay Materials LLC).

Agenda for Examiner Interview

- A. Ray Stewart will summarize current disclosure
- B. Ray Stewart will summarize disclosure of Trabert including diagram and description of process for making Trabert particles.
- C. Examiner input on rejections.

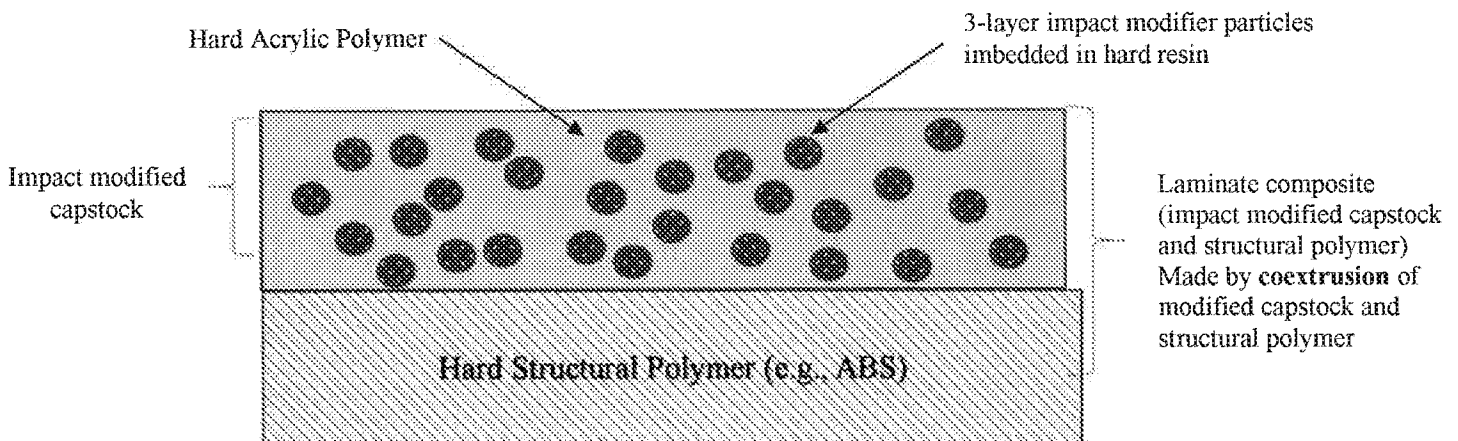
A. Summary of disclosure and pending independent claim in instant application (Ray).

Polymeric Sheet Composition with ABC Construction



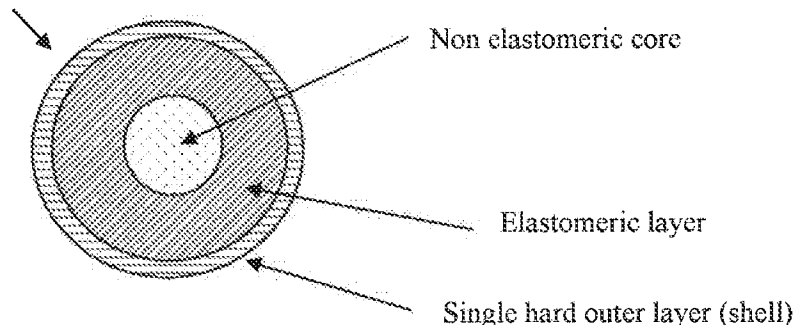
Three layer sheet (250 to 2,000 microns) made by coextrusion or lamination

B. Summary of Trabert.



Impact modifier particles are tiny (< 1 micron) spheres made by sequential emulsion polymerization of monomers in water followed by spray drying then compounded into thermoplastic polymer

Sub-micron 3-layer Impact Modifier Particle



- Trabert et al. discloses acrylic resin capstocks for coating structural plastics and methods of making a composite of an acrylic resin capstock and a structural plastic e.g., ABS, by standard lamination or feedblock coextrusion (See, e.g., Abstract, Col. 4, lines 27-33, and Example 2).
- The capstock is a methyl methacrylate resin comprising 3-layer polymeric particles less than 1 micron in diameter.
- The 3-layer particles are not made by lamination or feedblock coextrusion. The 3 layer polymeric particles of Trabert et al. are made by a three-stage, sequential addition of the components for each layer of the 3-layer particles by the procedure described in US 3,793,402, which is emulsion polymerization. The particles are then mixed with a methyl methacrylate copolymer (the acrylic polymer) by manual agitation in an extruder. This results in an impact modifier resin which has 3-layer particles dispersed in an acrylic polymer.

C. Examiner input on rejections.

1. We are having trouble understanding why the claimed polymeric sheets which have 2 outer layers are obvious over the single outer layer particles of Trabert and would like the Examiner's input.
2. We understand that in some cases size may be within the level of ordinary skill in the art, however; in this case the 3-layer polymeric particles of Trabert are required to be less than 1 micron in diameter (dimension of 250 to 350 nm) to achieve their technical effect, and numerous very small polymeric particles must be dispersed within the acrylic polymer of Trabert to create an impact modified resin. In contrast, the claimed polymeric sheet compositions have a thickness of from 250 microns to 2,000 microns. We would like to understand why the thickness of the claimed polymeric sheets is obvious given that they are more than 250 times the specific thickness of Trabert's particles.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

103606 7590 10/01/2020
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083

EXAMINER	
FERGUSON, LAWRENCE D	
ART UNIT	PAPER NUMBER
1781	

DATE MAILED: 10/01/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352

TITLE OF INVENTION: DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	01/01/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

103606 7590 10/01/2020
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352

TITLE OF INVENTION: DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	01/01/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FERGUSON, LAWRENCE D	1781	428-215000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352
103606	7590	10/01/2020	EXAMINER	
LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083			FERGUSON, LAWRENCE D	
			ART UNIT	PAPER NUMBER
			1781	

DATE MAILED: 10/01/2020

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/719,256	Applicant(s) Stewart et al.	
	Examiner LAWRENCE D FERGUSON	Art Unit 1781	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/21/20.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-34. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	5. ☐ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
---	--

/LAWRENCE D FERGUSON/
Examiner, Art Unit 1781

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Reasons for allowance

1. Claims 1-34 are allowed.

The restriction requirement of claims 18, 25 and 27-29, as set forth in the Office action mailed on February 20, 2020, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 18, 25 and 27-29 are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or suggest the recited polymeric sheet composition further including layers A and C comprising a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa, and an inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

The prior art does not teach motivation or suggestion for modification to make the invention as instantly claimed.

Any comments considered by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Ferguson whose telephone number is 571-272-1522. The examiner can normally be reached on Monday through Friday 9:00 AM – 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Vineis, can be reached on 571-270-1547. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

/LAWRENCE D FERGUSON/
Examiner, Art Unit 1781

<i>Index of Claims</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☒ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47
CLAIM		DATE								
Final	Original	02/14/2020	03/12/2020	07/01/2020	09/24/2020					
	1	÷	✓	✓	=					
	2	÷	✓	✓	=					
	3	÷	✓	✓	=					
	4	÷	✓	✓	=					
	5	÷	○	○	=					
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	30			=	=					
	31			=	=					
	32			=	=					
	33			=	=					
	34			=	=					

Issue Classification 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.	
	Examiner LAWRENCE D FERGUSON	Art Unit 1781	

CPC						
Symbol					Type	Version
B32B	/	27	/	08	F	2013-01-01
B32B	/	27	/	40	I	2013-01-01
B32B	/	27	/	36	I	2013-01-01
B32B	/	27	/	32	I	2013-01-01
A61C	/	7	/	08	I	2013-01-01
B32B	/	27	/	302	I	2013-01-01
B32B	/	2535	/	00	A	2013-01-01
B32B	/	2307	/	546	A	2013-01-01
B32B	/	2307	/	536	A	2013-01-01
B32B	/	2250	/	24	A	2013-01-01

CPC Combination Sets					
Symbol			Type	Set	Ranking
	/				

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 34	
/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781 (Primary Examiner) _____ (Date) _____		24 September 2020 O.G. Print Claim(s) 1	O.G. Print Figure 4

Issue Classification 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

INTERNATIONAL CLASSIFICATION			
CLAIMED			
B32B	/	27	/ 08
NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

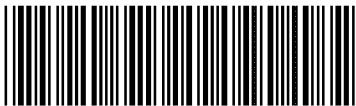
CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	34	
/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	24 September 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

Issue Classification 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19		28								
	2		11		20		29								
	3		12		21		30								
	4		13		22		31								
	5		14		23		32								
	6		15		24		33								
	7		16		25		34								
	8		17		26										
	9		18		27										

NONE	Total Claims Allowed:	
(Assistant Examiner)	(Date)	34
/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	24 September 2020	O.G. Print Claim(s)
(Primary Examiner)	(Date)	1
		O.G. Print Figure
		4

<i>Search Notes</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

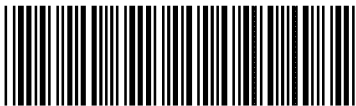
CPC - Searched*		
Symbol	Date	Examiner
B32B 7/02	03/12/2020	/LF/
Updated Search	07/01/2020	/LF/
Updated Search	09/24/2020	/LF/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	
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<i>Search Notes</i> 	Application/Control No. 16/719,256	Applicant(s)/Patent Under Reexamination Stewart et al.
	Examiner LAWRENCE D FERGUSON	Art Unit 1781

Search Notes		
Search Notes	Date	Examiner
East Search	03/12/2020	/LF/
CPC Search	03/12/2020	/LF/
NPL Search	03/12/2020	/LF/
Inventor Search	03/12/2020	/LF/
Assignee Search	03/12/2020	/LF/
Updated Search	07/01/2020	/LF/
Updated Search	09/24/2020	/LF/
CPC Search	09/24/2020	/LF/
NPL Search	09/24/2020	/LF/
Inventor Search	09/24/2020	/LF/
Interference Search	09/24/2020	/LF/
STIC Search	09/24/2020	/LF/

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
B32B	2250/24 ,2307/536 ,2307/546 ,2535/00 ,27/08 ,27/302 ,27/32 ,27/36 ,27/40	09/24/2020	/LF/
A61C	7/08	09/24/2020	/LF/

/LAWRENCE D FERGUSON/ Examiner, Art Unit 1781	
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Substitute for Form 1449A/B/PTO				Patent Application No.	16/719,256
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Confirmation No.	7352
				Attorney Docket No.	513043 (000550US)
				Client Reference No.	DD4105P/US05
Sheet	1	of	2		

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	1	6,390,812	B1	Chishti et al.	05/21/2002	
	2	6,454,565	B2	Phan et al.	09/24/2002	
	3	6,497,574	B1	Miller	12/24/2002	
	4	6,524,101	B1	Phan et al.	02/25/2003	
	5	6,572,372	B1	Phan et al.	06/03/2003	
	6	6,746,757	B1	Takagi et al.	06/08/2004	
	7	6,964,564	B2	Phan et al.	11/15/2005	
	8	7,121,825	B2	Chishti et al.	10/17/2006	
	9	7,210,926	B2	Tadros et al.	05/01/2007	
	10	8,235,713	B2	Phan et al.	08/07/2012	
	11	8,337,199	B2	Wen	12/25/2012	
	12	8,765,031	B2	Li et al.	07/01/2014	
	13	8,858,226	B2	Phan et al.	10/14/2014	
	14	9,351,809	B2	Phan et al.	05/31/2016	
	15	9,655,691	B2	Li et al.	05/23/2017	
	16	9,655,693	B2	Li et al.	05/23/2017	
	17	10,052,176	B2	Li et al.	08/21/2018	
	18	2006/0078841	A1	DeSimone et al.	04/13/2006	
	19	2008/0248438	A1	DeSimone et al.	10/09/2008	
	20	2011/0020761	A1	Kalili	01/27/2011	
	21	2015/0004553	A1	Li et al.	01/01/2015	
	22	2015/0140300	A1	Pudleiner et al.	05/21/2015	
	23	2015/0366637	A1	Kopelman et al.	12/24/2015	
	24	2015/0366638	A1	Kopelman et al.	12/24/2015	
	25	2017/0007361	A1	Borankay et al.	01/12/2017	
	26	2017/0007362	A1	Chen et al.	01/12/2017	
	27	2018/0318043	A1	Li et al.	11/08/2018	
	28	2019/0159870	A1	Li et al.	05/30/2019	
	29	2019/0231484	A1	Li et al.	08/01/2019	
	30	2011/0020761	A1	Kalili	01/27/2011	
	31	7,201,575	B2	Adell et al.	04/10/2007	
	32	2001/0041320	A1	Phan et al.	11/15/2001	
	33	2005/0100853	A1	Tadros et al.	05/12/2005	
	34	2005/0244793	A1	Adell et al.	11/03/2005	
	35	2006/0078841	A1	DeSimone et al.	04/13/2006	
	36	2009/0130624	A1	Sun et al.	05/21/2009	
	37	2011/0039223	A1	Li et al.	02/17/2011	
	38	2011/0207087	A1	Jones et al.	08/25/2011	

Examiner Signature	/LAWRENCE D FERGUSON/	Date Considered	09/24/2020
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* If the reference is not in English, then at least one of the following is provided: (a) an English translation in whole or in part or (b) a concise statement of relevance in the form of, for example, an English language counterpart, an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office.

Substitute for Form 1449A/B/PTO				Patent Application No.	16/719,256
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Confirmation No.	7352
				Attorney Docket No.	513043 (000550US)
Sheet	2	of	2	Client Reference No.	DD4105P/US05

FOREIGN PATENT DOCUMENTS							
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation *
		Office	Application or Patent Number	Kind Code			
	39	WO	2006/009745	A1	Dentsply. Int., Inc.	01/26/2006	
	40	WO	2010/074789	A1	Dow Global Tech., Inc.	07/01/2010	
	41	DE	2020013001392	U1	Scheu Dental GmbH	04/09/2013	(a)
	42	WO	2013/171124	A1	Bayer Material Science AG	11/21/2013	

OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation *
	43	International Search Report and Written Opinion from International Patent Application No. PCT/US2018/035384, 14 pages, August 22, 2018.	
	44	Campo, E. Alfredo, "Mechanical Properties of Polymeric Materials." Selection of Polymeric Materials: Plastics Design Library, 2008, 4 pages.	
	45	Bayer Product Information sheet for TEXIN® 990R, Pages 1-4, November 2002, Pittsburgh, PA.	
	46	Barner-Kowollik et al., 2016, "Polymer Interfaces: Synthetic Strategies Enabling Functionality, Adaptivity, and Spatial Control", Macromolecules, 2016, 49, 14, 5001-5016.	
	47	Desmopan (TPU) Product Range-Reference Data, Bayer Material Science, 2004-09.	
	48	Mid-West Innovators: Durometer, http://www.midwestinnovators.com/material-properties/durometer.html , 02/24/2020.	
	49	Thermoplastic-Polyurethane Elastomers (TPU), Technical Information, The Chemical Company BASF, 28 pages.	
	50	Barner-Kowollik et al., Macromolecules, Polymer Interfaces, Perspective pubs.acs.org/Macromolecules .	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.D.F/

Examiner Signature	/LAWRENCE D FERGUSON/	Date Considered	09/24/2020
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* If the reference is not in English, then at least one of the following is provided: (a) an English translation in whole or in part or (b) a concise statement of relevance in the form of, for example, an English language counterpart, an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office.

Atty Docket No.: 513043 (000550US) (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

STEWART and LAHLOUH

Application No.: 16/719,256

Filed: December 18, 2019

For: DUAL SHELL DENTAL APPLIANCE AND
MATERIAL CONSTRUCTIONS

: Confirmation No.: 7352

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: Art Unit: 1781

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: Examiner: FERGUSON, Lawrence D.

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OK TO ENTER: /L.D.F/

Mail Stop AF

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Commissioner:

This paper is filed in response to the Final Office Action mailed July 7, 2020 in the above-identified application. An Applicant Interview Summary of the telephonic interview which took place on August 19, 2020 is submitted herewith. This paper is fully responsive to the Final Office Action. Reconsideration and allowance are respectfully requested in view of the amendments and remarks below.

LISTING OF CLAIMS begins on **page 2** of this paper.

REMARKS begin on **page 6** of this paper.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	9	(Bay with Materials).as.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S2	127	(Ray with Stewart).in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S3	21	(John with Lahlouh).in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:09
S4	2	S2 and dual with shell	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:11
S5	7	S2 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:11
S6	4	S3 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:12
S7	3	dual with shell with dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:30
S8	2,015	outer with layers same flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:31
S9	1,887	S8 and (core or inner or intermediate or center or central) near3 layer	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:49
S10	1,264	S8 and (core or inner or intermediate or center or central) near3 layer with hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50

S11	0	S8 and (core or inner or intermediate or center or central) near3 layer with hardness with "D 85"	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S12	1	S8 and (core or inner or intermediate or center or central) near3 layer with hardness with "A 60"	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:50
S13	50,169	polymeric with sheet	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S14	297	S13 and elastomeric with (inner or intermediate or core) near3 (sheet layer)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S15	3	S13 and elastomeric with (inner or intermediate or core) near3 (sheet layer) same hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:52
S16	3	S15 and modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:53
S17	2	S15 and flexural same modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:53
S18	178	S14 and outer near3 layers	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:54
S19	2	S14 and outer near3 layers same flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 13:54
S20	1	"5318737".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:32
S21	1	"5318737".pn. and intermediate	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:33
S22	1	"5318737".pn. and (laminat\$4 or extrusion or coextrusion or extruding or thermoform\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:52

S23	1	"5318737".pn. and thick\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:54
S24	1	"5318737".pn. and total with thick\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/12 20:54
S25	1	16/719256	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S26	44,220	((A61C7/08 OR B32B2250/24 OR B32B2307/536 OR B32B2307/546 OR B32B2535/00 OR B32B27/08 OR B32B27/302 OR B32B27/32 OR B32B27/36 OR B32B27/40).CPC.)	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S27	36	S26 and dual with shell	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S28	1,958	S26 and dental	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S29	12	S27 and S28	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S30	727	S28 and elastomer\$4	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:21
S31	49	S30 and flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:22
S32	41	S31 and hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:22
S33	14	S32 and "D" with "85"	US-PGPUB; USPAT; USOCR	OR	ON	2020/07/01 21:22
S34	1	"5318737".pn.	US-PGPUB;	OR	ON	2020/08/19 08:44

			USPAT; USOCR			
S35	0	"2017590627"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:08
S36	0	"20170590627"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:08
S37	0	"2017512786"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:08
S38	113,484	outer near3 layer with "(A)"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:09
S39	12,654	outer near3 layer with "(A)" same "(C)"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:09
S40	960	outer near3 layer with "(A)" same "(C)" same thermoplastic	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:10
S41	69	outer near3 layer with "(A)" same "(C)" same thermoplastic same modulus	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:12
S42	60	S41 and (inner core) near3 layer	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:13
S43	34	S41 and (inner core) near3 layer with (elastomer elastomeric)	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:13
S44	12	S41 and (inner core) near3 layer with (elastomer elastomeric) same hardness	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:13
S45	1	16/719256	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:32

S46	45,385	((A61C7/08 OR B32B2250/24 OR B32B2307/536 OR B32B2307/546 OR B32B2535/00 OR B32B27/08 OR B32B27/302 OR B32B27/32 OR B32B27/36 OR B32B27/40).CPC.)	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:32
S47	3,778	S46 and polymeric with sheet	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:32
S48	279	S47 and elastomeric with layer	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:33
S49	234	S48 and thermoplastic	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:33
S50	54	S49 and flexural with modulus	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:33
S51	51	S50 and hardness	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:33
S52	1	S50 and hardness same "A 60"	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:33
S53	1	S50 and hardness same "D 85"	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 20:33
S54	83	"6390812"	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:05
S55	101	"6454565"	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:05
S56	128	"6497574"	US-PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:05
S57	292	"6524101"	US-PGPUB;	OR	ON	2020/09/24 21:05

			USPAT; USOCR			
S58	293	"6572372"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:05
S59	6	"6746757"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:05
S60	29	"6964564"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S61	58	"7121825"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S62	12	"7210926"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S63	20	"8235713"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S64	16	"8765031"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S65	13	"9351809"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S66	16	"9655691"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S67	10	"9655693"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S68	9	"10052176"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06

S69	2	"20060078841"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S70	1	"20080248438"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:06
S71	2	"20150140300"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S72	1	"20150366638"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S73	13	"20170007362"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S74	1	"20180318043"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S75	1	"20190231484"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S76	2	"20110020761"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S77	3	"7201575"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S78	1	"20010041320"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S79	4	"20090130624"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07
S80	2	"20110039223"	US- PGPUB; USPAT; USOCR	OR	ON	2020/09/24 21:07

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S81	26,029	polymeric with sheet	USPAT	OR	ON	2020/09/24 20:34
S82	6,149	S81 and outer with layers	USPAT	OR	ON	2020/09/24 20:34
S83	289	S82 and flexural with modulus	USPAT	OR	ON	2020/09/24 20:34
S84	178	S83 and elastomer\$4	USPAT	OR	ON	2020/09/24 20:34
S85	28	S83 and elastomer\$4 with hardness	USPAT	OR	ON	2020/09/24 20:35
S86	0	S83 and elastomer\$4 with hardness with "A 60"	USPAT	OR	ON	2020/09/24 20:35
S87	0	S83 and elastomer\$4 with hardness with "D 85"	USPAT	OR	ON	2020/09/24 20:35

9/24/2020 9:09:17 PM

C:\Users\lferguson\Documents\EAST\Workspaces\16719256.wsp



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BIB DATA SHEET

CONFIRMATION NO. 7352

SERIAL NUMBER 16/719,256	FILING or 371(c) DATE 12/18/2019 RULE	CLASS 428	GROUP ART UNIT 1781	ATTORNEY DOCKET NO. 513043 (000550US)	
APPLICANTS Bay Materials, LLC, Fremont, CA INVENTORS Ray F. Stewart, Redwood City, CA; John Lahlouh, San Jose, CA; ** CONTINUING DATA ***** This application is a CIP of 16/211,176 12/05/2018 PAT 10549511 which is a CIP of PCT/US2018/035384 05/31/2018 which claims benefit of 62/590,627 11/26/2017 and claims benefit of 62/512,786 05/31/2017 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 01/23/2020					
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and /LAWRENCE D FERGUSON/ Acknowledged Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY CA	SHEETS DRAWINGS 4	TOTAL CLAIMS 29	INDEPENDENT CLAIMS 3
ADDRESS LEYDIG, VOIT & MAYER (WALNUT CREEK) THE ATRIUM BUILDING 1981 N. BROADWAY, SUITE 375 WALNUT CREEK, CA 94596-5083 UNITED STATES					
TITLE DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS					
FILING FEE RECEIVED 5580	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 16/719,256

Confirmation No. 7352

Attorney Docket No. 513043 (000550US)

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR 1.97 and 1.98, the documents listed on the accompanying Form PTO-1449, Substitute Form PTO-1449, and/or USPTO Form SB/08 (hereinafter, individually or collectively referred to as "Form") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the documents in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the documents be entered into the record of the present application and that the Examiner initial the appropriate area on the accompanying Form, thereby indicating the Examiner's consideration of each of the documents.

The submission of the documents listed on the Form is for the purpose of providing a complete record and is not a concession that the documents listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any document submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the documents is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any document is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☐ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- ☐ Note: This submission includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), such that no reduction in patent term adjustment is warranted by the filing of this Information Disclosure Statement.
- ☒ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.D.F/

Application No. 16/719,256

Information Disclosure Statement

- ☐ the Statement under 37 CFR 1.97(e) (see “Statement under 37 CFR 1.97(e)” below).
- ☐ Note: This submission includes the Statement under 37 CFR 1.704(d) (see “Statement under 37 CFR 1.704(d)” below), such that no reduction in patent term adjustment is warranted by the filing of this Information Disclosure Statement.

– or –

- ☒ the fee set forth in 37 CFR 1.17(p) (see “Fees” below).
- ☐ **on or after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see “Statement under 37 CFR 1.97(e)” below), and the fee set forth in 37 CFR 1.17(p) (see “Fees” below).
- ☐ Note: This submission includes the Statement under 37 CFR 1.704(d) (see “Statement under 37 CFR 1.704(d)” below), such that no reduction in patent term adjustment is warranted by the filing of this Information Disclosure Statement.

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.D.F/

Application No. 16/719,256

Information Disclosure Statement

Citation to Other Patent Applications

- ☐ The following U.S. patent applications are hereby brought to the attention of the Examiner. The U.S. patent applications claim subject matter that may be considered by the Examiner to be similar to the subject matter claimed in the above-identified patent application. Accordingly, these U.S. patent applications and/or the prosecution pertaining thereto may include information considered to be material to the prosecution of the above-identified patent application. Since the Examiner has electronic access to the prosecution histories of these U.S. patent applications, copies of prosecution materials therefrom are not provided herewith, but will be promptly provided if the Examiner so desires and requests same.

U.S. APPLICATIONS		STATUS (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Never Issued: Abandoned/Expired
1.				
2.				
3.				

Copies of the Documents

- ☒ Copies of any U.S. patents and published patent applications that are listed on the accompanying Form are not enclosed herewith. Copies of any other documents identified on the accompanying Form are enclosed herewith.
- ☒ For each document not in the English language, at least one of the following is provided: (a) an English translation in whole or in part or (b) a concise statement of relevance in the form of, for example, an English language counterpart, an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office.
- ☒ The documents listed on the accompanying Form were previously identified in the parent application(s) of the present application, and copies of the documents were furnished at that time. Accordingly, additional copies of the documents are not submitted herewith, so as not to burden the file with duplicate copies of documents. The Examiner is respectfully requested to carefully review the documents in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the documents were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING OR 371(c) DATE	Patented	Pending	Abandoned
1. 16/211,176	Dec. 5, 2018	X		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.D.F/

Application No. 16/719,256

Information Disclosure Statement

2.				
3.				

Fee Calculation

- ☐ **No fee** is owed by the applicant(s).
- ☒ IDS Fee (37 CFR 1.17(p)) \$240.00
- ☐ Applicant(s) assert(s) small entity status. Therefore, the fee shown above is reduced by 50%, and the resulting fee is shown below.
- ☐ Applicant(s) certifies/certify micro entity status. Therefore, the fee shown above is reduced by 75%, and the resulting fee is shown below. Note: Form PTO/SB15A or B must either be enclosed or have been submitted previously
- ☒ **Total Fee Due** **\$240.00**

Fee Payment

- ☒ Charge the indicated **Total Fee Due** to Deposit Account No. 12-1216.
- ☒ Charge any additional fees owed in connection with this communication to Deposit Account No. 12-1216.
- ☒ Credit any refund to Account No. 12-1216.



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797

Telephone: 312-616-5600

Facsimile: 312-616-5700

Date: March 17, 2020

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.D.F/

/LAWRENCE D FERGUSON/

09/24/2020

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 16/719,256

Confirmation No. 7352

Inventor(s): Ray F. Stewart et al.

Filing or 371(c) Date: December 18, 2019

TC/AU: 1781

Examiner: Lawrence D. Ferguson

Docket No. 513043 (Client Reference No. DD4105P/US05)

Customer No. 103606

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Applicant traverses the statement of reasons for allowance to the extent it fails to attribute patentability to the claims taken as a whole. Applicant further traverses the statement to the extent the expressed reasons may be interpreted as defining or otherwise limiting the claims in a manner inconsistent with Applicant's description of the claimed invention and applicable law.

Respectfully submitted,



/Gerald T. Gray/

Gerald T. Gray, Reg. No. 41,797

Telephone: 312-616-5600

Facsimile: 312-616-5700

Date: November 11, 2020

Electronic Patent Application Fee Transmittal				
Application Number:		16719256		
Filing Date:		18-Dec-2019		
Title of Invention:		DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
First Named Inventor/Applicant Name:		Ray F. Stewart		
Filer:		Gerald Todd Gray./Christina Alton		
Attorney Docket Number:		513043 (000550US)		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1000	1000

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1000

Electronic Acknowledgement Receipt

EFS ID:	41098809
Application Number:	16719256
International Application Number:	
Confirmation Number:	7352
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	103606
Filer:	Gerald Todd Gray./Christina Alton
Filer Authorized By:	Gerald Todd Gray.
Attorney Docket Number:	513043 (000550US)
Receipt Date:	11-NOV-2020
Filing Date:	18-DEC-2019
Time Stamp:	17:37:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 1000
RAM confirmation Number	E2020AAH37199306
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	513043_20201111_ISSUE.pdf	84418	no	1
			5c4d18bdd2a63c448ce3217ea288dff96e2406e1		
Warnings:					
Information:					
2	Transmittal Letter	513043_20201111_ISSUE_TRA.pdf	79700	no	1
			57ab1f28cac292de3feb0b0d3c5f2bc9a5633552		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30309	no	2
			05cf640ca0ada6c6d9eaf27aa40e929d5a346911		
Warnings:					
Information:					
Total Files Size (in bytes):			194427		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

103606 7590 10/01/2020
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/18/2019	Ray F. Stewart	513043 (000550US)	7352

TITLE OF INVENTION: DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	01/01/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FERGUSON, LAWRENCE D	1781	428-215000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Leydig, Voit & Mayer, Ltd.

2 Gerald T. Gray

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Bay Materials, LLC

Fremont, CA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 121216

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Gerald T. Gray/

Date November 11, 2020

Typed or printed name Gerald T. Gray

Registration No. 41797



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/719,256	12/22/2020	10870263	513043 (000550US)	7352

103606 7590 12/02/2020
LEYDIG, VOIT & MAYER (WALNUT CREEK)
THE ATRIUM BUILDING
1981 N. BROADWAY, SUITE 375
WALNUT CREEK, CA 94596-5083

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Ray F. Stewart, Redwood City, CA;
Bay Materials, LLC, Fremont, CA
John Lahlouh, San Jose, CA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

AO 120 (Rev. 08/10)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
 filed in the U.S. District Court _____ for the District of Delaware _____ on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED 11/15/2021	U.S. DISTRICT COURT for the District of Delaware
PLAINTIFF BAY MATERIALS, LLC		DEFENDANT 3M COMPANY
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 10,870,263	12/22/2020	Bay Materials, LLC
2 10,946,630	3/16/2021	Bay Materials, LLC
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
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Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy