PTO/AIA/15 (03-13)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	22773-826.401
First Named Inventor	Chunhua Li
Title	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✔] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [ ] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✔] **Specification** [*Total Pages* 18] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [✔] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 8]
6. **Inventor's Oath or Declaration** [*Total Pages* ____] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d))
7. [✔] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ACCOMPANYING APPLICATION PAPERS

10. [ ] **Assignment Papers** (cover sheet & document(s))
    Name of Assignee _____
11. [ ] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [ ] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [✔] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [ ] **Other:** _____

***Note**: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

[✔] The address associated with Customer Number: 107046 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Charles Hagadorn, III/	Date	03/31/2017
Name (Print/Type)	Charles Hagadorn, III	Registration No. (Attorney/Agent)	62,367

This collection of information is required by 37 CFR 1.53(b). 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 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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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.

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FEE TRANSMITTAL

Complete if known	
Application Number	concurrently herewith
Filing Date	concurrently herewith
First Named Inventor	Chunhua Li
Examiner Name	
Art Unit	
Practitioner Docket No.	22773-826.401

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

TOTAL AMOUNT OF PAYMENT ($) 1740.00

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 23-2415 Deposit Account Name: Wilson Sonsini Goodrich & Rosati

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

	FILING FEES			SEARCH FEES			EXAMINATION FEES			
Application Type	**U ($)**	**S ($)**	**M ($)**	**U ($)**	**S ($)**	**M ($)**	**U ($)**	**S ($)**	**M ($)**	**Fees Paid ($)**
Utility	280	140*	70	600	300	150	720	360	180	1600.00
Design	180	90	45	120	60	30	460	230	115	
Plant	180	90	45	380	190	95	580	290	145	
Reissue	280	140	70	600	300	150	2,160	1,080	540	
Provisional	260	130	65	0	0	0	0	0	0	

* The $140 small entity status filing fee for a utility application is further reduced to $70 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	**Undiscounted Fee ($)**	**Small Entity Fee ($)**	**Micro Entity Fee ($)**
Each claim over 20 (including Reissues)	80	40	20
Each independent claim over 3 (including Reissues)	420	210	105
Multiple dependent claims	780	390	195

Total Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
10	-20 or HP =	_____	x _____	=	_____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
1	-3 or HP =	_____	x _____	=	_____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	**Fee ($)**	**Fee Paid ($)**
	_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $400 ($200 for small entity) ($100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**		**Fee ($)**		**Fee Paid ($)**
_____	- 100 =	_____	/ 50 =	_____ (round **up** to a whole number)	x	_____	=	_____

4. OTHER FEE(S) **Fees Paid ($)**

Non-English specification, $130 fee (no small or micro entity discount) _____

Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, $400 fee ($200 small or micro entity) _____

Other (e.g., late filing surcharge): Late surcharge for oath or declaration 140.00

SUBMITTED BY

Signature	/Charles Hagadorn, III/	Registration No. (Attorney/Agent) 62,367	Telephone
Name (Print/Type)	Charles Hagadorn, III		Date March 31, 2017

This collection of information is required by 37 CFR 1.136. 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, 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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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).
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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)).
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PATENT APPLICATION

MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

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Filed Electronically on: March 31, 2017

MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

CROSS-REFERENCE

[0001] This application is a divisional of U.S. Patent Application No. 13/470,681, filed May 14, 2012, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention generally relates to the field of orthodontics, and more particularly to the design of multilayer dental positioning appliances.

[0003] An objective of orthodontics is to move a patient's teeth to positions where function and/or aesthetics are optimized. Traditionally, appliances such as braces are applied to a patient's teeth by a treating practitioner and the set of braces exerts continual force on the teeth and gradually urges them toward their intended positions. Over time and with a series of clinical visits and reactive adjustments to the braces by the practitioner, the appliances to move the teeth toward their final destination.

[0004] More recently, alternatives to conventional orthodontic treatment with traditional affixed appliances (*e.g.*, braces) have become available. For example, systems including a series of preformed appliances/aligners have become commercially available from Align Technology, Inc., San Jose, CA, under the trade name Invisalign® System. The Invisalign® System is described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example in U.S. Pat. Nos. 6,450,807, and 5,975,893, as well as on the company's website, which is accessible on the World Wide Web (see, *e.g.*, the url invisalign.com"). The Invisalign® System includes designing and/or fabricating multiple, and sometimes all, of the aligners to be worn by the patient before the aligners are administered to the patient and used to reposition the teeth (*e.g.*, at the outset of treatment). Often, designing and planning a customized treatment for a patient makes use of computer-based 3-dimensional planning/design tools, such as Treat™ software from Align Technology, Inc. The design of the aligners relies on computer modeling of the patient's teeth in a series of planned successive tooth arrangements, and the individual aligners are designed to be worn over the teeth, such that each aligner exerts force on the teeth and elastically repositions the teeth to each of the planned tooth arrangements.

[0005] While recently developed orthodontic treatment technologies, such as those described above, represent a considerable advancement in the field of orthodontics, additional advancements remain of interest. For example, in some instances it may be advantageous to develop materials that

ClearCorrect Exhibit 1011, Page 6 of 890

improve properties of the appliances/aligners used for orthodontic treatment. As such, there is a need for shell aligners that can, for example, produce more continuous force and better bring a patient's teeth into a desired occlusion.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention provides multilayer orthodontic positioning appliances, as well as related methods and systems. The disclosed multilayer appliances include a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth. The multilayer appliances can include a hard polymer layer disposed between two soft polymer layers. The multilayer dental appliances of the present invention, among many aspects, provide, for example, improved material performance, stress relaxation properties and longer working range. In addition, the mechanical properties of the materials and appliances described herein can improve orthodontic treatments by, for example, reducing the need for midcourse corrections during treatment and the number of aligners used for a given treatment.

[0007] The disclosed methods include methods for making multilayer dental appliances. The disclosed systems including a plurality of appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth. The appliances can be successively worn by a patient to move teeth from one arrangement to a successive arrangement. At least one of the appliances in the system can include a hard polymer layer disposed between two soft polymer layers.

[0008] For a fuller understanding of the nature and advantages of the present invention, reference should be made to the ensuing detailed description and accompanying drawings. Other aspects, objects and advantages of the invention will be apparent from the drawings and detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 illustrates a jaw and an incremental positioning appliance for the jaw, in accordance with an embodiment of the present invention.

[0010] Figure 2 shows an arrangement of polymer layers in a sheet having a hard polymer layer disposed between two soft polymer layers, in accordance with an embodiment of the present invention.

[0011] Figure 3 depicts a method of making a multilayer dental appliance, in accordance with an embodiment of the present invention.

[0012] Figure 4 is a simplified block diagram illustrating a method for fabricating a dental appliance, in accordance with an embodiment of the present invention.

[0013] Figure 5 provides a stress relaxation comparison for dental appliances, in accordance with an embodiment of the present invention.

[0014] Figure 6 provides another stress relaxation comparison for dental appliances, in accordance with an embodiment of the present invention.

[0015] Figure 7 shows a long-term unloading comparison for dental appliances, in accordance with an embodiment of the present invention.

[0016] Figure 8 provides a long-term movement comparison for dental appliances, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0017] In the following description, various embodiments of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention 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.

[0018] Multilayer orthodontic positioning appliances are provided, as well as related methods and systems. During orthodontic treatment, it may be necessary to apply forces to a tooth to generate movement of the tooth to, for example, bring the patient's teeth into a better occlusion in a mesial or distal direction. The presently disclosed appliances, methods, and systems provide means by which such forces can be applied during orthodontic treatment where appliances having teeth receiving cavities are used, such as preformed appliances/aligners available from Align Technology, Inc., San Jose, CA, under the trade name Invisalign® System. As provided by the present invention, the aligners that include multilayer sheets can, for example, provide increased durability of the aligners so that they can better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment. In addition, the aligners have improved elastic properties that allow for less degradation in the shape of the teeth receiving cavities during a stage of treatment. For example, during a multistage orthodontic treatment, the force exerted by an aligner to perform defined tooth movement can degrade and may cause the treatment to include more aligners to reach a final ideal arrangement and/or result in a mid-course correction that could be prevented by using aligners with improved physical properties, such as those provided herein.

[0019] In one embodiment, the present invention provides a dental appliance for positioning a patient's teeth. The dental appliance can include a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, the appliance comprising a hard polymer layer disposed between a first soft polymer layer and a second soft polymer layer.

[0020] In another embodiment, the present invention provides an orthodontic system for positioning a patient's teeth. The orthodontic system can include a plurality of incremental position adjustment appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, wherein the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement, and wherein at least one of the appliances comprises a hard polymer layer disposed between a first soft polymer layer and a second soft polymer layer.

[0021] In yet another embodiment, the present invention provides a method of making a dental appliance for positioning a patient's teeth. The method can include providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer, providing a positive model of the patient's teeth in a target position; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

[0022] Referring now to the drawings, in which like reference numerals represent like parts throughout the several views, Figure 1 provides an appropriate starting point in a detailed discussion of various embodiments of the present invention with respect to tooth repositioning appliances designed to apply repositioning forces to teeth. A tooth repositioning appliance 10 can be worn by a patient in order to achieve an incremental repositioning of individual teeth in the jaw 12. The appliance can include a shell (*e.g.*, a polymeric shell) having teeth-receiving cavities that receive and resiliently reposition the teeth. In many embodiments, a polymeric appliance can be formed from a sheet of suitable layers of polymeric material. An appliance can fit over all teeth present in an upper or lower jaw, or less than all of the teeth. In some cases, only certain teeth received by an appliance will be repositioned by the appliance while other teeth can provide a base or anchor region for holding the appliance in place as it applies force against the tooth or teeth targeted for repositioning. In some cases, many or most, and even all, of the teeth will be repositioned at some point during treatment. Teeth that are moved can also serve as a base or anchor for holding the appliance as it is worn by the patient. Typically, no wires or other means will be provided for holding an appliance in place over the teeth. In some cases, however, it may be desirable or necessary to provide individual

anchors on teeth with corresponding receptacles or apertures in the appliance so that the appliance can apply a selected force on the tooth. Exemplary appliances, including those utilized in the Invisalign® System, are described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example, in U.S. Pat. Nos. 6,450,807, and 5,975,893, as well as on the company's website, which is accessible on the World Wide Web (see, *e.g.*, the url invisalign.com").

[0023] An appliance can be designed and/or provided as part of a set of a plurality of appliances. In such an embodiment, each appliance may be configured so a tooth-receiving cavity has a geometry corresponding to an intermediate or final tooth arrangement intended for the appliance. The patient's teeth can be progressively repositioned from an initial tooth arrangement to a target tooth arrangement by placing a series of incremental position adjustment appliances over the patient's teeth. A target tooth arrangement can be a planned final tooth arrangement selected for the patient's teeth at the end of all planned orthodontic treatment. Alternatively, a target arrangement can be one of many intermediate arrangements for the patient's teeth during the course of orthodontic treatment, which may include where surgery is recommended, where inter-proximal reduction (IPR) is appropriate, where a progress check is scheduled, where anchor placement is best, where palatal expansion is desirable, etc. As such, it is understood that a target tooth arrangement can be any planned resulting arrangement for the patient's teeth that follows one or more incremental repositioning stages. Likewise, an initial tooth arrangement can be any initial arrangement for the patient's teeth that is followed by one or more incremental repositioning stages. The adjustment appliances can be generated all at the same stage or in sets or batches, *e.g.*, at the beginning of a stage of the treatment, and the patient wears each appliance until the pressure of each appliance on the teeth can no longer be felt or has resulted in the maximum amount of expressed tooth movement for that given stage. A plurality of different appliances (*e.g.*, set) can be designed and even fabricated prior to the patient wearing any appliance of the plurality. After wearing an appliance for an appropriate period of time, the patient replaces the current appliance with the next appliance in the series until no more appliances remain. The appliances are generally not affixed to the teeth and the patient may place and replace the appliances at any time during the procedure (*e.g.*, patient-removable appliances). The final appliance or several appliances in the series may have a geometry or geometries selected to overcorrect the tooth arrangement, *i.e.*, have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over-correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, *i.e.*, to permit movement of individual teeth back toward

their pre-corrected positions. Over-correction may also be beneficial to speed the rate of correction, *i.e.*, by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, the use of an appliance can be terminated before the teeth reach the positions defined by the appliance.

[0024] In general, structures, methods and systems of the present invention utilize a multilayer sheet for use in orthodontic appliances. The multilayer sheet can include three layers, in which a hard polymer layer is disposed between two soft polymer layers. The multilayer sheets used in the present invention can be used in making dental aligners having improved durability for use, e.g., to the elastic properties of the multilayer sheet when formed into an aligner. In addition, the bonding strength between the layers further improves the durability of the aligners, for example, by withstanding teeth grinding by a patient.

[0025] Figure 2 shows a multilayer structure according to the present invention. As shown, a multilayer sheet 20 can include a three layer structure: a hard polymer layer 24 and two soft polymer layers 22, 26. The hard polymer layer can be disposed between a first soft polymer layer and a second soft polymer layer. In some embodiments, the hard polymer layer can be thicker than either of the soft polymer layers. The soft polymer layers can have the same or different thicknesses. For example, the hard polymer layer can range from a thickness of about 550 μm to about 750 μm. The soft polymer layers can range from a thickness of about 25 μm to about 100 μm. Multilayer sheets used for making appliances having a hard polymer layer disposed between two soft polymer layers can range from a thickness of about 600 μm to about 1000 μm. In some embodiments, the thicknesses of the various layers can be tailored for a particular stage of treatment for the patient.

[0026] Suitable polymeric materials for the hard polymer layer can include a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate or a combination thereof (e.g., a blend of at least two of the listed hard polymeric materials). In some embodiments, the hard polymer layer of the appliances can include polymeric materials, such as a polycarbonate, a co-polyester, a polyester, and a thermoplastic polyurethane. In some embodiments, the hard layer can be composed of multiple hard layers, e.g., two or three hard polymer layers 24-1, 24-2, 24-N co-extruded to form one hard layer.

[0027] The hard polymer layer of the appliances of the present invention can have a variety of physical properties that can, e.g., improve treatment options for a practitioner. For example,

physical properties such as tensile strength, elongation at yield, elongation at break, tensile modulus, flexural modulus, stress relaxation over time, and light transmission can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appliances can have a physical property of at least one of a tensile strength at yield of between about 4000 pounds per square inch (psi) and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation at 24 hours testing in a wet environment (e.g., between about 90%-100% relative humidity) is greater than 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

[0028] Suitable polymeric materials for the soft polymer layers of the appliance can include a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof (e.g., a blend of at least two of the listed soft polymeric materials). The soft polymer layers can be the same material or a different material. In certain embodiments, the first soft polymer layer and the second soft polymer layer are the same polymeric material.

[0029] The soft polymer layers of the appliances can have a variety of physical properties. For example, physical properties such as hardness, ultimate tensile strength, elongation at break, tensile modulus, compression set, flexural modulus, and light transmission can each be specifically tailored for a particular application. In some embodiments, the soft polymer layers of the appliances can independently have a physical property of at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200 %, a compression set at about 70°C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

[0030] As described herein, the layers of the appliances can include a hard polymer layer disposed between two soft polymer layers. In one embodiment, the multilayer appliances can include a hard polymer layer of one type of material (e.g., a co-polyester), and two soft polymer layers of other types of material that can be the same or different (e.g., two soft polymer layers of thermoplastic polyurethane elastomer). In some embodiments, the multilayer appliances can also include a hard polymer layer of at least two layers of polymer material. For example, the hard polymer layer can include several polymer layers laminated together to form the hard polymer layer. The laminated

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hard polymer layer can include at least two layers of any combination of the following polymer materials: a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate. Similarly, in some embodiments, the multilayer appliances can include a soft polymer layer of at least two layers of polymer material. For example, the soft polymer layers 22, 26 can include a layer of several polymer layers 22-1, 22-2, 22-N and 26-1, 26-2, 26-N, respectively, laminated together. The laminated soft polymer layers can include at least two layers of any combination of the following polymer materials: a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

[0031] The tooth positioning appliances can be fabricated using a variety of methods. For example, methods for making the appliances can include thermoforming a multilayer sheet into an aligner by heating the sheet and then molding the sheet to a particular configuration. Exemplary methods for fabricating the appliances, including those utilized in the Invisalign® System, are described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example, in U.S. Appl. No. 13/186,374 as well as on the company's website, which is accessible on the World Wide Web (see, *e.g.*, the url invisalign.com").

[0032] Figure 3 depicts an example embodiment of a process 30 for forming a multilayer tooth positioning appliance, in accordance with an embodiment of the present invention. As shown, a multilayer sheet 32 can be formed into a tooth positioning appliance 36. The multilayer sheet 32, as depicted, can include three layers: a hard polymer layer disposed between two soft polymer layers. In this example process, the tooth positioning appliance 36 can be produced with the use of a physical tooth model, or mold, 34. The tooth positioning appliance 36 can be produced by heating the thermoformable multilayer sheet 32 and then vacuum or pressure forming the sheet over the teeth in the physical tooth model 34. The tooth positioning appliance 36 is a direct representation of the physical tooth model. Excess material from the sheet can be trimmed to form a final tooth positioning appliance that can be used for orthodontic treatment of a patient.

[0033] One or a series of physical tooth models, such as the model described above, may be used in the generation of elastic repositioning appliances for orthodontic treatment. Similar to the process above, each of the appliances can be generated by thermoforming a multilayer polymeric material

over a mold of a desired tooth arrangement to form a dental appliance. The tooth positioning appliance of the desired tooth arrangement generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the elastic positioner over the teeth applies controlled forces in specific locations to gradually move the teeth into the desired configuration. Repetition of this process with successive appliances comprising new configurations eventually moves the teeth through a series of intermediate configurations to a final desired configuration.

[0034] The present invention includes a variety of methods for fabricating dental appliances. Figure 4 shows a simple schematic for a method 40 of fabricating a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, in accordance with an embodiment of the present invention. The method can include providing a multilayer sheet having a hard polymer layer disposed between two soft polymer layers (Step 42). The method can further include providing a positive physical model of a patient's teeth (Step 44). The tooth positioning appliance can be fabricated by thermoforming the multilayer sheet over the positive physical model (Step 46), in which the tooth positioning appliance is a negative of the positive model. As described above, the methods of fabrication can further include trimming or cutting portions of the sheet to render a final, usable appliance for orthodontic treatment.

[0035] Multilayer sheets of the present invention were analyzed and determined to provide a variety of improved properties for aligners used in orthodontic treatment. As further described herein, the multilayer sheets formed into aligners can, for example, provide increased durability of the aligners so that they can better withstand wear due to teeth grinding and other mechanical stresses put on the aligner during treatment. In addition, the aligners have improved elastic properties that allow for less degradation in the shape of the teeth receiving cavities during a stage of treatment. For example, during a multistage orthodontic treatment, the capability of an aligner to force tooth movement can degrade and may cause the treatment to include more aligners to reach a final ideal arrangement and/or result in a mid-course correction that could be prevented by using aligners with improved physical properties, such as those provided herein.

[0036] Figures 5-8 provide example test results that compare various physical properties of the multilayer sheet appliances of the present invention with other already existing aligner materials (Material 1). Samples of varied thicknesses were tested. For example, multilayer sheets were tested having a hard polymer layer with thicknesses ranging from about 580 μm to about 715 μm thick. In some examples, the hard layer was a co-polyester hard polymer layer. The soft layers tested ranged

between about 50 μm to about 100 μm. In some examples, the hard polymer layer was disposed between thermoplastic polyurethane elastomer soft polymer layers. As shown in Figures 5 and 6, one example of the multilayer sheet material (Material 2) showed improved stress relaxation properties as compared to another already existing material (Material 1) at room temperature and 37 °C. In addition, Figure 7 shows improved long-term unloading characteristics of the multilayer sheet Material 2 versus the already existing Material 1. The multilayer sheet showed less deflection under force loads. Figure 8 also shows improved long-term movement data for the multilayer sheet Material 2 versus Material 1.

[0037] The use of the terms "a" and "an" and "the" and similar referents in the context of describing 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. 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 and does not pose a limitation on the scope unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of at least one embodiment.

[0038] Variations of the embodiments described herein may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for embodiments to be constructed otherwise than as specifically described herein. Accordingly, suitable embodiments include all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is contemplated as being incorporated into some suitable embodiment unless otherwise indicated herein or otherwise clearly contradicted by context. The scope of the invention should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the pending claims along with their full scope or equivalents.

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CLAIMS

WHAT IS CLAIMED IS:

1. A dental appliance for positioning a patient's teeth, comprising:

a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, the appliance comprising a hard polymer layer disposed between a first soft polymer layer and a second soft polymer layer.

2. The dental appliance of claim 1, wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

3. The dental appliance of claim 1, wherein the hard polymer layer comprises a layer of a polycarbonate, a co-polyester, a polyester, or a thermoplastic polyurethane.

4. The dental appliance of claim 1, wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

5. The dental appliance of claim 1, wherein the hard polymer layer ~~comprises~~ a thickness in a range from about 400 tm to about 1100 gm, about 450 tm to about 1000 gm, about 500 tm to about 900 gm, or about 550 tm to about 750 gm.

6. The dental appliance of claim 1, wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend

elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

7. The dental appliance of claim 1, wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a thermoplastic co-polyester elastomer, a polyurethane elastomer, or a polyester elastomer.

8. The dental appliance of claim 1, wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

9. The dental appliance of claim 1, wherein the soft polymer layer comprises a thickness in a range from about 25 tm to about 100 gm, about 30 tm to about 90 gm, or about 35 gm to about 80 gm.

10. The dental appliance of claim 1, wherein the hard polymer layer, the first soft polymer layer and the second soft polymer layer combined comprises a thickness of about 500 tm to about 1200 gm, about 550 tm to about 1100 gm, or about 600 tm to about 1000 gm.

11. The dental appliance of claim 1, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds per square inch (psi) and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation at 24 hours testing in a high humidity environment of greater than about 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

12. The dental appliance of claim 1, wherein the first soft polymer layer and the second soft polymer layer each independently comprise at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200%, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural

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modulus of greater than about 35,000 psi,-and a light transmission between 400 nm and 800 nm of greater than about 75%.

13. An orthodontic system for positioning a patient's teeth, comprising:

a plurality of incremental position adjustment appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, wherein the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement, and wherein at least one of the appliances comprises a hard polymer layer disposed between a first soft polymer layer and a second soft polymer layer.

14. The orthodontic system of claim 13, wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

15. The orthodontic system of claim 13, wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

16. The orthodontic system of claim 13, wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

17. The orthodontic system of claim 13, wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two

layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

18. The orthodontic system of claim 13, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation at 24 hours testing in a high humidity environment greater than about 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

19. The orthodontic system of claim 13, wherein the first soft polymer layer and the second soft polymer layer each independently comprise at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200 %, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

20. A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer;

providing a positive model of the patient's teeth in a target position; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. The method of claim 20, wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

23. The method of claim 20, wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. The method of claim 20, wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. The method of claim 20, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation at 24 hours testing in a high humidity environment greater than about 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. The method of claim 20, wherein the first soft polymer layer and the second soft polymer layer each independently comprise at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200 %, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than

about 75%.

27. The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

28. The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer.

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ABSTRACT OF THE DISCLOSURE

Multilayer sheet tooth positioning appliances are provided, as well as related methods and systems.

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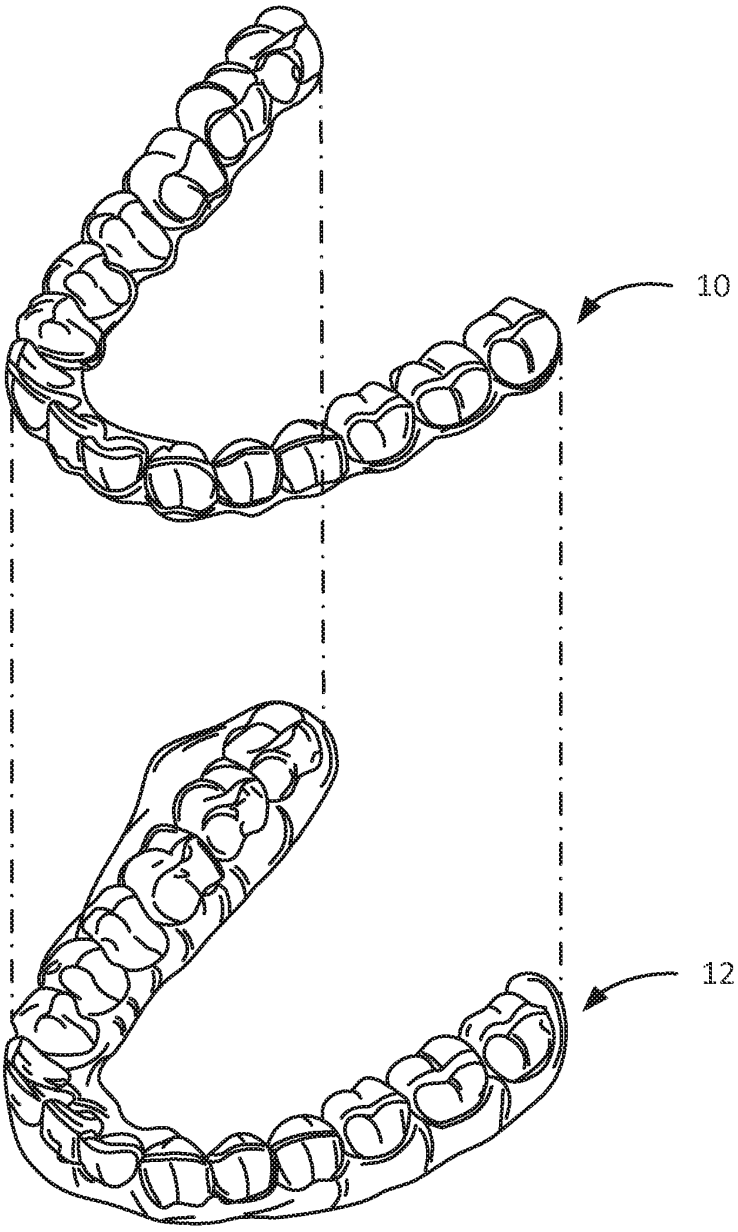


FIG. 1

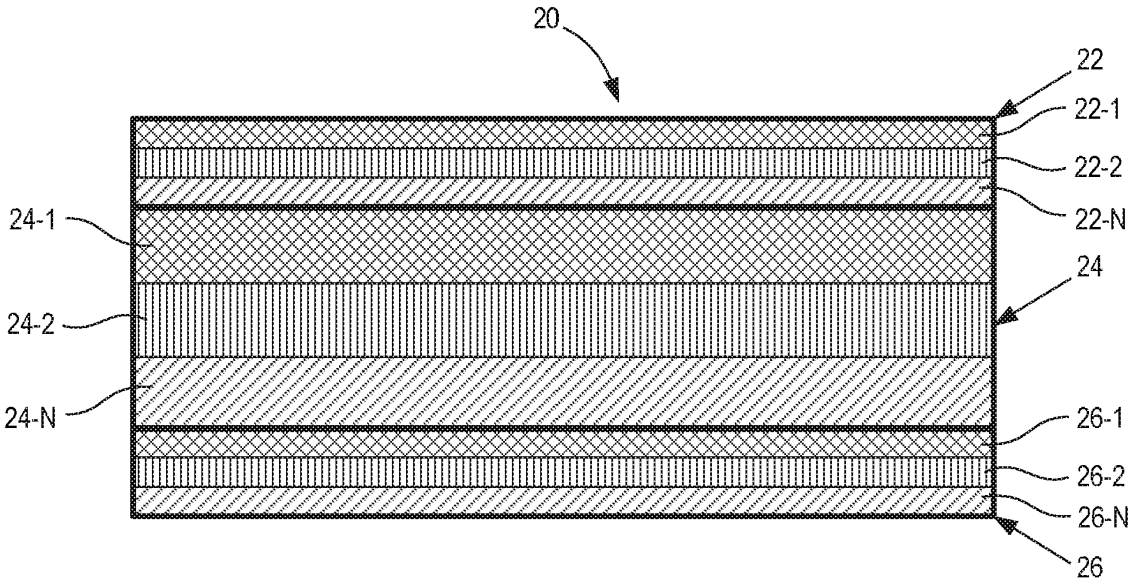


FIG. 2

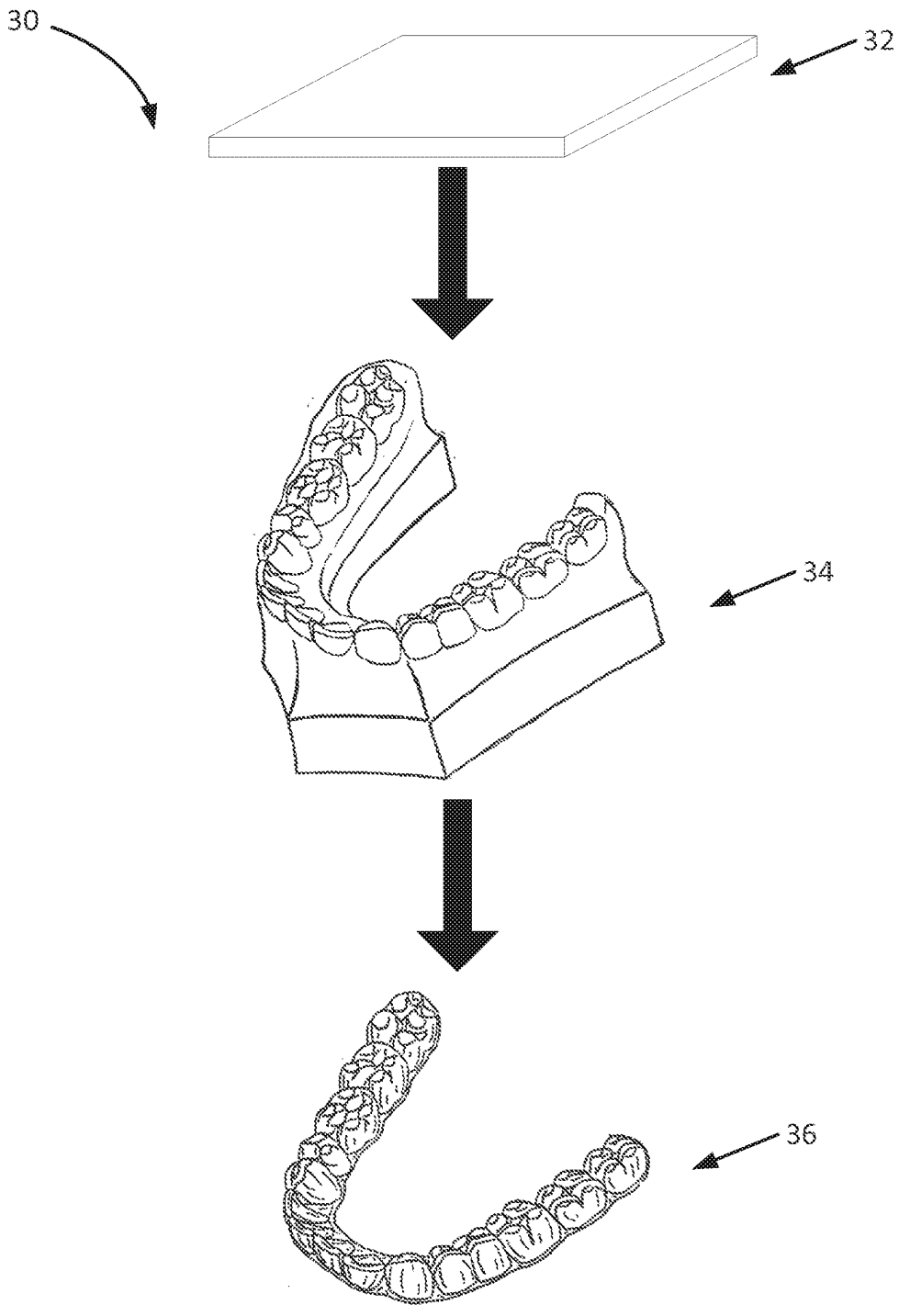


FIG. 3

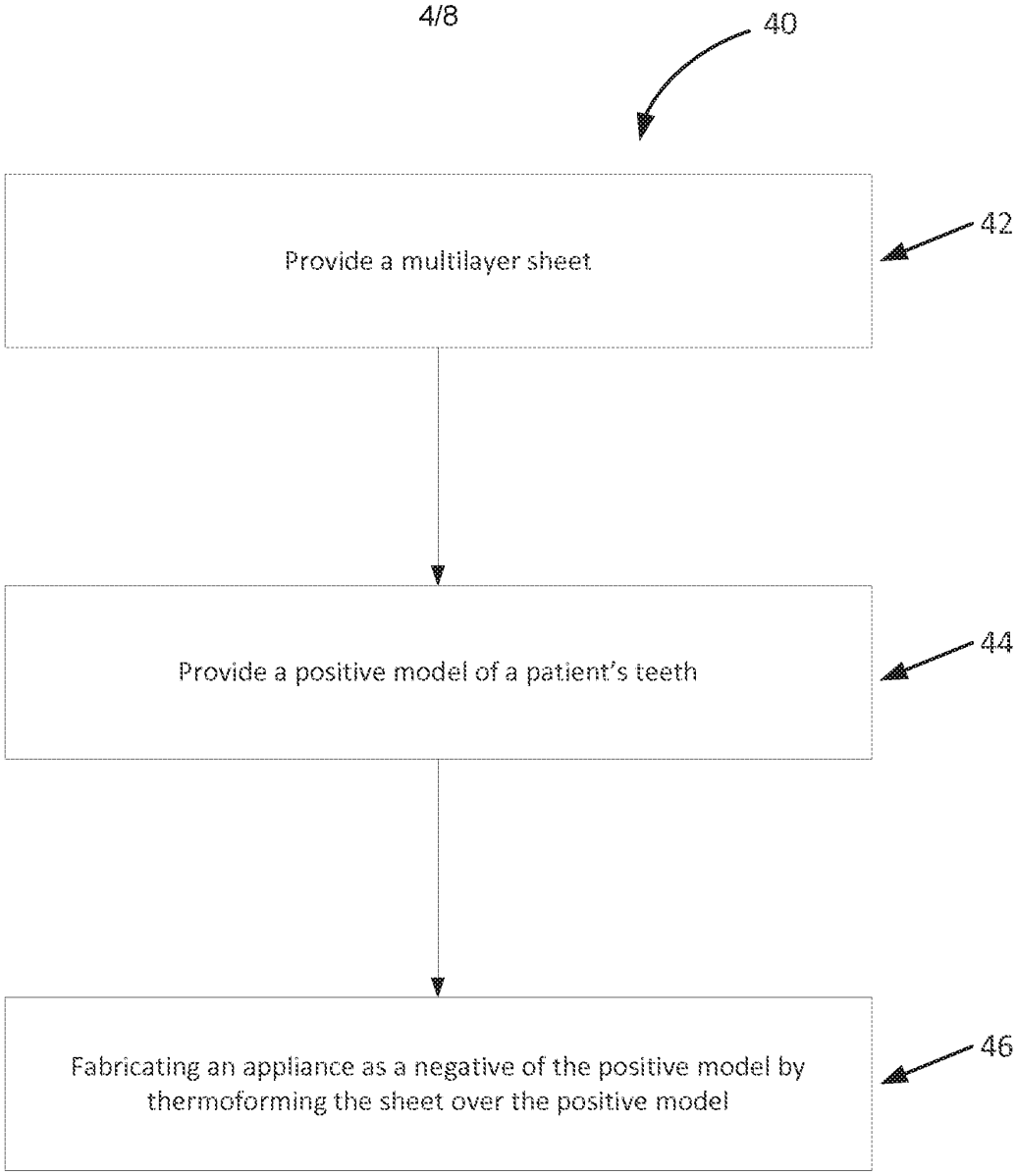

40
Provide a multilayer sheet
42
Provide a positive model of a patient's teeth
44
Fabricating an appliance as a negative of the positive model by thermoforming the sheet over the positive model
46

FIG. 4

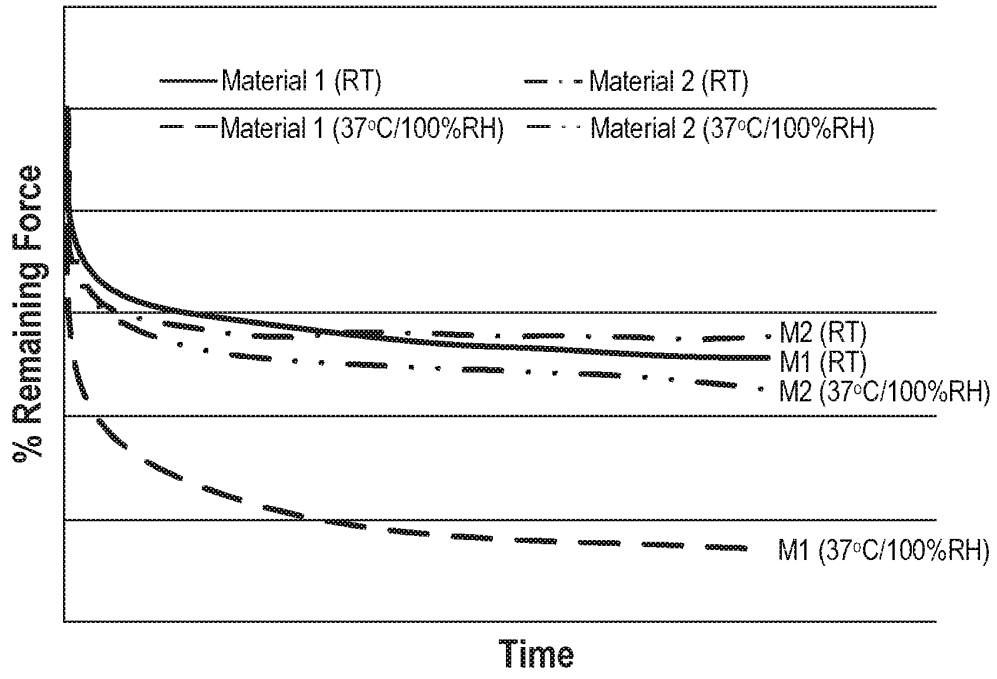

Material 1 (RT)
Material 2 (RT)
Material 1 (37°C/100%RH)
Material 2 (37°C/100%RH)
% Remaining Force
M2 (RT)
M1 (RT)
M2 (37°C/100%RH)
M1 (37°C/100%RH)
Time

FIG. 5

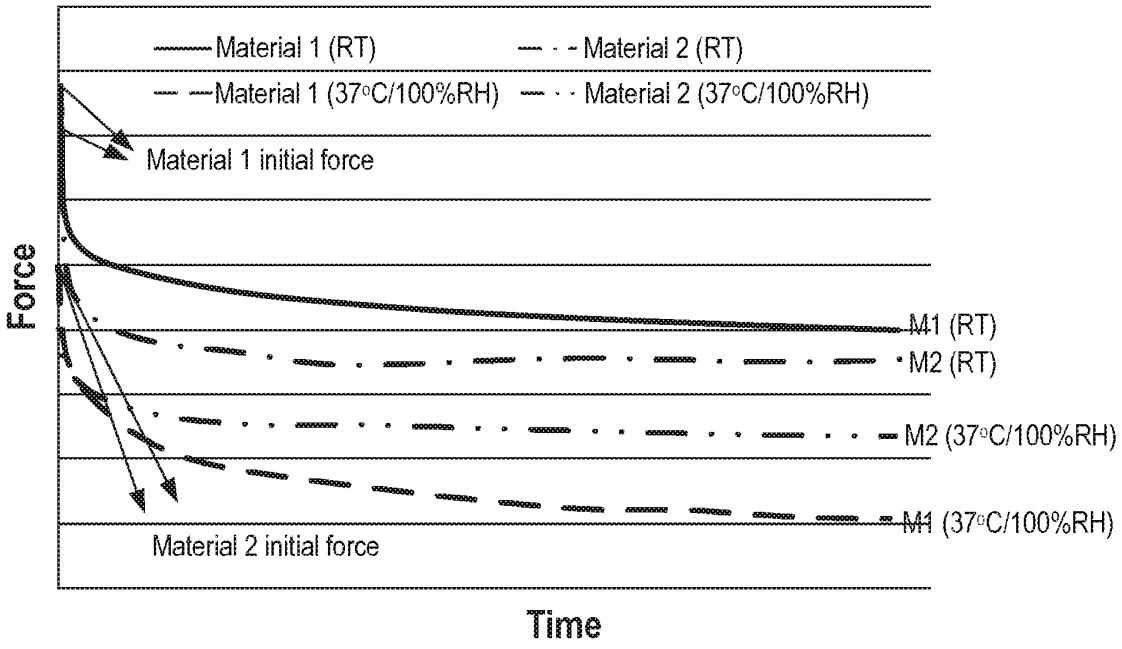

Material 1 (RT)
Material 2 (RT)
Material 1 (37°C/100%RH)
Material 2 (37°C/100%RH)
Material 1 initial force
Force
M1 (RT)
M2 (RT)
M2 (37°C/100%RH)
M1 (37°C/100%RH)
Material 2 initial force
Time

FIG. 6

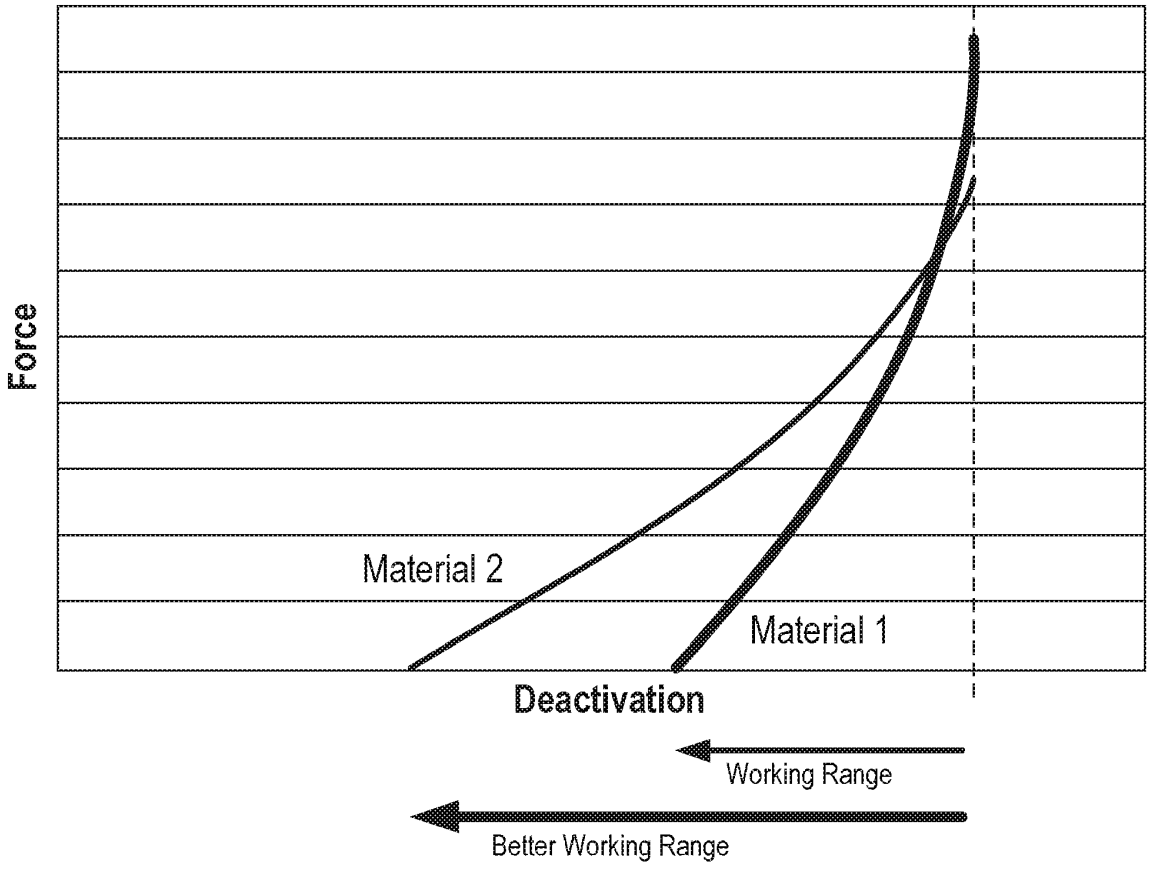

Force
Material 2
Material 1
Deactivation
Working Range
Better Working Range

FIG. 7

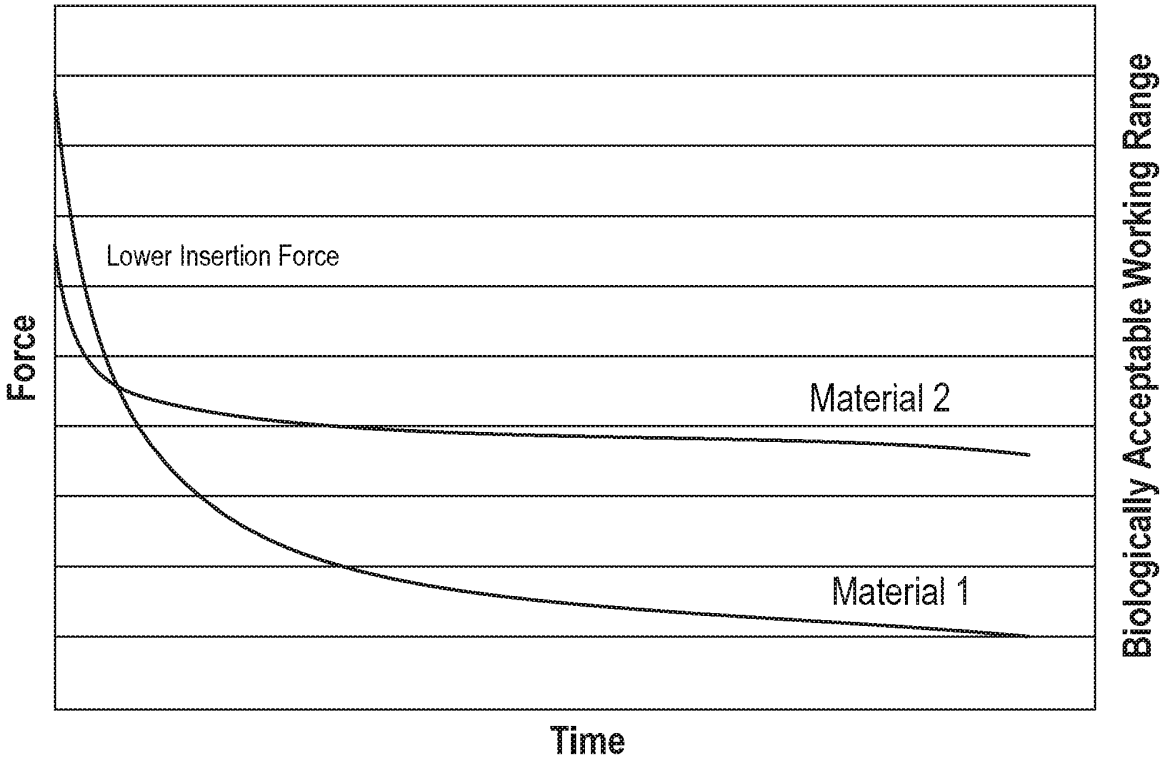

Force
Lower Insertion Force
Material 2
Material 1
Time
Biologically Acceptable Working Range

FIG. 8

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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.
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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City	Krefeld	State/Province	
Postal Code	47800	Country [i]	DE

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Klaus		MEYER	

Residence Information (Select One) ○ US Residency ◉ Non US Residency Active US Military Service

City	Dormagen	Country of Residence [i]	DE

Mailing Address of Inventor:

Address 1	Kamillenstr, 40		
Address 2			
City	Dormagen	State/Province	
Postal Code	41539	Country [i]	DE

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Joerg		NICKEL	

Residence Information (Select One) ○ US Residency ◉ Non US Residency Active US Military Service

City	Dormagen	Country of Residence [i]	DE

Mailing Address of Inventor:

Address 1	Krokusweg 2		
Address 2			
City	Dormagen	State/Province	
Postal Code	41539	Country [i]	DE

Inventor 6 Remove

Legal Name

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Craig		PEHLERT	

Residence Information (Select One) (•) US Residency ( ) Non US Residency Active US Military Service

City	Lenox	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	29 St. Ann's Avenue		
Address 2			
City	Lenox	State/Province	MA
Postal Code	01240	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	107046		
Email Address	patentdocket@wsgr.com	Add Email	Remove Email

Application Information:

Title of the Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		
Attorney Docket Number	22773-826.401	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	8	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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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	107046		

Domestic Benefit/National Stage Information:

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)
	Division of	13470681	2012-05-14

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Remove

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

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

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.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ 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.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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 — Remove

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	ALIGN TECHNOLOGY, INC.		
Mailing Address Information For Applicant:			
Address 1	2560 Orchard Parkway		
Address 2			
City	San Jose	**State/Province**	CA
Country	US	Postal Code	95131
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee 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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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.

Remove

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

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

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

Signature	/Charles Hagadorn, III/			Date (YYYY-MM-DD)	2017-03-31
First Name	Charles	Last Name	Hagadorn, III	Registration Number	62,367

Additional Signature may be generated within this form by selecting the Add button. Add

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.401
	Application Number	
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

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.**

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 the Freedom of Information Act requires disclosure of these records.

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 CooperationTreaty.

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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on March 31, 2017

WILSON SONSINI GOODRICH & ROSATI

By: /Kevin J. Chance/

Attorney Docket No.: 22773-826.401
Client Ref. No.: 1228.US.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: Not Yet Assigned
Chunhua Li et al.	
Application No.: Concurrently Herewith	Examiner: Not Yet Assigned
Filed: Concurrently Herewith	Art Unit: Not Yet Assigned
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	PRELIMINARY AMENDMENT
Customer No. 107046	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Prior to examination on the merits of the above-referenced application, please enter the following amendments and remarks:

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

Remarks begin on page 5 of this paper.

ClearCorrect Exhibit 1011, Page 41 of 890

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1.-19. (Canceled)

20. (Original) A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer;

providing a positive model of the patient's teeth in a target position; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. (Original) The method of claim 20, wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. (Original) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

23. (Original) The method of claim 20, wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. (Original) The method of claim 20, wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. (Original) The method of claim 20, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation at 24 hours testing in a high humidity environment greater than about 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. (Original) The method of claim 20, wherein the first soft polymer layer and the second soft polymer layer each independently comprise at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200 %, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

27. (Original) The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

28. (Original) The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. (Original) The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer.

REMARKS

Claims 1-19 are canceled without prejudice or disclaimer. Accordingly, claims 20-29 will be pending in the present application upon entry of this amendment. Please enter this amendment prior to substantive examination.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 23-2415.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-883-2500.

Respectfully submitted,

Dated: March 31, 2017

/Charles Hagadorn, III/

Charles Hagadorn, III
Reg. No. 62,367

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
Phone 650-493-9300
Fax 650-493-6811

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Charles C. Hagadorn III/Kevin Chance
Attorney Docket Number:	22773-826.401

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	280	280
UTILITY SEARCH FEE	1111	1	600	600
UTILITY EXAMINATION FEE	1311	1	720	720
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	140	140
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1740**

Electronic Acknowledgement Receipt	
EFS ID:	28806241
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Charles C. Hagadorn III/Kevin Chance
Filer Authorized By:	Charles C. Hagadorn III
Attorney Docket Number:	22773-826.401
Receipt Date:	31-MAR-2017
Filing Date:	
Time Stamp:	18:19:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1740
RAM confirmation Number	040317INTEFSW00005254232415
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	Transmittal of New Application	22773-826-401_UtilityTransmittal.PDF	276703 ffb4fd7fe2be376a244e794b84ca8e5c2fa2e1f7	no	2
Warnings:					
Information:					
2	Transmittal Letter	22773-826-401_FeeTransmittal.PDF	256885 acdea69dda514be81544ecd38dc4fe7636ee5f20	no	2
Warnings:					
Information:					
3		22773-826-401_DIV-App.pdf	538813 683fd1269da88f8c5a461e257be40e43c059178a	yes	26

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	11
	Claims	12	17
	Abstract	18	18
	Drawings-only black and white line drawings	19	26

Warnings:					
Information:					
4	Application Data Sheet	22773-826-401_ADS.PDF	1829700 bc4f06a07606b23ab792f9ad74da5536041bf0f9	no	10
Warnings:					
Information:					

5		22773-826-401_PAM.pdf	84138 b721e2515213e2c09b7e82797b327fe488dafec6	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5

Warnings:

Information:

6	Fee Worksheet (SB06)	fee-info.pdf	36567 aee653958e80eaa2ef99527de2587f3b5d2a20ba	no	2

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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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-RE35169	03-05-1996	LEMCHEN; Marc S. et al.	
	002	US-2467432	04-19-1949	KESLING; Harold D.	
	003	US-3407500	10-29-1968	KESLING; Peter C.	
	004	US-3600808	08-24-1971	JAMES; Jackson Reeve	
	005	US-3660900	05-09-1972	LAWRENCE; F. Andrews	
	006	US-3683502	08-15-1972	MELVIN; Wallshein	
	007	US-3738005	06-12-1973	COHEN; Mus et al.	
	008	US-3860803	01-14-1975	LEVINE; Richard Carl	
	009	US-3916526	11-04-1975	SCHUDY; Fred Frank	
	010	US-3922786	12-02-1975	LAVIN; Joseph L.	
	011	US-3950851	04-20-1976	BERGERSEN; Earl O.	
	012	US-3983628	10-05-1976	ACEVEDO; Raul	
	013	US-4014096	03-29-1977	DELLINGER; Eugene L.	
	014	US-4195046	03-25-1980	KESLING; Peter C.	
	015	US-4253828	03-03-1981	COLES; Donna C. et al.	
	016	US-4324546	04-13-1982	HEITLINGER; Paul et al.	
	017	US-4324547	04-13-1982	ARCAN; Mircea et al.	
	018	US-4348178	09-07-1982	KURZ; Craven H.	
	019	US-4478580	10-23-1984	BARRUT; Luc P.	
	020	US-4500294	02-19-1985	LEWIS; William D.	
	021	US-4504225	03-12-1985	YOSHII; Osamu	
	022	US-4505673	03-19-1985	YOSHII; Osamu	

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	023	US-4526540	07-02-1985	DELLINGER; Eugene L.	
	024	US-4575330	03-11-1986	HULL; Charles W.	
	025	US-4575805	03-11-1986	MOERMANN; Werner H. et al.	
	026	US-4591341	05-27-1986	ANDREWS; Lawrence F.	
	027	US-4609349	09-02-1986	CAIN; Steve B.	
	028	US-4611288	09-09-1986	DURET; Francois et al.	
	029	US-4656860	04-14-1987	ORTHUBER; Wolfgang et al.	
	030	US-4663720	05-05-1987	DURET; Francois et al.	
	031	US-4664626	05-12-1987	KESLING; Peter C.	
	032	US-4676747	06-30-1987	KESLING; Christopher K.	
	033	US-4742464	05-03-1988	DURET; Francois et al.	
	034	US-4755139	07-05-1988	ABBATTE; Gerard P. et al.	
	035	US-4763791	08-16-1988	HALVERSON; George E. et al.	
	036	US-4791156	12-13-1988	HOSTETTLER; Fritz	
	037	US-4793803	12-27-1988	MARTZ; Martin G.	
	038	US-4798534	01-17-1989	BREADS; Peter R.	
	039	US-4836778	06-06-1989	BAUMRIND; Sheldon et al.	
	040	US-4837732	06-06-1989	BRANDESTINI; Marco et al.	
	041	US-4850864	07-25-1989	DIAMOND; Michael K.	
	042	US-4850865	07-25-1989	NAPOLITANO; John R.	

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Sheet 3 of 32

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First Named Inventor	LI; Chunhua
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Attorney Docket Number	22773-826.401

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	043	US-4856991	08-15-1989	BREADS; Peter R. et al.	
	044	US-4877398	10-31-1989	KESLING; Peter C.	
	045	US-4880380	11-14-1989	MARTZ; Martin G.	
	046	US-4889238	12-26-1989	BATCHELOR; Jay A.	
	047	US-4890608	01-02-1990	STEER; Peter L.	
	048	US-4935635	06-19-1990	O'HARRA; Dale G.	
	049	US-4936862	06-26-1990	WALKER; Peter S. et al.	
	050	US-4937928	07-03-1990	VAN DER ZEL; Joseph M.	
	051	US-4941826	07-17-1990	LORAN; William et al.	
	052	US-4964770	10-23-1990	STEINBICHLER; Hans et al.	
	053	US-4975052	12-04-1990	SPENCER; William et al.	
	054	US-4983334	01-08-1991	ADELL; Loren S.	
	055	US-5011405	04-30-1991	LEMCHEN; Marc S.	
	056	US-5017133	05-21-1991	MIURA; Fujio	
	057	US-5024790	06-18-1991	GROSSMAN; David G. et al.	
	058	US-5027281	06-25-1991	REKOW; Elizabeth D. et al.	
	059	US-5035613	07-30-1991	BREADS; Peter R. et al.	
	060	US-5055039	10-08-1991	ABBATTE; Gerard P. et al.	
	061	US-5059118	10-22-1991	BREADS; Peter R. et al.	
	062	US-5100316	03-31-1992	WILDMAN; Alexander J.	
	063	US-5121333	06-09-1992	RILEY; Donald R. et al.	
	064	US-5125832	06-30-1992	KESLING; Peter C.	

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Sheet 4 of 32

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First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

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	065	US-5128870	07-07-1992	ERDMAN; Arthur G. et al.	
	066	US-5130064	07-14-1992	SMALLEY; Dennis R. et al.	
	067	US-5131843	07-21-1992	HILGERS; James J. et al.	
	068	US-5131844	07-21-1992	MARINACCIO; Paul J. et al.	
	069	US-5139419	08-18-1992	ANDREIKO; Craig A. et al.	
	070	US-5145364	09-08-1992	MARTZ; Martin G. et al.	
	071	US-5176517	01-05-1993	TRUAX; Lloyd H.	
	072	US-5184306	02-02-1993	ERDMAN; Arthur G. et al.	
	073	US-5186623	02-16-1993	BREADS; Peter R. et al.	
	074	US-5257203	10-26-1993	RILEY; Donald R. et al.	
	075	US-5273429	12-28-1993	REKOW; Dianne et al.	
	076	US-5278756	01-11-1994	LEMCHEN; Marc S. et al.	
	077	US-5328362	07-12-1994	WATSON; Sherman L. et al.	
	078	US-5338198	08-16-1994	WU; Chuang-Jy et al.	
	079	US-5340309	08-23-1994	ROBERTSON; James G.	
	080	US-5342202	08-30-1994	DESHAYES; Marie-Josephe	
	081	US-5368478	11-29-1994	ANDREIKO; Craig A. et al.	
	082	US-5382164	01-17-1995	STERN; Sylvan S.	
	083	US-5395238	03-07-1995	ANDREIKO; Craig A. et al.	
	084	US-5431562	07-11-1995	ANDREIKO; Craig A. et al.	
	085	US-5440326	08-08-1995	QUINN; Thomas J.	
	086	US-5440496	08-08-1995	ANDERSSON; Matts et al.	

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Sheet 5 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

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	087	US-5447432	09-05-1995	ANDREIKO; Craig A. et al.	
	088	US-5452219	09-19-1995	DEHOFF; Barry D. et al.	
	089	US-5454717	10-03-1995	ANDREIKO; Craig A. et al.	
	090	US-5456600	10-10-1995	ANDREIKO; Craig A. et al.	
	091	US-5474448	12-12-1995	ANDREIKO; Craig A. et al.	
	092	US-5518397	05-21-1996	ANDREIKO; Craig A. et al.	
	093	US-5528735	06-18-1996	STRASNICK; Steven L. et al.	
	094	US-5533895	07-09-1996	ANDREIKO; Craig A. et al.	
	095	US-5542842	08-06-1996	ANDREIKO; Craig A. et al.	
	096	US-5549476	08-27-1996	STERN; Sylvan S.	
	097	US-5562448	10-08-1996	MUSHABAC; David R.	
	098	US-5587912	12-24-1996	ANDERSSON; Matts et al.	
	099	US-5605459	02-25-1997	KURODA; Takayuki et al.	
	100	US-5607305	03-04-1997	ANDERSSON; Matts et al.	
	101	US-5614075	03-25-1997	ANDRE SR., LARRY E.	
	102	US-5621648	04-15-1997	CRUMP; Craig D.	
	103	US-5645420	07-08-1997	BERGERSEN; Earl O.	
	104	US-5645421	07-08-1997	SLOOTSKY; Gary Lee	
	105	US-5655653	08-12-1997	CHESTER; Bruce E.	
	106	US-5683243	11-04-1997	ANDREIKO; Craig A. et al.	
	107	US-5692894	12-02-1997	SCHWARTZ; Dann A. et al.	

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	108	US-5725376	03-10-1998	POIRIER; Michel	
	109	US-5725378	03-10-1998	WANG; Hong-Chi	
	110	US-5733126	03-31-1998	ANDERSSON; Matts et al.	
	111	US-5740267	04-14-1998	ECHERER; Scott J. et al.	
	112	US-5742700	04-21-1998	YOON; Douglas C. et al.	
	113	US-5799100	08-25-1998	CLARKE; Laurence P. et al.	
	114	US-5800174	09-01-1998	ANDERSSON; Matts	
	115	US-5823778	10-20-1998	SCHMITT; Stephen M. et al.	
	116	US-5848115	12-08-1998	LITTLE; Francis H. et al.	
	117	US-5857853	01-12-1999	VAN; Nifterick Willem Frederick et al.	
	118	US-5866058	02-02-1999	BATCHELDER; John Samuel et al.	
	119	US-5879158	03-09-1999	DOYLE; Walter A. et al.	
	120	US-5880961	03-09-1999	CRUMP; Craig D.	
	121	US-5880962	03-09-1999	ANDERSSON; Matts et al.	
	122	US-5934288	08-10-1999	AVILA; Ricardo Scott et al.	
	123	US-5957686	09-28-1999	ANTHONY; Wayne L.	
	124	US-5964587	10-12-1999	SATO; Mikio	
	125	US-5971754	10-26-1999	SONDHI; Anoop et al.	
	126	US-5975893	11-02-1999	CHISHTI; Muhammad et al.	
	127	US-6015289	01-18-2000	ANDREIKO; Craig A. et al.	
	128	US-6044309	03-28-2000	HONDA; Kenichi	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	129	US-6049743	04-11-2000	BABA; Masami	
	130	US-6062861	05-16-2000	ANDERSSON; Matts	
	131	US-6068482	05-30-2000	SNOW; Michael Desmond	
	132	US-6099314	08-08-2000	KOPELMAN; Avi et al.	
	133	US-6123544	09-26-2000	CLEARY; James D.	
	134	US-6152731	11-28-2000	JORDAN; Russell A. et al.	
	135	US-6183248	02-06-2001	CHISHTI; Muhammad et al.	
	136	US-6190165	02-20-2001	ANDREIKO; Craig A. et al.	
	137	US-6217325	04-17-2001	CHISHTI; Muhammad et al.	
	138	US-6217334	04-17-2001	HULTGREN; Bruce Willard	
	139	US-6244861	06-12-2001	ANDREIKO; Craig A. et al.	
	140	US-6309215	10-30-2001	PHAN; Loc X. et al.	
	141	US-6315553	11-13-2001	SACHDEVA; Rohit et al.	
	142	US-6322359	11-27-2001	JORDAN; Russell A. et al.	
	143	US-6350120	02-26-2002	SACHDEVA; Rohit et al.	
	144	US-6382975	05-07-2002	POIRIER; Michel	
	145	US-6398548	06-04-2002	MUHAMMAD; Chishti et al.	
	146	US-6402707	06-11-2002	ERNST; Maurice M.	
	147	US-6482298	11-19-2002	BHATNAGAR; Parijat	
	148	US-6524101	02-25-2003	PHAN; Loc X. et al.	
	149	US-6554611	04-29-2003	SHISHTI; Muhammad et al.	
	150	US-6572372	06-03-2003	PHAN; Loc X. et al.	

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Sheet 8 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

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	151	US-6629840	10-07-2003	CHISHTI; Muhammad et al.	
	152	US-6705863	03-16-2004	PHAN; Loc X. et al.	
	153	US-6722880	04-20-2004	CHISHTI; Muhammad et al.	
	154	US-7641828	01-05-2010	DESIMONE; Joseph M. et al.	
	155	US-8235713	08-07-2012	PHAN; Loc X. et al.	
	156	US-8496473	07-30-2013	PHAN; Loc X. et al.	
	157	US-20010041320	11-15-2001	PHAN; Loc et al.	
	158	US-20020006597	01-17-2002	ANDREIKO; Craig A. et al.	
	159	US-20030009252	01-09-2003	PAVLOVSKAIA; Elena et al.	
	160	US-20030139834	07-24-2003	NIKOLSKIY; Sergey et al.	
	161	US-20030224311	12-04-2003	CRONAUER; Edward A.	
	162	US-20040128010	07-01-2004	PAVLOVSKAIA; Elena et al.	
	163	US-20040146670	07-29-2004	CHIN; Albert et al.	
	164	US-20050055118	03-10-2005	NIKOLSKIY; Sergey et al.	
	165	US-20070148608	06-28-2007	TADROS; Safwat et al.	
	166	US-20080299507	12-04-2008	LI; Chunhua et al.	
	167	US-20090087808	04-02-2009	SOO; Chia et al.	
	168	US-20090239188	09-24-2009	TING; Kang et al.	
	169	US-20090246724	10-01-2009	CHEN; Yan et al.	
	170	US-20100055639	03-04-2010	LEWIS; Paul et al.	
	171	US-20150140300	05-21-2015	PUDLEINER; Heinz et al.	

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Sheet 9 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	172	US-20160228215	08-11-2016	LI; Chunhua et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	AU-3031677-A	05-10-1979	SUYEHIRO H.		☐
	002	AU-517102-B2	07-09-1981	HITO SUYEHIRO.		☐
	003	AU-5598894-A	06-08-1994	ORMCO CORP.		☐
	004	CA-1121955-A	04-20-1982	SUYEHIRO HITO.		☐
	005	DE-102004014023-A1	10-20-2005	KRD COATINGS GMBH [DE]		☒
	006	DE-102010009230-A1	08-25-2011	GIESECKE & DEVRIENT GMBH [DE]		☒
	007	DE-2749802-A1	05-11-1978	SUYEHIRO HITO.		☒

Examiner Signature		Date Considered	

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Sheet 10 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

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	008	DE-69327661-T2	07-20-2000	ORMCO CORP [US]		☒
	009	EP-0091876-A1	10-19-1983	DURET FRANCOIS [FR], et al.		☒
	010	EP-0299490-A2	01-18-1989	STEINBICHLER HANS [DE]		☒
	011	EP-0376873-A2	07-04-1990	SHAFIR AARON [IL], et al.		☐
	012	EP-0490848-A2	06-17-1992	NOBELPHARMA AB [SE]		☐
	013	EP-0541500-A1	05-12-1993	NOBELPHARMA AB [SE]		☐
	014	EP-0667753-B1	01-19-2000	ORMCO CORP [US]		☐
	015	EP-0731673-B1	05-30-2001	NOBEL BIOCARE AB [SE]		☐
	016	EP-0774933-B1	12-06-2000	SANDVIK AB [SE], et al.		☐
	017	ES-463897-A1	01-01-1980	HITO SUYEHIRO D [US]		☒

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 11 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	018	FR-2369828-A1	06-02-1978	SUYEHIRO HITO [US]		☒
	019	FR-2652256-A1	03-29-1991	JOURDA GERARD., et al.		☒
	020	GB-15500777	08-22-1979	HITO.		☐
	021	JP-08508174	09-03-1996	ANDREIKO et al.		☐
	022	JP-H0428359-A	01-30-1992	MITSUBISHI PETROCHEMICAL CO.		☒
	023	JP-S5358191-A	05-25-1978			☒
	024	WO-2013172812-A1	11-21-2013	BAYER MATERIALSCIENCE AG [DE], et al.		☐
	025	WO-9008512-A1	08-09-1990	DOLPHIN IMAGING SYSTEMS INC [US]		☐
	026	WO-9104713-A1	04-18-1991	JOURDA GERARD [FR], et al.		☒
	027	WO-9410935-A1	05-26-1994	ORMCO CORP [US]		☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 12 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

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	028	WO-9832394-A1	07-30-1998	HULTGREN BRUCE WILLARD [US]		☐
	029	WO-9844865-A1	10-15-1998	NOBEL BIOCARE AB [SE], et al.		☐
	030	WO-9858596-A1	12-30-1998	ALIGN TECHNOLOGY INC [US], et al.		☐

Examiner Signature		Date Considered	

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Sheet 13 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	001	AADR. AMERICAN ASSOCIATION FOR DENTAL RESEARCH, Summary of Activities, March 20-23,1980, Los Angeles, CA, p. 195.	☐
	002	ALCANIZ, et aL, "An Advanced System for the Simulation and Planning of Orthodontic Treatments," Karl Heinz Hohne and Ron Kikinis (eds.), Visualization in Biomedical Computing, 4th Intl. Conf., VBC '96, Hamburg, Germany, September 22-25, 1996, Springer-Verlag, pp. 511-520.	☐
	003	ALEXANDER et al., "The DigiGraph Work Station Part 2 Clinical Management," JCO, pp. 402-407 (July 1990).	☐
	004	ALTSCHULER, "3D Mapping of Maxillo-Facial Prosthesis," AADR Abstract #607, 2 pages total, (1980).	☐
	005	ALTSCHULER et al., "Analysis of 3-D Data for Comparative 3-D Serial Growth Pattern Studies of Oral-Facial Structures, " AADR Abstracts, Program and Abstracts of Papers, 57th General Session, IADR HP Annual Session, March 29, 1979 - April 1, 1979, New Orleans Marriot, Journal of Dental Research, Vol. 58, January 1979, Special Issue A, p. 221.	☐
	006	ALTSCHULER et al., "Laser Electro-Optic System for Rapid Three-Dimensional (3D) Topographic Mapping of Surfaces," Optical Engineering, 20(6):953-961 (1981).	☐
	007	ALTSCHULER et al., "Measuring Surfaces Space-Coded by a Laser-Projected Dot Matrix," SPIE Imaging Applications for Automated Industrial Inspection and Assembly, Vol. 182, p. 187-191 (1979).	☐
	008	ANDERSSON et al., "Clinical Results with Titanium Crowns Fabricated with Machine Duplication and Spark Erosion," Acta. Odontol. Scand., 47:279-286 (1989).	☐
	009	ANDREWS, The Six Keys to Optimal Occlusion Straight Wire, Chapter 3, pp 13-24 (1989).	☐

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Sheet 14 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

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	010	ANDREWS, The Six Keys to Optimal Occlusion Straight Wire, Chapter 3, pp 13-24 (NO DATE GIVEN).	☐
	011	Baird Equity Research. Align Technology, Inc. (ALGN): Analyst Day Recap. May 30, 2014. 12 pages.	☐
	012	Baird Equity Research. Align Technology, Inc. (ALGN): Impressive Quarter/Guide, Momentum Stronger than We Realized. October 18, 2013. 15 pages.	☐
	013	BARTELS, et al., An Introduction to Splines for Use in Computer Graphics and Geometric Modeling, Morgan Kaufmann Publishers, pp. 422-425 (1987).	☐
	014	BAUMRIND, "A System for Craniofacial Mapping Through the Integration of Data from Stereo X-Ray Films and Stereo Photographs," an invited paper submitted to the 1975 American Society of Photogram Symposium on Close-Range Photogram Systems, University of Ill., Aug. 26-30, 1975, pp. 142-166.	☐
	015	BAUMRIND et al., "A Stereophotogrammetric System for the Detection of Prosthesis Loosening in Total Hip Arthroplasty," NATO Symposium on Applications of Human Biostereometrics," July 9-13, 1978, SPIE, Vol. 166, pp. 112-123.	☐
	016	BAUMRIND et al., "Mapping the Skull in 3-D," reprinted from J. Calif. Dent. Assoc., 48(2), 11 pages total, (1972 Fall Issue).	☐
	017	BAUMRIND, "Integrated Three-Dimensional Craniofacial Mapping: Background, Principles, and Perspectives," Semin. in Orthod., 7(4):223-232 (December 2001).	☐
	018	BEGOLE et al., "A Computer System for the Analysis of Dental Casts," The Angle Orthod., 51(3):253-259 (July 1981).	☐

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	019	BERNARD et al.," Computerized Diagnosis in Orthodontics for Epidemiological Studies: A Progress Report," Abstract, J. Dental Res. Special Issue, Vol. 67, p. 169, paper presented at International Association for Dental Research 66th General Session, March 9-13, 1988, Montreal, Canada.	☐
	020	BHATIA et al., "A Computer-Aided Design for Orthognathic Surgery," Br. J. Oral Maxillofac. Surg., 22:237- 253 (1984).	☐
	021	BIGGERSTAFF, "Computerized Diagnostic Setups and Simulations," Angle Orthod., 40(1):28-36 (January 1970).	☐
	022	BIGGERSTAFF et al., "Computerized Analysis of Occlusion in the Postcanine Dentition," Am. J. Orthod., 61(3): 245-254 (March 1972).	☐
	023	BIOSTAR OPEATION & TRAINING MANUAL. Great Lakes Orthodontics, Ltd. 199 Fire Tower Drive, Tonawanda, New York. 14150-5890, 20 pages total (1990).	☐
	024	BIOSTAR OPEATION & TRAINING MANUAL. Great Lakes Orthodontics, Ltd. 199 Fire Tower Drive, Tonawanda, New York. 14150-5890, 20 pages total (NO DATE GIVEN).	☐
	025	BLU, et al., "Linear interpolation revitalized", IEEE Trans. Image Proc., 13(5):710-719 (May 2004.	☐
	026	Boedeker.com. Polycarbonate specifications [retrieved on 10 September 2013]. Retrieved from the Internet: http://www.boedeker.com/polyc_p.htm.	☐
	027	BOURKE, "Coordinate System Transformation," (June 1996), p. 1, retrieved from the Internet 11/05/2004, URL< http://astronomy.swin.edu.au/—pbourke/prolection/coords>.	☐

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	028	BOYD et al., "Three Dimensional Diagnosis and Orthodontic Treatment of Complex Malocclusions With the Invisalipn Appliance," Semin. Orthod., 7(4):274-293 (December 2001).	☐
	029	BRANDESTINI et al., "Computer Machined Ceramic Inlays: In Vitro Marginal Adaptation," J. Dent. Res. Special Issue, Abstract 305, Vol. 64, p. 208 (1985).	☐
	030	BROOK et al., "An Image Analysis System for the Determination of Tooth Dimensions from Study Casts: Comparison with Manual Measurements of Mesio-distal Diameter," J. Dent. Res., 65(3):428-431 (March 1986).	☐
	031	BURSTONE et al., Precision Adjustment of the Transpalatal Lingual Arch: Computer Arch Form IN Predetermination, Am, Journal of Orthodontics, Vol. 79, No. 2 (Feb. 1981), pp. 115-133.	☐
	032	BURSTONE (interview), "Dr. Charles J. Burstone on The Uses of the Computer in Orthodontic Practice (Part 1)," J. Clin. Orthod., 13(7):442-453 (July 1979).	☐
	033	BURSTONE (interview), "Dr. Charles J. Burstone on The Uses of the Computer in Orthodontic Practice (Part 2)," J. Clin. Orthod., 13(8):539-551 (August 1979).	☐
	034	Cardinal Industrial Finishes, Powder Coatings information posted at< http://www.cardinalpaint.com> on Aug. 25, 2000, 2 pages.	☐
	035	CARNAGHAN, "An Alternative to Holograms for the Portrayal of Human Teeth," 4th Int'l. Conf. on Holographic Systems, Components and Applications, Sept. 15, 1993, pp. 228-231.	☐
	036	CHACONAS et al., "The DigiGraph Work Station, Part 1, Basic Concepts," JCO, pp. 360-367 (June 1990).	☐
	037	CHAFETZ et al., "Subsidence of the Femoral Prosthesis, A Stereophotogrammetric Evaluation," Clin. Orthop. Relat. Res., No. 201, pp. 60-67 (December 1985).	☐

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	038	CHIAPPONE, (1980). Constructing the Gnathologic Setup and Positioner, J. Clin. Orthod, Vol. 14, pp. 121- 133.	☐
	039	COTTINGHAM, (1969). Gnathologic Clear Plastic Positioner, Am. J. Orthod, Vol. 55, pp. 23-31.	☐
	040	CRAWFORD, "CAD/CAM in the Dental Office: Does It Work?", Canadian Dental Journal, Vol. 57, No. 2, pp. 121-123 (February 1991).	☐
	041	CRAWFORD, "Computers in Dentistry: Part 1 CAD/CAM: The Computer Moves Chairside," Part 2 F. Duret — A Man with a Vision," Part 3 The Computer Gives New Vision — Literally," Part 4 Bytes 'N Bites — The Computer Moves from the Front Desk to the Operatory," Canadian Dental Journal, Vol. 54 (9), pp. 661-666 (1988).	☐
	042	CROOKS, "CAD/CAM Comes to USC," USC Dentistry, pp. 14-17 (Spring 1990).	☐
	043	CURETON, Correcting Malaligned Mandibular Incisors with Removable Retainers, J. Clin. Orthod, Vol. 30, No. 7 (1996) pp. 390-395.	☐
	044	CURRY et al., "Integrated Three-Dimensional Craniofacial Mapping at the Craniofacial Research Instrumentation Laboratory/University of the Pacific," Semin. Orthod., 7(4):258-265 (December 2001).	☐
	045	CUTTING et a/., "Three-Dimensional Computer-Assisted Design of Craniofacial Surgical Procedures: Optimization and Interaction with Cephalometric and CT-Based Models," Plast. 77(6):877-885 (June 1986).	☐
	046	DCS Dental AG, "The CAD/CAM 'DCS Titan System' for Production of Crowns/Bridges," DSC Production AG, pp. 1-7 (January 1992.	☐

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	047	Definition for gingiva. Dictionary.com pg 1-3. Retrieved from the internet 11/5/04< http://reference.com/search/search?q=gingiva>.	☐
	048	DEFRANCO et al., "Three-Dimensional Large Displacement Analysis of Orthodontic Appliances," J. Biomechanics, 9:793-801 (1976).	☐
	049	DENTAL INSTITUTE UNIVERSITY OF ZURICH SWITZERLAND, Program for International Symposium JD on Computer Restorations: State of the Art of the CEREC-Method, May 1991, 2 pages total.	☐
	050	DENTRAC CORPORATION, Dentrac document, pp. 4-13 (1992).	☐
	051	DENTRAC CORPORATION, Dentrac document, pp. 4-13 (NO DATE GIVEN).	☐
	052	DENT-X posted on 09/24/98 at< http://www.dent-x.com/DentSim.htm>, 6 pages.	☐
	053	DOYLE, "Digital Dentistry," Computer Graphics World, pp. 50-52, 54 (October 2000).	☐
	054	DuraClearTM product information, Allesee Orthodontic Appliances-Pro Lab, 1 page (1997).	☐
	055	DuraClearTM product information, Allesee Orthodontic Appliances-Pro Lab, 1 page (NO DATE GIVEN).	☐
	056	DURET et al., "CAD/CAM Imaging in Dentistry," Curr. Opin. Dent., 1:150-154 (1991).	☐
	057	DURET et al, "CAD-CAM in Dentistry," J. Am. Dent. Assoc. 117:715-720 (November 1988).	☐
	058	DURET, "The Dental CAD/CAM, General Description of the Project," Hennson International Product Brochure, 18 pages total, January 1986.	☐

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	059	DURET,"Vers Une Prosthese Informatisee," (English translation attached), Tonus, Vol. 75, pp. 55-57 (November 15, 1985).	☐
	060	ECONOMIDES, "The Microcomputer in the Orthodontic Office," JCO, pp. 767-772 (November 1979).	☐
	061	ELSASSER, Some Observations on the History and Uses of the Kesling Positioner, Am. J. Orthod. (1950) 36:368-374.	☐
	062	English translation of Japanese Laid-Open Publication No. 63-11148 to inventor T. Ozukuri (Laid-Open on January 18, 1998) pp. 1-7.	☐
	063	FELTON et al., "A Computerized Analysis of the Shape and Stability of Mandibular Arch Form," Am. J. Orthod. Dentofacial Orthop., 92(6):478-483 (December 1987).	☐
	064	FRIEDE et al., "Accuracy of Cephalometric Prediction in Orthognathic Surgery," Abstract of Papers, J. Dent. Res., 70:754-760 (1987).	☐
	065	FUTTERLING et a/., "Automated Finite Element Modeling of a Human Mandible with Dental Implants," JS WSCG '98 -Conference Program, retrieved from the Internet:< http://wscg.zcu.cz/wscg98/papers98/Strasser 98.pdf>, 8 pages.	☐
	066	GAO et al., "3-D element Generation for Multi-Connected Complex Dental and Mandibular Structure," Proc. Intl Workshop on Medical Imaging and Augmented Reality, pp. 267-271 (June 12, 2001).	☐
	067	GIM-ALLDENT Deutschland, "Das DUX System: Die Technik," 2 pages total (2002).	☐
	068	GOTTLEIB et al., "JCO Interviews Dr. James A. McNamura, Jr., on the Frankel Appliance: Part 2: Clinical 1-1 Management, "J. Clin. Orthod., 16(6):390-407 (June 1982).	☐

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	069	GRAYSON, "New Methods for Three Dimensional Analysis of Craniofacial Deformity, Symposium: JW Computerized Facial Imaging in Oral and Maxiiofacial Surgery," AAOMS, 3 pages total, (September 13, 1990).	☐
	070	GUESS et al., "Computer Treatment Estimates In Orthodontics and Orthognathic Surgery," JCO, pp. 262- 28 (April 1989).	☐
	071	HEAVEN et a/., "Computer-Based Image Analysis of Artificial Root Surface Caries," Abstracts of Papers," J. Dent. Res., 70:528 (April 17-21, 1991).	☐
	072	HIGHBEAM RESEARCH, "Simulating Stress Put on Jaw," Tooling & Production [online], November 1996, n pp. 1-2, retrieved from the Internet on 11/05/2004, URL http://static.highbeam.com/t/toolingampproduction/november011996/simulatingstressputonfa...> .	☐
	073	HIKAGE, "Integrated Orthodontic Management System for Virtual Three-Dimensional Computer Graphic Simulation and Optical Video Image Database for Diagnosis and Treatment Planning", Journal of Japan KA Orthodontic Society, February 1987, English translation, pp. 1-38, Japanese version, 46(2), pp. 248-269 (60 pages total).	☐
	074	HOFFMANN, et al., "Role of Cephalometry for Planning of Jaw Orthopedics and Jaw Surgery Procedures," (Article Summary in English, article in German), Informatbnen, pp. 375-396 (March 1991).	☐
	075	HOJJATIE et al., "Three-Dimensional Finite Element Analysis of Glass-Ceramic Dental Crowns," J. Biomech., 23(11):1157-1166 (1990).	☐
	076	HUCKINS, "CAD-CAM Generated Mandibular Model Prototype from MRI Data," AAOMS, p. 96 (1999).	☐

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Sheet 21 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	077	Important Tip About Wearing the Red White & Blue Active Clear Retainer System," Allesee Orthodontic Appliances-Pro Lab, 1 page 1998).	☐
	078	International Preliminary Report on Patentability dated 11/18/2014 for International PCT Patent Application No. PCT/US2012/037745.	☐
	079	International Search Report and Written Opinion dated 01/30/2013 for International PCT Patent Application No. PCT/US2012/037745.	☐
	080	JCO Interviews, Craig Andreiko , DDS, MS on the Elan and Orthos Systems," JCO, pp. 459-468 (Aug. 1994).	☐
	081	JCO Interviews, Dr. Homer W. Phillips on Computers in Orthodontic Practice, Part 2," JCO. 1997; 1983:819-831.	☐
	082	JERROLD, "The Problem, Electronic Data Transmission and the Law," AJO-DO, pp. 478-479 (Apr. 1988).	☐
	083	JONES et al., "An Assessment of the Fit of a Parabolic Curve to Pre- and Post-Treatment Dental Arches," Br. J. Orthod., 16:85-93 (1989).	☐
	084	JP FABER et al., "Computerized Interactive Orthodontic Treatment Planning," Am. J. Orthod., 73(1):36-46 (January 1978).	☐
	085	KAMADA et.al., Case Reports On Tooth Positioners Using LTV Vinyl Silicone Rubber, J. Nihon University School of Dentistry (1984) 26(1): 11 -29.	☐
	086	KAMADA et.al., Construction of Tooth Positioners with LTV Vinyl Silicone Rubber and Some Case KJ Reports, J. Nihon University School of Dentistry (1982) 24(1):1-27.	☐

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	087	KANAZAWA et al., "Three-Dimensional Measurements of the Occlusal Surfaces of Upper Molars in a Dutch Population," J. Dent Res., 63(11):1298-1301 (November 1984).	☐
	088	KESLING, Coordinating the Predetermined Pattern and Tooth Positioner with Conventional Treatment, KN Am. J. Orthod. Oral Surg. (1946) 32:285-293.	☐
	089	KESLING et al., The Philosophy of the Tooth Positioning Appliance, American Journal of Orthodontics and Oral surgery. 1945; 31:297-304.	☐
	090	KLEEMAN et al., The Speed Positioner, J. Clin. Orthod. (1996) 30:673-680.	☐
	091	KOCHANEK, "Interpolating Splines with Local Tension, Continuity and Bias Control," Computer Graphics, ri 18(3):33-41 (July 1984). KM Oral Surgery (1945) 31 :297-30.	☐
	092	KUNII et al., "Articulation Simulation for an Intelligent Dental Care System," Displays 15:181-188 (1994).	☐
	093	KURODA et al., Three-Dimensional Dental Cast Analyzing System Using Laser Scanning, Am. J. Orthod. Dentofac. Orthop. (1996) 110:365-369.	☐
	094	LAURENDEAU, et al., "A Computer-Vision Technique for the Acquisition and Processing of 3-D Profiles of 7 KR Dental Imprints: An Application in Orthodontics," IEEE Transactions on Medical Imaging, 10(3):453-461 (September 1991.	☐
	095	LEINFELDER, et al., "A New Method for Generating Ceramic Restorations: a CAD-CAM System," J. Am. 1-1 Dent. Assoc., 118(6):703-707 (June 1989).	☐
	096	Lubrizol.com. I sop last 2530 data sheet [retrieved on 10 September 2013]. Retrieved from the Internet: http://www.lubrizol.com/Medicai/TDS/Isoplast-2530.pdf.	☐

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	097	MANETTI, et al., "Computer-Aided Cefalometry and New Mechanics in Orthodontics," (Article Summary in English, article in German), Fortschr Kieferorthop. 44, 370-376 (Nr. 5), 1983.	☐
	098	MCCANN, "Inside the ADA," J. Amer. Dent. Assoc., 118:286-294 (March 1989).	☐
	099	MCNAMARA et al., "Invisible Retainers," J. Cfin. Orthod., pp. 570-578 (August 1985).	☐
	100	MCNAMARA et al., Orthodontic and Orthopedic Treatment in the Mixed Dentition, Needham Press, pp. 347-353 (January 1993).	☐
	101	MOERMANN et al., "Computer Machined Adhesive Porcelain Inlays: Margin Adaptation after Fatigue Stress," IADR Abstract 339, J. Dent. Res., 66(a):763 (1987).	☐
	102	MOLES, "Correcting Mild Malalignments - As Easy As One, Two, Three," AOA/Pro Corner, Vol. 11, No. 1, 2 pages (2002).	☐
	103	MORMANN et al., "Marginale Adaptation von adhasuven Porzellaninlays in vitro," Separatdruck aus: Schweiz. Mschr. Zahnmed. 95: 1118-1129, 1985.	☐
	104	NAHOUM, "The Vacuum Formed Dental Contour Appliance," N. Y. State Dent. J., 30(9):385-390 (November 1964).	☐
	105	NASH, "CEREC CAD/CAM Inlays: Aesthetics and Durability in a Single Appointment," Dent. Today, 9(8):20, 22-23 (October 1990).	☐
	106	NISHIYAMA et al., "A New Construction of Tooth Repositioner by LTV Vinyl Silicone Rubber," J. Nihon Univ. Sch. Dent., 19(2):93-102 (1977).	☐

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	107	PAUL et al., "Digital Documentation of Individual Human Jaw and Tooth Forms for Applications in Orthodontics, Oral Surgery and Forensic Medicine" Proc. of the 24th Annual Conf. of the IEEE Industrial Electronics Society (IECON '98), Sept. 4, 1998, pp. 2415-2418.	☐
	108	PINKHAM, "Foolish Concept Propels Technology," Dentist, 3 pages total, January/February 1989.	☐
	109	PINKHAM, "Inventor's CAD/CAM May Transform Dentistry," Dentist, 3 pages total, September 1990.	☐
	110	Plastics.ides.com. Polyurethane Thermoset Elastomer Typical Properties Generic [retrieved on 27 July 2014]. Retrieved from the Internet: http://plastics.ides.com/generics/57/c/t/polyurethane-thermoset-elastomer-tsu- properties-processing.	☐
	111	PONITZ, "Invisible Retainers," Am. J. Orthod., 59(3):266-272 (March 1971).	☐
	112	PROCERA RESEARCH PROJECTS, "PROCERA Research Projects 1993 — Abstract Collection," pp. 3- 7; 28 (1993).	☐
	113	PROFFIT et al., Contemporary Orthodontics, (Second Ed.), Chapter 15, Mosby Inc., pp 470-533 (October 1993.	☐
	114	RAINTREE ESSIX & ARS MATERIALS, INC., Raintree Essix, Technical Magazine Table of contents and Essix Appliances,< http:// www.essix.com/magazine/defaulthtml> Aug. 13, 1997.	☐
	115	REDMOND et al., "Clinical Implications of Digital Orthodontics," Am. J. Orthod. Dentofacial Orthop., 117(2):240-242 (2000).	☐

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	116	REKOW, "A Review of the Developments in Dental CAD/CAM Systems," (contains references to Japanese efforts and content of the papers of particular interest to the clinician are indicated with a one line summary of their content in the bibliography), Curr. Opin. Dent., 2:25-33 (June 1992).	☐
	117	REKOW, "CAD/CAM in Dentistry: A Historical Perspective and View of the Future," J. Can. Dent. Assoc., 58(4):283, 287-288 (April 1992).	☐
	118	REKOW, "Computer-Aided Design and Manufacturing in Dentistry: A Review of the State of the Art," J. Prosthet. Dent., 58(4):512-516 (October 1987).	☐
	119	REKOW, "Dental CAD-CAM Systems: What is the State of the Art?", J. Amer. Dent. Assoc., 122:43-48 1991.	☐
	120	REKOW et a/., "CAD/CAM for Dental Restorations - Some of the Curious Challenges," IEEE Trans. Biomed. Eng., 38(4):344-345 (April 1991.	☐
	121	REKOW et al., "Comparison of Three Data Acquisition Techniques for 3-D Tooth Surface Mapping," Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 13(1):344-345 1991.	☐
	122	REKOW, "Feasibility of an Automated System for Production of Dental Restorations, Ph.D. Thesis," Univ. of Minnesota, 244 pages total, November 1988.	☐
	123	RICHMOND et al., "The Development of a 3D Cast Analysis System," Br. J. Orthod., 13(1):53-54 (January 1986).	☐
	124	RICHMOND et al., "The Development of the PAR Index (Peer Assessment Rating): Reliability and Validity," Eur. J. Orthod., 14:125-139 (1992).	☐

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	125	RICHMOND, "Recording The Dental Cast In Three Dimensions," Am. J. Orthod. Dentofacial Orthop., 92(3):199-206 (September 1987).	☐
	126	RUDGE, "Dental Arch Analysis: Arch Form, A Review of the Literature," Eur. J. Orthod., 3(4):279-284 1981.	☐
	127	SAKUDA et al., "Integrated Information-Processing System In Clinical Orthodontics: An Approach with Use of a Computer Network System," Am. J. Orthod. Dentofacial Orthop., 101(3): 210-220 (March 1992).	☐
	128	SCHELLHAS et al., "Three-Dimensional Computed Tomography in Maxillofacial Surgical Planning," Arch. Otolamp!. Head Neck Sur9., 114:438-442 (April 1988).	☐
	129	SCHROEDER et al., Eds. The Visual Toolkit, Prentice Hall PTR, New Jersey (1998) Chapters 6, 8 & 9, (pages 153-210,309-354, and 355-428, respectively.	☐
	130	SHILLIDAY, (1971). Minimizing finishing problems with the mini-positioner, Am. J. Orthod. 59:596-599.	☐
	131	SIEMENS, "CEREC - Computer-Reconstruction," High Tech in der Zahnmedizin, 14 pages total (2004).	☐
	132	SIEMENS, "CEREC - Computer-Reconstruction," High Tech in der Zahnmedizin, 14 pages total (NO DATE GIVEN).	☐
	133	SINCLAIR, "The Readers' Corner," J. Clin. Orthod., 26(6):369-372 (June 1992).	☐
	134	SIRONA DENTAL SYSTEMS GmbH, CEREC 3D, Manuel utiiisateur, Version 2.0X (in French), 2003,114 pages total.	☐

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	135	STIFEL. TAM Survey. Properly Aligning Expectations Ahead of 4Q13 Guidance. Align Technology, Inc. October 10, 2013. 12 pages.	☐
	136	STOLL et al., "Computer-aided Technologies in Dentistry," (article summary in English, article in German), Dtsch Zahna'rztl Z 45, pp. 314-322 (1990).	☐
	137	STURMAN, "Interactive Keyframe Animation of 3-D Articulated Models," Proceedings Graphics Interface '84, May-June 1984, pp. 35-40.	☐
	138	The Choice Is Clear: Red, White & Blue .. . The Simple, Affordable, No-Braces Treatment," Allesee HI Orthodontic Appliances-Pro Lab product information for doctors. http://ormco.com/aoa/appliancesservices/RWB/doctorhtml>, 5 pages (May 19, 2003).	☐
	139	The Choice is Clear: Red, White & Blue ... The Simple, Affordable, No-Braces Treatment," Allesee HJ Orthodontic Appliances-Pro Lab product information for patients,< http://ormco.com/aoa/appliancesservices/RWB/patients.html>, 2 pages (May 19, 2003).	☐
	140	The Choice Is Clear: Red, White & Blue ... The Simple, Affordable, No-Braces Treatment," Allesee Orthodontic Appliances-Pro Lab product information, 6 pages (2003).	☐
	141	The Red, White & Blue Way to Improve Your Smile!" Allesee Orthodontic Appliances-Pro Lab product information for patients, 2 pages 1992.	☐
	142	TRUAX L., "Truax Clasp-Less(TM) Appliance System," Funct. Orthod., 9(5):22-4, 26-8 (September-October 1992).	☐
	143	TRU-TAIN ORTHODONTIC & DENTAL SUPPLIES, Product Brochure, Rochester, Minnesota 55902, 16 pages total (1996).	☐

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	145	U.S. Department of Commerce, National Technical Information Service, "Automated Crown Replication Using Solid Photography SM," Solid Photography Inc., Melville NY, October 1977, 20 pages total.	☐
	146	U.S. Department of Commerce, National Technical Information Service, "Holodontography: An Introduction to Dental Laser Holography," School of Aerospace Medicine Brooks AFB Tex, March 1973, 37 pages total.	☐
	147	U.S. Provisional Patent Application No. 60/050342, filed on June 20,1997, 41 pages total.	☐
	148	VAN DER LINDEN, "A New Method to Determine Tooth Positions and Dental Arch Dimensions," J. Dent. Res., 51(4):1104 (July-August 1972).	☐
	149	VAN DER LINDEN et al., "Three-Dimensional Analysis of Dental Casts by Means of the Optocom," J. Dent. Res., p. 1100 (July-August 1972).	☐
	150	VAN DER ZEL, "Ceramic-Fused-to-Metal Restorations with a New CAD/CAM System," Quintessence Int., 24(11):769-778 (1993.	☐
	151	VARADY et al., "Reverse Engineering Of Geometric Models—An Introduction," Computer-Aided Design, 29(4):255-268,1997.	☐
	152	VERSTREKEN et al., "An Image-Guided Planning System for Endosseous Oral Implants," IEEE Trans. Med. Imaging, 17(5):842-852 (October 1998).	☐
	153	WARUNEK et al., "Physical and Mechanical Properties of Elastomers in Orthodonic Positioners, Am J. Orthod. Dentofac. Orthop, Vol. 95, No. 5, (May 1989) pp. 399-400.	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 29 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	154	WARUNEK et.al., Clinical Use of Silicone Elastomer Applicances, JCO (1989) XXIII(10):694-700.	☐
	155	WELLS, Application of the Positioner Appliance in Orthodontic Treatment, Am. J. Orthodont. (1970) 58:351-366.	☐
	156	WILLIAMS, "Dentistry and CAD/CAM: Another French Revolution," J. Dent. Practice Admin., pp. 2-5 (January/March 1987).	☐
	157	WILLIAMS, "The Switzerland and Minnesota Developments in CAD/CAM," J. Dent. Practice Admin., pp. 50-55 (April/June 1987.	☐
	158	WISHAN, "New Advances in Personal Computer Applications for Cephalometric Analysis, Growth Prediction, Surgical Treatment Planning and Imaging Processing," Symposium: Computerized Facial Imaging in Oral and Maxilofacial Surgery Presented on September 13,1999.	☐
	159	WSCG'98 - Conference Program, "The Sixth International Conference in Central Europe on Computer Graphics and Visualization '98," February 9-13, 1998, pp. 1-7, retrieved from the Internet on 11/05/2004, URL<http://wscg.zcu.cz/wscg98/wscg98.h>.	☐
	160	XIA et al., "Three-Dimensional Virtual-Reality Surgical Planning and Soft-Tissue Prediction for Orthognathic Surgery," IEEE Trans. Inf. Technol. Biomed., 5(2):97-107 (June 2001).	☐
	161	YAMAMOTO et al., "Optical Measurement of Dental Cast Profile and Application to Analysis of Three-Dimensional Tooth Movement in Orthodontics," Front. Med. Biol. Eng., 1(2):119-130 (1988).	☐
	162	YAMAMOTO et al., "Three-Dimensional Measurement of Dental Cast Profiles and Its Applications to Orthodontics," Conf. Proc. IEEE Eng. Med. Biol. Soc., 12(5):2051-2053 (1990).	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 30 of 32

Complete if Known	
Application Number	15476655
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First Named Inventor	LI; Chunhua
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	163	YAMANY et al., "A System for Human Jaw Modeling Using Intra-Oral Images," Proc. of the 20th Annual Conf. of the IEEE Engineering in Medicine and Biology Society, November 1, 1998, Vol. 2, pp. 563-566.	☐
	164	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); I. The D.P. Concept and Implementation of Transparent Silicone Resin (Orthocon)," Nippon Dental Review, 452:61-74 (June 1980).	☐
	165	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); II. The D.P. Manufacturing Procedure and Clinical Applications," Nippon Dental Review, 454:107-130 (August 1980).	☐
	166	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); III. The General Concept of the D.P. Method and Its Therapeutic Effect, Part 1, Dental and Functional Reversed Occlusion Case Reports," Nippon Dental Review, 457:146-164 (November 1980).	☐
	167	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); III.- The General Concept of the D.P. Method and Its Therapeutic Effect, Part 2. Skeletal Reversed Occlusion Case Reports," Nippon Dental Review, 458:112-129 (December 1980).	☐
	168	You May Be A Candidate For This Invisible No-Braces Treatment," Allesee Orthodontic Appliances-Pro Lab product information for patients, 2 pages (2002).	☐
	169	You May Be A Candidate For This Invisible No-Braces Treatment," Allesee Orthodontic Appliances-Pro Lab product information for patients, 2 pages (NO DATE GIVEN).	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 31 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Charles Hagadorn/	Date (YYYY-MM-DD)	2017-03-31
Name/Print	Charles Hagadorn	Registration Number	62,367

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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.**

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.

Electronic Acknowledgement Receipt

EFS ID:	28807271
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	John K. Shimmick/Tony Zhang
Filer Authorized By:	John K. Shimmick
Attorney Docket Number:	22773-826.401
Receipt Date:	31-MAR-2017
Filing Date:	
Time Stamp:	20:28:19
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		IDS22773-826-401-03-31-2017.pdf	631832 93dd5effcb39b66020fcb30303e01a6f769bdd8a	yes	36

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	4
	Information Disclosure Statement (IDS) Form (SB08)	5	36
Warnings:			
Information:			
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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.

New Applications Under 35 U.S.C. 111
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.

National Stage of an International Application under 35 U.S.C. 371
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.

New International Application Filed with the USPTO as a Receiving Office
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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	Not assigned yet
Serial Number:	15/476,655	Examiner:	Not assigned yet
Filing or 371 (c) Date:	2017-03-31	**CONFIRMATION NO:**	**5936**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: March 31, 2017

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☒ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☒ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☐ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☐ a fee of $180.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* 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 or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.

-- AND/OR --

☐ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☐ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☒ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☒ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: 13/470,681.

Information Disclosure Statement(s) filed on: 11-22-2016 and 08-02-2012.

AND

☒ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22773-826.401).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: March 31, 2017

By: /Charles Hagadorn/
Charles Hagadorn
Reg. No. 62,367

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 107046

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on April 3, 2017

WILSON SONSINI GOODRICH & ROSATI

By: /Kevin J. Chance/

Attorney Docket No.: 22773-826.401
Client Ref. No.: 1228.US.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5936
Chunhua Li et al.	
Application No.: 15/476,655	Examiner: Not Yet Assigned
Filed: March 31, 2017	Art Unit: 3732
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	SECOND PRELIMINARY AMENDMENT
Customer No. 107046	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Prior to examination on the merits of the above-referenced application, please enter the following amendments and remarks:

Amendments to the Abstract begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks begin on page 6 of this paper.

ClearCorrect Exhibit 1011, Page 89 of 890

Electronic Acknowledgement Receipt	
EFS ID:	28819843
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Charles C. Hagadorn III/Kevin Chance
Filer Authorized By:	Charles C. Hagadorn III
Attorney Docket Number:	22773-826.401
Receipt Date:	03-APR-2017
Filing Date:	
Time Stamp:	18:04:22
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		22773-826-401_PAM.pdf	37085 aec26d6e402ce67ab1ca8ab9538fc7d40aabfcc4	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	6	6
	Claims	3	5
	Abstract	2	2
	Preliminary Amendment	1	1
Warnings:			
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<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.

REMARKS

Claim 30 is newly added. Claim 25 has been amended. Support for the new claim and amendment can be found throughout the originally filed application. Additionally, Applicants have amended the abstract to more accurately reflect the subject matter of the application. No new matter has been added by way of this amendment. Please enter this amendment prior to substantive examination.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Applicants believe no fee is due with this response. However, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 23-2415.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-883-2500.

Respectfully submitted,

Dated: April 3, 2017

/Charles Hagadorn, III/

Charles Hagadorn, III
Reg. No. 62,367

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
Phone 650-493-9300
Fax 650-493-6811

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1.-19. (Canceled)

20. (Original) A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer;

providing a positive model of the patient's teeth in a target position; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. (Original) The method of claim 20, wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. (Original) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

23. (Original) The method of claim 20, wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. (Original) The method of claim 20, wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. (Currently Amended) The method of claim 1, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 ~~pounds~~ psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet environment ~~greater than about 10%~~, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. (Original) The method of claim 20, wherein the first soft polymer layer and the second soft polymer layer each independently comprise at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200 %, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

27. (Original) The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

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28. (Original) The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. (Original) The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer.

30. (New) The method of claim 20, wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers.

Amendments to the Abstract:

Please replace the Abstract with the following:

A dental appliance for positioning a patient's teeth includes a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth. The appliance includes a hard polymer layer having a hard polymer layer elastic modulus disposed between a first soft polymer layer having a first soft polymer layer elastic modulus and a second soft polymer layer having a second soft polymer layer elastic modulus. The hard polymer layer elastic modulus is greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus. At least one of the first soft polymer layer and the second soft polymer layer has a flexural modulus of greater than about 35,000 psi.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/476,655	Filing Date 03/31/2017	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) 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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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

AMENDMENT	03/31/2017	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0	X $420 =	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

AMENDMENT	04/03/2017	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 11	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0	X $420 =	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

* 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 number found in the appropriate box in column 1.

LIE
DIANE FLOYD

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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/476,655	03/31/2017	3732	1740	22773-826.401	11	1

CONFIRMATION NO. 5936

107046
WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

FILING RECEIPT

OC000000090539026

Date Mailed: 04/12/2017

Receipt is acknowledged of this non-provisional 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 APPLICANT, 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 Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections 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**

Inventor(s)

Chunhua LI, Cupertino, CA;
Yan CHEN, Cupertino, CA;
Heinz PUDLEINER, Krefeld, GERMANY;
Klaus MEYER, Dormagen, GERMANY;
Joerg NICKEL, Dormagen, GERMANY;
Craig PEHLERT, Lenox, MA;

Applicant(s)

ALIGN TECHNOLOGY, INC., San Jose, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a DIV of 13/470,681 05/14/2012

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: 04/11/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/476,655**

Projected Publication Date: 07/20/2017

Non-Publication Request: No

Early Publication Request: No

Title

MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

Preliminary Class

433

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).

ClearCorrect Exhibit 1011, Page 99 of 890

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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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.

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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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/476,655

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	11 minus 20 =	*			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 420 =	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	1600

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	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".
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/476,655	03/31/2017	Chunhua LI	22773-826.401

CONFIRMATION NO. 5936

107046
WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

INFORMAL NOTICE

OC000000090539027

Date Mailed: 04/12/2017

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):
  Chunhua LI
  Yan CHEN
  Heinz PUDLEINER
  Klaus MEYER
  Joerg NICKEL
  Craig PEHLERT

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**.

/thaile/

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on May 3, 2017.

WILSON SONSINI GOODRICH & ROSATI

By: /Kevin J. Chance/

Attorney Docket No.: 22773-826.401

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5936
Chunhua Li et al.	
Application No.: 15/476,655	Examiner: Not Yet Assigned
Filed: March 31, 2017	Art Unit: 3732
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	RESPONSE TO INFORMATIONAL NOTICE TO APPLICANT
Customer No. 107046	

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to the Notice to Applicant, dated April 12, 2017, enclosed are the following to be made of record in the above-identified application:

1) Executed Declaration of Chunhua LI
2) Executed Declaration of Yan CHEN
3) Executed Declaration of Heinz PUDLEINER
4) Executed Declaration of Klaus MEYER
5) Executed Declaration of Joerg NICKEL
6) Executed Declaration of Craig PEHLERT

Although Applicant believes no fee is due, the Commissioner is hereby authorized to charge any fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 23-2415.

Respectfully submitted,

Dated: May 3, 2017

/Charles Hagadorn, III/

Charles Hagadorn, III
Registration No. 62,367

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
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PTO/AIA/01 (06-12)
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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	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

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 15/476,655 filed on March 31, 2017.

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.

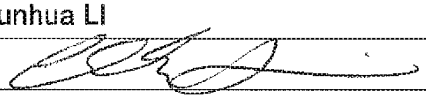
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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 INVENTOR

Inventor: Chunhua LI Date (Optional): 4/18/17

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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PTO/AIA/01 (06-12)
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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	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

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 15/476,655 filed on March 31, 2017.

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 INVENTOR

Inventor: Yan CHEN Date (Optional) :

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.

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LEGAL NAME OF INVENTOR

Inventor: Heinz PUDLEINER Date (Optional): 11.04.2017

Signature: H. Pudleiner

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.

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LEGAL NAME OF INVENTOR

Inventor: Klaus MEYER Date (Optional): April 11, 2017

Signature: Klaus Meyer

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.

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LEGAL NAME OF INVENTOR

Inventor: Joerg NICKEL Date (Optional): April 11, 2017

Signature: Joerg Nickel

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.

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LEGAL NAME OF INVENTOR

Inventor: Craig PEHLERT Date (Optional) :

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.

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Electronic Acknowledgement Receipt	
EFS ID:	29106938
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Charles C. Hagadorn III/Kevin Chance
Filer Authorized By:	Charles C. Hagadorn III
Attorney Docket Number:	22773-826.401
Receipt Date:	03-MAY-2017
Filing Date:	31-MAR-2017
Time Stamp:	15:59:34
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	Applicant Response to Pre-Exam Formalities Notice	22773-826-401_RespInfNotice.pdf	19513 b9416c17beffabd2fdccea4c7cf6c93931d3a68a	no	2

Warnings:

Information:					
2	Oath or Declaration filed	22773-826-401_Declarations_for_filing.PDF	1954600 f4ca37340de44ee82305ecaece7807da29cc0848	no	6
Warnings:					
Information:					
			Total Files Size (in bytes):	1974113	

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

PTO/AIA/80 (07-12)
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U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

☒ Practitioners associated with Customer Number: 107046

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☒ The address associated with Customer Number: 107046

OR

☐

Firm or Individual Name			
Address			
City			
Country			
Telephone		Email	

Assignee
ALIGN TECHNOLOGY, INC.
2560 Orchard Parkway
San Jose, CA 95131

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record
The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	5-9-13
Name	Roger E. George	Telephone	408-470-1000
Title	Vice President, Legal Affairs and General Counsel		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 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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Electronic Acknowledgement Receipt	
EFS ID:	29323807
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Charles C. Hagadorn III/Kevin Chance
Filer Authorized By:	Charles C. Hagadorn III
Attorney Docket Number:	22773-826.401
Receipt Date:	26-MAY-2017
Filing Date:	31-MAR-2017
Time Stamp:	12:18:47
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	Assignee showing of ownership per 37 CFR 3.73	22773-826-401_373cStatement.PDF	122827 5d925507371d1fa427f8cc4e6d09afe31ca656f9	no	3

Warnings:

Information:					
2	Power of Attorney	Align-POA.PDF	298295 9d0162de3f35dc7fa801a0448b9a097ffd3e1446	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	421122	

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PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: ALIGN TECHNOLOGY, INC.

Application No./Patent No.: 15/476,655 Filed/Issue Date: March 31, 2017

Titled: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

ALIGN TECHNOLOGY, INC., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: CHUNHUA LI AND YAN CHEN To: ALIGN TECHNOLOGY, INC.

   The document was recorded in the United States Patent and Trademark Office at

   Reel 042066, Frame 0076, or for which a copy thereof is attached.

2. From: CRAIG PEHLERT To: COVESTRO LLC

   The document was recorded in the United States Patent and Trademark Office at

   Reel 042066, Frame 0435, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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 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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STATEMENT UNDER 37 CFR 3.73(c)

3. From: DR. HEINZ PUDLEINER, KLAUS MEYER, AND JOERG NICKEL To: COVESTRO DEUTSCHLAND AKTIENGESELLSCHAFT

The document was recorded in the United States Patent and Trademark Office at
Reel 042066, Frame 0245, or for which a copy thereof is attached.

4. From: COVESTRO DEUTSCHLAND AKTIENGESELLSCHAFT AND COVESTRO LLC To: ALIGN TECHNOLOGY, INC.

The document was recorded in the United States Patent and Trademark Office at
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5. From: _____ To: _____

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6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Charles Hagadorn, III/	May 26, 2017
Signature	Date
Charles Hagadorn, III	62,367
Printed or Typed Name	Title or Registration 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.

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/476,655	03/31/2017	Chunhua LI	22773-826.401

CONFIRMATION NO. 5936

107046
WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

POA ACCEPTANCE LETTER

OC000000091724963

Date Mailed: 05/31/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/26/2017.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

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**.

/dgela/

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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15/476,655	03/31/2017	Chunhua LI	22773-826.401

CONFIRMATION NO. 5936

107046
WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

PUBLICATION NOTICE

OC000000092907996

Title:MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

Publication No.US-2017-0202641-A1
Publication Date:07/20/2017

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 Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6667101	12-23-2003	SILAGY; David [Fr] et al.	
	002	US-9655691	05-23-2017	LI; Chunhua [Us] et al.	
	003	US-9655693	05-23-2017	LI; Chunhua et al.	
	004	US-10052176	08-21-2018	LI; Chunhua [Us] et al.	
	005	US-20080230938	09-25-2008	GREFENSTEIN; Achim [De] et al.	
	006	US-20090130438	05-21-2009	NASSI; Aldo [It] et al.	
	007	US-20170007362	01-12-2017	CHEN; Yan [Us] et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	JP-2011079284-A	04-21-2011	NIPPON KARARINGU KK.		☒
	002	JP-H08508174-A	09-03-1996	ORMCO CORP.		☒
	003	RU-2008137623-A	03-27-2010	SYROM 90		☒
	004	RU-2201944-C2	04-10-2003	ATOFINA [FR]		☒

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 5

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	005	WO-2004041898-A1	05-21-2004	NOVEON IP HOLDINGS CORP [US]		☐
	006	WO-2006096558-A2	09-14-2006	ORTHOCLEAR HOLDINGS INC., et al.		☐
	007	WO-2010074789-A1	07-01-2010	DOW GLOBAL TECHNOLOGIES INC [US], et al.		☐
	008	WO-9711106-A1	03-27-1997	EASTMAN CHEM CO [US]		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 5

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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.	T[2]
	001	Co-pending US patent application No. US16/043,065, filed on 07-23-2018.	☐
	002	Co-pending US patent application No. US16/264,420, filed on 01-31-2019.	☐
	003	International search report with written opinion dated 06/28/2013 for PCT/EP2013/059701.	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 5

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Timothy R. Welch/	Date (YYYY-MM-DD)	2019-03-11
Name/Print	Timothy R. Welch	Registration Number	74838

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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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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.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	1748
Serial Number:	15/476,655	Examiner:	MONTIEL, CAROLINE
Filing or 371 (c) Date:	2017-03-31	**CONFIRMATION NO:**	**5936**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: March 12, 2019

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☒ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☒ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☐ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☐ a fee of $240.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $240.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* 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 or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☒ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22773-826.401).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: March 11, 2019

By: /Timothy R. Welch/
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
BMS121016WO1		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP2013/059701	10/05/2013	14/05/2012
Applicant		
BAYER MATERIALSCIENCE AG		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. _____
      [ ] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

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

"E" earlier application or patent but published on or after the international filing date

"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	Date of mailing of the international search report
19 June 2013	28/06/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lohner, Pierre

2

Form PCT/ISA/210 (second sheet) (April 2005)

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
		JP 4642745 B2	02-03-2011
		JP 2006515792 A	08-06-2006
		US 2004146670 A1	29-07-2004
		US 2005266109 A1	01-12-2005
		US 2008145469 A1	19-06-2008
		US 2010203181 A1	12-08-2010
		WO 2004069320 A1	19-08-2004
DE 102010009230 A1	25-08-2011	CN 102770271 A	07-11-2012
		DE 102010009230 A1	25-08-2011
		EP 2539147 A1	02-01-2013
		US 2012315484 A1	13-12-2012
		WO 2011104014 A1	01-09-2011
DE 102004014023 A1	20-10-2005	AT 439234 T	15-08-2009
		DE 102004014023 A1	20-10-2005
		EP 1577084 A1	21-09-2005

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2013/059701	10.05.2013	14.05.2012

International Patent Classification (IPC) or both national classification and IPC
INV. C08J5/18 C08L67/02 C08L69/00 C08L75/08 B32B27/36

Applicant
BAYER MATERIALSCIENCE AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Lohner, Pierre Telephone No. +49 89 2399-8622

Form PCT/ISA/237 (Cover Sheet) (July 2009)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-11
	No:	Claims	1, 2, 12-18
Inventive step (IS)	Yes:	Claims	3-11
	No:	Claims	1, 2, 12-18
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations

see separate sheet

Novelty (Article 33(2) PCT)

D1 (US2004/146670, examples 14-17) discloses a seven- or eight-layer tube formed by alternatively co-extruding "Melinar 5922C PET", corresponding to the polyester having a Tg of 80-200°C of the present application, and a blend comprising "Hytrel 7246", corresponding to the polyester having a Shore D hardness of 45-85.

The subject-matter of present claims 1, 2 and 12-18 is therefore not novel.

Bibliographic data

Title:	MULTILAYER HINGE SHEET, LASER-MARKING LAMINATE FOR ELECTRONIC PASSPORT, AND THE ELECTRONIC PASSPORT
Pub/Pat no:	JP2011079284A
Pub/Issue Date:	2011-04-21
Inventor(s):	SAKAGAMI TOSHIKI| WATANABE TAKASHI| SUEISHI HIROKI| HASHIMOTO AKIRA| INOUE HIRONORI|SAKAGAMI TOSHIKI |WATANABE TAKASHI |SUEISHI HIROKI |HASHIMOTO AKIRA |INOUE HIRONORI
Applicant(s):	NIPPON KARARINGU KK
Classification:	B32B7/02AI; B29C47/06AI; B42D15/10AI; C08J7/00AI; B29K69/00AN; B29L9/00AN
Application number:	JP20090235751 2009-10-09
Priority number:	JP20090235751 2009-10-09;

Abstract of JP2011079284A

PROBLEM TO BE SOLVED: To provide a multilayer hinge sheet which is excellent in tear/tensile strength and the bound part of which has light resistance and heat resistance and further exhibits excellent resistibility to repeated bending. ;SOLUTION: The multilayer hinge sheet C is obtained by layering a thermoplastic resin sheet P (a mark 3) having flexibility and heat weldability on another thermoplastic resin sheet R (a mark 5) having heat resistance and rigidity. The thermoplastic resin sheet P is formed of a thermoplastic resin X including the thermoplastic elastomer having 85 Shore A hardness and <70 Shore D hardness. The thermoplastic resin sheet R is formed of another thermoplastic resin Y having 1 GPa tensile modulus of elasticity measured according to ASTM D882, and 70°C glass transition temperature measured by a DSC method. ;COPYRIGHT: (C)2011,JPO&INPIT

(19)日本国特許庁(JP)　(12)公開特許公報(A)　(11)特許出願公開番号
特開2011-79284
(P2011-79284A)
(43)公開日　平成23年4月21日(2011.4.21)

(51)Int.Cl.		F I			テーマコード（参考）
B32B 7/02	(2006.01)	B32B	7/02	101	2C005
C08J 7/00	(2006.01)	C08J	7/00	302	4F073
B29C 47/06	(2006.01)	C08J	7/00	CER	4F100
B42D 15/10	(2006.01)	C08J	7/00	CEZ	4F207
B29K 69/00	(2006.01)	B32B	7/02	105	

審査請求 未請求　請求項の数 13　ＯＬ　（全 55 頁）　最終頁に続く

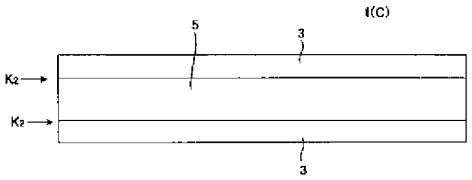
(21)出願番号　特願2009-235751 (P2009-235751)
(22)出願日　平成21年10月9日 (2009.10.9)

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弁理士　永岡　儀雄

最終頁に続く

(54)【発明の名称】積層ヒンジシート及び電子パスポート用レーザーマーキング積層体及び電子パスポート

(57)【要約】
【課題】引裂、引張強度に優れ、かつ、この綴じ部の耐光、耐熱性を有し、更には、繰り返し曲げに対する抵抗性に優れた積層ヒンジシートを提供する。
【解決手段】柔軟性と加熱融着性を有する熱可塑性樹脂シートＰ（符号３）と、耐熱性と剛性を有する熱可塑性樹脂シートＲ（符号５）とが積層された積層ヒンジシートであって、熱可塑性樹脂シートＰは、硬度ショアＡが８５以上、ショアＤが７０未満である熱可塑性エラストマーを含む熱可塑性樹脂Ｘを原料とするシートであり、熱可塑性樹脂シートＲは、ＡＳＴＭ　Ｄ８８２に準拠して測定した引張弾性率が１ＧＰａ以上、ＤＳＣ法によるガラス転移温度が７０℃以上である熱可塑性樹脂Ｙを原料とするシートである積層ヒンジシートＣ。
【選択図】図１



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【特許請求の範囲】
【請求項１】
柔軟性と加熱融着性を有する熱可塑性樹脂シートＰと、耐熱性と剛性を有する熱可塑性樹脂シートＲとが積層された積層ヒンジシートであって、
前記熱可塑性樹脂シートＰは、硬度ショアＡが８５以上、ショアＤが７０未満である熱可塑性エラストマーを含む熱可塑性樹脂Ｘを原料とするシートであり、
前記熱可塑性樹脂シートＲは、ＡＳＴＭ　Ｄ８８２に準拠して測定した引張弾性率が１ＧＰａ以上、ＤＳＣ法によるガラス転移温度が７０℃以上である熱可塑性樹脂Ｙを原料とするシートである積層ヒンジシートＣ。
【請求項２】
前記積層ヒンジシートが、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの３層を積層し、熱ラミネーションにより一体化させた請求項１に記載の積層ヒンジシートＣ。
【請求項３】
前記熱可塑性樹脂シートＰを外層とし、前記熱可塑性樹脂シートＲを内層とし、
前記熱可塑性樹脂シートＲの両面に前記熱可塑性樹脂シートＰの原料である前記熱可塑性樹脂Ｘが溶融押出成形により積層されて前記熱可塑性樹脂シートＰが形成されてなる請求項１に記載の積層ヒンジシートＣ。
【請求項４】
前記熱可塑性樹脂シートＰを外層とし、前記熱可塑性樹脂シートＲを内層として、２種３層共押出成形により積層された請求項１～３のいずれか１項に記載の積層ヒンジシートＣ。
【請求項５】
透明レーザーマーキングシートＡ／多層シートＢ／請求項１～４のいずれか１項に記載の積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層してなる電子パスポート用レーザーマーキング積層体であり、
前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなる単層シート、
又は、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層が、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、且つ、前記コア層が、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート１、
又は、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層が、ポリカーボネート樹脂を主成分とする透明樹脂からなり、且つ、前記コア層が、ポリカーボネート樹脂を主成分とする透明樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート２、として構成され、
前記多層シートＢは、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成される多層シートであって、
前記多層シートＢの両最外層である前記スキン層が、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなるとともに、

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前記多層シートＢのコア層が、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂からなり、
前記多層シートＢのスキン層及び／又はコア層には、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、着色剤の少なくとも１種以上を１質量部以上含有させてなり、
更に、前記多層シートＢの全厚さが１００～３００μｍであるとともに、前記コア層の厚さの、前記多層シートＢの全厚さに対して占める厚み比率が３０％以上、８５％未満である着色多層シートとして構成され、
前記積層ヒンジシートＣの厚さが８０～２５０μｍである電子パスポート用レーザーマーキング積層体。

【請求項６】
さらに、前記透明レーザーマーキングシートＡの、前記単層シートが、透明熱可塑性樹脂１００質量部に対して、滑剤０．０１～３質量部を含有するとともに、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する透明レーザーマーキングシート、又は、前記透明レーザーマーキングシートＡの、多層シート２における前記スキン層が、前記透明熱可塑性樹脂１００質量部に対して、滑剤０．０１～３質量部を含有するとともに、レーザー光エネルギー吸収材を０．０００５～１質量部、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する透明レーザーマーキングシートとして構成されている請求項５に記載の電子パスポート用レーザーマーキング積層体。

【請求項７】
前記透明レーザーマーキングシートＡのレーザー光エネルギー吸収材が、カーボンブラック、チタンブラック、及び金属酸化物からなる群より選択される少なくとも１種または２種以上を含有してなる請求項５又は６に記載の電子パスポート用レーザーマーキング積層体。

【請求項８】
前記多層シートＢのコア層及び／又はスキン層が熱可塑性樹脂１００質量部に対して、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する請求項５～７のいずれか１項に記載の電子パスポート用レーザーマーキング積層体。

【請求項９】
前記積層ヒンジシートＣの一端が前記透明レーザーマーキングシートＡ及び前記多層シートＢよりも５～１００ｍｍ長い張り出し部を有する請求項５～８のいずれか１項に記載の電子パスポート用レーザーマーキング積層体。

【請求項１０】
前記透明レーザーマーキングシートＡ、及び／又は多層シートＢの表面には平均粗さ（Ｒａ）０．１～５μｍのマット加工が施されている請求項５～９のいずれか１項に記載の電子パスポート用レーザーマーキング積層体。

【請求項１１】
さらに、偽造防止形成部が形成されている請求項５～１０のいずれか１項に記載の電子パスポート用レーザーマーキング積層体。

【請求項１２】
請求項９～１１のいずれか１項に記載の電子パスポート用レーザーマーキング積層体を使用して成形される電子パスポートであって、前記積層ヒンジシートＣの張り出し部が、電子パスポートの表紙または裏表紙にミシン綴じ及び／または接着してなる電子パスポート。

【請求項１３】
請求項５～１１のいずれか１項に記載の電子パスポート用レーザーマーキング積層体又は請求項１２に記載の電子パスポートに、レーザーマーキングする方法であって、
前記電子パスポート用レーザーマーキング積層体に積層した透明レーザーマーキングシ

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ートＡ側からレーザー光線を照射して印字する、レーザーマーキング方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、電子パスポートに用いられる積層ヒンジシート、積層ヒンジシートを用いた電子パスポート用レーザーマーキング積層体、及び電子パスポートに関する。とりわけ、加熱融着性、耐久性、折り曲げ性、加工性に優れた積層ヒンジシート、及びレーザー光線照射により多層シートに損傷なくマーキングされ、かつ、生地色と印字部とのコントラストが高く、鮮明な文字、記号、画像が得られ、耐熱性及び生産性にも優れた電子パスポート用レーザーマーキング積層体、及び電子パスポート用レーザーマーキング積層体を用いた電子パスポートに関するものである。
【背景技術】
【０００２】
国際交流が進展する中で、人材の移動も活発化している昨今、個人を特定し身元を証明する手段として、個人情報を記録したパスポートの重要性が高まっている。とくに、パスポートは、公的機関でもあり信頼性を有する国が発行するいわゆる身分証（身元照明証等）としての役割を果たすようになっている。
【０００３】
とりわけ、２００１年９月　世界同時多発テロ事件以降、各国の入出国管理を厳しくするために国連の専門機関　ＩＣＡＯ（Ｉｎｔｅｒｎａｔｉｏｎａｌ　Ｃｉｖｉｌ　Ａｖｉａｔｉｏｎ　Ｏｒｇａｎｉｚａｔｉｏｎ）が標準規格を制定して電子パスポート導入の取り組みが開始された。この取り組みの中で偽造防止が重要であり、そのために個人名、記号、文字、写真などをレーザーマーキングする技術が注目されてきている。
【０００４】
ところで、この電子パスポートは、個人を特定し証明し得るものであるから、国（或いは国の代行機関）以外の第三者が、個人情報の改竄や偽造等を容易に行えるものであれば、身分証への信頼性は落ち、国際交流の進展や人材の世界規模での移動に支障を与えることになりかねない。
【０００５】
そこで、前述の電子パスポートでは、如何に改竄や偽造を防止するかが重要な問題となっている。また、電子パスポートは、軽薄短小な規格からなるものであるため、個人名、記号、文字、写真等を、如何にコントラストが高く、鮮明に表示できるかは重要となり、さらに、コントラストが高く、鮮明な表示を実現できるかは、改竄や偽造等の未然防止にも繋がるため、市場の期待も大きい。
【０００６】
また、改竄や偽造等に加えて、電子パスポートは世界の至る所に携帯するものであり、耐久性が求められる。特にヒンジシートを介して、個人を特定し得るデータを電子パスポートに取り付けることが多いことから、ヒンジシートが損傷し難い耐久性を備えること、すなわち、ヒンジシートが電子パスポート本体より引きちぎれる等のダメージを未然に防ぐような耐久性を備えさせることが求められる。このような耐久性を備えさせることによって、発行者である公的機関等を除いた第三者が、ヒンジシート等を意図的に（故意に）別のものに交換する等といった改竄や偽造を確実に防ぐことできるため、早急の対応が求められている。
【０００７】
このような問題に対して、個人名、記号、文字、写真などをレーザーマーキングする技術、具体的にはレーザーマーキング用積層体が注目されており、たとえば、以下の特許文献１、２がある。
【０００８】
特許文献１では、外観の損傷がなく、コントラストが良好で、表面平滑性の優れたレーザーマーキングできる多層シートを得ることを目的に、少なくとも表層及び内層からなる

多層シートであって、（Ａ）透明の熱可塑性樹脂からなる表層と、（Ｂ）（ｂ－１）熱可塑性樹脂１００重量部に対し、（ｂ－２）レーザー光線を吸収するエネルギー吸収体０．０１～５重量部および（ｂ－３）着色剤０．５～７重量部を含有する熱可塑性樹脂組成物からなる内層とを、溶融共押し出しにて形成したレーザーマーキング用多層シートが開示されている。

【０００９】

特許文献２では、外観の損傷がなく、コントラストが良好で、表面平滑性の優れたレーザーマーキングでき、耐熱性の優れた多層シートを得ることを目的に、第一の表層／内層／第二の表層からなる多層シートであって、（Ａ）透明の熱可塑性樹脂１００重量部に対し、雲母及び／又はカーボンブラックを０．００１～５重量部を含有する熱可塑性樹脂組成物からなる透明な第一及び第二の表層と、（Ｂ）熱可塑性樹脂１００重量部に対し、レーザー光線を吸収するエネルギー吸収体０．００１～３重量部を含有する熱可塑性樹脂組成物からなる内層とから形成され、第一の表層／内層／第二の表層のシートの厚み構成比が１：４：１～１：１０：１であり、第一の表層／内層／第二の表層を、溶融共押し出しにて形成されたレーザーマーキング用多層シートが開示されている。

【００１０】

さらに、ヒンジシートが、情報ページを他のページ等と表紙に綴じこむためのシートとして開示された、たとえば、以下の特許文献３～８がある。

【００１１】

また、特許文献３では、印刷物シート等を糸綴じする際に綴じ代を設けて綴じる技術が開示されている。また、特許文献４では、透明層／着色層／透明層からなる情報ページを綴じる際に、透明層／着色層／透明層の両外層である透明層を張り出させて絞込み、この部分を綴じ代とする技術が開示されている。また、特許文献５では、フェイスフィルムとバックフィルムを絞り込み、その絞り込んだ部分を綴じ代とする技術が開示されている。

【００１２】

また、特許文献６では、プラスチックシートからなるプラスチックインレイを包むカバーフォイルからなる情報ページを他のページと共に綴じこむ技術が開示されている。また、特許文献７では、数枚の紙のシートを表紙に綴じる技術が開示されている。

【００１３】

また、特許文献８では、積層体の中央部に綴じるためのシート、すなわちヒンジシートを設ける技術が開示されている。

【先行技術文献】

【特許文献】

【００１４】

【特許文献１】特開２００２－２７３８３２号公報
【特許文献２】特許第３８８９４３１号公報
【特許文献３】特開平０９－１２３６３６号公報
【特許文献４】国際公開第９８／１９８７０号パンフレット
【特許文献５】特開２００１－２１３０７２号公報
【特許文献６】米国特許第００６１３５５０３Ａ号明細書
【特許文献７】特開２０００－２０３１７４号公報
【特許文献８】欧州特許第１５９２５６５Ｂ１号明細書

【発明の概要】

【発明が解決しようとする課題】

【００１５】

確かに、特許文献１、２におけるレーザーマーキング用多層シートでは、これらの多層シート同士や例えば、ＰＥＴＧシートやＡＢＳ樹脂シート等の熱可塑性樹脂シートとの加熱融着性に優れ、レーザー光照射によるレーザーマーキングにより文字、数字を印字するには充分な印字性が得られ、評価に値するものである。しかし、特許文献１では内層に着色剤０．５～７重量部を含有しており、前述のような個人情報を記録したパスポートのよ

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うな、いわゆる身分証では中間層であるインレイ層に印刷をする場合が一般的である。その場合には、最外層（オーバーレイ）に該多層シートを用いると、着色剤含有の影響で透明性が充分でない。そのため、印刷部分の画像鮮明性が阻害されるという問題があった。特許文献２の多層シートでは表層にもレーザー光吸収剤である雲母及び／又はカーボンブラックが含有されているため、前述のような個人情報を記録したパスポートのような、いわゆる身分証の最外層（オーバーレイ）に該多層シートを用いると、レーザー光照射により、表層に含有されているレーザー光吸収剤がレーザー光エネルギーを吸収して発泡等の現象が生じるため、表面の平滑性が低下する等の問題があった。

【００１６】

さらに、特許文献３では、積層体を他のシートと共に綴じる技術は開示されていない。また、特許文献４では、透明層／着色層／透明層の厚みと綴じ代部の厚みが異なるために、この様な積層体を大量に安定的に生産するのが困難である。また、特許文献５では、この技術についても、その製造方法に上記同様の問題があり、この様な積層体を大量に安定的に生産するのが困難である。また、特許文献６では、情報ページ部からカバーフォイルを複数枚張り出させて絞込み綴じ部とするために、上記同様の問題点がある。また、特許文献７では、数枚の紙のシートを合成樹脂のバンドで表紙に取り付けるものであり、綴じ部が厚くなり、製本した際に開いてくる問題があり、パスポートの様に大量に製本するには適さない。

【００１７】

さらに、特許文献８では、他と接続するためのシートが積層体の中央部ではあるが部分挿入しかされておらず、これでは積層体を加熱積層時に接続するためのシートが挿入された部分とそうでない部分とで厚み差が生じ、言い換えると、接続するためのシートが挿入された部分はそうでない部分より盛り上がる事になり、これが原因で製本されたパスポートが開いてくる事や、製本されたパスポートを複数冊立てた際に扇型となるために、それを１冊ずつ次工程である印字工程に送る際に送れない問題が生じてくる。更に、接合部のシート材料の記載としては一般的に層構造であり表層がＰＥ、コア層がＰＥＴと記載されているが、情報ページのシート材料がＰＣと記載されている事から、ＰＣシートと接合部の表層ＰＥとは加熱接着しないため、何らかの接着剤を必要とするが、それについては特に記載がなく、表紙等と高温活性接着剤を用いて接着する旨の記載のみである。従って、当該開示技術では、何らかの接着剤を接合部のシート材料の両面の表面に予め塗布しておく等の方法が必要であり、生産工程上煩雑である上に、この部分の接着強度についての記載がなく、開示技術としては不明である。

【００１８】

このように、いずれの特許文献においても、十分な問題解決には至っておらず、早期の改良が求められている。

【００１９】

本発明は上記問題点を解決すべくなされたものであり、加熱融着性、及び、電子パスポート用レーザーマーキング積層体の寸法精度に優れ、かつ表紙等と綴じて製本後に柔軟で繰り返し曲げに対する抵抗性に優れ、加えて、綴じ部の引裂、引張強度に優れ、実際の使用時における耐光劣化性等の経時安定性に優れた積層ヒンジシートを提供できる。とりわけ、複層構造の電子パスポート用レーザーマーキング積層体に好適に用いることができる。

【００２０】

また、レーザーマーキング性に優れ、かつ、生地色と印字部とのコントラストが高く、鮮明な文字、記号、画像が得られるとともに、多層シートの積層工程における加熱融着性に優れ、更には、全光線透過率の点からの透明性の向上、シートの搬送性、熱プレス後の金型からの離型性、耐熱性、折り曲げ性、耐摩耗性を兼ね揃えた電子パスポート用レーザーマーキング積層体を提供することにある。さらに、そのような電子パスポート用レーザーマーキング積層体を使用した電子パスポートを提供する。とりわけ、改竄防止、偽造防止に優れている。

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【００２１】
さらに、前述の電子パスポート用レーザーマーキング積層体を使用して電子パスポートを製造するに際し、ミシン掛け等の簡単な製造工程にて電子パスポート表紙または裏表紙に綴じるために、電子パスポート用レーザーマーキング積層体の中心部に強度性、柔軟性及び透明性を有するラミフィルムを用いた積層構造を有する電子パスポート用レーザーマーキング積層体、及び電子パスポート用レーザーマーキング積層体を用いた電子パスポートの製造方法を提供することにある。
【課題を解決するための手段】
【００２２】
本発明により、以下の積層ヒンジシート及び電子パスポート用レーザーマーキング積層体及び電子パスポートが提供される。
【００２３】
［１］　柔軟性と加熱融着性を有する熱可塑性樹脂シートＰと、耐熱性と剛性を有する熱可塑性樹脂シートＲとが積層された積層ヒンジシートであって、前記熱可塑性樹脂シートＰは、硬度ショアＡが８５以上、ショアＤが７０未満である熱可塑性エラストマーを含む熱可塑性樹脂Ｘを原料とするシートであり、前記熱可塑性樹脂シートＲは、ＡＳＴＭ　Ｄ８８２に準拠して測定した引張弾性率が１ＧＰａ以上、ＤＳＣ法によるガラス転移温度が７０℃以上である熱可塑性樹脂Ｙを原料とするシートである積層ヒンジシートＣ。
【００２４】
［２］　前記積層ヒンジシートが、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの３層を積層し、熱ラミネーションにより一体化させた［１］に記載の積層ヒンジシートＣ。
【００２５】
［３］　前記熱可塑性樹脂シートＰを外層とし、前記熱可塑性樹脂シートＲを内層とし、前記熱可塑性樹脂シートＲの両面に前記熱可塑性樹脂シートＰの原料である前記熱可塑性樹脂Ｘが溶融押出成形により積層されて前記熱可塑性樹脂シートＰが形成されてなる［１］に記載の積層ヒンジシートＣ。
【００２６】
［４］　前記熱可塑性樹脂シートＰを外層とし、前記熱可塑性樹脂シートＲを内層として、２種３層共押出成形により積層された［１］～［３］のいずれかに記載の積層ヒンジシートＣ。
【００２７】
［５］　透明レーザーマーキングシートＡ／多層シートＢ／［１］～［４］のいずれかに記載の積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層してなる電子パスポート用レーザーマーキング積層体であり、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなる単層シート、又は、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層が、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、且つ、前記コア層が、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート１、又は、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層が、ポリカーボネート樹脂を主成分とする透明樹脂からなり、且つ、前記コア層が、ポリカーボネート樹脂を主成分とする透明樹脂１００

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質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート２、として構成され、前記多層シートＢは、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成される多層シートであって、前記多層シートＢの両最外層である前記スキン層が、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなるとともに、前記多層シートＢのコア層が、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂からなり、前記多層シートＢのスキン層及び／又はコア層には、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、着色剤の少なくとも１種以上を１質量部以上含有させてなり、更に、前記多層シートＢの全厚さが１００～３００μｍであるとともに、前記コア層の厚さの、前記多層シートＢの全厚さに対して占める厚み比率が３０％以上、８５％未満である着色多層シートとして構成され、前記積層ヒンジシートＣの厚さが８０～２５０μｍである電子パスポート用レーザーマーキング積層体。

【００２８】

［６］　さらに、前記透明レーザーマーキングシートＡの、前記単層シートが、透明熱可塑性樹脂１００質量部に対して、滑剤０．０１～３質量部を含有するとともに、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する透明レーザーマーキングシート、又は、前記透明レーザーマーキングシートＡの、多層シート２における前記スキン層が、前記透明熱可塑性樹脂１００質量部に対して、滑剤０．０１～３質量部を含有するとともに、レーザー光エネルギー吸収材を０．０００５～１質量部、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する透明レーザーマーキングシートとして構成されている［５］に記載の電子パスポート用レーザーマーキング積層体。

【００２９】

［７］　前記透明レーザーマーキングシートＡのレーザー光エネルギー吸収材が、カーボンブラック、チタンブラック、及び金属酸化物からなる群より選択される少なくとも１種または２種以上を含有してなる［５］又は［６］に記載の電子パスポート用レーザーマーキング積層体。

【００３０】

［８］　前記多層シートＢのコア層及び／又はスキン層が熱可塑性樹脂１００質量部に対して、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する［５］～［７］のいずれかに記載の電子パスポート用レーザーマーキング積層体。

【００３１】

［９］　前記積層ヒンジシートＣの一端が前記透明レーザーマーキングシートＡ及び前記多層シートＢよりも５～１００ｍｍ長い張り出し部を有する［５］～［８］のいずれかに記載の電子パスポート用レーザーマーキング積層体。

【００３２】

［１０］　前記透明レーザーマーキングシートＡ、及び／又は多層シートＢの表面には平均粗さ（Ｒａ）０．１～５μｍのマット加工が施されている［５］～［９］のいずれかに記載の電子パスポート用レーザーマーキング積層体。

【００３３】

［１１］　さらに、偽造防止形成部が形成されている［５］～［１０］のいずれかに記載の電子パスポート用レーザーマーキング積層体。

【００３４】

［１２］　［９］～［１１］のいずれかに記載の電子パスポート用レーザーマーキング積層体を使用して成形される電子パスポートであって、前記積層ヒンジシートＣの張り出し部が、電子パスポートの表紙または裏表紙にミシン綴じ及び／または接着してなる電子パスポート。

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【００３５】
［１３］　［５］～［１１］のいずれかに記載の電子パスポート用レーザーマーキング積層体又は［１２］に記載の電子パスポートに、レーザーマーキングする方法であって、前記電子パスポート用レーザーマーキング積層体に積層した透明レーザーマーキングシートＡ側からレーザー光線を照射して印字する、レーザーマーキング方法。
【発明の効果】
【００３６】
本発明によれば、加熱融着性及び積層体の寸法精度に優れ、かつ表紙等と綴じて製本後に柔軟で繰り返し曲げに対する抵抗性に優れ、加えて、綴じ部の引裂、引張強度に優れ、実際の使用時における耐光劣化性等の経時安定性に優れた積層ヒンジシートを提供できるという優れた効果を奏する。とりわけ、複層構造の電子パスポート用レーザーマーキング積層体、及び電子パスポートに好適に用いることができる。
【００３７】
また、レーザーマーキング性に優れ、かつ、生地色と印字部とのコントラストが高く、鮮明な文字、記号、画像が得られるとともに、多層シートの積層工程における加熱融着性に優れ、更には、全光線透過率の点からの透明性の向上、シートの搬送性、熱プレス後の金型からの離型性、耐熱性、折り曲げ性、耐摩耗性を兼ね揃えた電子パスポート用レーザーマーキング積層体を提供できる。さらに、そのような電子パスポート用レーザーマーキング積層体を使用した電子パスポートを提供できるという優れた効果を奏する。とりわけ、改竄防止、偽造防止に優れている。
【００３８】
さらに、前述の電子パスポート用レーザーマーキング積層体を使用して電子パスポートを製造するに際し、ミシン掛け等の簡単な製造工程にて電子パスポート表紙または裏表紙に綴じるために、電子パスポート用レーザーマーキング積層体の中心部に強度性、柔軟性及び透明性を有するラミフィルムを用いた積層構造を有する電子パスポート用レーザーマーキング積層体、及び電子パスポート用レーザーマーキング積層体を用いた電子パスポートの製造方法を提供できるという優れた効果を奏する。
【図面の簡単な説明】
【００３９】
【図１】本発明の積層ヒンジシートの一実施形態を示す断面図であって、熱可塑性樹脂シートＰと熱可塑性樹脂シートＲを、シートＰ／シートＲ／シートＰの２種３層に積層させた状態を模式的に示した図である。
【図２Ａ】本発明の電子パスポート用レーザーマーキング積層体の一実施形態を示す模式図であって、透明レーザーマーキングシートＡが単層からなる透明レーザーマーキングシートであって、電子パスポート用レーザーマーキング積層体の断面を模式的に示した図である。
【図２Ｂ】本発明の電子パスポート用レーザーマーキング積層体の別の実施形態を示す模式図であって、透明レーザーマーキングシートＡが３層からなる透明レーザーマーキングシートであって、電子パスポート用レーザーマーキング積層体の断面を模式的に示した図である。
【図２Ｃ】本発明の電子パスポート用レーザーマーキング積層体の別の実施形態を示す模式図であって、透明レーザーマーキングシートＡが３層からなる透明レーザーマーキングシートであって、電子パスポート用レーザーマーキング積層体の断面を模式的に示した図である。
【図３】本発明の電子パスポート用レーザーマーキング積層体に張り出し部を設けた状態を断面で示すとともに、模式的に示した図である。
【図４】本発明の電子パスポート用レーザーマーキング積層体を、電子パスポートに使用する場合の一例を示す模式図である。
【図５Ａ】シートの柔軟性を測定する様子を模式的に示した側面図である。
【図５Ｂ】シートの柔軟性を測定する様子を模式的に示した側面図である。

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【図６】ミシン部強度を測定するための引張試験を模式的示す側面図である。
【発明を実施するための形態】
【００４０】
以下、本発明の積層ヒンジシート、電子パスポート用レーザーマーキング積層体、及び電子パスポートを実施するための形態について具体的に説明する。但し、本発明はその発明特定事項を備える積層ヒンジシート、電子パスポート用レーザーマーキング積層体、及び電子パスポートを広く包含するものであり、以下の実施形態に限定されるものではない。
【００４１】
［１］本発明の積層ヒンジシートの構成：
本発明の積層ヒンジシートは、図１に示されるように、柔軟性と加熱融着性を有する熱可塑性樹脂シートＰ（符号３）と、耐熱性と剛性を有する熱可塑性樹脂シートＲ（符号５）とが積層された積層ヒンジシートであって、熱可塑性樹脂シートＰは、硬度ショアＡが８５以上、ショアＤが７０未満である熱可塑性エラストマーを含む熱可塑性樹脂Ｘを原料とするシートであり、熱可塑性樹脂シートＲは、ＡＳＴＭ　Ｄ８８２に準拠して測定した引張弾性率が１ＧＰａ以上、ＤＳＣ法によるガラス転移温度が７０℃以上である熱可塑性樹脂Ｙを原料とするシートである積層ヒンジシートＣとして構成されている。
【００４２】
すなわち、本発明の積層ヒンジシートは、ヒンジシートを介して、個人を特定し得るデータ等を備えさせる（後述の）電子パスポート用レーザーマーキング積層体を電子パスポートに綴じやすくするために用いられる。以下、熱可塑性樹脂シートＰと、熱可塑性樹脂シートＲとを説明した後、夫々の関係について説明する。
【００４３】
［１－１］熱可塑性樹脂シートＰ：
熱可塑性樹脂シートＰは、柔軟性と加熱融着性を備える熱可塑性樹脂シートとして構成されている。この熱可塑性樹脂シートＰは、後述する熱可塑性樹脂ＸをＴダイ付溶融押出成形により単層ないし多層シートの外側層（スキン層）として形成されるが、これらの樹脂はいずれも比較的溶融温度や軟化温度が低く、かつ種々のプラスチック基材との融着性に優れるものであるため、後述する熱可塑性樹脂Ｙからなる熱可塑性樹脂シートＲとの加熱融着性に優れ、熱可塑性樹脂シートＲとの積層体シートが得られるものである。
【００４４】
［１－１－１］熱可塑性樹脂Ｘ：
熱可塑性樹脂Ｘは、硬度ショアＡ（以下、適宜「Ｓｈｏｒｅ－Ａ」ともいう）が８５以上、ショアＤ（以下、適宜「Ｓｈｏｒｅ－Ｄ」ともいう）が７０未満である熱可塑性エラストマーを含む熱可塑性樹脂である。このような材質である熱可塑性樹脂Ｘから、熱可塑性樹脂シートＰが構成されることにより、熱可塑性樹脂シートＰそのものが、柔軟性と加熱融着性を備えるだけでなく、この熱可塑性樹脂シートＰと後述の熱可塑性樹脂シートＲとから形成される、本発明の積層ヒンジシートにも、柔軟性と加熱融着性を備えさせることができる。すなわち、熱可塑性樹脂Ｘから、熱可塑性樹脂シートが形成されることにより、積層ヒンジシートの成形時に、熱可塑性樹脂シートを溶融させやすくなり、後述の熱可塑性樹脂シートＲと一体化させやすくなる。その結果、積層ヒンジシートの形成を容易に行える。換言すれば、熱可塑性樹脂シートが所望の材質（熱可塑性樹脂Ｘ）から形成されることで、熱可塑性樹脂シートが、熱可塑性樹脂シートＲに十分に融着し確実に一体化できる。
【００４５】
後述のような積層構造を有する積層体からなる電子パスポート用レーザーマーキング積層体、又は電子パスポートに使用する場合に、積層体内の積層ヒンジシートに隣接するインレイシートのスキン層との加熱融着を充分なものとする事ができる。
【００４６】
たとえば、この熱可塑性樹脂Ｘとして、熱可塑性ポリウレタンエラストマー（ＴＰＵ）

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、水添スチレン系エラストマー（ＳＥＰＳ）等を例示できる。

【００４７】

より具体的には、例えば、熱可塑性ポリウレタンエラストマーの場合は１７０～２４０℃にて、溶融押出させるものを例示できる。

【００４８】

また、熱可塑性樹脂シートを形成する際に、その機能を阻害しない範囲内で、無機フィラー、有機フィラー、他の熱可塑性樹脂等を混合してもよい。更に、滑剤、安定剤、光安定剤、酸化防止剤、紫外線吸収剤、顔料、染料などの着色剤等を添加、混合してもよい。具体的には、無機フィラーとしては雲母、マイカ、ミクロマイカ、シリカ、炭酸カルシウム等が挙げられ、有機フィラーとしては、ポリエステル繊維、ＰＰＳ繊維、ナイロン繊維などの有機繊維等が挙げられる。他の熱可塑性樹脂としては、アクリロニトリル－スチレン共重合体樹脂（ＡＳ樹脂）、ポリプロピレン樹脂、ＡＢＳ樹脂、アクリル樹脂、ポリカーボネート樹脂等が挙げられる。

【００４９】

より具体的には、断裁加工性及び耐熱性を向上させる目的で、ＡＳ樹脂、ポリプロピレン樹脂、ＡＢＳ樹脂、アクリル樹脂、ポリカーボネート樹脂等を少量配合することがある。または、無機フィラーとしては雲母、マイカ、ミクロマイカ、シリカを同目的で配合することがある。更に着色の目的で顔料、染料などの着色剤を配合、成形加工時や使用時の安定性を向上させる目的で滑剤、安定剤、光安定剤、酸化防止剤、紫外線吸収剤等を配合することがある。

【００５０】

［１－２］熱可塑性樹脂シートＲ：

本発明の積層ヒンジシートを構成する熱可塑性樹脂シートＲは、耐熱性と剛性を備える熱可塑性樹脂シートとして構成され後述の熱可塑性樹脂Ｙを原料とするシートとして構成されている。このように熱可塑性樹脂シートが構成されることにより、耐熱性と剛性を備えた中間層としての役割を熱可塑性樹脂シートに持たせることができ、さらに、後述の熱可塑性樹脂シートＲと一体化させた積層シートを形成しやすくできる。

【００５１】

［１－２－１］熱可塑性樹脂Ｙ：

熱可塑性樹脂Ｙは、ＡＳＴＭ　Ｄ８８２に準拠して測定した引張弾性率が１ＧＰａ以上、ＤＳＣ法によるガラス転移温度が７０℃以上である熱可塑性樹脂である。このような材質である熱可塑性樹脂Ｙから、熱可塑性樹脂シートＲが構成されることにより、熱可塑性樹脂シートＲそのものが、耐熱性と剛性を備えるだけでなく、この熱可塑性樹脂シートＲと前述の熱可塑性樹脂シートＰとから形成される、本発明の積層ヒンジシートにも耐熱性と剛性を備えさせることができる。すなわち、熱可塑性樹脂Ｙを原料として、熱可塑性樹脂シートＲが形成されることにより、積層ヒンジシートの謂わばコアとして、耐熱性と剛性を備える熱可塑性樹脂シートＲに、溶融させた、熱可塑性樹脂シートＰを融着させて一体化させやすくなる。その結果、積層ヒンジシートの形成を容易に行える。換言すれば、熱可塑性樹脂シートが所望の材質（熱可塑性樹脂Ｙ）を原料として形成されることで、熱可塑性樹脂シートＲと熱可塑性樹脂シートが十分に融着し確実に積層化できる。

【００５２】

なお、ＡＳＴＭ　Ｄ８８２は、「Ｓｔａｎｄａｒｄ　Ｔｅｓｔ　Ｍｅｔｈｏｄ　ｆｏｒ　Ｔｅｎｓｉｌｅ　Ｐｒｏｐｅｒｔｉｅｓ　ｏｆ　Ｔｈｉｎ　Ｐｌａｓｔｉｃ　Ｓｈｅｅｔｉｎｇ」に定められた薄いプラスチックシートの引張試験法である。

【００５３】

［１－３］熱可塑性樹脂シートＰと、熱可塑性樹脂シートＲとの関係：

本実施形態の積層ヒンジシートＣは、熱可塑性樹脂シートＰと、熱可塑性樹脂シートＲを積層させて形成される。この積層ヒンジシートＣは、（後述の）シートＡにレーザーマーキングにより書き込んだ画像、文字等の情報、及び、（後述の）シートＢに印刷等により印刷した画像、文字等の情報、更には後述するようないわゆるインレットシートに配設

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するＩＣチップ等の記憶媒体に記憶させた各種の情報を、パスポートの表紙と他のビザシート等と一体に堅固に綴じるために、非常に重要な役割を担うシートである。そのためシートＢまたは（後述の）他のシートとの堅固な加熱融着性、適度な柔軟性、加熱融着工程での耐熱性等が必要となる。加えて、例えば、この積層ヒンジシートＣを（パスポートの）表紙等にミシン綴じをする場合には、ミシン部の引裂、引張強度に優れ、かつ、この綴じ部の耐光、耐熱性を有し、更には、繰り返し曲げに対する抵抗性、言い換えるとヒンジ特性に優れる事が要求される。したがって、このような目的に合致する積層ヒンジシートＣとして前記素材が好適に用いられる。

【００５４】

ここで、熱可塑性樹脂シートＰと熱可塑性樹脂シートＲとの積層方法としては、熱可塑性樹脂シートＰの原料となる熱可塑性樹脂Ｘをダイ付の押出機で各樹脂所定の溶融温度にて溶融させて、Ｔダイからシート状に溶融押出させた直後に熱可塑性樹脂シートＲと接触・加圧により熱可塑性樹脂シートＲの片側に熱可塑性樹脂シートＰの層を形成した後、反転させ、同様にして熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの熱可塑性樹脂シートＲ側に熱可塑性樹脂シートＰの層を形成して熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの積層体シートを成形する方法、

【００５５】

または、２台のＴダイ付き溶融押出成形機を用いて、熱可塑性樹脂シートＰの原料となる熱可塑性樹脂Ｘをダイ付の押出機で各樹脂所定の溶融温度にて溶融させて、Ｔダイからシート状に溶融押出させた直後に熱可塑性樹脂シートＲと接触・加圧により熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの積層体シートを成形する方法、

【００５６】

更には、熱可塑性樹脂シートＰと熱可塑性樹脂シートＲの原料である熱可塑性樹脂Ｘと熱可塑性樹脂Ｙを別々にＴダイ付の押出機で各樹脂所定の溶融温度にて溶融させて、Ｔダイからシート状に溶融押出させた後、熱ロール等により熱ラミネーションすることにより熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの積層体シートを成形する方法、

【００５７】

更に別法として、熱可塑性樹脂シートＰと熱可塑性樹脂シートＲの原料である熱可塑性樹脂Ｘと熱可塑性樹脂Ｙを２種３層Ｔダイ付き多層溶融押出成形機（溶融押出成形機２台使用）を用いて、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの２種３層シートとして成形する方法等が挙げられる。

【００５８】

なお、前述のように、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの３層を積層し、熱ラミネーションにより一体化させた積層ヒンジシートであることも好ましい。成形しやすいといった利点がある。

【００５９】

さらに、熱可塑性樹脂シートＰを外層とし、熱可塑性樹脂シートＲを内層とし、熱可塑性樹脂シートＲの両面に熱可塑性樹脂シートＰの原料である熱可塑性樹脂Ｘが溶融押出成形により積層されて熱可塑性樹脂シートＰが形成されてなるヒンジシートを成形することも好ましい。この様に３層積層することにより、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ間の接触界面が強固に融着でき、かつ３層構造とすることにより積層シートのソリ等の変形のない平坦性に優れた積層シートができるため好ましい。

【００６０】

また、熱可塑性樹脂シートＰを外層とし、熱可塑性樹脂シートＲを内層とした積層ヒンジシートであって、熱可塑性樹脂シートＲを溶融押出成形直後に、その両面に熱可塑性樹脂シートＰを加圧または加圧・加熱接触させることにより、熱可塑性樹脂シートＰと熱可塑性樹脂シートＲとが、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの３層として積層されていることも好ましい形態の一つである。一般的に熱可塑性

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樹脂シートＲの溶融押出成形温度が熱可塑性樹脂シートＰの溶融押出成形温度より高温であるために、熱可塑性樹脂シートＰと熱可塑性樹脂シートＲの接触界面の温度を高く保つことが可能であり、そのために熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ間の接触界面が、更に強固に融着でき、かつ３層構造とすることにより積層シートのソリ等の変形のない平坦性に優れた積層シートができるため好ましい。

【００６１】

さらに、熱可塑性樹脂シートＰを外層とし、熱可塑性樹脂シートＲを内層として、２種３層共押出成形により積層された積層ヒンジシートも好ましい形態の一つである。すなわち、熱可塑性樹脂シートＰを外層とし、熱可塑性樹脂シートＲを内層とした積層ヒンジシートであって、熱可塑性樹脂シートＰの原料樹脂である熱可塑性樹脂Ｘ及び熱可塑性樹脂シートＲの原料樹脂である熱可塑性樹脂Ｙを、溶融共押出成形により２種３層共押出成形して、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰの３層積層ヒンジシートを得ることができる。この様に積層することにより、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ間の接触界面が一部融合され、かつ３層構造となることにより、積層シートのソリ等の変形のない平坦性に優れた積層シートができるため好ましい。

【００６２】

たとえば、図１に示されるように、前述のように熱可塑性樹脂Ｐを外層とし、前記熱可塑性樹脂Ｒを内層とした２種３層共押出成形により積層されていることにより、熱可塑性樹脂Ｐと熱可塑性樹脂Ｒとの界面K_1、K_2では、強固に一体化される。

【００６３】

なお、ヒンジシートの形状、大きさ等は、電子パスポート用レーザーマーキング積層体を綴じ込みしやすい形状、大きさ等であれば、とくに形状や、長さ寸法等は限定されるものではなく、必要に応じて適宜選択されることが好ましい。

【００６４】

ただし、後述のように、電子パスポート用レーザーマーキング積層体、電子パスポート等に使用される場合には、ヒンジシートＣの厚みが８０～２５０μｍ、さらに、好ましくは１００～２００μｍである。ヒンジシートＣの厚みが８０μｍ未満ではミシン綴じ部の強度が不足するため、電子パスポートから、個人の画像や文字、数字などの個人情報がレーザーマーキングされた多層シートが剥がされる懸念がある。また、２５０μｍを超えると電子パスポート用レーザーマーキング積層体の総厚みが厚くなりすぎ、ビザシート等他のシートと共に表紙に綴じた場合に電子パスポートが扇型になり、電子パスポートの製本工程での生産に支障をきたす問題が生じる他、ヒンジシートＣの剛性が大きくなりすぎて電子パスポートが自然に開いてくる問題も生じるため好ましくない。

【００６５】

また、電子パスポートや以前からある通常のパスポートでも同様であるが、電子パスポートでは、データページと称される個人データ・画像を記載したプラスチック多層シートを、ビザシート等他のシートと共に表紙に綴じて、または、ｅ－カードと称される個人の生体情報を記録するためのＩＣチップ入りの積層体を、ビザシート等他のシートと共に表紙に綴じて、ブランクパスポートを製本する。その後、製本したブランクパスポートに、パスポート申請のあった個人情報をレーザーマーキング等の方法で記載して使用する。この場合に、データページやｅ－カードの厚みが厚いとブランクパスポートが開いてきて、連続製造ができないという問題が生じやすく、これらは薄い方が好ましい。従って、データページの厚みは一般的に４００～６００μｍであるが、薄い方が好ましい。換言すれば、必然的にヒンジシートＣが２５０μｍを超えると、他の４枚のシートが非常に薄くなり、透明レーザーマーキングシートＡにあっては、レーザーマーキング性が劣る問題が発生し、多層シートＢにあっては、印刷の隠蔽性に劣る問題が生じるため使用困難となり易い。

【００６６】

ここで、前述した本実施形態の積層ヒンジシートと、たとえば、熱可塑性エラストマーからなるシートを、熱可塑性樹脂シートＰとし、ポリエステル樹脂、ナイロン樹脂からな

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るシートを、熱可塑性樹脂シートＲとして、各々単独で使用した所謂積層ヒンジシート（ｉ）、或いは、前述の構成からなる熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲの２種２層積層シートを対比すると次のような点で差異が生じる。すなわち、熱可塑性樹脂シートＰを単独の単層シートとしてヒンジシートに使用した場合は、ヒンジシートに隣接する多層シート（ＰＥＴＧ／ＰＣ／ＰＥＴＧ）との加熱積層による融着性及び柔軟性に優れ、表紙等とミシン綴じ部の強度も良好であるが、しかし、当該熱可塑性樹脂シートＰの柔軟性が良すぎて、加熱積層工程にヒンジシートを搬送する場合の搬送性に逆に問題が生じる。加えて、これらの樹脂は比較的軟化温度が低いため（凡そ１３０℃未満）、ロータリー真空プレス機にて１４０～１６０℃、９０～１２０秒での短時間加熱積層融着性に優れる反面、この加熱融着工程にてヒンジシートが他のシートより張り出している部分に“シワ”等が発生し、見栄えが悪いばかりでなく、表紙や他のシート等とミシン綴じする工程でトラブルを生じる問題がある。

【００６７】

また、熱可塑性樹脂シートＲを単独の単層シートとしてヒンジシートに使用した場合、一例として、熱可塑性樹脂シートＲとしてＰＥＴフィルムを単独で使用した場合は、ＰＥＴフィルムは引き裂き強度が弱いという問題があるため、表紙や他のシート等とミシン綴じ部の強度が不足するという問題が生じる。一方、ナイロン樹脂フィルムを単独で使用した場合は、加熱積層工程にて隣接する多層シート（ＰＥＴＧ／ＰＣ／ＰＥＴＧ）との加熱積層時に融着性に劣る問題があり、いずれも、偽造防止の点で大きな問題であり、この様なヒンジシートは使用不可である。

【００６８】

更に、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲの２種２層積層シートをヒンジシートに使用した場合は、熱可塑性樹脂シートＲとしてナイロンを使用すると、熱可塑性樹脂シートＲ側の加熱融着性が劣るため、この部分が簡単に手ではくりできてしまう。そのため、上記熱可塑性樹脂シートＲを単独の単層シートとしてヒンジシートに使用した場合と同様、偽造防止の点で大きな問題であり、この様なヒンジシートは使用不可である。更に、異種樹脂の２種２層積層シートでは各層の熱膨張係数が異なるため、加熱積層工程において、この様な２種２層積層シートはどちらかの方にソリが発生し、時にはシートが“カール”してしまう事が生じてミシン綴じが出来なくなる問題も発生する。そのため好ましくない。

【００６９】

また、積層ヒンジシートＣの一端が、透明レーザーマーキングシートＡ及び多層シートＢよりも５～１００ｍｍ長い張り出し部を有することが好ましい（図３符合２９の張り出し部参照）。積層ヒンジシートＣに張り出し部を形成することにより電子パスポートに組み付けやすくなるからである。すなわち、張り出し部は、積層ヒンジシートＣの長手方向の一端を透明レーザーマーキングシートＡ及び多層シートＢよりも長い張り出し部を用いてミシン綴じ及び／または接着により電子パスポートに組み付けるためのものである。

【００７０】

積層ヒンジシートＣに張り出し部を形成する場合に、張り出し部の長さは、ミシン綴じ及び／または接着作業性とミシン綴じ部の強度及び接着強度により決められることが好ましい。ただし、後述のように、電子パスポート用レーザーマーキング積層体、電子パスポート等に使用される場合には、張り出し部の寸法は、５～１００ｍｍであることが好ましく、より好ましくは５～５０ｍｍ、更に好ましくは５～２０ｍｍである。

【００７１】

このように、張り出し部を形成することにより、より一層（この張り出し部を用いて）ミシン綴じ及び／または接着により電子パスポートに組み付けしやすくなる。

【００７２】

なお、積層ヒンジシートＣに張り出し部を設けると、たとえば、後述する、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の５層積層体（５層からなる電子パスポート用レーザーマーキン

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グ積層体）、又は透明レーザーマーキングシートＡ／多層シートＢ／インレットシートＥ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の６層積層体（６層からなる電子パスポート用レーザーマーキング積層体）を、電子パスポート表紙または裏表紙にミシン綴じ及び／または接着してなる電子パスポートとして成形し易くなるから好ましい。

【００７３】

［２］本発明の電子パスポート用レーザーマーキング積層体の構成：

また、これまで説明した積層ヒンジシートを使用する電子パスポート用レーザーマーキング積層体であって、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層してなる電子パスポート用レーザーマーキング積層体であり、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなる単層シート、又は、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層が、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、且つ、前記コア層が、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート１、又は、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層が、ポリカーボネート樹脂を主成分とする透明樹脂からなり、且つ、前記コア層が、ポリカーボネート樹脂を主成分とする透明樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート２、として構成され、前記多層シートＢは、スキン層とコア層を有し、溶融押出成形により少なくとも３層のシートが積層されて形成される多層シートであって、前記多層シートＢの両最外層である前記スキン層が、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなるとともに、前記多層シートＢのコア層が、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂からなり、前記多層シートＢのスキン層及び／又はコア層には、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、染料、顔料等の樹脂の着色剤の少なくとも１種以上を１質量部以上含有させてなり、更に、前記多層シートＢの全厚さが１００～３００μｍであるとともに、前記コア層の厚さの、前記多層シートＢの全厚さに対して占める厚み比率が３０％以上、８５％未満である着色多層シートとして構成され、積層ヒンジシートＣの厚さが８０～２５０μｍである電子パスポート用レーザーマーキング積層体として構成されることが好ましい。

【００７４】

［２－１］本発明の電子パスポート用レーザーマーキング積層体の構成：

すなわち、第１の発明の電子パスポート用レーザーマーキング積層体としては、図２Ａに示されるように、これまで説明した積層ヒンジシートＣを使用する電子パスポート用レーザーマーキング積層体であって、透明レーザーマーキングシートＡ／多層シートＢ／前記積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層してなる電子パスポート用レーザーマーキング積層体であり、前記透明レーザーマーキングシートＡは、溶融押出成形により成形された透明レーザーマーキングシートであって、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からな

る単層シート１３として構成され、前記多層シートＢ（符号１５）は、スキン層１５ａとコア層１５ｂを有し、溶融押出成形により少なくとも３層のシートが積層されて形成される多層シートであって、前記多層シートＢの両最外層である前記スキン層１５ａが、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、具体例としては、テレフタル酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂、或いは前記共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂組成物からなるとともに、前記多層シートＢのコア層１５ｂが、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂からなり、前記多層シートＢのスキン層及び／又はコア層には、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、染料、顔料等の樹脂の着色剤の少なくとも１種以上を１質量部以上含有させてなり、更に、前記多層シートＢの全厚さが１００～３００μｍであるとともに、前記コア層の厚さの、前記多層シートＢの全厚さに対して占める厚み比率が３０％以上、８５％未満である着色多層シートとして構成され、前記積層ヒンジシートＣの厚さが８０～２５０μｍである電子パスポート用レーザーマーキング積層体１１Ａとして構成される。

【００７５】

［２－２］本発明の電子パスポート用レーザーマーキング積層体の構成：

また、第２の発明の電子パスポート用レーザーマーキング積層体としては、図２Ｂに示されるように、これまで説明した積層ヒンジシートＣを使用する電子パスポート用レーザーマーキング積層体であって、透明レーザーマーキングシートＡ／多層シートＢ／前記積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層してなる電子パスポート用レーザーマーキング積層体であり、前記透明レーザーマーキングシートＡ（符号２３）は、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層２３ａとコア層２３ｂを有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層２３ａが、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、具体例としては、テレフタル酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂、或いは前記共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂組成物からなり、且つ、前記コア層２３ｂが、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート１として構成され、前記多層シートＢ（符号１５）は、スキン層１５ａとコア層１５ｂを有し、溶融押出成形により少なくとも３層のシートが積層されて形成される多層シートであって、前記多層シートＢの両最外層である前記スキン層１５ａが、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、具体例としては、テレフタル酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂、或いは前記共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂組成物からなるとともに、前記多層シートＢのコア層１５ｂが、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂からなり、前記多層シートＢのスキン層及び／又はコア層には

、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、染料、顔料等の樹脂の着色剤の少なくとも１種以上を１質量部以上含有させてなり、更に、前記多層シートＢの全厚さが１００～３００μｍであるとともに、前記コア層の厚さの、前記多層シートＢの全厚さに対して占める厚み比率が３０％以上、８５％未満である着色多層シートとして構成され、前記積層ヒンジシートＣの厚さが８０～２５０μｍである電子パスポート用レーザーマーキング積層体１１Ｂとして構成される。

【００７６】

［２－３］本発明の電子パスポート用レーザーマーキング積層体の構成：

また、第３の発明の電子パスポート用レーザーマーキング積層体としては、図２Ｃに示されるように、これまで説明した積層ヒンジシートＣを使用する電子パスポート用レーザーマーキング積層体であって、透明レーザーマーキングシートＡ／多層シートＢ／前記積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層してなる電子パスポート用レーザーマーキング積層体であり、前記透明レーザーマーキングシートＡ（符号３３）は、溶融押出成形により成形された透明レーザーマーキングシートであって、スキン層３３ａとコア層３３ｂを有し、溶融押出成形により少なくとも３層のシートが積層されて形成され、両最外層である前記スキン層３３ａが、ポリカーボネート樹脂を主成分とする透明樹脂からなり、且つ、前記コア層３３ｂが、ポリカーボネート樹脂を主成分とする透明樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部含む透明ポリカーボネート樹脂組成物からなり、さらに、前記透明レーザーマーキングシートＡの全厚みが５０～２００μｍ、コア層厚み比率が３０～８５％未満である多層シート２、として構成され、前記多層シートＢ（符号１５）は、スキン層１５ａとコア層１５ｂを有し、溶融押出成形により少なくとも３層のシートが積層されて形成される多層シートであって、前記多層シートＢの両最外層である前記スキン層１５ａが、非結晶性の芳香族ポリエステル系樹脂を主成分とする樹脂からなり、具体例としては、テレフタル酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂、或いは前記共重合ポリエステル樹脂を主成分とする透明共重合ポリエステル樹脂組成物からなるとともに、前記多層シートＢのコア層１５ｂが、ポリカーボネート樹脂を主成分とする透明熱可塑性樹脂からなり、前記多層シートＢのスキン層及び／又はコア層には、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、染料、顔料等の樹脂の着色剤の少なくとも１種以上を１質量部以上含有させてなり、更に、前記多層シートＢの全厚さが１００～３００μｍであるとともに、前記コア層の厚さの、前記多層シートＢの全厚さに対して占める厚み比率が３０％以上、８５％未満である着色多層シートとして構成され、前記積層ヒンジシートＣの厚さが８０～２５０μｍである電子パスポート用レーザーマーキング積層体１１Ｃとして構成される。

【００７７】

以下、電子パスポート用レーザーマーキング積層体１１Ａ、１１Ｂ、及び１１Ｃの各構成について説明する。

【００７８】

［Ａ］透明レーザーマーキングシートＡ：

本発明の透明レーザーマーキングシートＡは、コア層のみの単層透明レーザーマーキングシートまたはスキン層とコア層を少なくとも３層から構成される透明レーザーマーキング多層シートのいずれかであり、溶融させて溶融押出成形により積層される透明多層シートである。

【００７９】

［Ａ－１］透明レーザーマーキングシートＡの構成：

透明レーザーマーキングシートＡが、単層構造の単層シートとして構成される場合には

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、溶融押出成形により成形されることが好ましい。

【００８０】

また、透明レーザーマーキングシートＡが、単層シートとして構成される場合には、ポリカーボネート樹脂（ＰＣ）、特に透明なポリカーボネート樹脂を主成分とする透明樹脂層から形成される。ただし、使用されるポリカーボネート樹脂は特に制限はないが、メルトボリュームレイトが４～２０のものを好適に使用できる。メルトボリュームレイトが４未満では、シートのタフネス性が向上するという点では意味はあるものの、成形加工性が劣ることから、実際の使用に難があるため好ましくない。また、メルトボリュームレイトが２０を超えると、シートのタフネス性に劣ることから、好ましくない。このように透明レーザーマーキングシートＡを、ポリカーボネート樹脂（ＰＣ）を主成分とする透明樹脂層から形成することによって、レーザー光照射によるマーキング部の発泡による、いわゆる「フクレ」を抑制及びレーザー光照射によるマーキング部分の耐磨耗性を向上させることができる。

【００８１】

また、透明レーザーマーキングシートＡが、単層シートとして構成される場合には、高い透明性を有している事が重要である。単層シートとして構成される透明レーザーマーキングシートＡの原料としては、ポリカーボネート樹脂の透明性を阻害しない樹脂、フィラー等であれば特に制限はないが、耐傷性を向上または耐熱性を向上させる目的で、汎用ポリカーボネート樹脂と特殊ポリカーボネート樹脂とのブレンドまたはポリカーボネート樹脂とポリアリレート樹脂とのブレンド等が挙げられる。

【００８２】

より好ましいのは、透明レーザーマーキングシートＡは、スキン層とコア層とからなる「少なくとも３層」構造の多層シート（以下、適宜、「多層シート」或いは「多層シートＡ」という）として構成されることである。ただし、この「３層シート」とは、「少なくとも３層」を意味するものであって、３層構造のシートに限られるものではない。換言すれば、透明レーザーマーキングシートＡにおいて、「３層シート」と言うのは、説明の便宜を図るものであり、「３層シート」とは、「少なくとも３層以上の層からなるシート」を意味するものであって、「３層」から成るシートに限定する趣旨ではない。つまり、３層以上の構成からなれば、５層から構成されても、７層から構成されても、或いは、それ以上の奇数層から形成されていても、多層シートとして本透明レーザーマーキングシートＡに含まれる。

【００８３】

また、透明レーザーマーキングシートＡが、スキン層とコア層とからなる「少なくとも３層」構造の多層シートとして構成される場合には、溶融押出成形により積層形成されることが好ましい。

【００８４】

なお、上述した「少なくとも３層」といった多層構造の多層シートとして、透明レーザーマーキングシートＡが構成される場合には、後述する透明レーザーマーキングシートＡのスキン層は、多層構造から構成される多層シートの最も外側の位置に配されるとともに、そのシートの両面に配され、さらに、両スキン層（の間）に、コア層が挟まれるように配されることが必要となる。なお、透明レーザーマーキングシートＡのスキン層の厚さは、特に限定されるものではないが、より好ましいのは、後述の所定範囲の厚さに形成されることである。

【００８５】

ただし、透明レーザーマーキングシートＡが上述の「それ以上の奇数層」から構成される場合であっても、あまりに多層構造からなる場合には、配されるスキン層とコア層との一層あたりの層厚が薄くなり過ぎてしまうと、積層時の加熱プレス工程での、いわゆる金型スティックが発生してしまうおそれがある。したがって、好ましいのは５層から、より好ましいのは３層から構成される多層シートである。

【００８６】

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すなわち、本実施形態における透明レーザーマーキングシートＡが前述のように奇数層から構成されるのは、偶数層からなる多層シートは、必ず奇数層からなる多層シートと同じ構成となるからである。例えば、４層からなる透明レーザーマーキングシートでは、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）、といった層の配置となったり、スキン層（ＰＣ）／コア層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＣ）、といった層の配置となり、結局のところ、奇数層から構成される透明レーザーマーキングシートと同様の構成となるからである。

【００８７】

たとえば、３層（いわゆる「３層シート」）から構成される透明レーザーマーキングシートＡを例にすると、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）、といった層の配列がなされるように、或いは、スキン層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＣ）、といった層の配列がなされるように、一方と他方の両最外側に２つのスキン層が配され、その２つのスキン層に挟まれるように、コア層が１層配されて多層シートが形成されることになる。また、５層から構成される多層シートを例にすると、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）、といった層の配列がなされるように、或いは、スキン層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＣ）、といった層の配列がなされるように、一方と他方の両最外側に２つのスキン層が配され、かつ、交互にスキン層とコア層を配列して、透明レーザーマーキングシートＡを形成してもよい。ここで、前述のように、コア層のみの単層透明レーザーマーキングシートとして構成しても、充分なレーザー発色性を有し、本発明の効果を奏することができるが、より好ましいのは、前述のような多層構造を有する多層シート１又は多層シート２として、透明レーザーマーキングシートＡを形成することである。このような多層構造を有する多層シート２として透明レーザーマーキングシートＡを構成することにより、コア層のみの単層シートとして形成される透明レーザーマーキングシートよりも更に、高パワーでレーザー光照射し、レーザーマーキング部の濃度を高めることができ、加えて、コア層マーキング部の発泡による、いわゆる「フクレ」が抑制でき表面平滑性を維持できるからである。その上、コア層マーキング部分の上層にスキン層が積層されているために、スキン層の無い場合と比較してマーキング部分の耐磨耗性がより向上するといった相乗効果も奏することができる。また、多層シート１として透明レーザーマーキングシートＡを構成することにより、充分な加熱融着性が確保でき、積層工程におけるシートの搬送性、熱プレス後の金型からの離型性、折り曲げ性、透明性等の点で、微調整が可能となる。

【００８８】

また、透明レーザーマーキングシートＡの全厚さ（総厚さ）は、単層シート或いは３層シート（多層シート１，多層シート２）のいずれでも、５０～２００μｍであることが好ましい。透明レーザーマーキングシートＡの全厚さが、５０μｍ未満であると、レーザーマーキング性が不十分となり好ましくない。また、多層シート１の場合には、多層シート積層工程における加熱融着時に金型に多層シートが貼りつくという、いわゆる金型スティックの問題が発生しやすくなる。このような支障を取り除くためには、加熱融着温度や、加熱融着時のプレス圧力、加熱融着時間等を制御する必要がある。しかし、この制御は煩雑となり、成形工程に支障をきたしやすいため、好ましくない。また、透明レーザーマーキングシートＡの全厚さが２００μｍを超えると、たとえば、その２００μｍを超えた透明レーザーマーキングシートＡと多層シートＢを使用して、電子パスポート用レーザーマーキング積層体を積層成形した場合には、全最大の厚さが８００μｍを超えて厚くなりすぎるため実用しづらくなる。

【００８９】

さらに、透明レーザーマーキングシートＡがスキン層とコア層からなる多層シート（いわゆる３層シート）の場合であって、多層シート２の場合には、透明レーザーマーキングシートＡの全厚さ（総厚さ）は、５０～２００μｍであるとともに、当該多層シートの全シート厚さに対して占める前記コア層の厚さの割合が３５％以上、８５％未満であることが

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好ましい。コア層の厚みが３５％未満では、レーザーマーキング性が劣り好ましくない。また、８５％を超えると、スキン層が薄くなりすぎ、高パワーでレーザー光を照射した場合に、コア層に配合したレーザー光エネルギー吸収剤がレーザー光エネルギーを吸収して熱に変換することにより、高熱が発生し、レーザー光照射部における、いわゆる「フクレ発生」を抑制する効果に乏しくなり好ましくない。また、仮に、レーザー光エネルギーを調整して、好ましいレーザー発色を得たとしても、スキン層の厚みが前述の所望範囲内であるものと比較して、レーザーマーキング部（レーザマーキングを施した領域）の耐磨耗性が充分でなく好ましくない。

【００９０】

また、透明レーザーマーキングシートＡがスキン層とコア層からなる多層シート（いわゆる３層シート）の場合であって、多層シート１の場合には、透明レーザーマーキングシートＡの全厚さ（総厚さ）は、５０～２００μｍであるとともに、当該多層シートの全シート厚さに対して占める前記コア層の厚さの割合が、３０％以上、８５％未満であることが好ましい。スキン層の厚さがあまりにも薄いと、金型スティックの発生及び熱融着性の低下が生じてしまい、他方、スキン層の厚さがあまりにも大きすぎると、後述するコア層の厚さが、必然的に薄くなってしまい、レーザーマーキング性が劣ったり、多層シート積層後にそりが発生したりするなどの問題が生じて望ましくないからである。

【００９１】

このように単層シート或いは多層シート１、２（３層シート）からなる透明レーザーマーキングシートＡにおける全体の厚さを所望の厚さとすることにより、透明レーザーマーキングシートＡの特性といった局所的な特性を引き出しやすくなる。さらに、この３層シート全体の総厚さだけに限らず、３層シートを構成するスキン層及びコア層の３層シートに占める厚さの割合も前述の所望の割合にすることにより、３層シート全体の厚さを所望範囲内にすることと相俟って、レーザーマーキング性を向上させやすくなる等、本発明の効果をより発揮させるため好ましい。

【００９２】

また、前記透明レーザーマーキングシートＡの全光線透過率が７０％以上であることが好ましく、より好ましいのは８５％以上である。たとえば、本実施形態の電子パスポート用レーザーマーキング積層体を、電子パスポートに使用する場合には、この用途では印刷を施すことが一般的である。そのため、透明レーザーマーキングシートＡの下部に、たとえば、文字、図形等の印刷を施した白色シート（以下、文字、図形等の印刷を施した白色シートの印刷を、適宜「印刷部」という）を積層するなどして、最外層である透明レーザーマーキングシートＡの非印刷部にレーザー光を照射し、黒色発色させて、画像や文字をマーキングさせ、印刷部でのデザイン性とレーザーマーキングによる偽造防止を組み合わせて使用する事が多い。このように組み合わせて製造し使用することで、その下地層が白い故に、印刷部の鮮明性及びレーザーマーキング部の黒／白コントラストにより鮮明な画像を得ることができる。すなわち、白色シート等を積層する場合には、この最外層の透明性を前述の所望範囲の全光線透過率にすることにより、これらの効果を最大限に発揮させられる（黒／白コントラストの鮮明性を際立たせることができる）。換言すれば、この最外層の透明性は印刷部の鮮明性及びレーザーマーキング部の黒／白コントラストの鮮明性を確保する上で重要であり、全光線透過率が７０％未満では黒／白コントラストが不十分となり充分なマーキング性が確保できない問題が生じることと、印刷は下地白色シート上に施すために、この印刷の視認性に問題を生じるため好ましくない。

【００９３】

ここで、「全光線透過率」とは、膜等に入射した光のうち、透過する光の割合を示す指標であり、入射した光がすべて透過する場合の全光線透過率は１００％である。なお、本明細書中の、「全光線透過率」は、ＪＩＳ－Ｋ７１０５（光線透過率及び全光線反射率）に準拠して測定した値を示したものであり、この全光線透過率の測定は、たとえば、日本電色工業製のヘイズメーター（商品名：「ＮＤＨ　２０００」）、分光光度計（商品名「ＥＹＥ７０００」マクベス社製）等を用いて測定できる。

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【００９４】
［Ａ－１－１］透明レーザーマーキングシートＡにおけるスキン層：
透明レーザーマーキングシートＡにスキン層を形成する場合、すなわち「３層構造」としての多層構造から多層シートが構成される場合には、そのスキン層は、多層シート（３層シート）の外側に配される両最外層として構成される。すなわち、このスキン層は、後述する多層シートにおけるコア層の両端面側（外側）から、挟み込むように配される、多層シート（３層シート）の表層（両最外層）としての役割を担っている。
【００９５】
ここで、スキン層の厚さは、それぞれ同一であることが好ましい。たとえば、多層シート２を構成するスキン層の場合であって、それぞれ異なる厚さのスキン層から多層シートとして透明レーザーマーキングシートＡを構成すると、電子パスポート用レーザーマーキング積層体やカードでは表と裏からレーザーマーキングする事が一般的となる。この場合に、前記積層体の最表層と最裏層であるスキン層の厚みが異なる事で、レーザー光照射によるコア層マーキングの発泡による、いわゆる「フクレ」抑制効果及びマーキング部の耐磨耗性効果が異なるため好ましくないからである。また、例えば、スキン層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＣ）といった３層から多層シートとして透明レーザーマーキングシートＡが構成される場合であって、コア層の厚さが３０％以上、８５％未満である場合には、スキン層は両面で１５％以上、７０％未満となる。スキン層の厚さが１５％未満であると、レーザー光照射によるコア層マーキング部の発泡による、いわゆる「フクレ」が抑制及びレーザー光照射によるマーキング部分の耐磨耗性が向上する効果が十分でない。他方、スキン層の厚さがあまりにも大きすぎると、レーザーマーキング層であるコア層の厚さが、必然的に薄くなってしまい、レーザーマーキング性が劣るため好ましくない。
【００９６】
また、たとえば、多層シート１を構成するスキン層の場合であって、それぞれ異なる厚さのスキン層から多層シートＡを構成すると、前述したように、多層シートのプレス工程等でシートのソリが生じて好ましくないからである。また、例えば、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）といった３層から多層シートＡが構成される場合であって、コア層の厚さが３０％以上、８５％未満である場合には、スキン層は両面で１５％以上、７０％未満となる。スキン層の厚さがあまりにも薄いと金型スティックの発生及び熱融着性の低下が生じてしまい、他方、スキン層の厚さがあまりにも大きすぎると、後述するコア層の厚さが、必然的に薄くなってしまい、レーザーマーキング性が劣ったり、多層シート積層後にそりが発生したりするなどの問題が生じて好ましくないから、所望の厚さに形成されることが好ましい。
【００９７】
また、多層シート２の場合には、このスキン層は、ポリカーボネート樹脂（ＰＣ）、特に透明なポリカーボネート樹脂を主成分とする透明樹脂層から形成されることが好ましい。ただし、使用されるポリカーボネート樹脂は特に制限はないが、メルトボリュームレイトが４～２０のものを好適に使用できる。メルトボリュームレイトが４未満では、シートのタフネス性が向上するという点では意味はあるものの、成形加工性が劣ることから、実際の使用に難があるため好ましくない。また、メルトボリュームレイトが２０を超えると、シートのタフネス性に劣ることから、好ましくない。このようにスキン層を、ポリカーボネート樹脂（ＰＣ）を主成分とする透明樹脂層から形成することによって、レーザー光照射によるコア層マーキング部の発泡による、いわゆる「フクレ」が抑制及びレーザー光照射によるマーキング部分の耐磨耗性を向上させることができる。
【００９８】
また、多層シート２の場合には、スキン層は高い透明性を有している事が重要であり、ポリカーボネート樹脂の透明性を阻害しない樹脂、フィラー等であれば特に制限はないが、スキン層の耐傷性を向上または耐熱性を向上させる目的で、汎用ポリカーボネート樹脂と特殊ポリカーボネート樹脂とのブレンドまたはポリカーボネート樹脂とポリアリレート

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樹脂とのブレンド等が挙げられる。

【００９９】

また、多層シート１の場合には、スキン層を形成する素材としては、ポリエステル系樹脂組成物、すなわち、後述の共重合ポリエステル樹脂、後述の滑剤と、を調製した、後述する実質的に非結晶性の芳香族ポリエステル系樹脂組成物からなる層として形成される。

【０１００】

（共重合ポリエステル樹脂）

多層シート１に用いられる共重合ポリエステル樹脂は、非結晶性の芳香族ポリエステル系樹脂組成物の主要な成分として配合されていることが好ましい。ここでいうポリエステル樹脂とは、芳香族ジカルボン酸とジオールの脱水縮合体をいい、本発明に用いられる実質的に非結晶性の芳香族ポリエステル樹脂とは、芳香族ポリエステル樹脂の中でも特に結晶性の低いものをいう。これらは、加熱プレス等で頻繁に加熱成形加工を行っても、結晶化による白濁や融着性の低下をおこさないものである。この共重合ポリエステル樹脂の具体例としては、スキン層には、テレフタル酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂が使用される。この共重合ポリエステル樹脂に含まれる、エチレングリコールと、１，４－シクロヘキサンジメタノールと、の成分量を調製する理由は、共重合ポリエステル樹脂において、エチレングリコール成分の置換量が１０モル％未満で得られる樹脂では十分な非晶性にならず、熱融着後の冷却工程で再結晶化が進み、熱融着性が劣るからである。また、７０モル％を超えて得られる樹脂では十分な非晶性にならず、熱融着後の冷却工程で再結晶化が進み、熱融着性が劣るからである。したがって、本実施形態のように、エチレングリコールと、１，４－シクロヘキサンジメタノールと、の成分量を調製して得られる樹脂は、十分な非晶性になり、熱融着性の点で優れているため、好ましい樹脂といえる。

【０１０１】

この共重合ポリエステル樹脂としては、例えば、ポリエチレンテレフタレートにおけるエチレングリコール成分の約３０モル％を１，４－シクロヘキサンジメタノールで置換した実質的に非結晶性の芳香族ポリエステル系樹脂（略称「ＰＥＴＧ」、（商品名　「イースター　コポリエステル」、イーストマンケミカル社製））が商業的に入手可能なものとして挙げられる。

【０１０２】

［Ａ－１－２］透明レーザーマーキングシートＡにおけるコア層：

コア層は、前述のように、透明レーザーマーキングシートＡを３層シート（多層シート１，２）からなる構成として、最外層にスキン層を形成する場合には、その３層シートの中心に配される、いわゆる核層として構成される。すなわち、３層シートから構成する場合には、コア層は、最外側に配された２つのスキン層に挟み込まれるように、３層シートの中核層として形成されている。

【０１０３】

ここで、多層シート２のコア層の厚さとしては、全シート中に占める厚さの割合が、３０％以上、８５％未満になるよう形成されることが好ましい。コア層の厚み比率が３０％以上となると、レーザー光照射によるコア層マーキング部の厚み効果により下地白色層による未発色部とのコントラストが高まり、マーキング部の視認性、鮮明性が向上する。他方、コア層の厚み比率が８５％を超えると、レーザー光照射によるコア層マーキングの発泡による、いわゆる「フクレ」抑制効果及びレーザー光照射によるマーキング部分の耐磨耗性が向上する効果が十分でない。また、コア層の厚み比率が３０％未満では、レーザーマーキング性が劣るため好ましくない。

【０１０４】

また、多層シート１のコア層の厚さとしては、全シート中に占める厚さの割合が、３０

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％以上、８５％未満になるよう形成されることが好ましい。コア層の厚み比率が８５％以上となると、透明レーザーマーキングシートＡの総厚みが５０～１５０μｍと薄いため、相対的にスキン層も薄くなってしまい、仮に、スキン層に滑剤が混合されていても、積層工程における加熱プレス工程にて透明レーザーマーキングシートＡが金型に貼りつくという金型スティックの問題が発生するので好ましくない。また、コア層の厚み比率が３０％未満では積層工程において、スキン層が厚いため金型スティックの問題が発生しないが、レーザーマーキング性が劣ったり、耐熱性が乏しくなるためシートのソリが生じて好ましくない。

【０１０５】

より好ましいのは、多層シート１、２のコア層の厚さの、全シート中に占める厚さの割合が、４０％以上８５％未満であることである。所謂３層透明レーザーオーバーシートの場合のコア層厚み比率は、レーザー発色性（コントラスト性）の主要因子となる。すなわち、ＰＣ／ＰＣ（レーザーマーク対応）／ＰＣ　の３層構造でも、ＰＥＴＧ／ＰＣ（レーザーマーク対応）／ＰＥＴＧ　の３層構造でも、コア層厚みがレーザーマーキング性の主因子であり、レーザーマーキング性からはコア層が厚い方が好ましい。また、スキン層の厚みは、インレイ層との加熱融着性に寄与するため、薄い方が好ましい。従って、３層透明レーザーマーキングオーバーシートのコア層厚み比率の規定は４０％以上～８５％未満がより好ましい。この点、８５％以上となる３層透明レーザーマーキングオーバーシートでは、余りにもスキン層が薄くなるために、２種３層共押出成形において、スキン層の厚み制御が困難となり、安定的に成形するのは困難となる。

【０１０６】

コア層を構成する材料（素材）としては、ポリカーボネート樹脂、特に透明なポリカーボネート樹脂が使用される。ただし、使用されるポリカーボネート樹脂は特に制限はないが、メルトボリュームレイトが４～２０のものを好適に使用できる。メルトボリュームレイトが４未満では、シートのタフネス性が向上するという点では意味はあるものの、成形加工性が劣ることから、実際の使用に難があるため好ましくない。また、メルトボリュームレイトが２０を超えると、シートのタフネス性に劣ることから、好ましくない。

【０１０７】

［Ａ－１－３］レーザー光エネルギー吸収材：

また、透明レーザーマーキングシートＡが単層構造である単層シートとして構成される場合には、透明レーザーマーキングシートＡには、或いは透明レーザーマーキングシートＡが少なくとも３層シートである多層シート１，２として構成される場合には、そのコア層には、ポリカーボネート樹脂を主成分とする透明樹脂１００質量部に対して、レーザー光エネルギー吸収材を０．０００５～１質量部が含まれることが好ましい。このように構成することにより、レーザーマークした際のレーザー発色性に優れ、生地色と印字部とのコントラストが高くなり、鮮明な文字、記号、画像が得られるので好ましい。

【０１０８】

また、レーザー光エネルギー吸収材としては、カーボンブラック、チタンブラック、金属酸化物、金属硫化物、及び金属窒化物からなる群から選ばれた少なくとも１種が挙げられる。より好ましいのは、レーザー光エネルギー吸収材が、単層シート、または多層シート１，２のコア層にカーボンブラック、チタンブラック、及び金属酸化物からなる群から選ばれた少なくとも１種または２種以上を含有しているものである。

【０１０９】

ここで、多層シート２に添加するカーボンブラック、チタンブラック、金属酸化物、金属硫化物、金属窒化物の平均粒子径は、１５０ｎｍ未満であることが好ましく、より好ましいのは１００ｎｍ未満であり、さらに、平均粒径が１０～９０ｎｍで、ジブチルフタレート（ＤＢＴ）吸油量６０～１７０ｍｌ／１００ｇｒのカーボンブラックまたは該カーボンブラックと平均粒子径は、１５０ｎｍ未満のチタンブラックまたは金属酸化物の併用が好ましい。カーボンブラック、チタンブラック、金属酸化物、金属硫化物、金属窒化物の平均粒径が１５０ｎｍを超えるとシートの透明性が低下したり、シート表面に大きな凹凸

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が発生したりする事があり好ましくない。さらに、カーボンブラックの平均粒径が１０ｎｍ未満ではレーザー発色性が低下すると共に、微細すぎて取扱いに難があり、好ましくない。また、ＤＢＴ吸油量が６０ｍｌ／１００ｇｒ未満では分散性が悪く、１７０ｍｌ／１００ｇｒを超えると隠蔽性に劣るため好ましくない。

【０１１０】

また、多層シート１に添加する、チタンブラック、金属酸化物、金属硫化物、金属窒化物の平均粒子径は、前述した多層シート１と同様であるが、多層シート１に添加する、カーボンブラックの平均粒径は、１０～９０ｎｍで、ジブチルフタレート（ＤＢＴ）吸油量６０～１７０ｍｌ／１００ｇｒのカーボンブラックが好ましい。カーボンブラックの平均粒径が１０ｎｍ未満ではレーザー発色性が低下すると共に、微細すぎ取扱に難があり、９０ｎｍを超えるとシートの透明性が低下したり、シート表面に大きな凹凸が発生したりする事があり好ましくない。また、ＤＢＴ吸油量が６０ｍｌ／１００ｇｒ未満では分散性が悪く、１７０ｍｌ／１００ｇｒを超えるといんぺい性に劣るため好ましくない。

【０１１１】

また、多層シート１，２に添加する金属酸化物としては、酸化物を形成する金属として、亜鉛、マグネシウム、アルミニウム、鉄、チタン、珪素、アンチモン、錫、銅、マンガン、コバルト、バナジウム、ビスマス、ニオブ、モリブデン、ルテニウム、タングステン、パラジウム、銀、白金などが挙げられる。更に、複合金属酸化物としてＩＴＯ、ＡＴＯ、ＡＺＯ等が挙げられる。

【０１１２】

また、多層シート１，２に添加する金属硫化物としては、硫化亜鉛、硫化カドミニウムなどが挙げられる。さらに、金属窒化物としては窒化チタンなどが挙げられる。

【０１１３】

このように、多層シート１，２に添加するエネルギー吸収体としては、カーボンブラック、金属酸化物、及び複合金属酸化物が好適に用いられ、各々単独または併用して用いられる。

【０１１４】

さらに、多層シート２へのエネルギー吸収体は、カーボンブラックを０．０００５～１質量部添加（配合）されることが好ましく、より好ましくは０．０００８～０．１質量部である。また、カーボンブラックと平均粒子径１５０ｎｍ未満の金属酸化物、金属硫化物、金属窒化物から選ばれた少なくとも１種とを併用する場合にはその混合物の配合量が０．０００５～１質量部配合されることが更に好ましく、最も好ましいのは０．０００８～０．５質量部である。

【０１１５】

ここで、多層シート２へのエネルギー吸収体の添加量（配合量）を所望量に調製するのは、透明レーザーマーキングシートＡは透明であることが好ましいからである。すなわち、電子パスポート用レーザーマーキング積層体や、電子パスポートに使用する場合、印刷を施した白色シート（インレイとよばれる層）上に、透明レーザーマーキングシート（オーバーレイとよばれる層）を積層するなどして使用されるが、印刷部を施していない部分のオーバーレイにレーザー光を照射し、黒色発色させて、画像や文字をマーキングさせ、印刷部でのデザイン性とレーザーマーキングによる偽造防止効果を組み合わせて使用する事が多い。このように組み合わせて製造し使用することで、その下地層が白い故に、印刷部の鮮明性及びレーザーマーキング部の黒／白コントラストにより鮮明な画像を得ることができる。換言すれば、前述のインレイ層上に積層されるオーバーレイ層の透明性が劣ると、印刷された画像、文字等が不鮮明となること、及びレーザーマーキング部の黒／白コントラストが劣ること等から実用上問題となる。そのために平均粒子径の小さいカーボンブラックが好ましく用いられ、また、カーボンブラックと他の金属酸化物、金属硫化物、金属炭酸塩及び金属ケイ酸塩から選ばれた少なくとも１種との混合物をレーザーエネルギー吸収剤として用いる場合も、これら金属酸化物、金属硫化物の平均粒子径が少なくとも１５０ｎｍ未満、好ましくは１００ｎｍ未満とするのである。

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【０１１６】
したがって、多層シート２に添加する、前述のレーザーエネルギー吸収体の平均粒子径が１５０ｎｍを超えると透明レーザーマーキングシートＡの透明性が低下して好ましくない。また、これらレーザーエネルギー吸収体の配合量も１質量部を超えると透明レーザーマーキングシートＡ（多層シート）の透明性が低下すると共に、吸収エネルギー量が多過ぎてしまい、樹脂を劣化させてしまう。その結果、充分なコントラストが得られない。他方、レーザーエネルギー吸収体の添加量が０．０００５質量部未満では充分なコントラストが得られず好ましくない。更に、レーザーエネルギー吸収体の添加量が１質量部を超えると、透明レーザーマーキングシートＡの透明性が低下して好ましくないだけでなく、異常な発熱を生じることにより、樹脂の分解・発泡が発生し、所望のレーザーマーキングができない。

【０１１７】
また、多層シート１へのエネルギー吸収体は、カーボンブラックを０．０００１～３質量部添加（配合）されることが好ましく、より好ましくは０．０００１～１質量部である。また、カーボンブラックと平均粒子径１５０ｎｍ未満の金属酸化物、金属硫化物、金属炭酸塩及び金属ケイ酸塩から選ばれた少なくとも１種とを併用する場合にはその混合物の配合量が０．０００１～６質量部配合され、より好ましくは０．０００１～３質量部である。このように、エネルギー吸収体の添加量（配合量）を調製するのは次の理由のためである。すなわち、透明レーザーマーキングシートＡは透明であることが好ましく、透明レーザーマーキングシートＡの下層である着色レーザーマーキング多層シートＢに印刷を施す場合が多く、その場合に透明レーザーマーキングシートＡの透明性が劣ると印刷された画像、文字などが不鮮明となり実用上問題となる。そのために平均粒子径の小さいカーボンブラックが好ましく用いられ、また、カーボンブラックと他の金属酸化物、金属硫化物、金属炭酸塩及び金属ケイ酸塩から選ばれた少なくとも１種との混合物をレーザーエネルギー吸収剤として用いる場合も、これら金属酸化物、金属硫化物、金属炭酸塩及び金属ケイ酸塩の平均粒子径が少なくとも１５０ｎｍ未満、好ましくは１００ｎｍ未満、更に好ましくは５０ｎｍ未満とするのである。

【０１１８】
したがって、多層シート１に添加する、レーザーエネルギー吸収剤の平均粒子径が１５０ｎｍを超えると透明レーザーマーキングシートＡの透明性が低下して好ましくない。また、レーザーエネルギー吸収剤の配合量も６質量部を超えると透明レーザーマーキングシートＡ（多層シート）の透明性が低下すると共に、吸収エネルギー量が多すぎ、樹脂を劣化させてしまい、充分なコントラストが得られない。他方、レーザーエネルギー吸収体の添加量が０．０００１質量部未満では充分なコントラストが得られず好ましくない。

【０１１９】
［Ａ－１－４］滑材、酸化防止剤及び／または着色防止剤：
また、本実施形態では、単層シート、又は多層シート１，２として構成される透明レーザーマーキングシートＡに滑剤を含有させることが好ましく、透明レーザーマーキングシートＡがいわゆる３層シートからなる場合には、スキン層に滑剤を含有させることが好ましい。滑剤を含有させることにより、加熱プレス時にプレス板に融着を防ぐことができるからである。

【０１２０】
さらに、本実施形態では、単層シート、又は多層シート１，２として構成される透明レーザーマーキングシートＡに必要に応じて、酸化防止剤及び／又は着色防止剤、及び紫外線吸収剤及び／又は光安定剤を含有させることも好ましく、透明レーザーマーキングシートＡがいわゆる３層シート（多層シート）からなる場合には、スキン層及び／またはコア層に、必要に応じて、酸化防止剤及び／又は着色防止剤、及び紫外線吸収剤及び／又は光安定剤を含有させることも好ましい。酸化防止剤及び／または着色防止剤の添加（配合）は成形加工時における分子量低下による物性低下及び色相安定化に有効に作用する。この酸化防止剤及び／又は着色防止剤としては、フェノール系酸化防止剤や亜燐酸エステル系

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着色防止剤が使用される。また、紫外線吸収剤及び／又は光安定剤の添加（配合）は透明レーザーマーキングシートＡの保管時及び最終製品である電子パスポートの実際の使用時における耐光劣化性の抑制に有効に作用する。

【０１２１】

フェノール系酸化防止剤の例としては、例えば、α－トコフェロール、ブチルヒドロキシトルエン、シナピルアルコール、ビタミンＥ、ｎ－オクタデシル－３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート、３－５－ジ－ｔ－ブチル－４－ヒドロキシトルエン；ペンタエリスリチル－テトラキス〔３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート〕、トリエチレングリコール－ビス〔３－（３－ｔ－ブチル－５－メチル－４－ヒドロキシフェニル）プロピオネート〕、１，６－ヘキサンジオール－ビス〔３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート〕、２－ｔｅｒｔ－ブチル－６－（３’－ｔｅｒｔ－ブチル－５’－メチル－２’－ヒドロキシベンジル）－４－メチルフェニルアクリレート、２，６－ジ－ｔｅｒｔ－ブチル－４－（Ｎ，Ｎ－ジメチルアミノメチル）フェノール、３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジルホスホネートジエチルエステル、２，２’－メチレンビス（４－メチル－６－ｔｅｒｔ－ブチルフェノール）、２，２’－メチレンビス（４－エチル－６－ｔｅｒｔ－ブチルフェノール）、４，４’－メチレンビス（２，６－ジ－ｔｅｒｔ－ブチルフェノール）、２，２’－メチレンビス（４－メチル－６－シクロヘキシルフェノール）、２，２’－ジメチレン－ビス（６－α－メチル－ベンジル－ｐ－クレゾール）、２，２’－エチリデン－ビス（４，６－ジ－ｔｅｒｔ－ブチルフェノール）、２，２’－ブチリデン－ビス（４－メチル－６－ｔｅｒｔ－ブチルフェノール）、４，４’－ブチリデンビス（３－メチル－６－ｔｅｒｔ－ブチルフェノール）、トリエチレングリコール－Ｎ－ビス－３－（３－ｔｅｒｔ－ブチル－４－ヒドロキシ－５－メチルフェニル）プロピオネート、１，６－ヘキサンジオールビス［３－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオネート］、ビス［２－ｔｅｒｔ－ブチル－４－メチル６－（３－ｔｅｒｔ－ブチル－５－メチル－２－ヒドロキシベンジル）フェニル］テレフタレート、３，９－ビス｛２－［３－（３－ｔｅｒｔ－ブチル－４－ヒドロキシ－５－メチルフェニル）プロピオニルオキシ］－１，１，－ジメチルエチル｝－２，４，８，１０－テトラオキサスピロ［５，５］ウンデカン、４，４’－チオビス（６－ｔｅｒｔ－ブチル－ｍ－クレゾール）、４，４’－チオビス（３－メチル－６－ｔｅｒｔ－ブチルフェノール）、２，２’－チオビス（４－メチル－６－ｔｅｒｔ－ブチルフェノール）、ビス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジル）スルフィド、４，４’－ジ－チオビス（２，６－ジ－ｔｅｒｔ－ブチルフェノール）、４，４’－トリ－チオビス（２，６－ジ－ｔｅｒｔ－ブチルフェノール）、２，２－チオジエチレンビス－［３－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオネート］、２，４－ビス（ｎ－オクチルチオ）－６－（４－ヒドロキシ－３’，５’－ジ－ｔｅｒｔ－ブチルアニリノ）－１，３，５－トリアジン、Ｎ，Ｎ’－ヘキサメチレンビス－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシヒドロシンナミド）、Ｎ，Ｎ’－ビス［３－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオニル］ヒドラジン、１，１，３－トリス（２－メチル－４－ヒドロキシ－５－ｔｅｒｔ－ブチルフェニル）ブタン、１，３，５－トリメチル－２，４，６－トリス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジル）ベンゼン、トリス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）イソシアヌレート、トリス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジル）イソシアヌレート、１，３，５－トリス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジル）イソシアヌレート、１，３，５－トリス（４－ｔｅｒｔ－ブチル－３－ヒドロキシ－２，６－ジメチルベンジル）イソシアヌレート、１，３，５－トリス２［３（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオニルオキシ］エチルイソシアヌレート、およびテトラキス［３－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオニルオキシメチル］メタンなどが挙げられる。

【０１２２】

なお、これらの例示の中でも、とりわけ、ｎ－オクタデシル－３－（３，５－ジ－ｔｅｒｔ－ブチル－ヒドロキシフェニル）プロピオネート、１，３，５－トリメチル－２，４，６－トリス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジル）ベンゼン、１，３，５－トリス（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシベンジル）イソシアヌレート、テトラキス［３－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオニルオキシメチル］メタンが好適であり、特にｎ－オクタデシル－３－（３，５－ジ－ｔｅｒｔ－ブチル－４－ヒドロキシフェニル）プロピオネートが好適である。上記ヒンダードフェノール系酸化防止剤は、単独でまたは２種以上を組合せて使用することができる。

【０１２３】

亜燐酸エステル系着色防止剤としては、例えば、トリフェニルホスファイト、トリス（ノニルフェニル）ホスファイト、トリデシルホスファイト、トリオクチルホスファイト、トリオクタデシルホスファイト、ジデシルモノフェニルホスファイト、ジオクチルモノフェニルホスファイト、ジイソプロピルモノフェニルホスファイト、モノブチルジフェニルホスファイト、モノデシルジフェニルホスファイト、モノオクチルジフェニルホスファイト、２，２－メチレンビス（４，６－ジ－ｔｅｒｔ－ブチルフェニル）オクチルホスファイト、トリス（ジエチルフェニル）ホスファイト、トリス（ジ－ｉｓｏ－プロピルフェニル）ホスファイト、トリス（ジ－ｎ－ブチルフェニル）ホスファイト、トリス（２，４－ジ－ｔｅｒｔ－ブチルフェニル）ホスファイト、トリス（２，６－ジ－ｔｅｒｔ－ブチルフェニル）ホスファイト、ジステアリルペンタエリスリトールジホスファイト、ビス（２，４－ジ－ｔｅｒｔ－ブチルフェニル）ペンタエリスリトールジホスファイト、ビス（２，６－ジ－ｔｅｒｔ－ブチル－４－メチルフェニル）ペンタエリスリトールジホスファイト、ビス（２，６－ジ－ｔｅｒｔ－ブチル－４－エチルフェニル）ペンタエリスリトールジホスファイト、フェニルビスフェノールＡペンタエリスリトールジホスファイト、ビス（ノニルフェニル）ペンタエリスリトールジホスファイト、ジシクロヘキシルペンタエリスリトールジホスファイトなどが挙げられる。

【０１２４】

さらに、他のホスファイト化合物としては二価フェノール類と反応し環状構造を有するものも使用できる。例えば、２，２’－メチレンビス（４，６－ジ－ｔｅｒｔ－ブチルフェニル）（２，４－ジ－ｔｅｒｔ－ブチルフェニル）ホスファイト、２，２’－メチレンビス（４，６－ジ－ｔｅｒｔ－ブチルフェニル）（２－ｔｅｒｔ－ブチル－４－メチルフェニル）ホスファイト、２，２’－メチレンビス（４－メチル－６－ｔｅｒｔ－ブチルフェニル）（２－ｔｅｒｔ－ブチル－４－メチルフェニル）ホスファイト、２，２’－エチリデンビス（４－メチル－６－ｔｅｒｔ－ブチルフェニル）（２－ｔｅｒｔ－ブチル－４－メチルフェニル）ホスファイトなどを挙げることができる。

【０１２５】

上記の中でもトリス（２，４－ジ－ｔｅｒｔ－ブチルフェニル）ホスファイトが特に好ましい。亜燐酸エステル系着色防止剤は、１種もしくは２種以上を混合して用いてもよい。また、フェノール系酸化防止剤と併用してもよい。

【０１２６】

紫外線吸収剤としては、例えば２－（２’－ヒドロキシ－５’－メチルフェニル）ベンゾトリアゾール、２－（２’－ヒドロキシ－３’，５’－ジ－ｔｅｒｔ－アミルフェニル）ベンゾトリアゾール、２－（２’－ヒドロキシ－３’，５’－ビス（α，α’－ジメチルベンジル）フェニルベンゾトリアゾール、２，２’メチレンビス［４－（１，１，３，３－テトラメチルブチル）－６－（２Ｈ－ベンゾトリアゾール－２－イル）フェノール］、メチル－３－［３－ｔｅｒｔ－ブチル－５－（２Ｈ－ベンゾトリアゾール－２－イル）－４－ヒドロキシフェニルプロピオネート－ポリエチレングリコールとの縮合物に代表されるベンゾトリアゾール系化合物を挙げることができる。

【０１２７】

更に、紫外線吸収剤としては、例えば、２－（４，６－ジフェニル－１，３，５－トリ

アジン－２－イル）－５－ヘキシルオキシフェノール、２－（４，６－ビス（２，４－ジメチルフェニル）－１，３，５－トリアジン－２－イル）－５－ヘキシルオキシフェノールなどのヒドロキシフェニルトリアジン系化合物を挙げることができる。

【０１２８】

さらに、紫外線吸収剤としては、例えば、２，２’－ｐ－フェニレンビス（３，１－ベンゾオキサジン－４－オン）、２，２’－ｍ－フェニレンビス（３，１－ベンゾオキサジン－４－オン）、および２，２’－ｐ，ｐ’－ジフェニレンビス（３，１－ベンゾオキサジン－４－オン）などの環状イミノエステル系化合物を挙げることができる。

【０１２９】

また、光安定剤としては、ビス（２，２，６，６－テトラメチル－４－ピペリジル）セバケート、ビス（１，２，２，６，６－ペンタメチル－４－ピペリジル）セバケート、テトラキス（２，２，６，６－テトラメチル－４－ピペリジル）－１，２，３，４－ブタンテトラカルボキシレート、テトラキス（１，２，２，６，６－ペンタメチル－４－ピペリジル）－１，２，３，４－ブタンテトラカルボキシレート、ポリ｛［６－（１，１，３，３－テトラメチルブチル）アミノ－１，３，５－トリアジン－２，４－ジイル］［（２，２，６，６－テトラメチルピペリジル）イミノ］ヘキサメチレン［（２，２，６，６－テトラメチルピペリジル）イミノ］｝、ポリメチルプロピル３－オキシ－［４－（２，２，６，６－テトラメチル）ピペリジニル］シロキサンなどに代表されるヒンダードアミン系のものも含むことができ、かかる光安定剤は前記紫外線吸収剤や場合によっては各種酸化防止剤との併用において、耐候性などの点においてより良好な性能を発揮する。

【０１３０】

滑材としては、脂肪酸エステル、脂肪酸アミド、脂肪酸金属塩が挙げられ、それらから選ばれる少なくとも１種の滑剤が添加されることが好ましい。

【０１３１】

脂肪酸エステル系滑剤としては、ブチルステアレート、セチルパルミレート、ステアリン酸モノグリセライド、ステアリン酸ジグリセライド、ステアリン酸トリグリセライド、モンタンワックス酸のエステル、ロウエステル、ジカルボン酸エステル、複合エステル等が挙げられ、脂肪酸アマイド系滑剤としては、ステアリン酸アマイド、エチレンビスステアリルアマイド等が挙げられる。また、脂肪酸金属塩系滑剤としては、ステアリン酸カルシウム、ステアリン酸マグネシウム、ステアリン酸亜鉛、ステアリン酸アルミウム、ステアリン酸バリウム等が挙げられる。

【０１３２】

さらに、前記透明レーザーマーキングシートＡの、単層シートが、透明熱可塑性樹脂１００質量部に対して、滑剤０．０１～３質量部を含有するとともに、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する透明レーザーマーキングシート、又は、前記透明レーザーマーキングシートＡの、多層シート２における前記スキン層が、透明熱可塑性樹脂１００質量部に対して、滑剤０．０１～３質量部を含有するとともに、レーザー光エネルギー吸収材を０．０００５～１質量部、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有する透明レーザーマーキングシートとして構成されていることが好ましい。

【０１３３】

ここで、滑剤の添加量としては、単層シート、多層シート１，２とともに０．０１～３質量部添加されることが好ましく、より好ましくは０．０２～１質量部である。０．０１質量部未満では加熱プレス時にプレス板に融着してしまい、３質量部を超えると電子パスポートやカードの多層積層加熱プレス時に層間熱融着性に問題が生じるため好ましくない。さらに、酸化防止剤及び／又は着色防止剤が０．１質量部未満では、溶融し押出させて成形する工程でのポリカーボネート樹脂の熱酸化反応及びそれに起因する熱変色といった不具合が生じやすく、５質量部を超えると、これら添加剤のブリードといった不具合が生じやすいため好ましくない。さらに、紫外線吸収剤及び／又は光安定剤が、０．１質量部

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未満では、その効果に乏しく耐光劣化、それに伴う変色といった不具合が生じやすく、５質量部を超えると、これら添加剤のブリードといった不具合が生じやすいため好ましくない。

【０１３４】

［Ｂ］多層シートＢの構成：

本発明の多層シートＢは、スキン層とコア層とからなる少なくとも３層構造のシートとして構成され、溶融押出成形により積層形成される。なお、本実施形態に係る３層シートは、「少なくとも３層」であって、３層構造のシートに限られたものではない。すなわち、本実施形態における多層シートＢにおいて、「３層シート」と言うのは、説明の便宜を図るものであり、「３層シート」とは「少なくとも３層以上の層からなるシート」を意味するものであって、「３層」から成るシートに限定する趣旨ではない。換言すれば、３層以上の構成からなれば、５層から構成されても、７層から構成されても、或いは、それ以上の奇数層から形成されていても、本実施形態の多層シートＢに含まれる。

【０１３５】

ただし、上述した多層構造から本実施形態の多層シートＢが構成される場合にも、後述するスキン層は、多層構造から構成されるシートの最も外側の位置に配されるとともに、そのシートの両面に配され、さらに、両スキン層（の間）に、コア層が挟まれるように配されることが必要となる。なお、スキン層の厚さは、特に限定されるものではないが、より好ましいのは、後述の所定範囲の厚さに形成されることである。

【０１３６】

他方、多層シートＢが上述の「それ以上の奇数層」から構成される場合であっても、あまりに多層構造からなる場合には、配されるスキン層とコア層との一層あたりの層厚が薄くなり過ぎてしまい、透明レーザーマーキングシートＡとの加熱融着性が劣る問題が発生する。したがって、好ましいのは５層から、より好ましいのは３層から構成されるである。

【０１３７】

ここで、多層シートＢが前述のように奇数層から構成されるのは、偶数層からなる多層シートは、必ず奇数層からなる多層シートと同じ構成となるからである。例えば、４層からなる多層シートでは、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）、といった層の配置となり、結局のところ、奇数層から構成される多層シートと同様の構成となるからである。

【０１３８】

また、たとえば、３層から構成される多層シートを例にすると、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）、といった層の配列がなされるように、一方と他方の両最外側に２つのスキン層が配され、その２つのスキン層に挟まれるように、コア層が１層配されて多層シートが型成されることになる。また、５層から構成される多層シートを例にすると、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）、といった層の配列がなされるように、一方と他方の両最外側に２つのスキン層が配され、かつ、交互にスキン層とコア層を配列して、多層シートを形成してもよい。このように多層構造を有する多層シートを形成することにより、充分な加熱融着性が確保できる。

【０１３９】

また、３層シート（多層シートＢ）の全厚さ（総厚さ）は、全厚さが１００～３００μｍからなるとともに、コア層の厚さの、多層シートＢの全厚さに対して占める厚み比率（厚さの割合）が３０％以上、８５％未満からなることが好ましい。３層シート（多層シートＢ）の全厚さが、１００μｍ未満であると、必然的に多層シートＢのスキン層であるＰＥＴＧ層が薄くなり、多層シート積層工程における加熱融着時に最外層に積層される透明レーザーマーキングシートＡ（「単層シート」及びいわゆる「３層シートの両方を含む）と多層シートＢ間の加熱融着性が確保できない。また、３層シート（多層シートＢ）の全厚さが３００μｍを超えると、その３００μｍを超えた３層シートを用いて電子パスポート

用レーザーマーキング積層体を成形した場合、全厚みが厚くなりすぎ使いづらくなる。さらに、多層シートＢは、全厚さに対して占めるコア層の厚さの割合が３０％以上、８５％未満からなることが好ましいのは、多層シートＢ上に印刷する場合のいんぺい性の確保や、マーキング部の視認性、鮮明性を確保するためである。すなわち、スキン層の厚さがあまりにも薄いと、多層シート積層工程における加熱融着時に最外層に積層される透明レーザーマーキングシートＡ（「単層シート」及びいわゆる「３層シートの両方を含む）と多層シートＢ間の加熱融着性が確保できない。他方、スキン層の厚さがあまりにも大きすぎると、後述するコア層の厚さが、必然的に薄くなってしまい、多層シートＢ上に印刷する場合のいんぺい性の確保ができず、更には、スキン層に着色剤を入れない場合には、最外層である透明レーザーマーキングシートに、レーザー光照射により黒色マーキングを行った場合のコントラストを確保できず、また、マーキング部の視認性、鮮明性を確保することができないという問題が生じて好ましくないからである。

【０１４０】

このように３層シート全体の厚さを所望の厚さとすることにより、多層シートＢの特性といった局所的な特性を引き出しやすくなるのみならず、本実施形態の電子パスポート用レーザーマーキング積層体全体の特性を引き出しやすくなる。さらに、この３層シート全体の総厚さだけに限らず、３層シートを構成するスキン層及びコア層の３層シートに占める厚さの割合も前述の所望の割合にすることにより、３層シート全体の厚さを所望範囲内にすることと相俟って、コントラスト性を向上させやすくなる等、本発明の効果をより発揮させるため好ましい。

【０１４１】

なお、多層シートの融着性といんぺい性、（透明レーザーマーキングシートＡの）レーザーマーキング部とのコントラストは多層シートの実用化や生産性、市場のニーズに応え得るものであるか等極めて重要な要素となるため、さらに後段にて、３層シート全体の総厚さと、スキン層、及びコア層との厚さとの関係について詳述する。

【０１４２】

［Ｂ－１］多層シートＢにおけるスキン層：

多層シートＢにおけるスキン層は、３層シートの外側に配される両最外層として構成される。すなわち、このスキン層は、後述する多層シートＢにおけるコア層の両端面側（外側）から、挟み込むように配される、３層シートの表層（両最外層）としての役割を担っている。

【０１４３】

スキン層の厚さは、それぞれ同一であることが好ましい。それぞれ異なる厚さのスキン層から多層シートＢを構成すると、多層シート積層工程における加熱融着時の、最外層の透明レーザーマーキング多層シートＡと多層シートＢ間の加熱融着性のバラツキの要因となり好ましくないばかりか、加熱プレス後の積層体（電子パスポート用レーザーマーキング積層体）に“ソリ”が発生する事があり好ましくない。また、例えば、スキン層（ＰＥＴＧ）／コア層（ＰＣ）／スキン層（ＰＥＴＧ）といった３層から多層シートＢが構成される場合であって、コア層の厚さが３０％以上、８５％未満である場合には、スキン層は両面で１５％以上、７０％未満となる。スキン層の厚さがあまりにも薄いと熱融着性の低下が生じてしまい、他方、スキン層の厚さがあまりにも厚すぎると、後述するコア層の厚さが、必然的に薄くなってしまう。この場合、コア層のみに着色剤を配合すると、１台の押出機のみに着色剤入りの樹脂を投入するだけでよいので、スキン層とコア層に着色剤を配合した場合よりも洗浄が極端にいえば半分の手間で済むが、多層シートＢ上に、部分または全面印刷した場合のいんぺい性が不足する。また、スキン層とコア層に着色剤を配合すると、前述したいんぺい性の問題は生じないが、例えば、２種の樹脂による３層シート溶融押出成形には２台の押出機を使用するが、この２台の押出機には着色剤入りの樹脂を投入する事となり、２種３層溶融押出成形により成形されたシート生産後のクリーンアップには着色剤の洗浄にはかなりの手間がかかり、生産性とコスト的な問題が生じやすい。したがって、前述のような所望範囲内で、３層シート（多層シートＢ）の全厚さ（総厚さ

）及び、全厚さに対して占めるコア層の厚さの割合が形成されること好ましい。

【０１４４】

このスキン層を形成する素材としては、ポリエステル系樹脂組成物、すなわち、後述の共重合ポリエステル樹脂であって、これらの材料を調製した、後述する実質的に非結晶性の芳香族ポリエステル系樹脂組成物からなる層として形成されることが好ましい。

【０１４５】

［Ｂ－１－１］共重合ポリエステル樹脂：

本実施形態に用いられる共重合ポリエステル樹脂は、非結晶性の芳香族ポリエステル系樹脂組成物の主要な成分として配合されていることが好ましい。ここでいうポリエステル樹脂とは、芳香族ジカルボン酸とジオールの脱水縮合体をいい、本発明に用いられる実質的に非結晶性の芳香族ポリエステル樹脂とは、芳香族ポリエステル樹脂の中でも特に結晶性の低いものをいう。これらは、加熱プレス等で頻繁に加熱成形加工を行っても、結晶化による白濁や融着性の低下をおこさないものである。この共重合ポリエステル樹脂の具体例としては、スキン層には、テレフタル酸単位を主とするジカルボン酸単位及びエチレングリコール単位（Ｉ）［以下、「エチレングリコール単位（Ｉ）」という］、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂が使用される。この共重合ポリエステル樹脂に含まれる、エチレングリコールと、１，４－シクロヘキサンジメタノールと、の成分量を調製する理由は、共重合ポリエステル樹脂において、エチレングリコール成分の置換量が１０モル％未満で得られる樹脂では十分な非晶性にならず、熱融着後の冷却工程で再結晶化が進み、熱融着性が劣るからである。また、７０モル％を超えて得られる樹脂では十分な非晶性にならず、熱融着後の冷却工程で再結晶化が進み、熱融着性が劣るからである。したがって、本実施形態のように、エチレングリコールと、１，４－シクロヘキサンジメタノールと、の成分量を調製して得られる樹脂は、十分な非晶性になり、熱融着性の点で優れているため、好ましい樹脂といえる。

【０１４６】

さらに、この共重合ポリエステル樹脂としては、例えば、ポリエチレンテレフタレートにおけるエチレングリコール成分の約３０モル％を１，４－シクロヘキサンジメタノールで置換した実質的に非結晶性の芳香族ポリエステル系樹脂（略称「ＰＥＴＧ」、（商品名「イースター　コポリエステル」、イーストマンケミカル社製））が商業的に入手可能なものとして挙げられる。

【０１４７】

［Ｂ－２］多層シートＢにおけるコア層：

コア層は、３層シートの中心に配される、いわゆる核層として構成される。すなわち、このコア層は、最外側に配された２つのスキン層に挟み込まれるように、３層シートの中核層として形成されている。このコア層の厚さとしては、全シート中に占める厚さの割合が、３０％以上、８５％未満になるよう形成されることが好ましい。より好ましいのは、４０％以上８０％未満である。コア層の厚み比率が８５％以上となると、多層シートＢの総厚みが１００～３００μｍと薄いため、相対的にスキン層も薄くなってしまい、多層シート積層工程における加熱融着時に最外層である透明レーザーマーキングシートＡ（「単層シート」及びいわゆる「３層シートの両方を含む）と多層シートＢ間の加熱融着性のバラツキの要因となり好ましくない。また、コア層の厚み比率が３０％未満では多層シートＢ上に印刷する場合のいんぺい性が確保できず、更には最外層である透明レーザーマーキングシートＡ（「単層シート」及びいわゆる「３層シートの両方を含む）にレーザー光照射により黒色マーキングを行った場合のコントラストを確保できず、マーキング部の視認性、鮮明性を確保することができないという問題が生じて好ましくない。

【０１４８】

コア層を構成する材料（素材）としては、ポリカーボネート樹脂、特に透明なポリカー

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ボネート樹脂が使用される。ただし、使用されるポリカーボネート樹脂は特に制限はないが、メルトボリュームレイトが４～２０のものを好適に使用できる。メルトボリュームレイトが４未満では、シートのタフネス性が向上するという点では意味はあるものの、成形加工性が劣ることから、実際の使用に難があるため好ましくない。また、メルトボリュームレイトが２０を超えると、シートのタフネス性に劣ることから、好ましくない。

【０１４９】

［Ｂ－２－１］染料、顔料等の樹脂の着色剤：

多層シートＢは、着色多層シートであり、多層シートＢのスキン層及び／又はコア層には、前記共重合ポリエステル樹脂１００質量部及び／又は前記ポリカーボネート樹脂１００質量部に対して、染料、顔料等の樹脂の着色剤の少なくとも１種以上を１質量部以上含有させていることが好ましい。この点で、透明レーザーマーキングシートＡと異なる。このように着色系染料、顔料等の樹脂の着色剤を１質量部以上配合するのは、後述するように、透明レーザーマーキングシートＡと着色多層シートＢの積層体シートを積層させた後レーザー光を照射してマーキングする場合にコントラストが良好になるためと、着色多層シートＢ上に印刷する場合のいんぺい性を確保するためである。

【０１５０】

この着色系染料、顔料等の樹脂の着色剤としては、白色顔料として酸化チタン、酸化バリウム、酸化亜鉛、黄色顔料として酸化鉄、チタンイエロー、赤色顔料として、酸化鉄、青色顔料としてコバルトブルー群青などが挙げられる。ただし、コントラスト性を高めるため、薄い色付、淡彩色系となるものが好ましい。

【０１５１】

より好ましいのは、コントラスト性の際立つ、白色系染料、顔料等の樹脂の着色剤が添加されることである。

【０１５２】

［Ｂ－３］滑材、酸化防止剤及び／または着色防止剤：

また、前述した単層シート及び多層シート（いわゆる３層シート）を含めた多層シートＢのコア層及び／又はスキン層が熱可塑性樹脂１００質量部に対して、酸化防止剤及び／又は着色防止剤０．１～５質量部、及び紫外線吸収剤及び／又は光安定剤０．１～５質量部含有することも好ましい形態の一つである。酸化防止剤及び／または着色防止剤を添加（配合）させる場合には、成形加工時における分子量低下による物性低下及び色相安定化に有効に作用し、紫外線吸収剤及び／又は光安定剤を添加（配合）させる場合には、電子パスポート用レーザーマーキング積層体の保管時及び最終製品である電子パスポートの実際の使用時における耐光劣化性の抑制に有効に作用するから好ましい。すなわち、このような構成にすることにより、適宜選択的に、酸化防止剤及び／又は着色防止剤、及び紫外線吸収剤及び／又は光安定剤を所望量含有させることができることに加えて、適宜、含有させる領域を選択できるため、シート全体として相乗的に本発明の効果をより奏することができる。

【０１５３】

なお、多層シートＢの滑材、酸化防止剤及び／または着色防止剤は、透明レーザーマーキングシートＡに含有される滑材、酸化防止剤及び／または着色防止剤と同じである。したがって、透明レーザーマーキングシートＡの説明（滑材、酸化防止剤及び／または着色防止剤）を参照されたい。

【０１５４】

［２－４］透明レーザーマーキングシートＡと多層シートＢの関係：

前述のように、透明レーザーマーキングシートＡと多層シートＢを積層することにより、本発明の効果を奏することができる。すなわち、透明レーザーマーキングシートＡは、ＰＣ（レーザーマーク対応）透明単層シートまたはＰＣ／ＰＣ（レーザーマーク対応）／ＰＣからなる透明なレーザーマーク３層シート（多層シート２）、として構成される場合には、その透明レーザーマーキングシートＡのレーザーを照射する面と反対の面には、さらに、ＰＥＴＧ／ＰＣ（白色系着色剤配合）／ＰＥＴＧ、からなる着色多層シートＢを積

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層することにより、上層（透明レーザーマーキングシートＡ）にレーザー照射してコア層ＰＣが黒発色した場合にコントラストを確保しマーキング部の視認性、鮮明性を発揮させるためである。更には、着色多層シートＢ上に画像、文字等を印刷することは一般的に為されるため、その印刷部分の鮮明性や印刷部の保護、すなわち、最外層に印刷を施した場合は、なんらかの摩擦、摩耗が発生した場合に印刷部が磨り減り視認性が大きく低下するが、透明レーザーマーキングシートＡの下層である多層シートＢの表面に印刷する事により、この問題を解決できるため重要である。

【０１５５】

また、多層シートＡが、ＰＥＴＧ／ＰＣ（レーザーマーク対応）／ＰＥＴＧ　からなる透明なレーザーマーク３層シートとして構成される場合には、その多層シートＡのレーザーを照射する面と反対の面には、さらに、ＰＥＴＧ／ＰＣ（着色レーザーマーク対応）／ＰＥＴＧ、からなる着色レーザーマーク多層シートＢを積層することにより、上層（多層シートＡ）にレーザー照射してコア層ＰＣが黒発色しても、レーザー光は更に通過して、下層（多層シートＢ）のコア層ＰＣも黒発色を生成する。これにより、レーザー光で発色した部分の黒化度が更に向上する。

【０１５６】

このように、レーザーマーキングによる画像（たとえば、人の顔等）の鮮明性を十分に引き出すには、反射率やコントラストを制御することが重要となる。たとえば、反射率が不十分であったり、コントラストが低かったりすると、画像の鮮明性が低下してしまうためである。また、たとえば、前述の多層シートＡ（ＰＥＴＧ／ＰＣ（レーザーマーク対応）／ＰＥＴＧ透明なレーザーマーク３層シート）に、レーザーマーク対応でないＰＥＴＧ／ＰＣ（白）／ＰＥＴＧ　の３層シートを加熱融着させて、電子パスポート用レーザーマーキング積層体を形成する場合には、下層の３層シートにＰＥＴＧ透明層があるため反射率が不十分となってしまい好ましくない。さらに、反射率やコントラストを考慮し、ＰＣ（白）シートを前述のＰＥＴＧ／ＰＣ（白）／ＰＥＴＧ　の３層シートに代えて、多層シートＡの下層に用いると、反射率がＰＥＴＧ／ＰＣ（白）／ＰＥＴＧ　の３層シートより向上するとともに、上層（多層シートＡ）のレーザーマーキングによる黒発色と下層（ＰＣシート）の白とのコントラストが向上する事で画像の鮮明性がよくなる。しかし、下層がＰＣ（白）シートでは上層との加熱融着性の問題が発生し、１２０～１５０℃程度の低温での加熱融着性が悪い。２１０～２４０℃に温度を上げれば加熱融着するが、これでは上層のＰＥＴＧ層が軟化、溶融してしまい電子パスポート用レーザーマーキング積層体を得ることができない。

【０１５７】

したがって、下層にもレーザーマーキング対応とする事で、上層にレーザー照射してコア層ＰＣが黒発色しても、レーザー光は更に通過して下層のコア層ＰＣも黒発色を生成する。これにより、レーザー光で発色した部分の黒化度が更に向上することにより、下層にＰＣ（白）シートを使用した場合と同等のコントラストが得られ、画像を鮮明にでき、しかも、加熱融着性における問題も生じさせないようにした。このように、本発明は所望の多層シートＡと多層シートＢとの組み合わせにより、相乗的に本発明の効果を発揮するものである。

【０１５８】

なお、前述では、本実施形態体の電子パスポート用レーザーマーキング積層体において、透明レーザーマーキングシートＡの下層に多層シートＢを積層する配置パターンついて説明したが、このような配置に限られるものではない。すなわち、必ずしも上層に透明レーザーマーキングシートＡを配置し、下層に多層シートＢを配置するものに限定されるものではない。たとえば、透明レーザーマーキングシートＡを下層に配置し、多層シートＢを上層に配置してもよい。このように、透明レーザーマーキングシートＡ（或いは多層シートＢ）を、上層又は下層に配置してもよいのは、レーザーマークした画像等を目視する位置（方向）が、上下方向に限られないからである。換言すれば、たとえば、パスポートのように冊子形式で、本実施形態体における電子パスポート用レーザーマーキング積層体

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を使用する場合には、見開き状にして平面視した場合に、上層に透明レーザーマーキングシートＡを配置し下層に多層シートＢを配置しても、次ページを開いて平面視した場合には、その透明レーザーマーキングシートＡと多層シートＢの配置位置は、丁度、上層に多層シートＢを配置し下層に透明レーザーマーキングシートＡを配置したことになってしまうからである。したがって、ここでの上層、下層は、説明の便宜を図るために用いたものであって、レーザー照射する側に透明レーザーマーキングシートＡが配置されることを意味する。このように配置されることにより、レーザーマークされた後の透明レーザーマーキングシートＡと多層シートＢとの、画像等の鮮明さや高コントラストを得ることができ、本発明の効果を奏することできるのである。

【０１５９】

さらに、本実施形態体における電子パスポート用レーザーマーキング積層体には、透明レーザーマーキングシートＡ／多層シートＢと積層させる場合に限らない。たとえば、多層シートＢの表面に各種印刷等を施した後、透明レーザーマーキングシートＡ／（印刷した）多層シートＢ／積層ヒンジシートＣ／（印刷した）多層シートＢ／透明レーザーマーキングシートＡと積層する場合、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡと積層する場合、多層シートＢ／積層ヒンジシートＣ／多層シートＢの積層体シートを加熱融着させて、この積層体シート表面に印刷等をした後、更に透明レーザーマーキングシートＡ／該積層体シート／透明レーザーマーキングシートＡを積層させる場合なども広く含まれる。使用目的や使用方法に応じて柔軟に対応可能となり、本発明の効果を奏することができる。

【０１６０】

［３］透明レーザーマーキングシートＡ及び多層シートＢの成形方法：

本発明において、透明レーザーマーキングシートＡ及び着色多層シートＢを得るには、例えば、各層の樹脂組成物を溶融押出成形して積層する方法、各層をフィルム状に形成し、これをラミネートする方法、２層を溶融押出して形成し、これに別途形成したフィルムをラミネートする方法等があるが、生産性、コストの面から溶融押出成形により積層することがより好ましい。

【０１６１】

具体的には、各層の樹脂組成物をそれぞれ配合し、あるいは必要に応じてペレット状にして、Ｔダイを共有連結した３層Ｔダイ押出機の各ホッパーにそれぞれ投入し、温度２００℃～３００℃の範囲で溶融して３層Ｔダイ溶融押出成形し、冷却ロール等で冷却固化して、３層積層体を形成することができる。なお、本発明における、透明レーザーマーキングシートＡ及び着色多層シートＢは、上記方法に限定されることなく、公知の方法により形成することができ、例えば、特開平１０－７１７６３号公報第（６）～（７）頁の記載に従って得ることができる。

【０１６２】

上述のようにして得られた透明レーザーマーキングシートＡ、多層シートＢ、積層ヒンジシートＣを所定の寸法に切断した後、積層し、ロータリー真空プレス機等を用いて、所望時間、所望圧力で、所望温度で加熱融着等によって接合して、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層を積層させた電子パスポート用レーザーマーキング積層体を得ることができる。また、透明レーザーマーキングシートＡおよび多層シートＢを各々溶融共押出成形にてシートを成形した後、例えば、透明レーザーマーキングシートＡ／多層シートＢを加熱ローラーにて加熱、加圧ラミネーションにより長尺の積層体シートを製造する。その後所定の寸法にカットして、積層体シート／積層ヒンジシートＣ／積層体シートに積層した後、加熱融着により上記同様、５層を積層させた電子パスポート用レーザーマーキング積層体を製造する方法などによっても電子パスポート用レーザーマーキング積層体を製造できる。

【０１６３】

ここで、所望時間、所望圧力、所望温度は、特に限定されるものではない。所望時間、

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所望圧力、所望温度は、必要に応じて適宜選択されることが好ましい。なお、一般的なものとして、所望時間は１０秒～６分程度、所望圧力１～２０ＭＰａ、所望温度１３０～１７０℃、より好ましい所望温度としては１４０～１６０℃を一例として挙げることができる。

【０１６４】

［４］その他の積層体：

前述のように、本発明の電子パスポート用レーザーマーキング積層体は、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　からなる５層積層体として構成されることが好ましい。すなわち、透明レーザーマーキングシートＡ／多層シートＢの積層体として構成することで、画像などの鮮明性を向上できる。また、電子パスポートでは、多層シートＢの片面に（透明レーザーマーキング層側に）、国などの固有の固定情報を印刷するが、その場合、白色系の多層シートＢ上に印刷した方が、画像などの鮮明性が際立つ。例えば、茶色や黒色などの濃色系の多層シートＢ上に印刷するより、前者の方が下地色の影響を受けずに鮮明な印刷ができるため好ましい。更に、この固定情報を多層シートＢ上に印刷した後に、透明レーザーマーキング層に、個人情報や個人画像等の可変情報をレーザーマーキングにて黒発色させる場合にも、固定情報印刷を白い部分の多い淡彩色とする事で、下地淡彩色とのコントラストが大きくなり鮮明な画像と文字が得られる。従って、着色された多層シートＢ（着色シートＢ）の色は白等の淡彩色がより好ましい。

【０１６５】

また、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の５層積層体として構成する事で、表面及び／または裏面のどちらからでもレーザーマーキングする事ができる。また、これら５層積層体を加熱プレス成形により加熱融着した場合に、得られた５層積層体には、そりがほとんど発生しないことも特長といえる。なお、各層の厚みは、透明レーザーマーキングシートＡが５０～２００μｍ、多層シートＢが１００～３００μｍ、積層ヒンジシートＣが８０～２５０μｍであることが好ましい。

【０１６６】

好ましいのは、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の５層積層体構成であって、積層ヒンジシートＣが熱可塑性樹脂シートＰと熱可塑性樹脂シートＲとの積層ヒンジシートであり、熱可塑性樹脂シートＰ／熱可塑性樹脂シートＲ／熱可塑性樹脂シートＰからなる３層構造である事を特長とするものである。この様な３層構造とする事で平坦性を有する積層ヒンジシートを得ることができ、所定のサイズにカットした枚葉シートの搬送性と柔軟性に優れ、更に、多層シートＢとの加熱融着性に優れ、加熱積層工程での貼りだし部のシワ等の外観異常の発生も抑制でき、この貼りだし部を用いて表紙や他のシートと共にミシン綴じした場合のミシン部の破壊強度にも優れる５層積層体を製造することができる。

【０１６７】

ここで、本実施形態のような５層積層体は種々の方法で製造できる。例えば、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　を積層した後、加熱プレスにて熱融着（熱ラミネーション）させる事で５層積層体を製造できる。

【０１６８】

また、前述の様な積層体に印刷を施したい場合には、多層シートＢの片面に光または熱硬化型インクで印刷・硬化した後、さらに、透明レーザーマーキングシートＡ／印刷多層シートＢ／積層ヒンジシートＣ／印刷多層シートＢ／透明レーザーマーキングシートＡ　を積層した後、加熱プレスにて熱融着（熱ラミネーション）させるか、または、多層シートＢ／積層ヒンジシートＣ／多層シートＢを加熱プレスにて熱融着により積層した後、この積層体表面に印刷した後、透明レーザーマーキングシートＡを透明レーザーマーキングシートＡ／（多層シートＢ／積層ヒンジシートＣ／多層シートＢ）積層体／透明レーザー

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マーキングシートＡ　と積層して加熱プレスする事によっても製造できる。

【０１６９】

更に、多層シートＢの片面に光または熱硬化型インクで印刷・硬化した後、その印刷面に接着剤の１種であるバーニッシュを薄く塗布、必要に応じて乾燥後に、透明レーザーマーキングシートＡ／バーニッシュ塗布印刷多層シートＢ／積層ヒンジシートＣ／バーニッシュ塗布印刷多層シートＢ／透明レーザーマーキングシートＡ　を積層して加熱プレスする事によって強固に加熱融着させる事ができる。

【０１７０】

また、透明レーザーマーキングシートＡの片面（多層シートＢの印刷面と加熱融着させる面）に熱活性型接着剤を３～２０μｍ、好ましくは３～１０μｍ、更に好ましくは５～１０μｍの乾燥厚みに予め塗布しておき、前記同様、透明レーザーマーキングシートＡ（片面熱活性型接着剤層）／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ（片面熱活性型接着剤層）を積層した後、加熱プレスにて熱融着（熱ラミネーション）する事により強固に加熱融着させる事ができる。

【０１７１】

また、この様な積層体に印刷を施す場合に、より好ましいのは、多層シートＢの片面に光または熱硬化型インクで印刷・硬化した後、透明レーザーマーキングシートＡ／印刷多層シートＢ／積層ヒンジシートＣ／印刷多層シートＢ／透明レーザーマーキングシートＡ　を積層させ、その後加熱プレスにて熱融着（熱ラミネーション）させるか、または、多層シートＢの片面に光または熱硬化型インクで印刷・硬化した後、その印刷面に接着剤の１種であるバーニッシュを薄く塗布、必要に応じて乾燥後に、透明レーザーマーキングシートＡ／バーニッシュ塗布印刷多層シートＢ／積層ヒンジシートＣ／バーニッシュ塗布印刷多層シートＢ／透明レーザーマーキングシートＡ　を積層、または、透明レーザーマーキングシートＡの片面に前記の様に熱活性接着剤をプレ塗工した後、熱活性接着剤をプレ塗工透明レーザーマーキングシートＡ／印刷多層シートＢ／積層ヒンジシートＣ／印刷多層シートＢ／熱活性接着剤をプレ塗工透明レーザーマーキングシートＡ　を積層して加熱プレスする事によって、電子パスポート用レーザーマーキング積層体を形成することである。本発明の効果を奏するだけでなく、成形しやすい等の利便性が向上するためである。

【０１７２】

ただし、このようなもの限定されるものではなく、本発明の構成、効果を逸脱しない範囲内で、前述の５層積層体を形成してもよい。

【０１７３】

また、熱融着（熱ラミネーション）の場合の加熱プレス温度は積層ヒンジシートＣの種類によっても異なるが、１３０～１７０℃、好ましくは１４０～１６０℃である。加熱プレス温度が１３０℃未満では接着不良が生じることがあり、１７０℃を超えると５層積層体のソリ、チヂミまたはシートのはみ出しや印刷インクの焼けなどによる変色などの異常が生じて好ましくない。

【０１７４】

［５］マット加工：

また、透明レーザーマーキングシートＡ、及び／又は多層シートＢの表面には平均粗さ（Ｒａ）０．１～５μｍのマット加工が施されていることが好ましい。このように、前述の夫々のシート表面に、適宜選択的に、マット加工を形成する理由は、例えば、透明レーザーマーキングシートＡと多層シートＢを加熱プレス成形する場合、前述のようにマット加工が施されていると、透明レーザーマーキングシートＡと多層シートＢの間の空気が抜けやすくなるからである。他方、積層工程に搬送する場合に、これらのシートがマット加工していないと、吸引・吸着して搬送して、これらのシートを位置合わせして積層した後、空気を注入して多層シートを脱着する際、脱着困難であったり、脱着できても積層位置がずれたりするなどの問題が生じやすい傾向がある。また、マット加工の平均粗さ（Ｒａ）が５μｍを超えると、透明レーザーマーキングシートＡと、多層シートＢとの間の熱融着性が低下しやすくなる傾向がある。さらに、適宜選択可能とすることにより、電子パス

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ポート用レーザーマーキング積層体全体として、調整しやすくなるから好ましい。

【０１７５】

さらに、表面の平均粗さ（Ｒａ）が０．１μｍ未満では前述したようにシート搬送時・積層時に、シートが搬送機に貼りつくという問題等が発生しやすい傾向がある。

【０１７６】

［６］インレットシート：

また、必要に応じて、インレットシートを用いてＩＣチップ（「ＩＣ－Ｃｈｉｐ」ともいう）とアンテナ（「Ａｎｔｅｎｎａ」ともいう）を配置させることも好ましい。たとえば、通常はＰＥＴＧ等の原料から成形されるシートに、ＩＣ－Ｃｈｉｐとアンテナを配置し、これをインレットシートとするとともに、このインレットシートを積層ヒンジシートの片側に配置するが、これまで説明した積層ヒンジシートＣに、直接ＩＣ－Ｃｈｉｐとアンテナを配置したインレットシート兼用積層ヒンジシートとして構成してもよい。ＩＣチップ及びアンテナを配設させやすく、また、いわゆるＩＣチップ内蔵型の電子パスポート用レーザーマーキング積層体として対応できるからである。

【０１７７】

また、２００～３００μｍ程度のＰＥＴＧ等の熱可塑性樹脂シートを切削してＩＣ－ＣｈｉｐとＡｎｔｅｎｎａを挿入してインレットシートを作成し、オーバーシート／インレイシート／インレットシート／積層ヒンジシート／インレイシート／オーバーシートの構成として使用してもよい。さらに、オーバーシート／インレイシート／積層ヒンジシート／インレットシート／インレイシート／オーバーシートの構成としてｅ－Ｃａｒｄ対応にしてもよい。

【０１７８】

なお、インレットシートを、前述のインレットシート兼用積層ヒンジシートのように兼用として構成せずに、別体として構成する場合には、たとえば、実質的に非結晶性の芳香族ポリエステル系樹脂、或いは前記樹脂組成物からなる熱可塑性樹脂シート、具体的には、テレフタル酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂からなる熱可塑性樹脂シートに、ＩＣチップとアンテナを配置したシートを配設してインレットシートを形成し、そのインレットシートＥを、ＩＣチップ及びアンテナを被覆するように、積層ヒンジシートの片面に積層して、インレットシートを形成した後、透明レーザーマーキングシートＡ、多層シートＢの夫々を積層させて、加熱プレスすると、積層体が形成できる。更には、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシート／インレットシートＥ／多層シートＢ／透明レーザーマーキングシートＡの様に構成した後、加熱プレスによる積層体を形成してもよい。なお、これらのように構成をとることにより加熱プレス時の応力や熱等からＩＣチップ及びアンテナが損傷することを防ぐことができるため好ましい。

【０１７９】

ただし、この例に限定されるものではなく、本発明の趣旨を逸脱しない範囲で、適宜、変更、修正が行われるものも、本発明に含まれる。

【０１８０】

なお、インレットシートを積層させる場合には、積層ヒンジシートＣ（或いは、インレットシート兼用ヒンジシート）の一端に、透明レーザーマーキングシートＡ及び多層シートＢよりも５～１００ｍｍ長い張り出し部を備えさせるとともに、その張り出し部を用いて（介して）、インレットシートが電子パスポートにミシン綴じ及び／または接着されて電子パスポートに組み付けられるように構成されることも好ましい形態の一つである。

【０１８１】

なお、インレットシートの材料として、前述の実質的に非結晶性の芳香族ポリエステル系樹脂、或いは前記樹脂組成物からなる熱可塑性樹脂シート、具体的には、「テレフタル

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酸単位を主とするジカルボン酸単位とエチレングリコール単位（Ｉ）、及び、１，４－シクロヘキサンジメタノール単位（ＩＩ）を主とするグリコール単位からなるポリエステルであって、かつ、エチレングリコール単位（Ｉ）と１，４－シクロヘキサンジメタノール単位（ＩＩ）とが、（Ｉ）／（ＩＩ）＝９０～３０／１０～７０モル％である共重合ポリエステル樹脂」の代わりに、たとえば、接着性シートを使用することも好ましい。その後の、インレットシートを成形する加熱プレス行程を省略できるだけでなく、過度の加熱プレス時に負荷されやすい応力や熱等から、ＩＣチップ及びアンテナが損傷すること低減できるからである。このような接着性シートとしては、たとえば、厚さが約３０μｍ程度のポリエステル系接着性シート（例えば、東亜合成株式会社製　アロンメルトＰＥＳ－１１１ＥＥシート）などを挙げることができるが、このようなものに限定されるものではない。なお、前述の共重合ポリエステル樹脂、或いは、接着性シートを使用する場合にも、インレットの厚みは、一般的に、２００～３００μｍであるが、全体として前述の所望範囲内であることが好ましい。

【０１８２】

なお、これまで前述した電子パスポート用レーザーマーキング積層体であって、多層シートＢの表面に印刷した後、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の５層積層体、又は、透明レーザーマーキングシートＡ／多層シートＢ／インレットシートＥ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の６層積層体として形成されることが好ましい。このように電子パスポート用レーザーマーキング積層体を成形することにより、レーザーマーキング性に優れ、かつ、生地色と印字部とのコントラストが高く、鮮明な文字、記号、画像が得られるため、本発明の効果を奏することができる。

【０１８３】

たとえば、ＩＣ－Ｃｈｉｐとアンテナを配置したｅ－カード（ｅ－Ｃａｒｄ）においては、ＩＣ－Ｃｈｉｐとアンテナを配置したインレットシートＥを使用する場合には、前述のデータページでの基本構成である透明レーザーマーキングシートＡ／多層シートＢ／ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５層積層体（５層からなる電子パスポート用レーザーマーキング積層体）のヒンジシートの片側に配置されることになる。より具体的には、透明レーザーマーキングシートＡ／多層シートＢ／インレットシートＥ／ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの６層積層体（６層からなる電子パスポート用レーザーマーキング積層体）の構成となる。更に、ヒンジシートにＩＣ－Ｃｈｉｐとアンテナを配置してインレットシートとヒンジシートを兼ね備えたヒンジシートＣ（以下、適宜ヒンジシートＣ（２）という）を用いる場合には、透明レーザーマーキングシートＡ／多層シートＢ／インレットシートＥ／ヒンジシートＣ（２）／多層シートＢ／透明レーザーマーキングシートＡの５層積層体としてもよい。

【０１８４】

［７］電子パスポート：

また、前述した電子パスポート用レーザーマーキング積層体を使用して成形される電子パスポートであって、前記積層ヒンジシートＣの張り出し部が、電子パスポートの表紙または裏表紙にミシン綴じ及び／または接着してなる電子パスポートとして成形することが好ましい。このように構成することにより、電子パスポートを成形し易くなるため好ましい。たとえば、前述した電子パスポート用レーザーマーキング積層体を用いるとともに、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の５層積層体、又は透明レーザーマーキングシートＡ／多層シートＢ／インレットシート／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡ　の６層積層体として構成される場合には、積層ヒンジシートＣの張り出し部を用いて電子パスポート表紙または裏表紙にミシン綴じ及び／または接着して電子パスポートとして成形することできる。

【０１８５】

具体的には、図４に示されるようなパスポートを例示できる。このパスポートは、図２

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Ａ～図２Ｃに示されるような電子パスポート用レーザーマーキング積層体を用意し、図３に示されるように、必要に応じてミシン綴じ部２７等を形成するとともに、さらに図４に示されるような、表紙４９、本実施形態を用いた積層体５１、ビザシート５３、ＩＣチップ５５等を配置して作成されている。ただし、これは一例であって、必ずしもこのような構成、作成方法等に限られるものではない。

【０１８６】

［８］偽造防止形成部：

さらに、偽造防止形成部が形成されていることが好ましい。偽造防止形成部が施される（設けられる）ことにより、前述までの特徴と相俟って、確実に偽造等を防止できるからである。ここで、偽造防止形成部としては、レーザー照射による文字、画像（人物画像）の他、たとえば、ホログラム、マイクロ文字、マイクロウェーブ文字、エンボス文字、斜め印刷（斜め文字等）、レンチキュラ、ブラックライト印刷、パール印刷等を透明レーザーマーキングシートＡ、多層シートＢ、積層ヒンジシートＣ、インレットシートの少なくとも一つに施したものを例示できる。

【０１８７】

［９］レーザーマーキング方法：

本実施形態における電子パスポート用レーザーマーキング積層体は、レーザー光線を照射して発色させるものであるが、レーザー光としては、Ｈｅ－Ｎｅレーザー、Ａｒレーザー、$ＣＯ_2$レーザー、エキシマレーザー等の気体レーザー、ＹＡＧレーザー、Ｎｄ・$ＹＶＯ_4$レーザー等の固体レーザー、半導体レーザー、色素レーザー等が挙げられる。これらのうち、ＹＡＧレーザー、Ｎｄ・$ＹＶＯ_4$レーザーが好ましい。

【０１８８】

なお、前述したように、上記樹脂組成物には、必要に応じて、その特性を損なわない範囲で、他の添加剤、例えば離型剤、安定剤、酸化防止剤、紫外線吸収剤、強化剤などを添加することができる。

【０１８９】

本実施形態のレーザーマーキング方法において、レーザー光線としては、レーザビームは、シングルモードでもマルチモードでもよく、また、ビーム径が２０～４０μｍのように絞ったもののほか、ビーム径が８０～１００μｍのごとく広いものについても用いることができるが、シングルモードで、ビーム径が２０～４０μｍの方が、印字発色部と下地のコントラストを３以上とし、コントラストが良好な印字品質を得る点で好ましい。

【０１９０】

このように本実施形態の電子パスポート用レーザーマーキング積層体に、レーザー光線を照射すると、単層シート、多層シート２の場合には、レーザーマーキング多層シートを構成する透明レーザーマーキングシートＡが発色するが、この透明レーザーマーキングシートＡは耐熱性の高いポリカーボネート樹脂が主成分であるから、高パワーのレーザー光を照射することが可能であり、それによって容易かつより鮮明に画像等を描くことができる。とりわけ、透明レーザーマーキングシートＡをＰＣ／ＰＣ（レーザー発色層）／ＰＣの３層とする多層シート２の場合には、ＰＣレーザー発色層上にＰＣ透明スキン層を設けることにより、ＰＣレーザー発色層単層では更なる高パワーのレーザー光を照射によって“発泡”によってシート表面の「フクレ」現象が発生する条件においても、ＰＣ透明スキン層効果により「フクレ」現象が抑制されるため、更に鮮明に画像等を描くことができる。このＰＣ透明スキン層効果はこれだけにとどまらず、ＰＣレーザー発色層単層の場合は該シートが外部との摩擦によりマーキング部が直接削られていくのに対して、ＰＣ透明スキン層を付与することによりＰＣ透明スキン層が削られてもレーザーマーキング部は削られないため、レーザーマーキング部の耐磨耗性はより優れるといえる。

【０１９１】

更に、ポリカーボネート樹脂からなるシートは耐熱性が高い故に、該樹脂シートの多層積層体では加熱融着温度を２００～２３０℃という高温にする必要があり、加熱プレス工程の生産性にも問題が生じるが、それにもまして、通常電子パスポートのプラスチックデ

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ータシートでは、インレイ層といわれる中間層上に種々の印刷を施すことが一般的であるが、インレイ層に印刷を施してから多層積層加熱プレス工程において加熱融着温度を２００～２３０℃という高温にした場合、印刷が“ヤケル”ことが多々あり、印刷した文字、画像が変退色を生じることがあり好ましくない。

【０１９２】

この問題に対して、オーバーレイであるＰＣレーザー発色層透明単層シートまたはＰＣ／ＰＣ（レーザー発色層）／ＰＣの透明３層シートの下地層であるインレイに本発明のＰＥＴＧ／ＰＣ（着色）／ＰＥＴＧ　着色３層シートを積層することにより、ＰＥＴＧのガラス転移温度が約８０℃とポリカーボネート樹脂のそれより約６０～７０℃低いために、加熱融着温度を１３０～１７０℃、好ましくは１４０～１６０℃にすることで、約６０～７０℃程度下げることができる。そのため、前記印刷層の印刷した文字、画像の変退色を抑制することができる。したがって、本実施形態の電子パスポート用レーザーマーキング積層体は、レーザーマーク性に優れ、その表層、又は表層のコア層にレーザー光照射により黒色発色をさせて画像や文字をマーキングさせるが、その下地層が白い故に黒／白コントラストにより鮮明な文字、画像を描くことができる。

【０１９３】

また、透明レーザーマーキングオーバーシート（オーバーレイ）に、ＰＥＴＧ／ＰＣ（レーザー発色層）／ＰＥＴＧ　３層共押出シート（多層シート１）を用いることにより、ＰＥＴＧスキン層によるコア層ＰＣ（レーザー発色層）のマーキングの耐擦傷性や耐磨耗性に優れる点の他、ＰＥＴＧスキン層による印刷インレイ層との加熱融着性、特に、１５０～１７０℃での比較的低い加熱温度下での加熱融着性に優れるという効果がある。このように本実施形態の透明レーザーマーキング単層及び多層シートを用いることで、レーザーマーク性に優れ、透明レーザーマーキング層自体に深くマーキングでき、印字濃度及びマーキング部の耐擦傷性や耐磨耗性に優れるマーキングが可能となる。

【０１９４】

より好ましいのは、前述の電子パスポート用レーザーマーキング積層体に、レーザーマーキングする方法であって、図２Ａ、２Ｃに示されるように電子パスポート用レーザーマーキング積層体に積層した（電子パスポート用レーザーマーキング積層体を構成する）透明レーザーマーキングシートＡ側から（単層シート、又は多層シート２のＡ側から）、或いは図２Ｂに示されるように電子パスポート用レーザーマーキング積層体に積層した（電子パスポート用レーザーマーキング積層体を構成する）多層シートＡ側から（多層シート１のＡ側から）、レーザー光線を照射して印字することである。このように本実施形態の透明レーザーマーキング（多層）シート側から、所望のレーザー光線７を照射することにより、容易かつ鮮明に画像等を描くことができる。したがって、レーザーマーキング性、加熱融着性に優れ、更にマーキング部の耐磨耗性にも優れたものとすることができる。また、多層シート１を使用することによって、多層シートＢ、及び／又は積層ヒンジシートＣ、及び／又はインレットシートＥと相俟って、レーザーマーク性に優れ、その表面、又は支持体と被覆体の界面部にレーザー光線で黒下地に白文字、白色記号及び白色図柄などを、より一層容易かつ鮮明に描くことが出来、特に、バーコード等の情報コードを解像度よくマーキングすることが可能となる。

【０１９５】

［１０］用途：

また、本実施形態における電子パスポート用レーザーマーキング積層体は、電子パスポートに好適に用いることができる。

【０１９６】

たとえば、電子パスポートとして用いる場合には、透明レーザーマーキングシートＡ、及び多層シートＢを２つずつ用意する。さらに、積層ヒンジシートＣを用意する。積層ヒンジシートＣは、前述の透明レーザーマーキングシートＡ、多層シートＢ、透明レーザーマーキングシートＡ、及び多層シートＢの順に配列させた際に、透明レーザーマーキングシートＡ／多層シートＢ／積層ヒンジシートＣ／多層シートＢ／透明レーザーマーキング

シートＡの順になるように配置する。こうして、積層一体化させることにより、電子パスポート用レーザーマーキング積層体となる。このように積層ヒンジシートＣを使用することで、電子パスポート用レーザーマーキング積層体を綴じやすくできる。また、必要に応じてミシン綴じ部等を形成するとともに、さらに、図４に示されるような、表紙４９、本実施形態を用いた積層体５１、ビザシート５３、ＩＣチップ５５等を配置し、電子パスポートを作成してもよい。ただし、これは一例であって、必ずしもこのような構成に限られるものではない。

【実施例】

【０１９７】

以下、本発明を実施例によってさらに具体的に説明するが、本発明はこれによって限定されるものではない。また、実施例における各種の評価、測定は、下記方法により実施した。

【０１９８】

［１］積層ヒンジシート：

以下の実施例１～３、比較例１～４について、［１－１］カットシート作業性、［１－２］シートの柔軟性、［１－３］ミシン部強度、［１－４］加熱融着性、［１－５］耐熱性について下記の実験を行った。

【０１９９】

［１－１］カットシート作業性：

１１０×３００ｍｍに打ち抜き刃でカット時のカット性とその後の加熱積層工程に搬入する際の作業性を以下の判定基準で評価して、カットシート作業性を評価した。

《判定基準》

○：カット性と作業性良好である。

△：カット性良好であるが、作業性に問題有り。

×：カット性に問題あり。作業性は問題なし。

××：カット性と作業性に問題あり。

【０２００】

［１－２］シートの柔軟性：

幅１ｃｍ×長さ１０ｃｍのカットシートを作製、そのカットシートを図５Ａの様に、台より５ｃｍの長さで貼り出した後、試験片であるカットシートの貼りだし部の垂れる程度を測定して、以下の判定基準で評価して、シートの柔軟性を評価した。より具体的には、図５Ａに示されるように、カットシート６１を、水平台６３に載置し、そのカットシート６１の上部を支持板６５で押さえて、図５Ｂに示されるように、カットシート６１の貼りだし部６１ａの垂れる程度を測定した。

《判定基準》

◎：シートの“垂れ”が、２ｃｍ以上となり優れている。

○：シートの“垂れ”が、１～２ｃｍ未満となり良好である。

△：シートの“垂れ”が、０．４～１ｃｍ未満となり不具合が生じやすい。

×：シートの“垂れ”が、０．４ｃｍ未満となり悪い。

【０２０１】

［１－３］ミシン部強度：

図６に示されるように、２×１０ｃｍのヒンジシート試験片を作製し、その下に紙を敷き、工業用ミシンにて、ピッチ＝５ｍｍでミシン穴６７をあけ、その後、紙を除去した後、試験速度＝３００ｍｍ／ｍｉｎで図に示される矢印Ｘ，Ｙ方向に引っ張る引張試験を行い、ミシン部強度（Ｎ／ｃｍ）を測定し、以下の判定基準にて評価した。

《判定基準》

◎：ミシン部強度＝４０（Ｎ／ｃｍ）以上、または、ミシン部以外で破壊が生じ、その強度が、強度＝４０（Ｎ／ｃｍ）以上であり極めて優れている。

○：ミシン部強度＝２０（Ｎ／ｃｍ）以上、４０（Ｎ／ｃｍ）未満であり良い。

△：ミシン部強度＝１０（Ｎ／ｃｍ）以上、２０（Ｎ／ｃｍ）未満であり不具合が生

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じやすい。
×：ミシン部強度＝１０（Ｎ／ｃｍ）未満であり悪い。
【０２０２】
［１－４］加熱融着性：
透明レーザーマーキングシートＡと多層シートＢを１００×３００ｍｍにカット、ヒンジシートを１１０×３００ｍｍにカットした。次に、透明レーザーマーキングシートＡ及び多層シートＢの一端に離型剤を塗布した後、透明レーザーマーキングシートＡ／多層シートＢ／ヒンジシート／多層シートＢ／透明レーザーマーキングシートＡの５枚のシートを２枚のクロムメッキ鋼板で挟み、ロータリー真空プレス機（日精樹脂工業製）を用いて、１００℃にて９０秒間予熱後、１６０℃、実面圧力２０ｋｇｆ／ｃｍ^{2}にて９０秒間加圧した。さらに、９０秒間冷却した後、積層体シートを取り出し、離型剤塗布部分を含め、幅２０ｍｍの試験片を切り出し、試験速度３００ｍｍ／ｍｉｎにてはくり試験を行い、ヒンジシートと多層シートＢとの加熱融着性を以下の判定基準にて評価した。尚、透明レーザーマーキングシートＡは、後述の（製造例１）透明レーザーマーキングシートＡ〔１〕を、多層シートＢは、後述の（製造例１１）多層シートＢ〔１〕を使用した。
《判定基準》
◎：はくり強度が５０Ｎ／ｃｍ以上またはシートの材料破壊が見られ極めて良好である。
○：はくり強度が２０Ｎ／ｃｍ以上５０Ｎ／ｃｍ未満であり良好である。
△：はくり強度が１０Ｎ／ｃｍ以上２０Ｎ／ｃｍ未満で不具合が生じやすい。
×：はくり強度が１０Ｎ／ｃｍ未満であり、悪い。
××：加熱融着せず（手で簡単にはくり可能なため）、製造できない。
【０２０３】
［１－５］耐熱性：
前記、加熱融着試験後の積層体にて、透明レーザーマーキングシートＡ及び多層シートＢよりヒンジシートが積層体の一端にて１０ｍｍ張り出している部分の外観を目視評価して、加熱融着積層工程におけるヒンジシートの耐熱性を評価した。
《判定基準》
◎：シワ発生もみられず良好である。
○：わずかにシワ発生がみられるが、問題のないレベルである。
△：シワ発生がみられる。
×：シワ発生大または一部軟化して垂れがみられ悪い。
××：軟化して垂れているため非常に悪い。
【０２０４】
（実施例１）積層ヒンジシートＣ〔１〕：
熱可塑性樹脂シートＰとして、熱可塑性ポリウレタンエラストマー（ＴＰＵ）、日本ミラクトラン株式会社製　無黄変タイプ　「ミラクトラン　ＸＮ－２００４」、硬度（Ｓｈｏｒｅ－Ａ）９５、を使用、熱可塑性樹脂シートＲとして、ポリエステルフィルム（以下、適宜「ＰＥＴフィルム」ともいう）引張弾性率が４ＧＰａ、ガラス転移温度（フィルム）が１１０℃の、東レ株式会社製　「ルミラー　Ｕ１２」、厚さ５０μｍを使用した。さらに、ＴＰＵを１８５℃にてＴダイ押出機から溶融押出すると共に、Ｔダイ出口にてＰＥＴフィルムとロール圧着させ、ＴＰＵ／ＰＥＴフィルムからなる積層フィルムを作製した。その後、更に、この積層フィルムのＰＥＴフィルム側にＴＰＵを１８５℃にてＴダイ押出機から溶融押出してＴダイ出口にてロール圧着させ、総厚みが１１０μｍのＴＰＵ／ＰＥＴフィルム／ＴＰＵ　からなる積層ヒンジシートを成形した。
【０２０５】
（実施例２）積層ヒンジシートＣ〔２〕：
熱可塑性樹脂シートＰとして、実施例１のＴＰＵに代えて、水添スチレン系エラストマー（ＳＥＰＳ）、クラレ株式会社製、「セプトン　２１０４」硬度（Ｓｈｏｒｅ－Ａ）９８を用い、熱可塑性樹脂シートＲとして、実施例１と同様のＰＥＴフィルムを用い、２３

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０℃にてＴダイ押出機から溶融押出すると共に、Ｔダイ出口にてＰＥＴフィルムとロール圧着させ、ＰＥＴＧ／ＰＥＴフィルムからなる積層フィルムを作製した。その後、更に、この積層フィルムのＰＥＴフィルム側にＰＥＴＧを２７０℃にてＴダイ押出機から溶融押出してＴダイ出口にてロール圧着させ、総厚みが１１０μｍのＳＥＰＳ／ＰＥＴフィルム／ＳＥＰＳ　からなる積層ヒンジシートを成形した。

【０２０６】

（実施例３）積層ヒンジシートＣ〔３〕：

熱可塑性樹脂シートＲとして、実施例１のＰＥＴフィルムに代えて、ＰＥＮフィルム、引張弾性率が６ＧＰａ、ガラス転移温度（フィルム）が１５５℃　帝人株式会社製　「テオネックス　Ｑ５１ＤＷ」　厚さ３８μｍを使用するとともに、熱可塑性樹脂シートＰとして実施例１のＴＰＵを用いた。さらに、実施例１と同様にして、総厚みが１１０μｍのＴＰＵ／ＰＥＮフィルム／ＴＰＵからなる　積層ヒンジシートを成形した。

【０２０７】

（比較例１）ヒンジシートＣ〔４〕：

熱可塑性ポリウレタンエラストマー（ＴＰＵ）として、日本ミラクトラン株式会社製　無黄変タイプ　「ミラクトラン　ＸＮ－２００４」、硬度（Ｓｈｏｒｅ－Ａ）９５、を使用して、１８５℃にてＴダイ押出機にて厚み１５０μｍのＴＰＵ単独シート（ＴＰＵフィルム）のヒンジシートを得た。

【０２０８】

（比較例２）ヒンジシートＣ〔５〕：

ポリエステルフィルム（ＰＥＴフィルム）として、引張弾性率が４ＧＰａ、ガラス転移温度（フィルム）が１１０℃の、東レ株式会社製「ルミラー　Ｕ１２」を、厚さ１２５μｍに成形したヒンジシートを使用した。

【０２０９】

（比較例３）ヒンジシートＣ〔６〕：

硬度（Ｓｈｏｒｅ－Ｄ）８０、共重合ポリエステル樹脂（ＰＥＴＧ）、イーストマンケミカル株式会社製、「Ｅａｓｔｅｒ　コポリエステル　６７６３」を使用するとともに、実施例１のポリエステルフィルム（ＰＥＴフィルム）を使用した。さらに、実施例１と同様にして、２７０℃にてＴダイ押出機にて総厚みが１１０μｍのＰＥＴＧ／ＰＥＴフィルム／ＰＥＴＧからなるヒンジシートを成形した。

【０２１０】

（比較例４）ヒンジシートＣ〔７〕：

水添スチレン系エラストマー（ＳＥＰＳ）、クラレ株式会社製、「セプトン　４０３３」硬度（Ｓｈｏｒｅ－Ａ）７６を用いるとともに、実施例１と同様のＰＥＴフィルムを用いた。さらに、実施例２と同様にして、２３０℃にてＴダイ押出機にて、総厚みが１１０μｍのＳＥＰＳ／ＰＥＴフィルム／ＳＥＰＳからなるヒンジシートを成形した。

【０２１１】

【表１】

	実施例１	実施例２	実施例３
構成	TPU／PETﾌｨﾙﾑ／TPU	SEPS／PETﾌｨﾙﾑ／SEPS	TPU／PENﾌｨﾙﾑ／TPU
総厚み	１１０μｍ	１１０μｍ	１１０μｍ
カットシート作業性	○	○	○
シートの柔軟性	○	○	○
ミシン部強度	◎	◎	◎
加熱融着性	◎	◎	◎
耐熱性	◎	◎	◎

【０２１２】

【表２】

	比較例１	比較例２	比較例３	比較例４
構成	ＴＰＵﾌｨﾙﾑ	ＰＥＴﾌｨﾙﾑ	PETG／PETﾌｨﾙﾑ／PETG	SEPS／PETﾌｨﾙﾑ／SEPS
総厚み	１５０μｍ	１２５μｍ	１１０μｍ	１１０μｍ
カットシート作業性	××	○	○	×
シートの柔軟性	◎	△	×	○
ミシン部強度	△	×	○	△
加熱融着性	◎	○	◎	△
耐熱性	×	◎	○	×

【０２１３】

（考察１）

表１、表２に示すように、実施例１～３は、引裂、引張強度に優れ、かつ、この綴じ部の耐光、耐熱性を有し、更には、繰り返し曲げに対する抵抗性に優れたものであった。

【０２１４】

これに対して、比較例１のヒンジシートでは、ＴＰＵ単独シートであったため、ミシン部強度が弱く不具合が生じやすく、また、耐熱性試験においてもシワの発生が大きく生じ、また一部軟化して垂れがみられた。さらに、カット性作業性が著しく悪く生産性の低いものであることが確認された。また、比較例２では、ヒンジシートの柔軟性が乏しいことが確認され、ミシン部強度も悪いことが確認された。また、比較例３では、ヒンジシートの柔軟性が十分ではないことが裏づけられた。このようなヒンジシートを使用する場合には、パスポートの通常に伴うページ等の折畳み等、通常の使用に支障を生じ得るものであり、この点からも実現性が乏しいものであることが確認された。さらに、比較例４では、カット性作業性が悪く生産性の低いものであることが確認された。また耐熱性の点でも問題が確認された。このように、いずれの比較例においても実用化するには問題があり、この点からもいずれの実施例も優れた効果を得るものであることが実証された。

【０２１５】

［２］電子パスポート用レーザーマーキング積層体及び電子パスポート：

次に、前述の積層ヒンジシートと、後述の透明レーザーマーキングシートＡ、多層シートＢを使用した実施例４～１０と、比較例５～１３について、下記の実験を行った。

【０２１６】

［２－１］透明レーザーマーキングシートＡの透明性：

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透明レーザーマーキングシートＡの全光線透過率を、分光光度計（商品名「ＥＹＥ７０００」マクベス社製）を用いて測定した。

《判定基準》

○：全光線透過率８０％以上で良好である。△：全光線透過率６０％以上８０％未満、×：全光線透過率６０％未満で悪い。

【０２１７】

［２－２］シートの搬送性：

透明レーザーマーキングシートを１００×３００ｍｍにカットした後、シート搬送機で搬送し、加熱プレス機金型に該シートを所定位置に載せる際、以下の判定基準にてシートの搬送性を評価した。

《判定基準》

○：問題なし。

△：シートを吸着→搬送→脱着時、シートが吸着部より脱着しにくくシートがずれる。

×：シートが吸着部より脱着困難で悪い。

【０２１８】

［２－３］積層加熱プレス成形後の離型性：

真空プレス機（日精樹脂工業製）を用いて、積層したシートを２枚のクロムメッキ鋼板で挟み、プレス温度１００℃で２分間予熱後、１７０℃、実面圧力１２ｋｇｆ／ｃｍ^{2}にて２分間保持した。その後、室温まで冷却した後、クロムメッキ鋼板で挟んだ試料をクロムメッキ鋼板ごと取り出し、試料からクロムメッキ鋼板を引き剥がした際の金型離型性を以下のように評価した。

《判定基準》

○：容易にはくり可、△：金型にわずかに付着し、剥がす事は可能であるがシート表面に傷が生じて使用不可、×：金型に付着。

【０２１９】

［２－４］気泡抜け性：

前記のように加熱プレス後の積層体中の残存気泡状態を観察して、気泡抜け性を以下のように評価した。

《判定基準》

○：積層体中に気泡なし、△：積層体中わずかに気泡残存、×：積層体中に多量の気泡残存。

【０２２０】

［２－５］加熱融着性：

透明レーザーマーキングシートＡと多層シートＢの一端に離型剤を塗布した後、透明レーザーマーキングシートＡ／多層シートＢ／ヒンジシートＣ／多層シートＢ／透明レーザーマーキングシートＡの５枚のシートを２枚のクロムメッキ鋼板で挟み、真空プレス機（日精樹脂工業製）を用いてプレス温度１００℃で２分間予熱後、１６０℃、実面圧力１２ｋｇｆ／ｃｍ^{2}にて２分間保持した。その後、室温まで冷却した後、積層体シートを取り出し、離型剤塗布部分から手で引き剥がして積層体間の加熱融着性を以下の様に評価した。

《判定基準》

◎：はくりが無く加熱融着性に優れる、○：ごく一部をはくりできるが、シート破壊が生じる。（材料破壊）、△：かなりの強い力でははくり可能。×：全面はくり、××：加熱プレス後にはくり発生またはごく小さい力で全面はくりが生じた。

【０２２１】

［２－６］レーザーマーキング性：

前記加熱積層体シートを用いて、　Ｎｄ・ＹＶＯ$_4$レーザー（商品名「ＬＴ－１００ＳＡ」、レーザーテクノロジー社製及び、商品名「ＲＳＭ１０３Ｄ」、ロフィンシナール社製）を使用して、レーザーマーキング性を評価した。具体的には、レーザーマーキング性

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は４００ｍｍ／ｓｅｃのレーザー照射速度にてマーキングを行い、画像の鮮明性とマーキング部の表面状態から以下のように判定した。

《判定基準》

◎：鮮明性に優れる、レーザー光照射部のフクレ等異常無し、

○：鮮明性良好、レーザー光照射部のフクレ等異常無し、

△：鮮明性不十分、または、レーザー光照射部にわずかなフクレ、

×：鮮明性悪い、または、レーザー光照射部のフクレ大。

【０２２２】

［２－７］コントラスト性：

多層シートＢに印刷した後、前記［２－５］、［２－６］の工程処理をし、レーザーマーキングによる画像等と、印刷による画像等のコントラストを目視評価にて判定した。

《判定基準》

○：レーザーマーキングによる画像と、印刷による画像の鮮明性、視認性に変化なし、

△：レーザーマーキングによる画像と、印刷による画像との鮮明性、視認性が低下、

×：レーザーマーキングによる画像と、印刷による画像との鮮明性、視認性が低下。

【０２２３】

［２－８］電子パスポート用レーザーマーキング積層体の耐磨耗性：

レーザー光を照射させ黒色レーザーマーキング部を形成した前記［２－６］の加熱融着積層体の耐磨耗性を試験した。具体的には、ラビングテスター（井元製作所製）を用いて、＃００スチールウール（荷重５００ｇｒ）にて５０回（２５往復）行い、テスト前後の状態を目視評価にて判定した。

《判定基準》

◎：マーキング部の異常がみられず、画像の鮮明性、視認性に変化なし、

○：マーキング部の削れはあるが、画像の鮮明性、視認性が良好、

△：マーキング部の削れ進行しており、画像の鮮明性、視認性が低下、

×：マーキング部の削れが大きく生じ、画像の鮮明性、視認性が著しく低下。

【０２２４】

（製造例１）透明レーザーマーキングシートＡ〔１〕：

スキン層として、ポリカーボネート（商品名「タフロンＦＮ２５００Ａ」出光興産製、メルトボリュームレイト＝８ｃｍ^3／１０ｍｉｎ）を用い、コア層として、上記ポリカーボネートに、レーザー光線を吸収するエネルギー吸収体としてカーボンブラック（三菱化学製＃１０、平均粒子径７５ｎｍ、ＤＢＰ吸油量８６ｍｌ／１００ｇｒ）を０．００１５質量部を配合すると共に、フェノール系酸化防止剤として、ｎ－オクタデシル－３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート（商品名「イルガノックス１０７６」、チバ・スペシャルティ・ケミカルズ社製））を０．１部、及び、紫外線吸収剤として、２－（２’－ヒドロキシ－３’，５’－ジ－ｔ－ブチルフェニル）－５－クロロベンゾトリアゾール（商品名「チヌビン３２７」、チバ・スペシャルティ・ケミカルズ社製）を、０．２部配合して、Ｔダイ溶融押出成形によりスキン層／コア層／スキン層の３層の透明レーザーマーキングシートＡを得た。シートの総厚さは１００μｍであり、表裏のスキン層の厚さを同じ厚さとするとともに、層の構成をスキン層（１８μｍ）／コア層（６４μｍ）／スキン層（１８μｍ）の構成にして、コア層の厚さ比率を６４％にした。さらに、両面の平均表面粗さ（Ｒａ）については、０．５～１．８μｍ、になるようマット加工が施された３層透明レーザーマーキングシートＡ〔１〕を得た。

【０２２５】

（製造例２）透明レーザーマーキングシートＡ〔２〕：

シートの総厚さは１００μｍで、表裏のスキン層の厚さを同じ厚さとするとともに、層の構成をスキン層（２８μｍ）／コア層（４４μｍ）／スキン層（２８μｍ）の構成にして、コア層の厚さ比率を４４％にした他は製造例１と同様にして、透明レーザーマーキングシートＡ〔２〕を得た。

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【０２２６】
（製造例３）透明レーザーマーキングシートＡ〔３〕：
シートの総厚さは１００μｍで、表裏のスキン層の厚さを同じ厚さとするとともに、層の構成をスキン層（４５μｍ）／コア層（１０μｍ）／スキン層（４５μｍ）の構成にして、コア層の厚さ比率を１０％にした他は製造例１と同様にして、透明レーザーマーキングシートＡ〔３〕を得た。
【０２２７】
（製造例４）透明レーザーマーキングシートＡ（単層シートＡ）〔４〕：
ポリカーボネート（商品名「タフロンＦＮ２５００Ａ」出光興産製、メルトボリュームレイト＝８ｃｍ^3／１０ｍｉｎ）を用い、レーザー光線を吸収するエネルギー吸収体としてカーボンブラック（三菱化学製＃１０、平均粒子径７５ｎｍ、ＤＢＰ吸油量８６ｍｌ／１００ｇｒ）を０．００１５質量部を配合すると共に、フェノール系酸化防止剤として、（ｎ－オクタデシル－３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート（「イルガノックス１０７６」チバ・スペシャルティ・ケミカルズ社製）を０．１部、及び、紫外線吸収剤として、２－（２’－ヒドロキシ－３’，５’－ジ－ｔ－ブチルフェニル）－５－クロロベンゾトリアゾール（商品名「チヌビン３２７」、チバ・スペシャルティ・ケミカルズ社製）０．２部、Ｔダイ溶融押出成形によりシートの総厚さは１００μｍの透明レーザーマーキング単層シートＦを得た。さらに、両面の平均表面粗さ（Ｒａ）については、０．５～１．８μｍ、になるようマット加工が施された透明レーザーマーキング単層シートＡ〔４〕を得た。
【０２２８】
（製造例５）透明レーザーマーキングシートＡ〔５〕：
スキン層として、非結晶性ポリエステル（商品名「イースターＧＮ０７１」イーストマンケミカル社製、ＥＧ／ＣＨＤＭ＝７０／３０モル％）１００質量部に、滑剤としてステアリン酸カルシウム０．３質量部を配合した。コア層としてポリカーボネート（商品名「タフロンＦＮ２５００Ａ」出光興産製、メルトボリュームレイト＝８ｃｍ^3／１０ｍｉｎ）を用い、レーザー光線を吸収するエネルギー吸収体としてカーボンブラック（三菱化学製＃１０、平均粒子径７５ｎｍ、ＤＢＰ吸油量８６ｍｌ／１００ｇｒ）を０．００１５質量部を配合すると共に、フェノール系酸化防止剤として、（ｎ－オクタデシル－３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート（「イルガノックス１０７６」チバ・スペシャルティ・ケミカルズ社製）を０．１部、及び、紫外線吸収剤として、２－（２’－ヒドロキシ－３’，５’－ジ－ｔ－ブチルフェニル）－５－クロロベンゾトリアゾール（商品名「チヌビン３２７」、チバ・スペシャルティ・ケミカルズ社製）０．２部、を配合して、Ｔダイ溶融押出成形によりスキン層／コア層／スキン層の３層の透明レーザーマーキングシートＡ〔６〕を得た。さらに、シートの総厚さは１００μｍであり、表裏のスキン層の厚さを同じ厚さとするとともに、層の構成をスキン層（１８μｍ）／コア層（６４μｍ）／スキン層（１８μｍ）の構成にして、コア層の厚さ比率を６４％にした。さらに、両面の平均表面粗さ（Ｒａ）については、０．５～１．８μｍ、になるようマット加工が施された３層透明レーザーマーキングシートＡ〔５〕を得た。
【０２２９】
（製造例６）透明レーザーマーキングシートＡ〔６〕：
製造例５と同様にして、シートの総厚さを１００μｍにするとともに、表裏のスキン層の厚さを同じ厚さとして、層の構成をスキン層（４０μｍ）／コア層（２０μｍ）／スキン層（４０μｍ）に構成するとともに、コア層の厚さを比率２０％にした。さらに、両面の平均表面粗さ（Ｒａ）については、０．５～１．８μｍ、になるようマット加工が施された３層透明レーザーマーキングシートＡ〔６〕を得た。
【０２３０】
（製造例７）透明レーザーマーキングシートＡ〔７〕：
製造例５において、層の構成をスキン層（５μｍ）／コア層（９０μｍ）／スキン層（５μｍ）に構成するとともに、コア層の厚さを比率９０％にした他は、製造例５と同様に

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して透明レーザーマーキングシートＡ〔７〕を製造したが、あまりにもスキン層が薄いために、スキン層の厚み制御が困難であり、特に、両面のスキン層を同じに制御することが困難であった。

【０２３１】

（製造例８）透明レーザーマーキングシートＡ〔８〕：

製造例５において、非結晶性ポリエステルに滑剤を加えなかった他は、製造例５と同様にして透明レーザーマーキングシートＡ〔８〕を得た。

【０２３２】

（製造例９）透明レーザーマーキングシートＡ〔９〕：

製造例５において、３層シートのコア層にレーザー光エネルギー吸収剤　カーボンブラックを配合しなかった他は製造例５と同様にして、透明レーザーマーキングシートＡ〔９〕を得た。

【０２３３】

（製造例１０）透明レーザーマーキングシートＡ〔１０〕：

製造例５において、３層シートのコア層にレーザー光エネルギー吸収剤　カーボンブラック５質量部配合した他は製造例５と同様にして、透明レーザーマーキングシートＡ〔１０〕を得た。

【０２３４】

（製造例１１）多層シートＢ〔１〕：

スキン層として非結晶性ポリエステル（商品名「イースターＧＮ０７１」イーストマンケミカル社製、ＥＧ／ＣＨＤＭ＝７０／３０モル％）を、コア層としてポリカーボネート（商品名「タフロンＦＮ２５００Ａ」出光興産製、メルトボリュームレイト＝８ｃｍ^3／１０ｍｉｎ）を用い、かつ、非結晶性ポリエステルに滑剤としてステアリン酸カルシウム０．３質量部を配合した。さらに、上記ポリカーボネートに、フェノール系酸化防止剤として、（ｎ－オクタデシル－３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート（「イルガノックス１０７６」チバ・スペシャルティ・ケミカルズ社製）を０．１部、及び、紫外線吸収剤として、２－（２′－ヒドロキシ－３′，５′－ジ－ｔ－ブチルフェニル）－５－クロロベンゾトリアゾール（商品名「チヌビン３２７」、チバ・スペシャルティ・ケミカルズ社製）０．２部、及び酸化チタン５部を配合して、Ｔダイ溶融押出成形によりスキン層／コア層／スキン層の３層の多層シートＢを得た。シートの総厚さ２００μｍにするとともに、表裏のスキン層の厚さを同じ厚さとし、層の構成をスキン層（２５μｍ）／コア層（１５０μｍ）／スキン層（２５μｍ）の構成にするとともに、コア層の厚さを比率７５％にした。さらに、両面の平均表面粗さ（Ｒａ）については、０．５～１．８μｍ、になるようマット加工が施された多層シートＢを得た。

【０２３５】

（製造例１２）多層シートＢ〔２〕：

前記多層シートＢにおいて、シート総厚みを２００μｍとし、層の構成をスキン層（５５μｍ）／コア層（５５μｍ）／スキン層（１２μｍ）の構成にするとともに、コア層の厚さを比率４５％にした他は製造例１１と同様にして、多層シートＢ〔２〕を得た。

【０２３６】

（製造例１３）多層シートＢ〔３〕：

前記多層シートＢにおいて、シート総厚みを２００μｍとし、層の構成をスキン層（１２μｍ）／コア層（１７６μｍ）／スキン層（１２μｍ）の構成にするとともに、コア層の厚さを比率８８％にした他は製造例１１と同様にして、多層シートＢ〔３〕を得た。

【０２３７】

（製造例１４）多層シートＢ〔４〕：

前記多層シートＢにおいて、シート総厚みを２００μｍとし、層の構成をスキン層（８０μｍ）／コア層（４０μｍ）／スキン層（８０μｍ）の構成にするとともに、コア層の厚さを比率２０％にした他は製造例１１と同様にして、多層シートＢ〔４〕を得た。

【０２３８】

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（製造例１５）多層シートＢ〔５〕：
スキン層として、ポリカーボネート（商品名「タフロンＦＮ２５００Ａ」出光興産製、メルトボリュームレイト＝８ｃｍ^3／１０ｍｉｎ）を用い、コア層として、上記ポリカーボネートに、酸化チタン５質量を配合すると共に、フェノール系酸化防止剤として、ｎ－オクタデシル－３－（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート（商品名「イルガノックス１０７６」、チバ・スペシャルティ・ケミカルズ社製））を０．１部、及び、紫外線吸収剤として、２－（２’－ヒドロキシ－３’，５’－ジ－ｔ－ブチルフェニル）－５－クロロベンゾトリアゾール（商品名「チヌビン３２７」、チバ・スペシャルティ・ケミカルズ社製）を、０．２部配合して、Ｔダイ溶融押出成形によりシートの総厚さを２００μｍとし、表裏のスキン層の厚さを同じ厚さとし、層の構成をスキン層（４０μｍ）／コア層（１２０μｍ）／スキン層（４０μｍ）の構成であるコア層の厚さを比率６０％にした。さらに、両面の平均表面粗さ（Ｒａ）については、０．５～１．８μｍ、になるようマット加工が施された多層シートＢ〔５〕を得た。
【０２３９】
上述の製造例１～１５を、表３及び表４に示す構成により、実施例４～１０及び、比較例５～１３として、各種評価を行った。その結果を表３及び表４に示す。
【０２４０】

【表３】

	透明レーザーマーキングシートA	多層シートB	シートC	積層体構成	透明性	搬送性	離型性	気泡抜け性	加熱融着性	レーザーマーキング性	コントラスト性	耐磨耗性
実施例4	A〔1〕	B〔1〕	C1	A1/B1/C1/B1/A1	○	○	○	○	◎	○	○	◎
実施例5	A〔2〕	B〔1〕	C1	A2/B1/C1/B1/A2	○	○	○	○	◎	○	○	◎
実施例6	A〔4〕	B〔1〕	C1	A4/B1/C1/B1/A4	○	○	○	○	◎	◎	○	○
実施例7	A〔5〕	B〔1〕	C1	A5/B1/C1/B1/A5	○	○	○	○	◎	○	○	◎
実施例8	A〔1〕	B〔2〕	C1	A1/B2/C1/B2/A1	○	○	○	○	◎	○	○	◎
実施例9	A〔1〕	B〔1〕	C2	A1/B1/C2/B1/A1	○	○	○	○	◎	○	○	◎
実施例10	A〔1〕	B〔1〕	C3	A1/B1/C3/B1/A1	○	○	○	○	◎	○	○	◎

【０２４１】

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【表４】

	透明レーザーマーキングシートA	多層シートB	シートC	積層体構成	透明性	搬送性	離型性	気泡抜け性	加熱融着性	レーザーマーキング性	コントラスト性	耐磨耗性
比較例5	A[3]	B[1]	C1	A3/B1/C1/B1/A3	○	○	○	○	○	×	×	◎
比較例6	A[6]	B[1]	C1	A6/B1/C1/B1/A6	○	○	○	○	○	×	×	◎
比較例7	A[7]	B[1]	C1	A7/B1/C1/B1/A7	—	—	—	—	—	—	—	—
比較例8	A[8]	B[1]	C1	A8/B1/C1/B1/A8	○	○	×	○	○	○	○	◎
比較例9	A[9]	B[1]	C1	A9/B1/C1/B1/A9	○	○	○	○	○	×	×	◎
比較例10	A[10]	B[1]	C1	A10/B1/C1/B1/A10	○	○	○	○	○	×	×	◎
比較例11	A[1]	B[3]	C1	A1/B3/C1/B3/A1	○	○	○	○	△	○	○	◎
比較例12	A[1]	B[4]	C1	A1/B4/C1/B4/A1	○	○	○	○	○	○	○	◎
比較例13	A[1]	B[5]	C1	A1/B5/C1/B5/A1	○	○	○	○	○	○	×	◎

【０２４２】

（考察２）

表３、表４に示すように、実施例１～３のヒンジシートを使用した実施例４～１０はい

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ずれもシートの搬送性、積層加熱プレス後の離型性、気泡抜け性及び熱融着性に優れ、かつ、優れたレーザーマーキング性を有するものであった。

【０２４３】

これに対して、比較例５では、透明レーザーマーキングシートＡ〔３〕（製造例３）の、コア層の厚さ比率を１０％にしたため、レーザーマーキング性、コントラスト性が悪いものとなった。このコア層厚み比率ではコア層厚みが極端に薄いために、厚み比率を制御して安定した３層シートを得ることが難しく、工業生産は困難と考えられる。比較例６では透明レーザーマーキングシートＡ〔６〕（製造例６）の、コア層の厚さを比率２０％にしたため、レーザーマーキング性、コントラスト性が悪いものとなっている。また、比較例７では、透明レーザーマーキングシートＡ〔７〕（製造例７）の、コア層の厚さを比率９０％にして３層共押出を試みたが、スキン層が余りにも薄いために、安定的にこの層を含む構成では、十分な製造できなかったため、測定不能として表４には「－」と記している。更に、比較例８では、透明レーザーマーキングシートＡ〔８〕に滑剤を加えなかったため、離型性が悪いものとなった。同様に、比較例９では、透明レーザーマーキングシートＡ〔９〕にレーザー光エネルギー吸収剤としてカーボンブラックを配合しなかったため、レーザーマーキング性、コントラスト性が劣るものであった。また、比較例１０では、透明レーザーマーキングシートＡ〔１０〕のコア層にレーザー光エネルギー吸収剤　カーボンブラック５質量部配合したため、シート自体が黒色を呈しており、その結果として、透明性の低下とレーザー光照射により、ＰＣ樹脂の焼けと発泡が発生して、とても実用に供するものではない。

【０２４４】

さらに、比較例１１では、多層シートＢ〔３〕（製造例１３）の、コア層の厚さを比率８８％にしたため、加熱融着性が不充分であったが、そもそも、製造例１３の３層シートではコア層厚み比率が８８％と高く、それ故、総厚み２００μｍでもスキン層厚みが１２μｍしかなく、各層の厚みを制御して安定的に３層シートを生産することが難しく、工業生産は困難と考えられる。比較例１２では、多層シートＢ〔４〕（製造例１４）のコア層厚さを比率２０％としたため、いんぺい性に劣り、レーザーマーキング部のコントラスト性に劣る結果となった。また、比較例１３では、多層シートＢ〔５〕（製造例１５）ＰＣ／ＰＣ／ＰＣ　３層シートを使用したため、オーバーシートである透明レーザーマーキングシートＡとの加熱融着性及びヒンジシートとの加熱融着性に劣る結果となった。

【産業上の利用可能性】

【０２４５】

本発明の積層ヒンジシートは、電子パスポート用レーザーマーキング積層体に好適に用いることができ、さらに、電子パスポート用レーザーマーキング積層体の製造の際に、加熱融着性及び積層体の寸法精度に優れ、かつ表紙等と綴じて製本後に柔軟で繰り返し曲げに対する抵抗性に優れ、加えて、綴じ部の引裂、引張強度に優れ、実使用時の耐光劣化性等の経時安定性に優れたヒンジシートとして好適に用いることができる。また、本発明の電子パスポート用レーザーマーキング積層体は、透明レーザーマーキングシートＡ及び着色レーザーマーキング多層シートＢは非ＰＶＣ系の多層シートであり、透明レーザーマーキングシートＡ／多層シートＢ／シートＣ／多層シートＢ／透明レーザーマーキングシートＡの積層体構造とすることにより、レーザー光照射により文字、数字のみならず画像についても鮮明で優れたレーザーマーキング性を有し、多層シートの積層、加熱プレス工程においても、シートの搬送性、積層性、加熱融着性及び積層体シートの変形“ソリ”もなく耐熱性に優れた多層シートであり、更に、これら電子パスポート用レーザーマーキング積層体を電子パスポートに製本するに際してもミシン綴じ等の簡単な方法で製本可能であり、レーザーマーキングにより偽造防止に非常に有効であることから、電子パスポートに好適に使用できるものである。

【符号の説明】

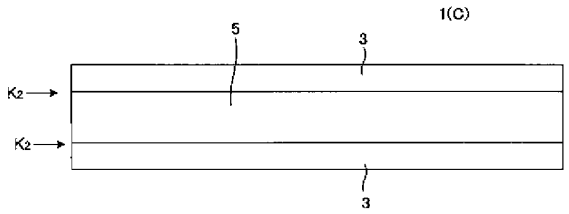
【０２４６】

１：積層ヒンジシート、３：熱可塑性樹脂Ｐ、５：熱可塑性樹脂Ｒ、１１Ａ，１１Ｂ，１

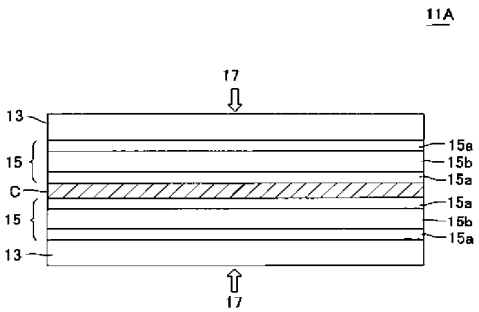
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１Ｃ：電子パスポート用レーザーマーキング積層体、１３：透明レーザーマーキングシートＡ、１３ａ：（透明レーザーマーキングシートＡの）スキン層、１３ｂ：（透明レーザーマーキングシートＡの）コア層、１５：多層シートＢ、１５ａ：（多層シートＢの）スキン層、１５ｂ：（多層シートＢの）コア層、１７：レーザー光線、２３：透明レーザーマーキングシートＡ、２３ａ：（透明レーザーマーキングシートＡの）スキン層、２３ｂ：（透明レーザーマーキングシートＡの）コア層、２７：ミシン綴じ部、２９：張り出し部、４９：表紙、５１；積層体、５３：ビザシート、５５：ＩＣチップ、６１：カットシート、６１ａ：貼りだし部、６３：水平台、６５：支持板、６７：ミシン穴。

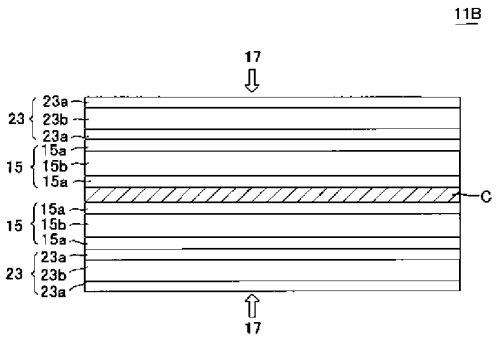
【図１】



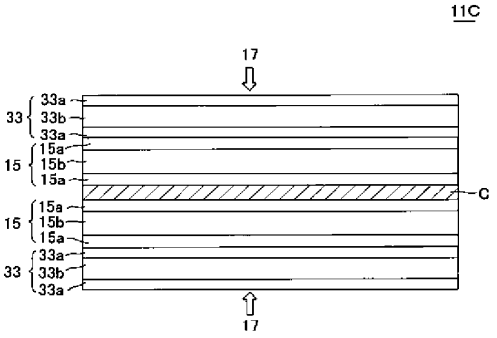
【図２Ａ】



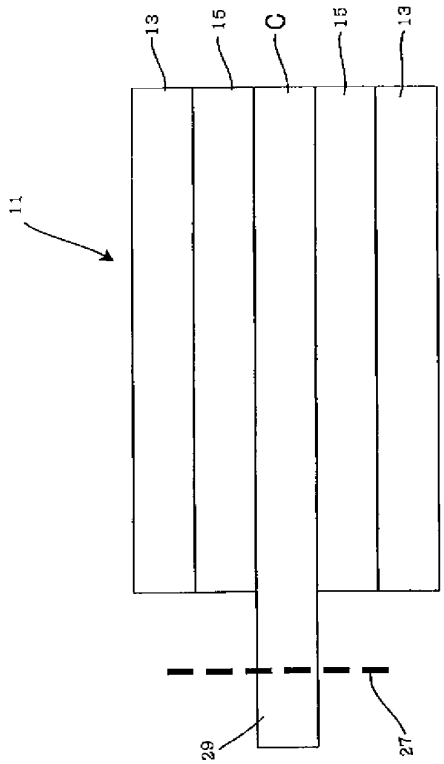
【図２Ｂ】



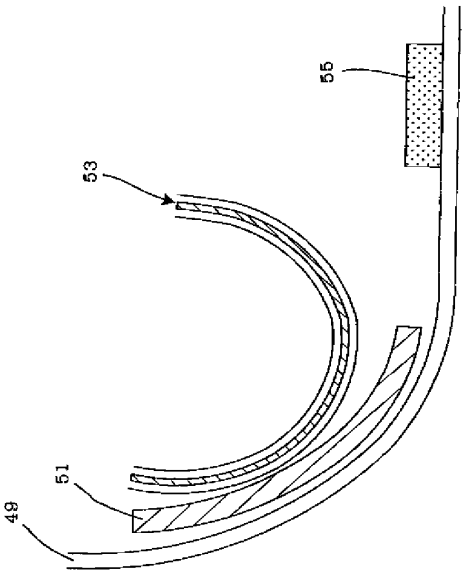
【図２Ｃ】



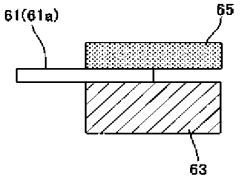
【図３】



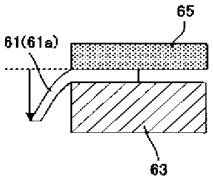
【図４】



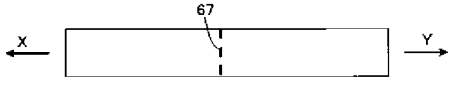
【図５Ａ】



【図５Ｂ】



【図６】



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BA03 BA03D BA03E BA05 BA10A BA10C CA05D CA05E CA06D CA06E
CA07E CA19D CA30D CA30E EH17 EH17D EH17E EH20 GB71 HB40D
JA05B JA12D JB16A JB16B JB16C JB16D JB16E JJ03B JK01B JK07B
JK09 JK12A JK12C JK13A JK13C JK15E JL12A JL12C JN01D JN01E
JN02E YY00A YY00B YY00C
4F207 AA24 AA28 AB12 AB16 AB18 AG01 AG03 KA01 KA17 KB22

Patents

Order orthodontic appliances forming method and apparatus

Abstract

translated from Japanese

(57) System (10) and method for digital mandibular and teeth shape data (26) from an orthodontic appliance (25) is automatically designed and manufactured SUMMARY patient (14), preferably the patient's mouth from the model (20) by performing scanning to generate a two-dimensional or three-dimensional images, digitizing the selected point of the contour and on its teeth and jaw of the patient. The scanned individual computers from the patient data (30) calculates the final tooth position draw the archwire following, preferably, moves to the calculated position teeth design the instrument (25) comprising archwire and the bracket. Lower teeth is modified to best fit on the smooth curve of the distal end of the disposed gum on arch defined teeth by the lower jaw. The teeth bite by placing all of the lower teeth in a plane except the cuspids drawn crown long axis of the tooth is optimally tilted in the treatment to adapt to them. Superimposed to the upper incisors and canines ridges are calculated. Each bracket having a base and archwire support, using the blade of the cutting machine (39), archwire groove to the fastened to the tiltable holder blank is cut in order inclination, depth, position and curvature . Holder and blade are moved by a command from the computer (30c). Archwire is formed automatically optimal smooth arcuate and optimal low profile bracket design by wire vendor (40). Preferably, bow equation is converted into a series of circle segments form for machine control instructions are initiated by a cubic spline equation numerical forming apparatus. Having a surface numerical control machine (41) at the same time designed made automatically positions the instrument to a connection point on the tooth orient the placement jigs is ordered shaping on the contour of the teeth ing. Brackets, mechanical (38-41) make the wire and the jig is driven by a command drawn from the digital representation of the digitized tooth and jaw shape data and the tooth finishing position and instrument design.

JPH08508174A

JP Application

Application number: JP51232494A

Other languages: Japanese

Other versions: JP3380553B2 (Grant)

Inventor: エイ．アンドレイコ，クレイグ，エイ．ベイン，マーク

Original Assignee: オルムコ コーポレイション

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External links: Espacenet, Global Dossier, Discuss

Classifications

A61C3/00 Dental tools or instruments

View 12 more classifications

Claims (1)

translated from Japanese

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【公報種別】特許法第１７条第１項及び特許法第１７条の２の規定による補正の掲載
【部門区分】第１部門第２区分
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【公表番号】特表平８－５０８１７４
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【国際特許分類第７版】
A61C 7/20
7/14
7/28
【ＦＩ】
A61C 7/00 A
B

手　続　補　正　書

平成１２年６月１２日

特許庁長官殿

1. 事件の表示
平成６年特許願第５１２３２４号

2. 補正をする者
事件との関係　特許出願人

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氏　名　（８６６９）　宮崎　昭　　印省

4. 補正により増加する請求項の数　9

5. 補正対象書類名
請求の範囲

6. 補正対象項目名
請求の範囲

7. 補正の内容　別紙のとおり

請　求　の　範　囲

1. 患者の口腔の解剖学的形状を測定する段階と、前記患者の個々の歯の前記形状を表す歯の３次元的形状データを備えたディジタル化された解剖学的形状データを前記測定段階から得る段階と、前記ディジタル化された解剖学的形状データに少なくとも部分的に依存するディジタル化された数学的アーチ形状モデルを作成するためにプログラムされたディジタル・コンピュータで前記ディジタル化された解剖学的形状データを処理することにより理想的な歯のアーチ形状を得る段階と、得られた前記の理想的な歯のアーチ形状に沿って歯に中断の違和感に間隔をあけるために、およびそれぞれの個々の歯に対する前記３次元的歯形状に少なくとも部分的に基づく位置および方位に対し得られた前記の理想的な歯のアーチ形状に対して歯の位置および方位を定めるために、前記ディジタル化された解剖学的形状データおよび前記ディジタル化された数学的アーチ形状モデルから歯の集成位置を前記コンピュータで得る段階と、複数個の歯のおのおのに装具連結点を設定する段階と、ディジタル化された前記３次元的歯形状データと、設定された前記装具連結点と、得られた前記歯の完成位置とから、装具のそれぞれの連結点における歯と得られた前記歯の完成位置における面とを相互連結する手法の装具構成体をカスタム歯科矯正装具が有するように、ディジタル化された前記３次元的歯形状データからコンピュータでもって前記カスタム歯科矯正装具を設計する段階と、前記装具設計段階の結果に関連する幾何学的情報を含みかつ機械が読み出し得る制御信号を生成する段階と、前記設計された装具構成体を有するカスタム歯科矯正装具を作成するように前記制御信号に含まれる前記形状り法情報に従って前記装具を成形するために機械が読み出し得る前記制御信号に応答する機械でカスタム歯科矯正装具を製造する段階と、を有する、患者の口腔の中の好ましい完成位置に患者の歯を配置するためのカスタム歯科矯正装具を製造する方法。

2. 第１項記載の方法において、前記歯が下顎歯および上顎歯を有し、かつ前記解剖学的形状測定段階が、患者の下顎を測定する段階と、それにより下顎の形状のディジタル化されたデータを生成する段階と、患者の上顎歯および上顎骨を測定する段階と、それにより個々の下顎歯形状および個々の上顎骨形状のディジ

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タル化されたデータを生成する段階とを有し、かつ前記アーチ形状を得る段階が前記ディジタル化された下顎形状データから下顎骨格アーチ形状をコンピュータで得る段階を有し、かつ前記歯の完成位置を得る段階が前記下顎骨格アーチ形状に対して歯を配列するために前記歯形状データと前記得られた下顎骨格アーチ形状とから歯の完成位置を得る段階を有する、前記方法。

３．第１項または第２項に記載の方法において、前記アーチ形状を得る段階が、前記ディジタル化された解剖学的形状データに基づいて曲線を定める段階と、滑らかで連続したアーチ形状方程式を生成するために最適化の統計的方法により前記曲線を滑らかにする段階とを有し、かつ前記完成位置を得る段階および前記装具構成体設計段階が前記アーチ形状方程式に少なくとも部分的に基づいて行われる、前記方法。

４．第１項または第２項に記載の方法において、コンピュータの中のアーチ形状方程式により前記得られたアーチ形状をディジタルに表示する段階と、一連の逐次の接触ラセグメントにより前記アーチ形状方程式をディジタルに表示する段階とをさらに有し、かつ前記装具設計段階が前記アーチ形状方程式の何セグメントから得られる円セグメント長および円セグメント半径を表す一連のディジタル値に少なくとも部分的に従ってアーチ形の装具を設計する段階を有し、かつ前記装具製造段階が、前記セグメント長およびセグメント半径を変換して前記制御信号を生ずるための一連の命令にする段階と、前記信号に応答して前記設計された装具構成体に整合する信号に応答してその初のおのおのセグメント長に対応する半径に前記装具を順次に作成する段階とを有する、前記方法。

５．第１項または第２項に記載の方法において、前記測定段階が患者の複数個の歯のおのおのの唇側表面および舌側表面の二の種々の点のデータをディジタル化する段階を有し、かつ前記点に基してそれぞれの歯の直近長軸の方位のディジタル表示を前記ディジタル化した唇側表面データおよび舌側表面データから得る段階と、前記ディジタル化されたデータと前記得られたディジタル表示とから歯の完成位置を計算する段階とをさらに有し、かつ前記計算された完成位置が好ましい直近長軸方位を有する、前記方法。

６．第５項記載の方法において、複数の患者に対して前記好ましい直近長軸方位を計算する段階と、前記計算された好ましい直近長軸方位の記録を作成する段階と、患者のおのおのの個人データを記録する段階と、前記計算された好ましい直近長軸方位を前記個人データと関連させる段階と、前記関連に基づいて患者を集団毎に分類する段階と、前記集団毎の患者に対し好ましい直近長軸方位の統計的記録を作成する段階と、をさらに有する前記方法。

７．第１項または第２項に記載の方法において、前記装具設計段階が歯の形状のデータから装具配置ジグ構成体を設計する段階を有し、かつ装具配置ジグ構成体のおのおのの上の連結点の位置およびそれへの装具の連結を容易にするためにそれぞれの歯の表面に適合するジグ表面を有し、かつ前記制御信号生成段階が設計された前記装具配置ジグ構成体に少なくとも部分的に基づいて制御信号を生成する段階をさらに有し、かつ前記装具製造段階が設計された前記配置ジグ構成体に整合した制御信号に応答して装具配置ジグを機械で自動的に製造する段階を有する、前記方法。

８．第１項または第２項に記載の方法において、患者のそれぞれの上側咬合面と下顎後部歯との咬合対を識別する段階と、該所望した位置にある時両顎の下側歯の最高頂度から前記対の上側歯の最低限度までの垂直距離をおのおのの対に対しディジタル化された前記歯形状データから決定する段階と、その上の最高点が咬合平面な咬合表面の上の垂直位置にある患者の下顎歯の完成位置をディジタル化された前記データから計算して調整された最大垂直距離を適宜する段階と、前記咬合表面のそれぞれの上および下の範囲内の患者の上犬歯および下犬歯の完成位置を計算する段階と、をさらに有する前記方法。

９．第１項または第２項に記載の方法において、患者の前歯からの最適の間隔を得るためにおよび患者の反対側の顎の歯との最適の咬合を得るために、連続位置決定段階が、装具の対の形状寸法をディジタル化する段階と、ディジタル化された前記歯形状データから患者の反対側の顎の歯の表面の上の種々の点における関係を計算する段階と、患者の前歯からの最適の間隔を得るためにおよび患者の反対側の顎の歯との最適の咬合を得るために装具が連結されるべき患者の１つの顎の歯の表面の上の位置をディジタル化された前記データから計算する段階と、患者の歯に装具を連結するために計算された前記位置に従って装具構成体を設計する段階と、を有する前記方法。

１０．患者１２の口腔１５から解剖学的形状２０～２４を測定し、そしてそれにより患者の個々の歯の形状を表す３次元的歯形状データを備えたディジタル化された解剖学的形状データ３６を生ずるための装置３０、３０ａ、３３、４３、５０、５７と、ディジタル化された前記解剖学的形状データに少なくとも依存するディジタル化されたアーチ形状モデルを得るために特別にプログラムされたディジタル・コンピュータ３０ｂでディジタル化された前記データ２６から理想的歯科アーチ形状を得るための、かつ得られた前記理想的歯科アーチ形状に沿って歯を中間の逸した方位に間隔をあけるためにおよびそれぞれの個々の歯に対する前記３次元的歯形状データに少なくとも基づく位置および方位に得られた前記理想的歯科アーチ形状に対し歯の位置および方位を定めるために得られた前記ディジタル化されたデータ２８および得られた前記ディジタル化されたアーチ形状から歯の完成位置を得るための、かつ前記に従って製造されたカスタム装具が得られた前記完成位置の歯との直結点で隣り合互に連結する寸法を有するように前記ディジタル化された歯形状データと設定された装具連結点と得られた前記歯完成位置と装具構成体とから多数個の歯設計のおのおのに関して装具連結点を設定するための、かつ設計された前記装具構成体に関連する形状寸法情報を有する機械コード４２を作成するための、プログラム装置を備えたディジタル・コンピュータ３０ｂ、３０ｃと、設計された前記装具構成体を備えた装具を作成するように前記形状寸法情報に従って装具２５を作成するために前記機械コード４２に応答してカスタム歯科矯正装具２５を自動的に作成するための機械３８、３９、４０、４１と、を有するカスタム歯科矯正装具製造装置。

１１．第１０項記載の装置において、前記製造機械３８が、それに送られるワイヤ形状制御信号に応答して長い歯科矯正アーチワイヤ材料６９を制御された形状に作成するための装置６６～７１を備えたアーチワイヤ作成機４０と、前記信号が前記アーチワイヤ作成機に送られる時前記作成機が個々の患者の口腔１８の解剖学的形状に整合するカスタム歯科矯正アーチワイヤ８４を作成するようにディジタル・アーチワイヤ形状データに応答してワイヤ形状制御信号を発生するための装置を備えたプログラム装置と、を有する前記装置。

１２．第１１項記載の装置において、得られた前記ディジタル・アーチワイヤ形状データが、得られた前記ディジタル・アーチワイヤ形状データの長さ成分に関連するワイヤ長データと、得られた前記ディジタル・アーチワイヤ形状データの湾曲成分に関連するワイヤ湾曲データとを有し、かつ前記湾曲成分が前記長さ成分の関数であり、かつ前記ワイヤ形状制御信号が、前記ワイヤ長データを運ぶワイヤ供給制御信号と、前記ワイヤ湾曲データを担うワイヤ湾曲制御信号とを有し、かつ前記プログラム装置が、前記ワイヤ供給制御信号を発生するための装置と、ワイヤ湾曲制御信号を発生しおよび前記アーチワイヤ作成機に前者信号を送る装置とを有し、かつ前記アーチワイヤ作成機４０が、前記ワイヤ供給制御信号に応答して前記歯科矯正アーチワイヤ材料６９を縦方向に供給するための装置６８と、前記ワイヤ湾曲制御信号に応答してかつ前記アーチワイヤ材料６９の供給と同期して前記ワイヤ供給装置６８により供給される前記アーチワイヤ材料６９を横方向に湾曲させるための装置７０とを有する、前記装置。

１３．第３３項～第４０項のいずれかに記載の装置において、前記製造機械３８が、製造のためにその上にブラケット・ブランク８０を取り付けるための装置をその上に有するホールダ７３を備えたブラケット作成装置９９と、そのブラケット・ベースの取り付け表面に関して計算された形状寸法の溝を有するブラケットを作成するために、前記ホールダ７３に取り付けられた前記ブラケット・ブランク８０を成形するための装置７７を備え、前記制御信号に応答してそれに送られる機械制御信号に応答して前記ホールダ７３に取り付けられたブラケット・ブランク８０の少なくとも１つの表面を作成するための装置７５～７７とを有する、前記装置。

１４．第１３項記載の装置において、溝のおのおのが横断斜を定める通常平行な上側面および下側面を有し、かつ溝のおのおのが横位置を定める前記ブラケット・ベースに最も近いその端部に隣ベースを有し、かつブラケットの指付け表面に対する溝のそれぞれの計算された形状寸法関係が前記取付け表面に対する横断斜および横位置を含有して有し、かつ発生された機械制御信号が前記取付け表面に対して前記計算された横断斜および前記計算された横位置の溝８０ｂを有するブラケットを作成するために前記作成装置７５～７７に前記ブラケット・ブランク

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８０を成形させるための機械制御命令を運び、かつそれぞれのブラケットの前記溝８０８がその上に前記ブラケットが取り付けられるべき歯に隣接してカスタム湾曲を有するアーチワイヤ６４を受け入れるように調整され、かつブラケットの前記取付け表面に対する溝のそれぞれの計算された形状と法関係がそれに隣接するアーチワイヤ６４のカスタム湾曲に整合した頂点の湾曲を有し、かつ発生された前記機械制御信号が計算された前記溝湾曲の溝を有するブラケットを作成するために前記作成装置に前記ブラケット・ブランク８０を成形させるための機械制御命令を運ぶ、前記装置。

１５．第１０項～第１４項のいずれかに記載の装置において、前記ホールダ７３および前記作成装置７５～７７がスタンド７２に取り付けられ、かつ前記スタンド７２に対しておよび前記作成装置７５～７７に対して前記ホールダ７３の角度方位を定めるための装置７４と、前記制御信号に応答して前記スタンド７２に対しておよび前記ホールダ７３に対して前記成形装置７７を並進移動させるための装置７５、７６とをさらに有する、前記装置。

１６．第１０項～第１５項のいずれかに記載の装置において、前記製造機械３８が、患者の歯の上にカスタム歯科矯正装具の位置を定めるジグを作成するための装置８１と、それに送られる制御信号に応答してジグ作成材料のブランク８３の表面の外形を成形するための装置８１と、を備えたジグ作成機４１を有し、かつ前記測定装置３０、３０ａ、３３、４３、５０、５７が患者１２の歯の形状のディジタル化された記録および歯の表面上の装具連結点の歯形状記録に対する位置のディジタル化された記録を供給するための装置を有し、かつ前記プログラム装置が、ディジタル化された歯形状記録とディジタル化された連結点記録とから、歯の前進の外側表面の湾曲の部分に整合するジグ配置表面を定めかつ歯の前記接合点に対し前記外側表面の湾曲の部分が有するのと同じ位置を前記ジグ配置表面に対して有する装具取付け表面を定めるジグ形状寸法を計算するための装置を有し、かつ前記発生装置が前記計算されたジグ形状寸法に従いジグ６２を作成するための機械制御命令を運ぶ機械制御信号を発生するための装置を有する、前記装置。

１７．患者の口腔の中の好ましい完成位置に患者の歯を位置付けるためのカスタム歯科矯正装具を作成する方法において、

患者の口腔の解剖学的形状を測定して、ディジタル化された解剖学的形状データを生成し、

前記ディジタル化された解剖学的形状データから、専用にプログラム化されたディジタル・コンピュータによりアーチ形状を得、

前記ディジタル・コンピュータによる歯の完成位置を前記ディジタル化された解剖学的形状データと前記アーチ形状から得、

前記ディジタル化された解剖学的形状データ、前記設定された装具連結点、および前記歯の完成位置から、前記ディジタル・コンピュータにより装具構成体を設計し、

前記装具構造体にしたがってカスタム歯科矯正装具を作成する、ことを備えた方法。

１８．患者の口腔の中の好ましい完成位置に患者の歯を位置付けるためのカスタム歯科矯正装具を製造する方法において、

患者の口腔の解剖学的形状を測定して、ディジタル化された解剖学的形状データを生成し、

前記ディジタル化された解剖学的形状データから、専用にプログラム化されたディジタル・コンピュータによりアーチ形状を得、

前記ディジタル・コンピュータによる歯の完成位置を前記ディジタル化された解剖学的形状データと前記アーチ形状から得、

複数の歯のそれぞれの一つに複数の装具連結点を設定し、

前記ディジタル化された解剖学的形状データ、前記設定された複数の装具連結点、および前記歯の完成位置により作成されかつ前記装具連結点のところで歯に連結されるカスタム歯科矯正装具が、前記歯の完成位置を得たときに、頭和歯に力が作用せず、むしろ、歯を前記完成位置に同かわせるようにする装具構造体を前記コンピュータで設計し、

前記装具構造体にしたがって機械コードを生成し、

前記装具構造体に適合するように前記機械コードに応じてＮＣ工作機によりカスタム歯科矯正装具を作成する、ことを備えた方法。

１９．患者の口腔の中の好ましい完成位置に患者の歯を位置付けるためのカスタム歯科矯正装具を作成する方法において、

患者の口腔の解剖学的形状を検知して、ディジタル化された解剖学的形状データを生成し、

前記ディジタル化された解剖学的形状データから、専用にプログラム化されたディジタル・コンピュータによりアーチ形状を得、

前記ディジタル・コンピュータによる歯の完成位置を前記ディジタル化された解剖学的形状データと前記アーチ形状から得、

前記ディジタル化された解剖学的形状データ、前記設定された装具連結点、および前記歯の完成位置から、前記ディジタル・コンピュータにより装具構成体を設計し、

前記装具構造体にしたがってカスタム歯科矯正装具を作成する、ことを備えた方法。

２０．歯を装具により装着前の位置から装着後の位置へ押し付けることによって歯列不正の矯正をすべく処置位置へ向けて患者の口腔内の初期の歯列不正における前処置位置で歯を動かすためのカスタム歯科矯正装具を作成する方法において、

歯列不正の前記前処置位置における歯を走査して歯の形状の三次元データを生成し、

歯列不正を矯正しようとする歯列アーチ上の歯の処置位置を決定し、決定された処置位置のデータを生成し、

コンピュータにより前記生成されたデータを処理し、これによって、患者の歯を装具の装着前の位置から前記決定された処置位置と相互関係にある装着後の位置へ動かすためのカスタム歯科矯正装具を設計することを備え、該カスタム歯科矯正装具の設計は、

歯の三次元領域に合致した前記カスタム歯科矯正装具の三次元接触面と相互関係にある三次元データと、前記カスタム歯科矯正装具により歯に作用する力で歯を前記装具の装着前の位置から装着後の位置へ押し付けるために前記カスタム歯科矯正装具の接触面に接触すべき前記三次元領域の少なくとも一部分と、前記カスタム歯科矯正装具を作成する方法において、

患者の口腔の解剖学的形状を測定して、ディジタル化された解剖学的形状データを生成し、

前記ディジタル化された解剖学的形状データから、専用にプログラム化されたディジタル・コンピュータによりアーチ形状を得、

前記ディジタル・コンピュータによる歯の完成位置を前記ディジタル化された解剖学的形状データと前記アーチ形状から得、

複数の歯のそれぞれの一つに複数の装具連結点を設定し、

前記ディジタル化された解剖学的形状データ、前記設定された複数の装具連結点、および前記歯の完成位置により作成されかつ前記装具連結点のところで歯に連結されるカスタム歯科矯正装具が、前記歯の完成位置を得たときに、頭和歯に力が作用せず、むしろ、歯を前記完成位置に同かわせるようにする装具構造体を前記コンピュータで設計し、

前記装具構造体にしたがって機械コードを生成し、

前記装具構造体に適合するように前記機械コードに応じてＮＣ工作機によりカスタム歯科矯正装具を作成する、ことを備えた方法。

２１．第２０項記載の方法において、前記カスタム歯科矯正装具の一つまたはそれ以上の部品を作成することは、患者の歯を続けて処置するための前記アーチ構造を有する一連のアーチ部品を作成することで、これによって、患者の歯を連続した工程で歯列不正の前処置位置から前記アーチ部品の連続した置き換えにより前処置位置に向けて動かす、ことを含む方法。

２２．第２１項記載の方法において、前記一連のアーチ部品を作成することは、向上アーチ幾何学構造を有する進行的に増大する強さ（stiffness）のある一連のアーチワイヤを作成することにより実行される。

２３．第２０項記載の方法において、前記カスタム歯科矯正装具の部品を作成することは、

領域を前記歯の表面に接触させかつ前記アーチ構造を含めるように前記三次元接触面を有する患者の歯の上に装着すべき一つまたはそれ以上の部品を作成し、

少なくとも一つの前記部品に取り替え可能にかつ結合可能な位置合わせジグを作成し、該ジグは歯の前記三次元接触面を有し前記部品を歯の三次元領域に配置させるためのものである、ことを含む方法。

２４．第２０項記載の方法において、前記部品を作成することは少なくとも三つの部品を作成することを含み、これは、

前記カスタム歯科矯正装具により歯に力を加える領域に接触させるための歯の

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前記三次元接触面を有するブラケットを作成し、

前記アーチ構造を有するアーチワイヤを作成し、

前記カスタム歯科矯正装具を歯に位置付けるための歯の領域に接触させるように前記三次元接触面を有するジグを作成する、ことを含む、方法。

25. 歯を装具により装着前の位置から装着後の位置へ歯列不正の矯正をすべく処置位置へ向けて患者の口腔内の初期の歯列不正における前処置位置で歯を動かすためのカスタム歯科矯正装具を作成する方法において、

歯列不正の前記前処置位置における歯を走査して歯の形状の三次元データを生成し、

前記三次元データをコンピュータで処理し、歯列不正を矯正しようとする歯列アーチ上の歯の処置位置を決定して該決定された処置位置のデータを生成し、

該データをさらにコンピュータで処理して、装具の装着前の位置から装着後の位置に患者の歯を前記決定された処置位置に向けて動かすようにカスタム歯科矯正装具を設計することを備え、該カスタム歯科矯正装具の設計は、

歯の三次元領域に合致した前記カスタム歯科矯正装具の三次元接触面と相互関係にある三次元データと、前記カスタム歯科矯正装具を歯の上に配置するように、前記カスタム歯科矯正装具の接触面により接触すべき少なくとも前記三次元領域の一部分とを定め、

前記装具の装着後の位置に対応する前記歯列アーチ上の相対位置に歯を押し付けるための力を生成するように前記カスタム歯科矯正装具のアーチ構造と相互関係にあるデータを定め、

前記接触面と相互関係にある三次元データと前記アーチ構造と相互関係に有るデータを処理して、前記三次元接触面と相互関係にある前記定められたデータに基づいて構造形状を生成するように作成装置が操作され、

前記歯の三次元領域上に前記部品を配置するように前記三次元接触面を有する位置付けジグを作成する、ことを備えた方法。

Bibliographic data

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Abstract of RU2201944C2

FIELD: polymer materials. SUBSTANCE: film contains in following succession: protective layer A containing substances selected from (i) saturated polyesters such as polyethylene terephthalate, polybutylene terephthalate, copolyesters, and polyester-ethers and (ii) polyolefins homo- or copolymers; transparent layer B containing 0-100% fluorine-containing polymer B1 and 100-0% polymer B2 chiefly consisting of alkyl (meth)acrylate units; layer C based on polyamide finished in amino groups; layer D consisting of polyolefin functionalized by unsaturated carboxylic acid anhydride; and connecting polyolefin layer A. Invention also relates to polypropylene warp coated with thermoformated layered film. EFFECT: improved warp-film adhesion, reduced manufacture time, and eliminated necessity of solvent. 10 cl, 12 tbl, 11 ex

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(12) ОПИСАНИЕ ИЗОБРЕТЕНИЯ К ПАТЕНТУ РОССИЙСКОЙ ФЕДЕРАЦИИ

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(54) ТЕРМОФОРМУЕМАЯ МНОГОСЛОЙНАЯ ПЛЕНКА ДЛЯ ЗАЩИТЫ ОСНОВ И ПОЛУЧАЕМЫХ ИЗДЕЛИЙ

(57)

Изобретение относится к термоформуемой многослойной пленке для защиты основ и получаемых в результате этого изделий. Пленка содержит в следующей последовательности: защитный слой A, содержащий вещества, выбранные из (i) насыщенных сложных полиэфиров, таких как полиэтилентерефталат, полибутилентерефталат, сложные сополиэфиры и поли- простые эфиры - сложные эфиры, и (ii) полиолефинов-гомополимеров или сополимеров, прозрачный слой B, содержащий от 0 до 100% фторсодержащего полимера B1 и от 100 до 0% полимера B2, состоящего в основном из алкил(мет)акрилатных звеньев, слой C на основе полиамида с концевыми аминогруппами, слой D, состоящий из полиолефина, функционализированного ангидридом ненасыщенной карбоновой кислоты, связующий слой E из полиолефина. Изобретение относится также к основе, состоящей из полипропилена, покрытой термоформуемой многослойной пленкой. Изобретение позволяет улучшить адгезию пленки с основой, уменьшается время изготовления, отпадает необходимость в растворителе. 2 с. и 8 з.п.ф-лы, 12 табл.

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(54) THERMOFORMATED LAYERED FILM FOR PROTECTING WARPS AND FURTHER MANUFACTURED PRODUCTS

(57) Abstract:

FIELD: polymer materials. SUBSTANCE: film contains in following succession: protective layer A containing substances selected from (i) saturated polyesters such as polyethylene terephthalate, polybutylene terephthalate, copolyesters, and polyester-ethers and (ii) polyolefins homo- or copolymers; transparent layer B containing 0-100% fluorine-containing polymer B1 and 100-0% polymer B2 chiefly consisting of alkyl (meth)acrylate units; layer C based on polyamide finished in amino groups; layer D consisting of polyolefin functionalized by unsaturated carboxylic acid anhydride; and connecting polyolefin layer A. Invention also relates to polypropylene warp coated with thermoformated layered film. EFFECT: improved warp-film adhesion, reduced manufacture time, and eliminated necessity of solvent. 10 cl, 12 tbl, 11 ex

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Настоящее изобретение относится к термоформуемой многослойной пленке для защиты основ и получаемых в результате этого изделий.

В настоящее время, в частности в автомобильной промышленности, используются многочисленные кузовные детали из пластмасс, такие как бамперы, смотровые зеркала, капот и постепенно увеличивающиеся в количестве другие детали, такие как детали дверей и крылья. Преимуществом этих деталей является их большая легкость по сравнению с такими же деталями из стали, их неподверженность коррозии и лучшие механические свойства. Эти детали изготовляют литьем под давлением расплавленного материала и/или термоформованием термопластичного материала. Однако существует одна техническая трудность, состоящая в том, что пластмасса окрашивается труднее, чем сталь. Решение проблемы состоит в покрытии деталей окрашенной пленкой, которая может быть как однослойной, так и многослойной. Обычно такую пленку помещают на дно литейной формы, после чего заливают расплавленный пластический материал (основу) и после охлаждения и извлечения из формы получают деталь, покрытую цветной пленкой. Такой процесс называют "литьем поверх". Сцепление пленки происходит путем взаимодействия расплавленного пластического материала с пленкой, приводящего к плавлению поверхности пленки со стороны подачи расплавленного пластического материала и последующей сварки. Можно также совместно экструдировать основу и цветную пленку, накладывать основу на цветную пленку или же производить горячую прессовку основы на цветную пленку с возможным последующим термоформованием и того и другого вместе.

Настоящее изобретение относится к такого рода пленкам и основам, покрытым в соответствии с описанной выше технологией.

В патенте США 5514427 предлагается использовать технологию, называемую "solvent cast" (литье с растворителем), с целью равномерного диспергирования в многослойной пленке пигментов, красителей и наполнителей. Технология "solvent cast" состоит в приготовлении вначале жидкой композиции термопластичного полимера в растворителе, содержащем собственно полимеры, и диспергировании пигментов и добавок, соответствующих данным техническим условиям, после этого полученную таким образом жидкую композицию равномерно наносят на конвейер. Последний направляют в сушильную печь, в которой растворители удаляются путем испарения, а композиция плавится, образуя сплошной слой. Непрерывную пленку после этого сматывают. Структура пленки по ходу изнутри (со стороны основы, выполненной из полиолефина или акрилонитрил-бутадиен-стирола) в направлении к наружной части содержит слой хлорсодержащего полиолефина, акриловый адгезионный слой и пигментированный слой на основе фторсодержащего полимера и алкилметакрилата.

В патенте WO 99/37479 описывается многослойная пленка, полученная с помощью способа "solvent cast" и ламинирования, которая в направлении изнутри (со стороны основы) к наружной части содержит соответственно адгезионный слой типа "pressure sensitive adhesive" (чувствительное к давлению клеящее вещество), непрозрачный слой пигментированного фторсодержащего полимера, где добавки не проявляют определенной ориентации, и прозрачный слой на основе фторсодержащего полимера.

В патенте EP 949120 предлагается многослойная пленка, состоящая (в направлении изнутри в направлении к наружной части) из полимерного подложечного слоя (полиолефин, акрилонитрил-бутадиен-стирол, полиамид...), метакрилового слоя-основы, цветного пигментированного фторсодержащего слоя (без определенной ориентации) и фторсодержащего прозрачного слоя, причем на этой пленке могут быть отлиты различные основы, такие как полиолефины или полиамиды.

В патенте США 5725712 предлагается термоформуемая многослойная пленка, полученная ламинированием по ходу изнутри в направлении к наружной части адгезионного слоя, цветного пигментированного слоя, в котором добавки не проявляют определенной ориентации, и прозрачного слоя.

В патенте США 5707697 описывается устойчивая к атмосферным воздействиям декоративная наружная кузовная деталь. Эта деталь состоит из многослойной пленки, полученной способом "solvent cast" с последующим ламинированием, и основы. Структура пленки в направлении изнутри в направлении к наружной части включает хлорсодержащий полиолефин, способный к адгезии с полиолефиновой основой, цветной пигментированный слой на основе фторсодержащего полимера, где добавки не проявляют определенней ориентации, и блестящего прозрачного слоя из фторсодержащего полимера.

В патенте WO 9640480 описывается многослойная структура, которая в направлении изнутри в направлении к наружной части включает слой жесткости (типа акрилонитрил-бутадиен-стирол), покрытый с помощью совместной экструзии адгезивной заготовкой (акриловой), далее цветной слой из сополимера на основе PVDF (полифенилиденфторида) в смеси с производным акриловой кислоты и прозрачный поверхностный слой, состоящий из смеси гомополимера PVDF и акрилового производного.

В патенте WO 9403337 предлагается многослойный материал, состоящий в направлении изнутри наружу из основы, адгезионного слоя, состоящего из совместимого с основой соединения, усиливающего слоя, цветного слоя, содержащего пигменты в акриловой, уретановой или виниловой матрице, и, наконец, прозрачного слоя на основе PVDF (поливинилиденфторида) и PMMA (полиметилметакрилата), имеющего градиент состава. Усиливающий слой может состоять из PBT (полибутилентерефталата), PET (полиэтилентерефталата), ABS (акрилонитрил-бутадиен-стирола), PVC (поливинилхлорида), PA (полиамида), сложного полиэфира, PC, полиолефина,

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сополимера этилена с алкил(мет)акрилатом, акрилового полимера или смеси по меньшей мере каких-либо двух из этих полимеров.

В патенте США 5658670 описывается двухслойная пленка, полученная совместной экструзией и горячим прессованием слоя PVDF или производных и слоя PA, полиуретана или модифицированного амином полиолефина.

В патентной заявке JP 09/193189 A, опубликованной 29 июля 1997 г., описывается пленка, содержащая 4 слоя, представляющих собой в направлении изнутри наружу соответственно слой полипропилена, слой полипропилена с добавкой (пигменты), слоя сополимера этилен/глицидилметакрилат и прозрачный поверхностный слой на основе полиметилметакрилата (PMMA).

В патентах FR 2740384 и FR 2740385 описывается пленка, состоящая из трех или четырех слоев на основе полиамида и химически модифицированного полипропилена, позволяющего получать декоративные поверхности.

Недостатком существующих пленок является адгезия слоя фторсодержащего полимера к другим слоям. В настоящей работе найдены многослойные пленки, пригодные для защиты и придания декоративного вида основам, у которых наружный слой состоит из фторсодержащего полимера, PMMA или их смеси и которые проявляют превосходную адгезию с основой. Пленку изобретения также намного легче изготовлять, чем существующие пленки, в частности отсутствует необходимость в растворителе.

Настоящее изобретение относится к термоформуемой многослойной пленке, содержащей в следующей последовательности:

- защитный слой A,
- прозрачный слой B, содержащий (по массе из общих 100%) от 0 до 100% фторсодержащего полимера B1 и от 100 до 0% полимера B2, состоящего в основном из алкил(мет)акрилатных звеньев,
- слой C на основе полиамида с концевыми аминогруппами,
- слой D, состоящий из полиолефина, функционализированного ангидридом ненасыщенной карбоновой кислоты,
- связующий слой E из полиолефина.

Эту пленку получают совместной экструзией различных слоев, причем слой A может быть ламинирован с использованием обычных для термопластов способов. Эту пленку затем используют для покрытия различных основ, например, путем отливки основы в расплавленном состоянии на многослойной пленке, расположенной на дне литейной формы, причем слой A пленки примыкает при этом к стенке формы.

Настоящее изобретение относится также к основам, которые покрывают этими пленками.

Защитный слой A является временным слоем, обеспечивающим защиту блестящего и прозрачного слоя B на стадиях загрузки-выгрузки пленки, термоформования и отливки. Этот защитный слой позволяет поддерживать и улучшать данное состояние поверхности. Таким образом, этот слой может быть гладким или шероховатым в зависимости от желаемого состояния поверхности. Этот слой устраняет необходимость использования вспомогательного агента для извлечения из формы, который мог бы ухудшить состояние поверхности B. Толщина этого слоя составляет преимущественно от 10 до 150 и предпочтительно от 50 до 100 мкм. Материалы, пригодные для использования при изготовлении этого слоя, могут быть выбраны из (i) насыщенных сложных полиэфиров, таких как PET, PBT, сложные сополиэфиры и поли-простые эфиры-сложные эфиры и (ii) полиолефинов-гомополимеров и -сополимеров, таких как полиэтилены и полипропилены. В качестве примера можно назвать PET, продаваемый фирмой DuPont под маркой MYLAR®. Этот слой может содержать различные наполнители, такие как TiO_2, кремнезем, каолин, карбонат кальция, чешуйки алюминия и их производные.

Прозрачный поверхностный слой (B) образован из полимера или смеси полимеров, позволяющих получать прозрачную блестящую поверхность, устойчивую к химическим воздействиям, воздействиям внешней среды или УФ лучам. Толщина этого слоя составляет преимущественно от 10 до 200 и предпочтительно от 70 до 140 мкм.

В качестве примера фторсодержащего полимера B1 могут быть, в частности, названы:

- PVDF, гомополимеры винилиденфторида (VF2) и сополимеры винилиденфторида, содержащие преимущественно по меньшей мере 50 мас.%. VF2 и по меньшей мере еще один фторсодержащий мономер, такой как хлортрифторэтилен (CTFE), гексафторпропилен (HFP), трифторэтилен (VF3), тетрафторэтилен (TFE),
- гомо- и сополимеры трифторэтилена (VF3),
- сополимеры и, в частности, тройные сополимеры, в которых объединены остатки звеньев хлортрифторэтилена (CTFE), тетрафторэтилена (TFE), гексафторпропилена (HFP) и/или этилена и, возможно, звеньев VF2 и/или VF3.

Из фторсодержащих полимеров B1 предпочтительно используют PVDF.

Если слой B содержит B1, рекомендуется добавить другой полимер (B2), позволяющий усилить сцепление со слоем C. Этот полимер (B2), состоящий в основном из звеньев алкил(мет)акрилата, может также содержать функции кислоты, хлорангидрида кислоты, спирта, ангидрида. В качестве примера полимера B2 можно назвать гомополимеры алкил(мет)акрилатов. Алкил(мет)акрилаты описаны в KIRK-OTHMER, Encyclopedia of chemical technology, 4-ое издание. Том 1, с. 292-293, и том 16, с. 475-478. Можно также назвать сополимеры по крайней мере двух из этих (мет)акрилатов и сополимеры по крайней мере одного (мет)акрилата с по меньшей мере одним мономером, выбранным из акрилонитрила, бутадиена, стирола и изопрена при условии, что содержание (мет)акрилата составляет не менее 50 мол.%. Предпочтительным B2 является PMMA. Эти полимеры (B2) состоят либо из названных выше мономеров и, возможно, сомономеров и не содержат ударных модификаторов, либо они содержат ударный акриловый модификатор. Ударными акриловыми модификаторами являются, например, статистические сополимеры или

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последовательности по крайней мере одного мономера, выбранного из стирола, бутадиена, изопрена и по крайней мере одного мономера, выбранного из акрилонитрила и алкил(мет) акрилатов, которые могут относиться к типу core-shell (ядро-оболочка). Эти ударные акриловые модификаторы могут быть смешаны со свежеприготовленным полимером B2, или введены в процессе полимеризации B2, или приготовлены одновременно в процессе полимеризации B2. Количество ударного акрилового модификатора может, например, варьировать от 0 до 30 частей на 100-70 частей B2 и предпочтительно от 5 до 20 частей на 95-80 частей B2. Не выходя за рамки изобретения, можно использовать в качестве B2 смесь двух или нескольких из названных выше полимеров. Слой B может содержать B1 или B2. Для слоя B, содержащего B1, предпочтительное содержание B1 составляет от 50 до 100 частей на 0-50 частей B2 и еще более предпочтительно содержание B1 от 60 до 80 частей (по массе) на 40-20 частей B2. Однако технический результат достигается при любом соотношении B1 и B2. Подходящими для B2 полимерами являются SUMIPEX TR® от Sumitomo и OROGLASS HT121® от Atoglass, а для B2 KYNAR 720® от Elf Atochem. Этот слой может содержать различные органические и/или неорганические наполнители, например УФ-поглотители из семейства TINUVIN® фирмы Ciba Speciality chemicals. Этот слой может также содержать пигменты или красители. Слой проявляет очень хорошую сопротивляемость в отношении различных применяемых в автомобиле жидкостей, таких как бензин, охлаждающая жидкость, жидкость для мойки стекла, тормозная жидкость, моторное масло и жидкость для гидравлической передачи. Достигается очень хорошая сохранность во времени состояния и внешнего вида пленки.

При использовании метода экструзии можно получить ориентацию в направлении протекания пигментов или красителей в этом слое, что придает пленке свойство анизотропии. Для этой цели достаточно использовать пигменты, обладающие анизотропным параметрическим отношением. Используя пигменты с изотропным параметрическим отношением (параметрическое отношение близкое к 1), можно успешно подавить названный выше эффект. Ориентация пигментов дает интерференционный эффект.

Слой C представляет собой полиамидный гомополимер или сополимер с концевыми аминогруппами или смесь полиамидов, из которых по крайней мере один имеет концевые аминогруппы. Под полиамидом подразумеваются продукты конденсации:

- одной или нескольких аминокислот, таких как аминокапроновые кислоты, 7-аминогептановая, 11-аминоундекановая и 12-аминододекановая кислоты, или одного или нескольких лактамов, таких как капролактам, энантолактам и лауролактам;
- одной или нескольких солей или смесей диаминов, таких как гексаметилендиамин, додекаметилендиамин, метаксилендиамин, бис-п-аминоциклогексилметан и триметилгексаметилендиамин, с двухосновными кислотами, такими как изофталевая, терефталевая, адипиновая, азелаиновая, суберовая, себациновая и додекандикарбоновая кислоты.

В качестве примера полиамида можно назвать полиамиды PA 6, PA 6-6, PA 11 и PA 12.

Могут быть с успехом использованы и сополиамиды. Можно назвать сополиамиды, получаемые конденсацией по меньшей мере двух α,ω-аминокарбоновых кислот или их лактамов или одного лактама и одной α,ω-аминокарбоновой кислоты. Можно также назвать сополиамиды, получаемые конденсацией по меньшей мере одной α,ω-аминокарбоновой кислоты (или лактама), по меньшей мере одного диамина и по меньшей мере одной дикарбоновой кислоты.

В качестве примера лактамов можно назвать лактамы с 3-12 атомами углерода в главном цикле, которые могут быть замещенными. Можно, например, назвать β,β-диметилпропиолактам, α,α-диметилпропиолактам, амилолактам, капролактам, каприлолактам и лауролактам.

В качестве примера α,ω-аминокарбоновой кислоты можно назвать аминоундекановую и аминододекановую кислоту. В качестве примера дикарбоновой кислоты можно назвать адипиновую кислоту, себациновую кислоту, изофталевую кислоту, бутандиовую кислоту, 1,4-циклогександикарбоновую кислоту, терефталевую кислоту, натриевую или литиевую соли сульфоизофталевой кислоты, димеризованные жирные кислоты (содержание димера в таких димеризованных жирных кислотах не менее 98% и они преимущественно являются гидрогенизированными) и додекандиовую кислоту $HOOC-(CH_2)_{10}-COOH$.

Диамин может представлять собой алифатический диамин с 6-12 атомами углерода, он может быть насыщенным арильным и/или циклическим диамином. В качестве примеров можно назвать гексаметилендиамин, пиперазин, тетраметилендиамин, октаметилендиамин, декаметилендиамин, додекаметилендиамин, 1,5-диаминогексан, 2,2,4-триметил-1,6-диаминогексан, диамино-полиолы, изофорондиамин (IPD), метилпентаметилендиамин (MPDM), бис(аминоциклогексил)метан (BACM) и бис(3-метил-4-аминоциклогексил)метан (BMACM).

В качестве примеров сополиамидов можно назвать сополимеры капролактама и лауриллактама (PA 6/12), сополимеры капролактама, адипиновой кислоты и гексаметилендиамина (PA 6/6-6), сополимеры капролактама, лауриллактама, адипиновой кислоты и гексаметилендиамина (PA 6/12/6-6), сополимеры капролактама, лауриллактама, 11-аминоундекановой кислоты, азелаиновой кислоты и гексаметилендиамина (PA 6/6-9/11/12), сополимеры капролактама, лауриллактама, 11-аминоундекановой кислоты, адипиновой кислоты и гексаметилендиамина (PA 6-6/11/12), сополимеры лауриллактама, азелаиновой кислоты и гексаметилендиамина (PA 6-9/12). Сополиамид преимущественно выбирают из PA 6/12 и PA 6/6-6. Преимущество этих сополиамидов состоит в их более низкой

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температуре плавления по сравнению с температурой плавления PA 6.

Для получения концевых аминогрупп достаточно проводить синтез в присутствии избытка диамина или в случае полиамидов (и сополиамидов), получаемых из лактама или α,ω-аминокарбоновой кислоты, использовать в качестве ограничителя цепи диамин или моноамин.

В качестве примера можно назвать (1) смеси смешивающихся полиамидов и (2) однофазные смеси, образующиеся при трансамидировании полиамида и аморфного полуароматического полиамида. Предпочтительными смесями являются смеси, сохранившие кристалличность и прозрачность, т.е. микрокристаллические смеси, например смеси, содержащие (по массе) 70% PA 12 и 30% PA 12/BMACM-I/BMACM-N, "I" и "T", обозначая соответственно изо- и терефталевую кислоты. Можно также упомянуть PA BMACM-12 и PA PACM-12 (PACM обозначает 4-аминодициклогексилметан).

Не выходя за рамки изобретения, можно использовать смеси полиамидов с полиолефином. Основой этих смесей является преимущественно полиамидная матрица, т. е. эти смеси содержат от 55 до 100 вес. частей полиамида и от 0 до 45 вес. частей полиолефина. В последний могут быть введены функциональные группы, или же он может представлять собой смесь полиолефина, имеющего функциональные группы, с полиолефином без функциональных групп. Можно, например, использовать функционализированные и нефункционализированные полиолефины, описанные для слоя D.

Особенно подходящим полиамидом является PA 12 AESNO TL® от Elf Atochem®, делающий возможным в том случае, когда B2 содержит функции, образовывать в процессе химической реакции устойчивую во времени ковалентную связь с функциями кислоты, хлорангидрида кислоты или спиртовой функцией полимера B2. Толщина этого слоя преимущественно составляет от 5 до 200 или более предпочтительно от 70 до 140 мкм. Этот слой может содержать различные органические и/или неорганические наполнители, например УФ-поглотители из семейства TINUVIN® от Ciba Speciality chemicals. Этот слой может также содержать пигменты или красители.

При использовании метода экструзии можно получить ориентацию в направлении протекания пигментов или красителей в этом слое, что придает пленке анизотропность. Для этой цели достаточно использовать пигменты, обладающие анизотропным параметрическим отношением. Используя пигменты с изотропным параметрическим отношением (параметрическое отношение, близкое к 1), можно успешно подавить названный выше эффект. Ориентация пигментов дает интерференционный эффект.

Слой C наряду со слоем B создает внешний вид и защиту для основы.

Слой D состоит из полиолефина с функциональными группами ангидрида ненасыщенной карбоновой кислоты. Наличие ангидридной функции делает возможной реакцию имидирования с аминными функциями слоя C, что в свою очередь делает возможным образование устойчивой во времени связи. Такой функционализированный полиолефин при описании часто называют соэкструзионной связкой.

Полиолефин традиционно является гомополимером или сополимером α-олефинов или диолефинов, таких, например, как этилен, пропилен, бутен-1, октен-1, бутадиен. В качестве примера можно назвать:

- гомополимеры и сополимеры этилена, в частности LDPE, HDPT, LLDPE (linear low-density polyethylene или линейный полиэтилен высокой плотности), VLDPE (very low-density polyethylene или линейный полиэтилен с очень низкой плотностью) и металлоценовый полиэтилен;
- гомополимеры и сополимеры пропилена;
- сополимеры этилен/α-олефин, такие как этилен/ пропилен, EPR (этилен-пропиленовый каучук) и сополимеры этилен/пропилен/диен (EPDM) ;
- блок-сополимеры стирол/этилен-бутен/стирол (SEBS), стирол/бутадиен/стирол (SBS), стирол/изопрен/стирол (SIS) и стирол/этилен-пропилен/стирол (SEPS);
- сополимеры этилена с по меньшей мере одним соединением, выбранным из солей или эфиров ненасыщенных карбоновых кислот, такие как алкил(мет)акрилат (например, метилакрилат), или виниловые эфиры ненасыщенных карбоновых кислот, такие как винилацетат, в которых пропорция сомономера может достигать 40 мас.%.

Функционализированный полиолефин слоя D может быть полимером α-олефинов, имеющим звенья ангидрида ненасыщенной карбоновой кислоты. В качестве примера можно назвать упомянутые выше полиолефины, привитые или сополимеризованные с ангидридами ненасыщенных карбоновых кислот. Используются известные способы прививки. Не выходя за рамки изобретения, можно использовать ненасыщенные карбоновые кислоты, а также производные и ангидриды этих кислот. В качестве примера можно назвать акриловую кислоту, метакриловую кислоту, малеиновую кислоту, фумаровую кислоту, итаконовую кислоту, кротоновую кислоту, итаконовый ангидрид, ангидрид норборнен-2,3-дикарбоновой кислоты, малеиновый ангидрид и его замещенные аналоги, такие, например, как ангидрид диметилмалеиновой кислоты. В качестве примеров производных могут быть названы соли, амиды, имиды, сложные эфиры, такие как одно- и двухзамещенные натриевые соли малеиновой кислоты, акриламид, малеимид и диметилфумарат. (Мет)акриловая кислота может быть полностью или частично нейтрализована такими металлами как Zn, Ca, Li. Функционализированный полиолефин представляет собой, например, смесь PE/EPR, массовое отношение компонентов которого может варьировать в широких пределах, например от 40/60 до 90/10. Эта смесь может быть совместно привита ангидридом, в частности малеиновым ангидридом, при степени прививки, например, от 0,01 до 5 мас.%.

Слой D представляет собой преимущественно полипропиленовую основу, состоящую главным образом из

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гомополипропилена или сополимера, функционализированного прививкой по меньшей мере одной ненасыщенной карбоновой кислотой, ангидридом ненасыщенной карбоновой кислоты или производными этих кислот и ангидридов. Такие продукты уже упоминались выше. Прививают преимущественно полипропилен с индексом MFI (Melt Flow Index или индекс текучести в расплавленном состоянии) от 0,1 до 10 г/10 мм (при 230°C под нагрузкой 2,16 кг), используя малеиновый ангидрид в присутствии инициаторов пероксидного типа. Количество эффективно привитого малеинового ангидрида может составлять от 0,01 до 10 мас. % от привитого полипропилена. Привитой полипропилен может быть разбавлен полипропиленом, каучуками EPR, EPDM или сополимерами пропилена с α-олефином. В соответствии с другим вариантом можно также производить совместную прививку смеси полипропилена и EPR или EPDM, т.е. добавлять ненасыщенную карбоновую кислоту, ее ангидрид или их производные в смесь полипропилена и EPR или EPDM в присутствии инициатора.

В качестве примеров составляющих слоя D можно назвать смеси, содержащие (по массе):

- 0-50 и предпочтительно 10-40% по меньшей мере одного полиэтилена или сополимера этилена;
- 50-100 и предпочтительно 60-90% по меньшей мере одного полимера, выбранного из полипропилена или сополимера пропилена, гомополимера и сополимера 1-бутена или гомополистирола или его сополимера, из которых предпочтителен полипропилен;
- эти же смеси, привитые функциональным мономером, выбираемым из карбоновых кислот и их производных, хлорангидридов кислот, изоцианатов, оксазолинов, эпоксидов, аминов и гидроксидов, предпочтительно из ангидридов ненасыщенных дикарбоновых кислот;
- эти же привитые смеси, которые могут быть разбавлены по меньшей мере одним полиолефином, преимущественно содержащим пропиленовые звенья, или по меньшей мере одним полимером с эластомерными свойствами или их смесью.

Пригодными для использования в слое D полимерами являются, например, привитые полипропилены фирм Elf Atochem и DuPont, продаваемые соответственно под названиями OVERACPPET® и BYNEL 50E561®.

Толщина слоя D преимущественно составляет от 10 до 250 или более предпочтительно от 40 до 110 мкм. Этот слой может содержать различные органические и/или неорганические наполнители, например УФ-поглотители из семейства TINUVIN® от Ciba Speciality chemicals. Этот слой может также содержать пигменты или красители.

При использовании метода экструзии можно получить ориентацию в направлении протекания пигментов или красителей в этом слое, что придает пленке анизотропность. Для этой цели достаточно использовать пигменты, обладающие анизотропным параметрическим отношением. Используя пигменты с изотропным параметрическим отношением (параметрическое отношение, близкое к 1), можно успешно подавить названный выше эффект. Ориентация пигментов дает интерференционный эффект.

Связующий слой E, обеспечивающий склеивание с основой, является полиолефином (полиолефины были определены для слоя D). Полиолефины обладают достаточными совместимостью и сродством для склеивания со слоем D и основой. Хорошо подходит для этой цели полипропилен. Материалами, прекрасно подходящими для создания слоя D, являются полипропилены 3051 BN1 и 3060MN5 фирмы Apprgl. Толщина этого слоя преимущественно составляет от 400 до 800 или более предпочтительно от 500 до 600 мкм. Этот слой может содержать различные органические и/или неорганические наполнители, например УФ-поглотители из семейства TINUVIN® от Ciba Speciality chemicals. Этот слой может также содержать пигменты или красители.

При использовании метода экструзии можно получить ориентацию в направлении протекания пигментов или красителей в этом слое, что придает пленке анизотропность. Для этой цели достаточно использовать пигменты, обладающие анизотропным параметрическим отношением. Используя пигменты с изотропным параметрическим отношением (параметрическое отношение, близкое к 1), можно успешно подавить названный выше эффект. Ориентация пигментов дает интерференционный эффект.

Пленку изобретения изготовляют совместной экструзией с использованием обычной для термопластов технологии, состоящей в продавливании расплавленного материала разных слоев через плоские фильеры, расположенные очень близко одна к другой. При объединении расплавленных материалов образуется многослойная пленка, которую охлаждают пропусканием через вальцы с регулируемой температурой. Подбирая скорости вальцов, расположенных в продольном направлении, и/или вальцов, расположенных в поперечном направлении, можно вызвать растяжение в продольном и/или поперечном направлении.

Индексы MFI разных слоев подбирают как можно более близкими друг к другу в интервале от 1 до 20 и предпочтительно от 4 до 7 (230°C, нагрузка 2,16 кг). Эта подборка входит в обязанности специалиста по совместной экструзии.

Многослойная пленка изобретения является удобной для покрытия основ либо способом "литья поверх", либо совместной экструзией, либо наслоением, либо горячей прессовкой. Предпочтительно использование способа "литья поверх". Если пресс-форма имеет простую конфигурацию, заливки расплавленной основы достаточно для того, чтобы прижать пленку к стенке формы - в этом случае используется пленка без предварительной подготовки (как получено). Если же пресс-форма имеет усложненную конфигурацию, то для того, чтобы избежать напряжений в пленке и обеспечить хороший контакт пленки со стенками формы прежде чем поместить пленку в пресс-форму пленку необходимо предварительно отформовать. Можно использовать другую пресс-форму с той же конфигурацией и с помощью детали, обладающей такой же конфигурацией, но

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выполняющей роль модели, подвергнуть пленку термоформованию. Можно также использовать и ту же самую пресс-форму, которая используется для отливки основы. В случае же промежуточных по отношению к названным выше условий можно не проводить термоформования пленки, а использовать ее как таковую в пресс-форме и с помощью сжатого воздуха со стороны, откуда производится заливка основы, прижимать пленку к стенкам формы.

Если пленку нужно подвергнуть термоформованию, ее составляющие должны обладать температурным интервалом термоформования, составляющим как можно более широкую область перекрывания. Примером являются представленные в приведенной ниже таблице 1 температуры плавления (т.пл.), минимальные температуры термоформования (т. тф. мин.) и максимальные температуры термоформования (т. тф. макс.) различных составляющих слоев пленки изобретения.

Разные слои могут содержать наполнители и добавки, не влияющие на характеристики прозрачности верхнего слоя (B), цвета и результирующую окраску всей структуры в целом.

Изобретение представляет особую ценность в отношении основ из полипропилена.

Пример 1

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 2.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 60 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см^3/10 мин (230°C, 5 кг) и 40 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI (текучести расплава) 2 г/10 мин (230°C, 3,8 кг) и 0,6 мас.% Tinuvin® 1577 (УФ-поглотитель, продаваемый фирмой Ciba Speciality chemicals) в расчете на общую массу смолы. Толщина этого слоя 100 мкм. Этот слой соэкструдируется на слое C, состоящем из ULTRAMID® B36F (PA 6 с концевыми аминогруппами, MVI 5 см^3/10 мин при 235°C, 2,16 кг). Толщина этого слоя 35 мкм. Этот слой соэкструдируется на слое D, представляющем собой Bynel® 50E561 (модифицированный ангидридом полипропилен, MVI 5 см^3/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 94 мас. % полипропилена APPRYL 3050 BN1 (гомополимерный полипропилен/ MVI 5 см^3/10 мин при 190°C, 2,16 кг) и 6 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 550 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL® 3131 MU7 фирмы APPRYL.

Пример 2

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 3.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 60 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см^3/10 мин (230°C, 5 кг) и 40 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)) и 0,6 мас.% Tinuvin® 1577 (УФ-поглотитель, продаваемый фирмой Ciba Speciality chemicals) в расчете на общую массу смолы. Толщина этого слоя 100 мкм. Этот слой соэкструдируется на слое C, состоящем из ULTRAMID® B36F (PA 6 с концевыми аминогруппами, MVI 5 см^3/10 мин при 235°C, 2,16 кг). Толщина этого слоя 35 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (модифицированный малеиновым ангидридом полипропилен, MFI 4 г/10 мин при 190°Cб 2,16 кг).

Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 94 мас.% полипропилена APPRYL 3050 BN1 (гомополимерный полипропилен, MVI 5 см^3/10 мин при 190°C, 2,16 кг) и 6 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 550 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C.

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Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 3

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 4.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 80 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/10 мин (230°C, 5 кг) и 20 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)) и 0,6 мас.% Tinuvin® 1577 (УФ-поглотитель, продаваемый фирмой Ciba Speciality chemicals) в расчете на общую массу смолы. Толщина этого слоя 100 мкм. Этот слой соэкструдируется на слое C, состоящем из RILSAN® AESNO TL (PA 12 с концевыми аминогруппами, MVI 2,5 (235°C, 2,16 кг)) фирмы ELF ATOCHEM. Толщина этого слоя 35 мкм. Этот слой соэкструдируется на слое D, представляющем собой Bynel ® 50E561 (модифицированный ангидридом полипропилен с индексом текучести 5 г/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 94 мас. % полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190 °C, 2,16 кг) и 6 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 550 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 4

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 5.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 80 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/10 мин (230 °C, 5 кг) и 20 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из ORGALLOY® A (смесь 65% PA-6 с концевыми аминогруппами с MFI 15-17 г/10 мин (235°C, 2/16 кг), 27% PEBD с MFI 1 г/10 мин (190°C) и 8% сополимера этилена с бутилакрилатом (5,5%) и малеиновым ангидридом (3,6%), MFI 5 г/10 мин). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (модифицированный малеиновым ангидридом полипропилен, MFI 4 г/10 мин при 190°C, 2,16 кг).

Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 5

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 6.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с

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тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 80 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/10 мин (230°C, 5 кг) и 20 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из ULTRAMID® B35F (PA 6/6-6 с концевыми аминогруппами, MVI 7 см^3/10 мин при 235°C, 2,16 кг). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 6

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 7.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 60 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/10 мин (230°C, 5 кг) и 40 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из RILSAN® AESNO TL (PA 12 с концевыми аминогруппами, MVI 2,5 (235°C, 2,16 кг)) фирмы ELF ATOCHEM. Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 7

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 8.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 80 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/10 мин (230°C, 5 кг) и 20 мас.%. OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из ULTRAMID® B36F (PA 6 с концевыми аминогруппами, MVI 5 см^3/10 мин при 235°C, 2,16 кг). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI

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6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 8

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 9.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 80 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см^3/10 мин (230°C, 5 кг) и 20 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из RILSAN® AESNO TL (PA 12 с концевыми аминогруппами, MVI 2,5 (235°C, 2,16 кг)) фирмы ELF ATOCHEM. Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 9

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 10.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 60 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см^3/10 мин (230°C, 5 кг) и 40 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из ULTRAMID® B35F (PA 6/6-6 с концевыми аминогруппами, MVI 7 см^3/10 мин при 235°C, 2,16 кг). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг). Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.%. зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL ® 3131 MU7 фирмы APPRYL.

Пример 10

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 11.

Для осуществления совместной экструзии были использованы пластинчатый блок

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распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 60 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/10 мин (230°C, 5 кг) и 40 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое

C, состоящем из ORGALLOY® A (смесь 65% PA-6 с концевыми аминогруппами с MFI 15-17 г/10 мин (235°C, 2,16 кг), 27% PEBD с MFI 1 г/10 мин (190°C) и 8% сополимера этилена с бутилакрилатом (5,5%) и малеиновым ангидридом (3,6%), MFI 5 г/10 мин). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг).

Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL® 3131 MU7 фирмы APPRYL.

Пример 11

Изготовлены пленки по изобретению на машине ER-WE-PA®, оборудованной 4 экструдерами, названными соответственно O, I, A и B, характеристики которых приведены в таблице 12.

Для осуществления совместной экструзии были использованы пластинчатый блок распределения слоев и фильера плечикового типа шириной 950 мм. Прокатку пленки проводили на горизонтальном каландре с тремя валками с независимым регулированием температуры. Во всех случаях пленки изготовляли со скоростью 5 м/мин при температуре валков 30°C (ближайший к фильере валок), 40°C (промежуточный валок) и 20°C (наиболее удаленный от фильеры валок).

Слой B состоит из смеси 60 мас.% Kynar® 720 (гомополимер PVDF с индексом MVI (Melt volume index или индекс объемной текучести в расплавленном состоянии) 10 см ^{3}/мин (230°C, 5 кг) и 40 мас.% OROGLAS® HT 121 (PMMA (сополимер MMA и метакриловой кислоты) с 3,8% кислоты и индексом MFI 2 г/10 мин (230°C, 3,8 кг)). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое C, состоящем из ULTRAMID® B36F (PA 6 с концевыми аминогруппами, MVI 5 см^3/10 мин при 235°C, 2,16 кг). Толщина этого слоя 25 мкм. Этот слой соэкструдируется на слое D, представляющем собой OREVAC PP-FT (полипропилен, привитой малеиновым ангидридом, MFI 4 г/10 мин при 190°C, 2,16 кг).

Толщина этого слоя 75 мкм. Этот слой соэкструдируется на слое E, состоящем из смеси 97 мас.% полипропилена APPRYL 3060 MN5 (блок-сополимерный полипропилен с MVI 6,5 см^3/10 мин при 190°C, 2,16 кг) и 3 мас.% зеленой master batch (маточной смеси) SANYLENE® AU VERDE A13 GR фирмы CLARIANT. Толщина этого слоя 450 мкм.

Слой B экструдируется с температурным профилем в пределах от 180 до 260°C. Слой C экструдируется с температурным профилем в пределах от 200 до 250°C. Слой D экструдируется с температурным профилем в пределах от 180 до 230°C. Слой E экструдируется с температурным профилем в пределах от 200 до 230°C. Температура фильеры и распределительной системы составляет 265°C. Полученную таким образом структуру подвергают после этого термоформованию при 190°C и помещают в пресс-форму для проведения "литья поверх" с использованием полипропилена APPRYL® 3131 MU7 фирмы APPRYL.

Формула изобретения:

1. Термоформуемая многослойная пленка, содержащая в следующей последуемости:

защитный слой A, содержащий вещества, выбранные из (i) насыщенных сложных полиэфиров, таких, как полиэтилентерефталат, полибутилентерефталат, сложные сополиэфиры и поли-простые эфиры-сложные эфиры, и (ii) полиолефинов-гомополимеров или сополимеров, таких как полиэтилены и полипропилены; прозрачный слой B, содержащий (по массе из общих 100%) от 0 до 100% фторсодержащего полимера B1 и от 100 до 0% полимера B2, состоящего в основном из алкил(мет)акрилатных звеньев; слой C на основе полиамида с концевыми аминогруппами; слой D, состоящий из полиолефина, функционализированного ангидридом ненасыщенной карбоновой кислоты; связующий слой E из полиолефина.

2. Пленка по п.1, в которой фторсодержащим полимером B1 является полифенилиденфторид.

3. Пленка по п. 1 или 2, в которой полимером B2 является

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полиметилметакрилат.

4. Пленка по любому из пп.1-3, в которой полиамид слоя C выбирают из полиамидов PA 6, PA 12 и PA 6/6-6, имеющих концевые аминогруппы.

5. Пленка по любому из пп.1-4, в которой функционализированным полиолефином слоя D является привитой полипропилен, который может быть разбавлен полипропиленом, этилен/пропиленовым каучуком, этилен/пропилен/диеновым сополимером или сополимерами пропилена с каким-либо α-олефином.

6. Пленка по любому из пп.1-4, в которой функционализированный полиолефин слоя D образуется при совместной прививке смеси полипропилена с этилен-пропиленовым каучуком или этилен-пропилен-диеновым сополимером.

7. Пленка по любому из пп.1-4, в которой функционализированный полиолефин слоя D представляет собой смесь, содержащую (по массе): 0-50% и, предпочтительно, 10-40% по меньшей мере одного полиэтилена или сополимера этилена; 50-100% и, предпочтительно, 60-90% по меньшей мере одного полимера, выбранного из полипропилена или сополимера пропилена, гомо- и сополимера 1-бутена, гомо- или сополимера стирола, предпочтительно полипропилена; которая привита ангидридом ненасыщенной карбоновой кислоты и может быть разбавлена по меньшей мере одним полиолефином, преимущественно содержащим пропиленовые звенья, или по меньшей мере одним полимером с эластомерными свойствами, или их смесью.

8. Пленка по любому из пп.1-7, в которой полиолефином слоя E является полипропилен.

9. Основа, покрытая пленкой, по любому из пп.1-8, в которой слой E пленки примыкает к основе.

10. Основа по п.9, состоящая из полипропилена.

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Таблица 1

Температурный интервал термоформования

Продукт	Т.пл. (°С)	Т.тф. мин	Т.тф. макс
Гомополимерный полипропилен	165-175	Т.тф-25°С	Т.тф+5°С
Сополимерный полипропилен	160-171	Т.тф-20°С	Т.тф+30°С
Полипропилен с малеин.функц.	160-175	Т.тф-25°С	Т.тф+5°С
PA-6	210-221	Т.тф-25°С	Т.тф+5°С
PA 6/6-6	180-190	Т.тф-25°С	Т.тф+20°С
PA 11	183-192	Т.тф-25°С	Т.тф+5°С
PA 12	178-180	Т.тф-25°С	Т.тф+20°С
Смесь PA 6 и полиолефина	200-225	Т.тф-25°С	Т.тф+20°С
Гомополимерный PVDF	168-172	Т.тф-25°С	Т.тф+20°С
PMMA	T.g. 90-105	T.g.+20°C	T.g.+60°C
PVDF/PMMA (60/40)	168-172	Т.тф-25°С	Т.тф+5°С

Таблица 2

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер О	90	32
Экструдер I	60	30
Экструдер А	50	24
Экструдер В	38	24

Таблица 3

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер О	90	32
Экструдер I	60	30
Экструдер А	50	24
Экструдер В	38	24

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Таблица 4

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

Таблица 5

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

Таблица 6

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

Таблица 7

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

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Таблица 8

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

Таблица 9

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

Таблица 10

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

Таблица 11

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

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Таблица 12

Характеристики экструдеров

	Диаметр винта в мм	Длина/диаметр
Экструдер O	90	32
Экструдер I	60	30
Экструдер A	50	24
Экструдер B	38	24

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(54) МНОГОСЛОЙНАЯ ПЛАСТИКОВАЯ ПЛЕНКА

(57) Формула изобретения

1. Многослойная пленка для эластичной упаковки, содержащая, по меньшей мере:

слой подложки (B) на основе полипропилена, имеющий первую и вторую стороны;

первый слой покрытия (A), связанный с первой стороной указанного слоя подложки (B);

второй слой покрытия (C), связанный со второй стороной указанного слоя подложки (B), указанный второй слой покрытия имеет свободную внешнюю поверхность;

при этом, по меньшей мере, к одному из указанных первому (A) и второму (C) слоям покрытия добавлен силиконовый полимер с очень высокой вязкостью, используемый в качестве смазывающего средства; и на указанный первый слой покрытия (A) нанесен защитный слой металлизации (A').

2. Многослойная пленка по п.1, характеризующаяся тем, что указанный силиконовый полимер добавлен ко второму слою покрытия (C).

3. Многослойная пленка по п.1, где указанный силиконовый полимер имеет вязкость более 15000000 сСт.

4. Многослойная пленка по п.1, где указанный силиконовый полимер имеет средневесовую молекулярную массу более 300000 Mw.

5. Многослойная пленка по п.2, где указанный силиконовый полимер имеет вязкость более 15000000 сСт.

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6. Многослойная пленка по п.1, где указанный силиконовый полимер является единственным смазывающим средством или его комбинируют с одним или более дополнительными смазывающими средствами в количествах не более 500 м.д.

7. Многослойная пленка по одному из пп.2-5, где указанный силиконовый полимер является единственным смазывающим средством или его комбинируют с одним или более дополнительными смазывающими средствами в количествах не более 500 м.д.

8. Многослойная пленка по одному из пп.1-6, где количество указанного силиконового полимера составляет от 0,5 до 2,0 мас.% в пересчете на массу указанного первого или второго слоя покрытия (A, C), к которому он добавлен.

9. Многослойная пленка по одному из пп.1-6, где указанный защитный слой металлизации (A') образован слоем вакуумной металлизации.

10. Многослойная пленка по одному из пп.1-6, где указанный защитный слой металлизации (A') представляет собой слой на основе алюминия.

11. Многослойная пленка по одному из пп.1-6, где указанный защитный слой металлизации (A') имеет толщину в интервале 100-300 (E).

12. Многослойная пленка по одному из пп.1-6, где указанный защитный слой металлизации (A') имеет оптическую плотность (OD) в интервале от 1 до 3.

13. Многослойная пленка по одному из пп.1-6, где значение коэффициента динамического трения (COF) меньше или равно 0,35.

14. Многослойная пленка по одному из пп.1-6, где указанный первый слой покрытия (A) имеет толщину в интервале от 0,5 до 2 мкм, предпочтительно в интервале от 0,6 до 0,8 мкм.

15. Многослойная пленка по одному из пп.1-6, где указанный второй слой покрытия (C) имеет толщину в интервале от 0,5 до 3 мкм.

16. Многослойная пленка по одному из пп.1-6, где указанный слой подложки (B) указанной пленки имеет толщину в интервале от 10 до 100 мкм.

17. Многослойная пленка по одному из пп.1-6, где первый и/или второй слой покрытия (A; C) состоит из, по меньшей мере, одного из следующих полимеров: C_2-C_3-сополимер, C_3-C_4-сополимер, C_2-C_3-C_4-терполимер, сополимер этилена и винилового спирта или из их комбинаций.

18. Многослойная пленка по одному из пп.1-6, где, по меньшей мере, в один из указанных слоев покрытия (A; C) добавлен антиадгезив такой, как аморфный кремний, карбонат кальция, силикат магния, силикат алюминия, или сшитый полиметакрилат, или сшитый полисилоксан.

19. Многослойная пленка по одному из пп.1-6, которая содержит дополнительные средства, которые улучшают адгезию указанного защитного слоя металлизации (A') или улучшают барьерные характеристики такие, как сополимеры полиолефинов с привитым малеиновым ангидридом, терпеновые смолы, карбоцепные полимеры, которые добавлены к указанному первому и/или второму слою покрытия (A; C), к которым добавлен упомянутый силиконовый полимер.

20. Многослойная пленка по одному из пп.1-6, где указанный слой подложки (B) состоит из 100%-ного изотактического полипропилена, смеси изотактического полипропилена с изотактическим полипропиленом с высокой степенью кристалличности, изотактического полипропилена бимодальной структуры, который может содержать до 1% C_2, смеси двух изотактических полипропиленов, один из которых имеет показатель изотактичности ниже или равный 2%, или полипропилена с бимодальным молекулярно-массовым распределением, и содержащего максимально до 1% этилена.

21. Многослойная пленка по одному из пп.1-6, которая имеет структуру A-B-C.

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22. Многослойная пленка по одному из пп.1-6, которая имеет структуру A-D-B-C с промежуточным соединяющим слоем (D) между указанным первым слоем покрытия (A) и указанным слоем подложки (B).

23. Многослойная пленка по одному из пп.1-6, которая имеет структуру A-D-B-D-C с соединяющим слоем (D) между слоем подложки и указанным первым слоем покрытия (A), а также с соединяющим слоем (D) между указанным слоем подложки (B) и указанным вторым слоем покрытия (C).

24. Многослойная пленка по п.22, где указанный соединяющий слой (D) состоит из сополимера полиолефина, к которому привит малеиновый ангидрид.

25. Многослойная пленка по одному из пп.1-6, где в указанный слой подложки (B) добавлены порообразующие средства такие, как PBT, $CaCO_3$, EVOH или подобные.

26. Многослойная пленка по п.22, где указанные порообразующие средства добавлены в соединяющий слой (D).

27. Многослойная пленка по одному из пп.1-6, где указанные первый и/или второй слои покрытия (A; C), на которые наносят защитный слой металлизации (A'), были обработаны коронным разрядом, предпочтительно в отсутствие O_2 и предпочтительно в присутствии смесей газов на основе N_2 и CO_2, перед напылением указанного защитного слоя (A').

28. Многослойная пленка по одному из пп.1-6, где указанные первый и/или второй слои покрытия (A; C), на которые наносят указанный защитный слой (A'), были обработаны при помощи смешанной системы коронный разряд-пламя перед напылением указанного защитного слоя (A').

29. Многослойная пленка по одному из пп.1-6, где указанный второй слой покрытия (C) является термосвариваемым.

30. Многослойная пленка по одному из пп.1-6, где указанный силиконовый полимер добавлен в толщу указанных первого и/или второго защитного слоя (A; C).

31. Способ получения металлизированной многослойной пластиковой пленки, включающий следующие операции:

экструзия пленки с образованием многослойной структуры, содержащей, по меньшей мере, слой подложки (B), первый слой покрытия (A), связанный с первой стороной указанного слоя подложки (B), и второй слой покрытия (C), связанный со второй стороной указанного слоя подложки (B), при этом указанный первый слой покрытия (A) образует первую внешнюю поверхность указанной многослойной структуры, указанный второй слой покрытия (C) образует вторую внешнюю поверхность указанной многослойной структуры;

металлизация указанной второй внешней поверхности указанной многослойной структуры с образованием металлизированного защитного слоя (A');

сматывание полученной таким образом пленки в рулон;

при этом используют силиконовый полимер с очень высокой вязкостью в качестве смазывающего средства, связанного, по крайней мере, с одним из указанных первым и/или вторым слоем покрытия (A; C).

32. Способ по п.31, где указанный силиконовый полимер добавляют в полимерную массу перед экструзией.

33. Способ по п.31, где указанный силиконовый полимер добавляют к первому слою покрытия (A).

34. Способ по п.32, где указанный силиконовый полимер добавляют к первому слою покрытия (A).

35. Способ по одному из пп.31-34, где указанный силиконовый полимер имеет вязкость более 15000000 сСт.

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36. Способ по одному из пп.31-34, где указанный силиконовый полимер имеет средневесовую молекулярную массу более 300000 (Mw).

37. Способ по одному из пп.31-34, где указанный силиконовый полимер используют в качестве единственного смазывающего средства или в комбинации с одним или более дополнительными смазывающими средствами в количествах не более 500 м.д.

38. Способ по одному из пп.31-34, где количество указанного силиконового полимера составляет от 0,5 до 2,0 мас.% относительно массы указанного первого и/или второго слоя покрытия (A; C), к которому он добавлен.

39. Способ по одному из пп.31-34, где указанный слой металлизации (A') представляет собой слой алюминия.

40. Способ по одному из пп.31-34, где указанный силиконовый полимер добавляют в смесь, по меньшей мере, одного из указанных первого и/или второго слоев покрытия (A; C), связанных со слоем подложки (B).

41. Способ по одному из пп.31-34, где указанный силиконовый полимер наносят на слой, расположенный на первой стороне слоя подложки (B), и когда пленку сматывают в рулон, при контакте с соответствующей внешней стороной пленки, он переносится на другую сторону слоя подложки (B).

42. Способ по одному из пп.31-34, включающий операцию активации поверхности, по меньшей мере, одной из внешних сторон пленки для увеличения поверхностной энергии указанной стороны перед переносом указанного силиконового полимера на указанную сторону, например, путем плазменной обработки, обработки пламенем или обработки коронным разрядом.

43. Способ по одному из пп.31-34, включающий последующую операцию запаивания, по меньшей мере, одного из указанных слоев (A; C; D) на конце указанной пленки с образованием замкнутой упаковки.

44. Способ по одному из пп.31-34, включающий операции:

экструзия пленки, имеющей многослойную структуру, указанный силиконовый полимер связан, по меньшей мере, с первым слоем покрытия A;

сматывание указанной пленки с образованием рулона;

перематывание указанной пленки в камере для металлизации;

металлизация указанной второй внешней поверхности указанной многослойной структуры с образованием металлизированного защитного слоя (A');

перематывание полученной таким образом металлизированной пленки в рулон;

предоставление возможности силиконовому полимеру перемещаться с первого слоя покрытия на слой металлизации.

45. Способ по одному из пп.31-34, включающий операцию совместной экструзии промежуточного соединяющего слоя (D), находящегося между указанным слоем подложки (B) и, по меньшей мере, одним из указанных первым (A) и вторым (C) слоем покрытия.

46. Пленка по одному из пп.1-6, которая представляет собой полученную совместной экструзией двуосно-ориентированную пленку.

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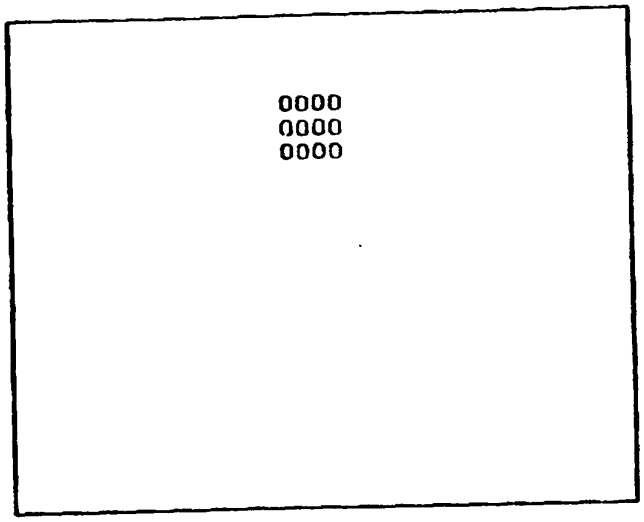
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(57) Abstract

This invention relates to a molded object prepared from a copolyester having an inherent viscosity of 0.4 to 1.1 dL/g, wherein the acid component comprises repeat units from 90 to 40 mole % terephthalic acid and from 10 to 60 mole % of one or more additional dibasic acids selected from the group consisting of isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid, diphenyldicarboxylic acid, and stilbenedicarboxylic acid; wherein the glycol component comprises repeat units from 1,4-cyclohexanedimethanol.

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POLYESTER MOLDING COMPOSITIONS

This invention relates to certain molded objects comprising poly(1,4-cyclohexylenedimethylene terephthalate) copolyesters which have improved toughness, clarity and stress crack resistance.

Background of the Invention

Various polymeric materials have been widely used over the past 60 years for molding toothbrushes, tool handles, windshield scrapers, steering wheels, hair brushes, cutlery, eyeglass frames and the like. In many of these applications, the molded part must be clear, tough, impact resistant, stress crack resistant, hydrolysis resistant as well as having a pleasing feel and appearance.

Plasticized cellulose acetate propionate (CAP) compositions have been used successfully in the past for toothbrush handles. Such compositions have good clarity, sparkle and overall appearance. However, design changes in toothbrush handles to increase the bristle density has led to cracking in certain brushes. The cracks which occur during bristle insertion are a result of insufficient weld-line strength. Increased plasticizer concentrations improve the weld-line strength but this leads to decreased stiffness which can result in inadequate bristle retention.

Certain rigid polyurethane materials have been evaluated in this application but this polymer is difficult to mold, and the urethane linkages in the polymer chain can hydrolyze in the presence of moisture during molding.

Polyester materials such as poly(ethylene terephthalate) (PET) and poly(1,4-cyclohexylenedimethylene terephthalate) (PCT) have many

desirable properties for molded parts but these polymers are readily crystallizable and provide hazy or opaque objects when molded in thick parts. Modification of PET polymers with high levels of glycol components other than ethylene glycol provide clear, tough molded parts but they tend to stress crack in the presence of certain toothpaste solutions containing mint oil.

For example, U. S. Patent 2,901,466 (1959) assigned to Eastman Kodak Company describes a wide range of linear polyesters and polyesteramides derived from 1,4-cyclohexanedimethanol (CHDM). Many of the compositions are readily crystallizable and molded parts are hazy or opaque. Thus, they are not suitable for clear, molded objects.

There is a need in the art, therefore, for molding compositions which have visual clarity and which have improved molding and physical property requirements.

Summary of the Invention

This invention relates to molded objects prepared from a copolyester having an inherent viscosity of 0.4 to 1.1 dL/g,

wherein the acid component comprises repeat units from 90 to 40 mole % terephthalic acid and from 10 to 60 mole % of one or more additional dibasic acids selected from the group consisting of isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid, diphenyldicarboxylic acid, and stilbenedicarboxylic acid; and,

wherein the glycol component comprises repeat units from 1,4-cyclohexanedimethanol.

These molded objects have the advantage of having improved clarity and stress crack resistance. They also have good physical properties including strength, stiffness, impact resistance and hydrolysis resistance.

Brief Description of the Drawings

Fig. 1 – illustrates the molded plaques used to determine chemical resistance

Fig. 2 – illustrates the testing apparatus used to determine stress crack resistance

Description of the Invention

It has been found that certain PCT copolyesters are highly suitable for molding clear, tough, stress crack resistant parts.

The molded objects are prepared from a copolyester having an inherent viscosity of 0.4 to 1.1 dL/g,

where the acid component comprises repeat units from 90 to 40 mole %, preferably 85 to 52 mole %, more preferably, 83 to 52 mole % terephthalic acid and from 10 to 60 mole %, preferably 15 to 48 mole, preferably 17 to 48 mole %, of one or more additional dibasic acids selected from the group consisting of isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid, diphenyldicarboxylic acid, and stilbenedicarboxylic acid;

where the glycol component comprises repeat units from 1,4–cyclohexanedimethanol, preferably 80 to 100 mole % 1,4–cyclohexanedimethanol, more preferably, 85 to 100 mole %, even more preferably 90 to 100 mole %, and even more preferably 95 to 100 mole %.

When using the cyclohexanedicarboxylic acids, they may be in the *cis* or *trans* forms or as *cis/trans* isomer mixtures. The lower alkyl esters, such as the methyl esters, may be used instead of the dibasic acids in preparing the molding compositions of this invention.

When cyclohexanedicarboxylic acid is used, 1,3– and 1,4–cyclohexanedicarboxylic acid are preferred. When naphthalenedicarboxylic acid is used, 2,6–, 2,7–, 1,4– and 1,5–naphthalenedicarboxylic acid are preferred.

The molded objects of the invention, may comprise up to 10 mole % of even further additional dibasic acids. These dibasic acids may be selected from one or more of the group consisting of aromatic dicarboxylic acids, aliphatic dicarboxylic acids, and cycloaliphatic dicarboxylic acids, each preferably having 4 to 40 carbon atoms. More specifically, these additional dibasic acids can be selected from one or more of the group consisting of phthalic acid, cyclohexanediacetic acid, succinic acid, glutaric acid, adipic acid, azelaic acid, sebacic acid, isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid, diphenyldicarboxylic acid, and stilbenedicarboxylic acid.

Preferred additional carboxylic acids are selected from the group consisting of isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid, diphenyldicarboxylic acid, and stilbenedicarboxylic acid. Even more preferred additional dibasic acids include isophthalic acid, cyclohexanedicarboxylic acid and naphthalenedicarboxylic acid.

The glycol component may contain up to 20 mole % of one or more additional aliphatic or alicyclic glycols, preferably containing 2 to 20 carbon atoms. These additional glycols may be selected from the group consisting of ethylene glycol, diethylene glycol, triethylene glycol, propanediol, butanediol, pentanediol, hexanediol, neopentyl glycol and tetramethylcyclobutanediol. Ethylene glycol is particularly preferred.

Very small amounts (less than 1.5 mole%) of certain branching agents such as trimellitic anhydride, trimellitic acid, pyromellitic dianhydride, trimesic acid, hemimellitic acid, glycerol, trimethylolpropane, pentaerythritol, 1,2,4-butanetriol, 1,2,6-hexanetriol, sorbitol, 1,1,4,4-tetrakis(hydroxymethyl)cyclohexane, dipentaerythritol and the like may be used.

The copolyesters of this invention are readily prepared using melt phase or solid state polycondensation procedures well known in the art. They may be made by batch or continuous processes. Examples of these processes can be found in U.S. Patent Nos. 4,256,861, 4,539,390, and 2,901,466 and include preparation by direct condensation or by ester interchange.

Specifically, the polymers of this invention may be prepared according to the methods described in United States Patent 2,901,466. However, the preparation of the polymers of this invention is not particularly limited to the method described in United States Patent 2,901,466. This patent discloses interchange reactions as well as polymerization build-up processes. Briefly, a typical procedure consists of at least two distinct stages; the first stage, known as ester-interchange or esterification, is conducted under an inert atmosphere at a temperature of 150 to 250°C for 0.5 to 8 hours, preferably from 180 to 240°C for 1 to 4 hours. The glycols, depending on their reactivities and the specific experimental conditions employed, are commonly used in molar excesses of 1.05 – 2.5 per total moles of acid-functional monomers. The second stage, referred to as polycondensation, is conducted under reduced pressure at a temperature of 230 to 350°C, preferably 265 to 325°C, and more preferably 270 to 300°C for 0.1 to 6 hours, preferably 0.25 to 2 hours. Stirring or

appropriate conditions are used in both stages to ensure adequate heat transfer and surface renewal of the reaction mixture. The reactions of both stages are facilitated by appropriate catalysts, especially those well-known in the art, such as alkoxy titanium compounds, alkali metal hydroxides and alcoholates, salts of organic carboxylic acids, alkyl tin compounds, metal oxides, and so forth.

Suitable copolyesters will have inherent viscosity (I.V.) values of about 0.4 to about 1.1 dL/g. Such values are obtained in a 60/40 phenol/tetrachlorethane solution containing 0.5 grams (g) of polymer in 100 milliliters (mL) of solution. It is preferred that the copolyesters have I.V. values of at least 0.5 dL/g.

Preferred copolyesters must have glass transition temperatures (Tg) of at least 70°C as determined by Differential Scanning Calorimetry (DSC) and a crystallization half-time of at least 1 minute as measured by a small angle laser light scattering technique.

The technique for determining the crystallization haze half-times consists primarily in following the increase in depolarization of plane-polarized light by the polyester. The method used in this invention is primarily that shown in "A New Method for Following Rapid Rates of Crystallization", I. Poly (hexamethylene adipamide), J. H. Magill, Polymer, Vol. 2, page 221-233 (1961) with the exception that Magill uses a polarizing microscope as the source of light and light-collection lenses. In measuring the crystallization half-times of the present invention, a helium-neon laser [with a small angle light scattering technique (SALS)] was used as was shown by Adams and Stein in J. Polymer Sci. A2, Vol. 6 (1962).

Crystallization half–times are measured at the time in which the transmitted intensity is half of the maximum intensity achieved.

The method used is generally as follows:

(1) Melt the sample to remove existing crystallinity;

(2) Crystallize the sample polyester at a pre–determined temperature;

(3) Record the transmitted light intensity plotted versus time;

(4) Find the time at which the transmitted intensity is half of the maximum intensity achieved.

The above procedure is repeated at different temperatures until a minimum value for the crystallization half–time can be measured. "Minimum value" refers to the lowest measurable point on a curve plotted using the temperature data and corresponding crystallization half–time data.

The term "crystallization haze half–time as measured from the melt phase" as defined herein is the procedure as describe above.

It is preferred that the molded objects of the invention have a crystallization haze half–time of greater than 1 minute, preferably greater than 3 minutes, and more preferably greater than 5 minutes.

When the molded objects of the invention have crystallization haze half–times as described, they are generally visually clear for regions of a molded object having a thickness of from 1 to 11.5 mm, preferably 3 to 11.5."

It is also preferable that molded objects prepared from the blends of the invention have a diffuse transmittance value of less than about 60%, more preferably, less than about 40%, and more preferably,

less than about 20% as determined by ASTM Method D1003. When the diffuse transmittance value is less than about 60%, the molded objects are visually clear.

Also, the molded objects of the invention demonstrate improved stress cracking resistance as determined for test specimens which are 0.32 centimeters thick under a flexural load with 1.4% strain and with 2.7% strain and as demonstrated more fully in the following Examples.

This stress cracking resistance testing is preferably performed in the presence of a flavorant. More preferably, the flavorant is a mint oil. Of the possible mint oils, it is preferable that the mint oil is either peppermint oil or spearmint oil.

The stress cracking resistance measurements used in the invention are also preferably performed in the presence of a toothpaste solution comprising water and a toothpaste containing greater than 0.6 weight % mint oil or, more specifically, in the presence of peppermint oil directly as described more fully in the following Examples.

Other ingredients may be used in the toothpaste solutions including glycerine, sodium bicarbonate, water, hydrated silicate, polyethylene glycol, sodium laural sulfate, sodium laural sarcosinate, sodium pyrophosphates, sodium phosphates, sorbitol, sodium benzoate, sodium saccharin, xantham gum, cellulose gum, flavorants, sodium saccharin, FD&C blue #1 and FD&C yellow #10, FD&C red 30, 1-hydroxy-2-propanone, 3-octanol, 4-methyl-1-(1-methylethyl)cyclohexene, pulegone, dodecanol, 3-phenyl-2-propenal, dodecanol, eugenol and titanium dioxide.

Flavorants useful in performing the tests of the invention include peppermint oil, curly mint oil, anise oil, Japanese anise oil, caraway oil, eucalyptus oil,

fennel oil, cinnamon oil, clove oil, geranium oil, sage oil, pimento oil, thyme oil, and majoram oil.

Mint oil may contain several ingredients including, but not limited to: limonene, cineole, menthone, menthol, and carvone.

The copolyesters may be used in clear form or they may be colored or pigmented with additives or copolymerizable colorants. Typically useful copolymerizable colorants are described in U. S. Patents 5,030,708 (1991), 5,102,980 (1992) and 5,194,571 (1993) all assigned to Eastman Kodak Company, incorporated herein by reference.

Other additives such as stabilizers, antioxidants, mold release agents, fillers and the like may also be used if desired. Polymer blends may be used.

The copolyesters of this invention are easy to mold into desired shapes such as toothbrush handles, hair brush handles, ice scrapers, cutlery or cutlery handles, tool handles, automotive steering wheels, eyeglass frames and the like. This invention can be further illustrated by the following examples of preferred embodiments thereof, although it will be understood that these examples are included merely for purposes of illustration and are not intended to limit the scope of the invention unless otherwise specifically indicated. The starting materials are commercially available unless otherwise indicated. Percentages are by weight unless otherwise stated.

I. PREPARATION OF COPOLYESTERS AND MOLDED OBJECTS

Example 1 – Comparative – Preparation of Copolyesters containing terephthalate, ethylene glycol and 3 mole% 1,4–cyclohexanedimethanol

A 5000 mL stainless steel reactor equipped with an agitator shaft, nitrogen inlet, and an outlet to allow for removal of volatile materials was charged with 679.7 grams (3.5 mole) of dimethyl terephthalate (DMT), 427.8 grams (6.9 mole) of ethylene glycol (EG), 16.4 grams (0.11 mole) of 1,4–cyclohexanedimethanol (CHDM) (70 % *trans* isomer/30 % *cis* isomer) and 1.35 mL of a 3.30% (w/v) solution of titanium (IV) isopropoxide in n–butanol. The reactor was purged with nitrogen and heated to 200°C under a slow nitrogen sweep with agitation and held for one hour. The reactor temperature was raised to 220°C and held for two hours. The temperature was raised to 280°C and the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm was attained over a 30 minute period. The reactor was stirred under vacuum for one hour. The vacuum was then displaced with a nitrogen atmosphere and the polymer was extruded through an opening in the bottom of the reactor. The extruded rod was cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.70 deciliters (dL)/g according to ASTM D3835–79. The diol component of the polymer consisted of 96 mole% EG, 3 mole% CHDM and 1 mole% diethylene glycol (DEG) as measured by gas chromatography on a hydrolyzed sample. A glass transition temperature (T_g) of 78°C and a melting point (T_m) of 248°C were measured by DSC (differential scanning calorimetry) analysis. The crystallization haze half–time as measured from the melt phase was 0.8

minutes. The sample was dried at 150°C in a dehumidifier drier for about 4 hours and injection molded into clear plaques that were 7.5 centimeters (cm) square and 0.32 cm thick. Located approximately 1 cm from the plaque edge was an area 1.1 cm by 0.6 cm which contains twelve holes approximately 0.1 cm in diameter as shown in Figure 1. This area of the plaque was used to simulate the head of a toothbrush into which bristles would be inserted.

Example 2 – Comparative – Preparation of Copolyester containing terephthalate, EG and 31 mole% CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 679.5 grams (3.5 mole) DMT, 365.6 grams (5.9 mole) EG, 160.4 grams (1.1 mole) CHDM and 2.05 mL of a 3.30% (w/v) solution of titanium isopropoxide in n–butanol. The diol interchange step was conducted at 200°C for one hour and at 210°C for two hours. The polycondensation step was conducted at a vacuum of 0.5 mm Hg for one hour. The polymer was extruded from the bottom of the reactor. The extruded rod was cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.74 dL/g. The diol component of the polymer consisted of 68 mole% EG, 31 mole% CHDM and 1 mole% DEG. The amorphous copolymer possessed a T_g of 80°C as determined by DSC analysis. The crystallization haze half–time as measured from the melt phase was greater than 1 hour. The sample was dried at 65°C in a dehumidifier drier for about 16 hours. It was injection molded into clear specimens set forth in Example 1.

Example 3 – Comparative – Preparation of Copolyester containing terephthalate, EG and 62 mole% CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 679.7 grams (3.5 mole) DMT, 305.6 grams (4.9 mole) EG, 302.5 grams (2.1 mole) CHDM and 2.06 mL of a 3.30% (w/v) solution of titanium isopropoxide in n–butanol. The diol interchange step was conducted at 200°C for one hour and at 210°C for two hours. The polycondensation step was conducted at a vacuum of 0.5 mm Hg for 45 minutes. The polymer was extruded from the bottom of the reactor. The extruded rod was cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.72 dL/g. The diol component of the polymer consisted of 37 mole% EG, 62 mole% CHDM and 1 mole% DEG. A T_g of 82°C and a T_m of 225°C were obtained for the copolymer by DSC analysis. The crystallization haze half–time as measure from the melt phase was 28 minutes. The sample was dried at 65°C in a dehumidifier drier for about 16 hours and injection molded into clear specimens set forth in Example 1.

Example 4 – Comparative – Preparation of Copolyester containing terephthalate, EG and 81 mole% CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 679.2 grams (3.5 mole) DMT, 248.1 grams (4.0 mole) EG, 432.9 grams (3.0 mole) CHDM and 2.38 mL of a 3.30% (w/v) solution of titanium isopropoxide in n–butanol. The diol interchange step was conducted at 200°C for one hour and at 210°C for two hours. The polycondensation step was conducted at a

vacuum of 0.5 mm Hg for 40 minutes. The polymer was extruded from the bottom of the reactor, cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.76 dL/g and the diol component of the polymer consisted of 18 mole% EG, 81 mole% CHDM and 1 mole% DEG. A T_g of 87°C and a T_m of 257°C were obtained for the copolymer by DSC analysis. The crystallization haze half-time as measured from the melt phase was 3 minutes. The sample was dried at 150°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 5 – Comparative – Preparation of Copolyester containing 95 mole% terephthalate, 5 mole% isophthalate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 645.2 grams (3.3 mole) DMT, 34.1 grams (0.2 mole) dimethyl isophthalate (DMI), 555.7 grams (3.9 mole) CHDM and 2.68 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 300°C under a slow nitrogen sweep with agitation. The reactor temperature was held for 30 minutes and then the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm Hg was attained over a 30 minute period. The vacuum and temperature was held for 50 minutes. The polymer was extruded from the bottom of the reactor. The extruded rod was cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.78 dL/g and the polymer consisted of 95 mole% terephthalate and 5 mole% isophthalate as measured by ^1H NMR. A T_g of 92°C and a T_m of 287°C were obtained for the copolymer by DSC

analysis. The crystallization haze half-time as measured from the melt phase was 0.5 minutes. The sample was dried at 150°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 6 – Example of the Invention – Preparation of Copolyester Containing 83 Mole% terephthalate, 17 Mole% isophthalate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 577.3 grams (3.0 mole) DMT, 101.9 grams (0.5 mole) DMI, 565.4 grams (3.9 mole) CHDM and 2.67 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 290°C under a slow nitrogen sweep with agitation. The reactor temperature was held for 30 minutes and then the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm Hg was attained over a 30 minute period. The vacuum and temperature was held for 43 minutes. The polymer was extruded from the bottom of the reactor, cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.70 dL/g and the polymer consisted of 83 mole% terephthalate and 17 mole% isophthalate as measured by ^{1}H NMR. A T_g of 89°C and a T_m of 262°C were obtained for the copolymer by DSC analysis. The crystallization haze half-time as measured from the melt phase was 1.5 minutes. The sample was dried at 150°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 7 – Example of the Invention – Preparation of Copolyester containing 70 mole% terephthalate, 30 mole% isophthalate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 476.3 grams (2.5 mole) DMT, 204.1 grams (1.0 mole) DMI, 555.8 grams (3.9 mole) CHDM and 2.67 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 290°C under a slow nitrogen sweep with agitation. The reactor temperature was held for 30 minutes and then the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm Hg was attained over a 30 minute period. The vacuum and temperature was held for 53 minutes. The polymer was extruded from the bottom of the reactor. The extruded rod was cooled in an 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.70 dL/g and the polymer consisted of 70 mole% terephthalate and 30 mole% isophthalate as measured by ^{1}H NMR. An amorphous polymer was recovered that had a Tg of 87°C as measured by DSC. The crystallization haze half-time as measured from the melt phase was 6.8 minutes. The sample was dried at 65°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 8 – Example of the Invention – Preparation of Copolyester containing 61 mole% terephthalate, 39 mole% 1,4-cyclohexanedicarboxylate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 404.7 grams (2.1 mole) DMT,

243.6 grams (1.4 mole) of dimethyl 1,4-cyclohexanedicarboxylate (DMCD) (35% *trans* isomer/65% *cis* isomer), 580.4 grams (4.03 mole) of CHDM and 2.65 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 220°C for 60 minutes under a slow nitrogen sweep with sufficient agitation. After raising the temperature to 290°C the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm Hg was attained in 30 min. The vacuum and temperature was held for 120 minutes to perform the polycondensation. The vacuum was then displaced with a nitrogen atmosphere and the polymer was drained from the bottom of the reactor, cooled in an 5°C water bath and pelletized. An inherent viscosity of 0.70 dL/g was determined for the recovered polymer. The polymer contained 61 mole% terephthalate and 39 mole% 1,4-cyclohexanedicarboxylate (51% *trans* isomer/49% *cis* isomer) as measured by ^{1}H NMR. A T_g of 72°C and a T_m of 223°C were obtained for the copolymer by DSC analysis. The crystallization haze half-time as measured from the melt phase was 15 minutes. The sample was dried at 65°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 9 – Example of the Invention – Preparation of Copolyester containing 52 mole% terephthalate, 48 mole% 1,4-cyclohexanedicarboxylate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 404.7 grams (2.1 mole) of dimethyl terephthalate (DMT), 243.6 grams (1.4 mole) of dimethyl 1,4-cyclohexanedicarboxylate (95 % *trans* isomer/5 % *cis* isomer), 580.4 grams (4.03 mole) of CHDM

and 2.68 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 290°C under a slow nitrogen sweep with agitation. The reactor temperature was held for 30 minutes and then the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm was attained over a 30 minute period. The vacuum and temperature was held for 53 minutes. The polymer was extruded from the bottom of the reactor through an orifice. The extruded rod was cooled in an 5°C water bath and pelletized. An inherent viscosity of 0.74 dL/g was determined for the recovered polymer. The polymer contained 52 mole% terephthalate and 48 mole% 1,4-cyclohexanedicarboxylate (88% *trans* isomer/12% *cis* isomer) as measured by ^{1}H NMR. A glass transition temperature T_g of 78°C and a T_m of 225°C were obtained for the polymer by DSC analysis. The crystallization haze half-time as measured from the melt phase was 11.5 minutes. The sample was dried at 65°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 10 - Example of the Invention - Preparation of Copolyester containing 70 mole% terephthalate, 30 mole% 2,6-naphthalenedicarboxylate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 477.0 grams (2.5 mole) DMT, 203.9 grams (1.0 mole) DMI, 565.4 grams (3.9 mole) CHDM and 2.67 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 290°C under a slow nitrogen sweep with agitation. The reactor temperature was held for 30 minutes and then the nitrogen purge was removed and a

vacuum was applied such that a vacuum of < 0.5 mm was attained over a 30 minute period. The vacuum and temperature was held for 43 minutes. The polymer was extruded from the bottom of the reactor. The extruded rod was cooled in a 5°C water bath and pelletized. The recovered polymer pellets had an inherent viscosity of 0.64 dL/g and the polymer consisted of 70 mole% terephthalate and 30 mole% naphthalate as measured by ^{1}H NMR. A T_g of 103°C and a T_m of 246°C were obtained for the polymer by DSC analysis. The crystallization haze half-time as measured from the melt phase was 9 minutes. The sample was dried at 85°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

Example 11 — Example of the Invention — Preparation of Copolyester containing 68 mole % terephthalate, 32 mole % 1,4- cyclohexanedicarboxylate and CHDM

The apparatus and procedure set forth in Example 1 was used. The following amounts of reactants were charged to the reactor: 461.8 grams (2.4 mole) of dimethyl terephthalate (DMT), 224.0 grams (1.1 mole) of dimethyl 1,4-cyclohexanedicarboxylate (95% *trans* isomer/5 % *cis* isomer), 580.4 grams (4.03 mole) of CHDM and 2.68 mL of a 3.30% (w/v) solution of titanium isopropoxide in n-butanol. The reactor was purged with nitrogen and heated to 290°C under a slow nitrogen sweep with agitation. The reactor temperature was held for 30 minutes and then the nitrogen purge was removed and a vacuum was applied such that a vacuum of < 0.5 mm was attained over a 30 minute period. The vacuum and temperature was held for 50 minutes. The polymer was extruded from the bottom of the reactor through an orifice. The extruded rod was cooled in an 5°C water

bath and pelletized. An inherent viscosity of 0.70 dL/g was determined for the recovered polymer. The polymer contained 68 mole% terephthalate and 32 mole% 1,4-cyclohexanedicarboxylate (89% *trans* isomer/11 % *cis* isomer) as measured by ^{1}H NMR. A glass transition temperature T_g of 82°C and a T_m of 245°C were obtained for the polymer by DSC analysis. The crystallization haze half-time from the melt was 2 minutes. The sample was dried at 65°C in a dehumidifier drier for about 4 hours and injection molded into clear specimens set forth in Example 1.

II. PREPARATION FOR AND PERFORMANCE OF STRESS CRACKING RESISTANCE METHODS USING PEPPERMINT OIL AND TOOTHPASTE SOLUTION

A. Preparation of Toothpaste Solution

A toothpaste solution using Toothpaste A as described in the following Tables was prepared using the following procedure. In a 500 ml container, 50 grams of solid toothpaste was added 120 ml of plain tap water. The mixture was sealed and then stirred using a magnetic stirring bar and a magnetically driven stirring plate. After a 30 minute mixing time the dispersion was applied to the test specimens using an applicator brush and observed. The same toothpaste solution was used throughout each testing cycle. The following morning the test specimens from Examples 1-10 were inspected and ranked on their appearance using the craze ranking system. Crazes are precursors to cracks which form due to the interaction of the solvent with the polymer matrix. Crazes are similar to cracks, but crazes contain highly oriented fibrils of polymer which span its faces. Crazes are not necessarily structural defects, but often lead to the formation of true cracks.

After the ranking, the test specimens were wetted with the toothpaste solution. The specimens were wet with the toothpaste solution 8 hours later and observed the following morning.

The stress crack resistance to pepper mint oil was determined using the same methodology as the toothpaste solution testing.

Peppermint oil has the following composition:

Peppermint Oil Composition

Compound	Weight Percent
Dimethylsulfide	0.02
2 Methyl propanal	0.03
3 methyl propanal	<0.01
2 Methyl butanal	<0.01
3 Methyl butanal	0.15
2 Ethyl furan	0.03
trans–2,5–Diethyl THF	0.02
α–Pinene	0.66
Sabinene	0.42
Myrcene	0.18
α–Terpinene	0.34
Limonene	1.33
1,8 Cineole	4.80
trans–Ocimene	0.03
cis–Ocimene	0.31
G–Terpinene	0.56
trans–2–Hexenal	0.07
para–Cymeme	0.10
Terpeniolene	0.16
Hexanol	0.13
3 Octyl acetate	0.03
cis–3–Hexenol	0.01
3–Octanol	0.21
trans–2–Hexenol	0.02
Sabinene hydrate	0.80
Menthone	20.48
Menthofuran	1.67
D–Isomenthone	2.77
B–Bourbonol	0.37
Neomenthylacetate	0.21
Linalool	0.26
cis–Sabinene hydrate	0.07
Menthyl acetate	5.02
Isopulegol	0.07
Neoisomenthyl acetate	0.26
Neomenthol	3.34
β–Caryophyllene	2.13

Terpinene—4—ol	0.98
Neoisoisopulegol	0.03
Neoisomenthol	0.78
Menthol	43.18
Pulegone	0.77
trans—β Farenscene	0.29
Isomenthol	0.19
Humelene	0.03
α—Terpineol	0.16
Germacrene—*D*	2.29
Piperitone	0.96
Viridiflorol	0.26
Eugenol	0.02
Thymol	0.04

B. Toothpaste and Peppermint Oil Resistance Testing of Molded Articles

Plaques molded from Examples 1—10 were mounted in a testing rig shown in Figure 2. In Figure 2 the parts labelled A are clamps to hold the test specimen, B is the curved portion of the rig which determines the strain the test specimens are under and C is the molded plaque under strain. The testing rig was configured such that the flexural strain on each specimen is 2.7%. The testing rigs were used to simulate end—use conditions such as bristle insertion. The specimens remained in the testing rigs for 7 days and observed each day for the formation of crazes. A ranking system from 1—3 was used to identify the severity of crazing on each specimen, (visual observation codes as referred to herein). In this system, visual observation code 1 was assigned to test plaques that exhibit no change during the testing period. As the severity of crazing increases the ranking increases in value.

Table 1 illustrates the effect of 2.7% flexural strain on the test specimens fabricated from pellets of Examples 1—5. No effect was observed on all test specimens. This indicates that placement of the test

specimens in the testing apparatus does not induce crazing.

The effect of the toothpaste solution on Examples 1–5 under flexural strain are shown in Table 2. The data in Table 2 indicates that as the CHDM content of the copolyesters is increased relative to the EG content the resistance to stress cracking of the test specimen improves. At high levels of CHDM as illustrated by Examples 4 and 5, no effect was observed. The same trend was observed when peppermint oil was used as the chemical agent as shown in Table 3.

The data in Tables 2 and 3 indicate that Examples 4 and 5 have superior resistance to stress cracking when exposed to toothpaste solution and peppermint oil under flexural strain than Examples 1–3. Examples 3, 4 and 5 were injection molded into cylindrically shaped articles that were approximately 20 cm in length. The diameter of each article varied between 5 and 11.5 mm. The molded articles prepared from Example 3 were clear throughout. The molded articles prepared from Examples 4 and 5 were not completely clear. They contained opaque sections, generally in the area of the article with the largest diameter. This result indicated that the copolyesters represented by Examples 4 and 5 are resistance to stress cracking however; molded articles with thick sections of materials in Examples 4 and 5 were not preferred.

In Table 4, the effect of 2.7% flexural strain on specimens fabricated from Examples 6–10 is shown. The data in Table 4 indicates that placement of the test specimens in the testing apparatus does not induce crazing. The data in Table 5 indicates that the plaques molded from Examples 6–10 do not show any effect when tested under flexural strain in the presence of toothpaste solution. The data in Table 6 indicates that

Examples 6–10 all show improved stress crack resistance to peppermint oil under flexural strain than Examples 1–3. Pellets from Examples 6–10 were injection molded into cylindrically shaped articles 20 cm long. The diameter of each article varied between 5 and 11.5 mm. The molded articles prepared from Example 6 contained opaque sections particularly in the thickest sections, while the articles prepared from Examples 7–10 were clear throughout. This result indicates that certain copolyesters can be used to produce molded articles with thick sections that have excellent clarity and are resistance to stress cracking by toothpaste and peppermint oil.

Pellets from Example 6 were injection molded into cylindrically shaped articles 20 cm long. The diameter of each article varied between 5 and 7 mm. The molded articles were clear throughout. This result indicates that certain copolyesters can be used to produce molded articles that have excellent clarity and are resistant to stress cracking by toothpaste and peppermint oil.

Table 1. Effect of 2.7% Flexural Strain on Copolyesters Without Use of Toothpaste A Solution or Peppermint Oil

Time (hrs.)	Example 1	Example 2	Example 3	Example 4	Example 5
18	1	1	1	1	1
42	1	1	1	1	1
66	1	1	1	1	1
90	1	1	1	1	1
162	1	1	1	1	1
186	1	1	1	1	1

Visual Observation Codes:

1 = No effect
2 = test specimen is lightly crazed. Crazes are shallow and randomly located
3 = test specimen is heavily crazed. Crazes are deep and randomly located

Table 2. Effect of Toothpaste A Solution on Copolyesters at 2.7% Flexural Strain

Time (hrs.)	Example 1	Example 2	Example 3	Example 4	Example 5
18	3	3	3	1	1
42	3	3	3	1	1
66	3	3	3	1	1
90	3	3	3	1	1
162	3	3	3	1	1
186	3	3	3	1	1

Visual Observation Codes:

1 = No effect
2 = test specimen is lightly crazed. Crazes are shallow and randomly located
3 = test specimen is heavily crazed. Crazes are deep and randomly located

Table 3. Effect of Peppermint Oil on Copolyesters at 2.7% Flexural Strain

Time (hrs.)	Example 1	Example 2	Example 3	Example 4	Example 5
2	3S	3S	3S	2	2
18	3S	3S	3S	2	2
42	3S	3S	3S	2	2
66	3S	3S	3S	2	2
90	3S	3S	3S	2	2
114	3S	3S	3S	2	2

Visual Observation Codes:

1 = No effect
2 = test specimen is lightly crazed. Crazes are shallow and randomly located
3 = test specimen is heavily crazed. Crazes are deep and randomly located
S = test specimen swelled

Table 4. Effect of 2.7% Flexural Strain on Copolyesters Without the Use of Toothpaste Solution or Peppermint Oil

Time (hrs.)	Example 6	Example 7	Example 8	Example 9	Example 10	Example 11
18	1	1	1	1	1	1
42	1	1	1	1	1	1
66	1	1	1	1	1	1
90	1	1	1	1	1	1
162	1	1	1	1	1	1
186	1	1	1	1	1	1

Visual Observation Codes:

1 = No effect
2 = test specimen is lightly crazed. Crazes are shallow and randomly located
3 = test specimen is heavily crazed. Crazes are deep and randomly located

Table 5. Effect of Toothpaste A Solution on Copolyesters at 2.7% Flexural Strain

Time (hrs.)	Example 6	Example 7	Example 8	Example 9	Example 10
18	1	1	1	1	1
42	1	1	1	1	1
66	1	1	1	1	1
90	1	1	1	1	1
162	1	1	1	1	1
186	1	1	1	1	1

Visual Observation Codes:

1 = No effect
2 = test specimen is lightly crazed. Crazes are shallow and randomly located
5 = test specimen is heavily crazed. Crazes are deep and randomly located

Table 6. Effect of Peppermint Oil on Copolyesters at 2.7% Flexural Strain

Time (hrs.)	Example 6	Example 7	Example 8	Example 9	Example 10
1	2	2	3S	2	2
22	2	2	3S	2	3
46	2	2	3S	2	3
70	2	2	3S	2	3
94	2	2	3S	2	3
118	2	2	3S	2	3

Visual Observation Codes:

1 = No effect
2 = test specimen is lightly crazed. Crazes are shallow and randomly located
3 = test specimen is heavily crazed. Crazes are deep and randomly located
S = test specimen swelled

Comparison of Tensile Strength of Molded Articles Before and After Exposure to Toothpaste Solution

In Tables 7 and 8, the effect of the toothpaste solutions on retained tensile strength are displayed. Pellets of the examples listed in the tables were molded into tensile bars of 0.32 cm thickness as per ASTM method D638. One sample of the bars was tested as per ASTM D638 without any exposure to the toothpaste solution to establish a control standard. Additional bars were held in the strain rig described in the previous section at flexural strains of either 1.4% and 2.7%. The toothpaste solution was applied to these bars for one week as described in the previous section.

After exposure, the bars were removed from the rig and tested per ASTM D638. The ratio of tensile strength of the exposed specimen to the tensile strength of the control standard multiplied times 100% is the percent retained strength. Any Example which shows a retained strength of more than 90%, preferably, more than 95%, more preferably, more than 98%, and even more preferably, 100%, is deemed to possess sufficient chemical resistance for toothbrush applications.

The data in Table 7 confirm that Examples 1–3 possess inferior chemical resistance after exposure to Toothpaste A. The data in Table 8 show how increasing the flavorant level in the toothpaste affect Examples 2, 3, 6 and 11. The flavorant level was determined to be the total percentage of Limonene, Cineole, Methone, Menthol and Carvone, as determined by gas chromatography combined with mass spectroscopy. The levels of these components are also listed in Table 8. These five components are the chief compounds present in peppermint and spearmint oils. Levels of other components are listed in Table 9.

Table 7.

Example	Percentage of Retained Strength* @ 1.4% Flexural Strain	@ 2.7% Flexural Strain
1	30	27
2	0	0
3	38	0
4	98	98
5	100	100
6	100	100
7	100	100
8	100	100
9	100	100
10	100	100
11	100	100

Table 8

	Percent By Weight Flavorant	Example 2 VO Code* (% Retained Strength)	Example 3 VO Code* (% Retained Strength)	Example 6 VO Code* (% Retained Strength)	Example 11 VO Code* (% Retained Strength)
Toothpaste A*	0.800%	3 (0%)		1 (100%)	1 (100%)
Toothpaste B*	0.475%	1 (97%)	2 (98%)	1 (100%)	1 (100%)
Toothpaste C*	0.685%	2 (81%)	2 (98%)	1 (100%)	1 (100%)
Toothpaste D*	0.480%	2 (67%)		1 (100%)	1 (100%)
Toothpaste E*	0.845%	3 (0%)	3 (0%)	1 (100%)	1 (100%)
Toothpaste F*	0.740%	3 (0%)		1 (100%)	1 (100%)

Flavorant Compositions by Weight Percentages for Toothpastes A – F:

	Limonene	Cineole	Menthone	Menthol	Carvone	Total
Toothpaste A:	<0.01	0.02	0.105	0.67	0.01	0.800
Toothpaste B:	0.02	<0.01	0.01	0.215	0.23	0.475
Toothpaste C:	<0.01	0.015	0.09	0.57	0.01	0.685
Toothpaste D:	0.01	<0.01	0.05	0.31	0.11	0.480
Toothpaste E:	0.02	0.035	0.245	0.465	0.08	0.845
Toothpaste F:	0.02	0.035	0.19	0.485	0.01	0.740

VO Code* = Visual Observation Code

Table 9

CONCENTRATION (WEIGHT %) OF OTHER COMPOUNDS DETECTED IN TOOTHPASTES BY GAS CHROMATOGRAPHY/MASS SPECTROSCOPY

	Glycerin	Comp. 1	Comp. 2	Comp. 3	Comp. 4	Comp. 5	Comp. 6	Comp. 7	Comp. 8	Comp 9	Comp 10
Toothpaste A	21.62	0.01		0.025	0.025	0.085	0.275	0.115			0.07
Toothpaste B	18.06				0.01	0.055	0.155		0.55	0.01	
Toothpaste C	9.52			0.02		0.095	0.175	0.11	0.06	0.03	
Toothpaste D	8.98	0.07	0.01	0.01		0.065	0.275		0.105	0.05	0.05
Toothpaste E	21.67	0.05	0.01	0.05	0.025	0.01	0.28		0.13		0.08
Toothpaste F	12.15	0.04	0.01	0.04		0.04	0.14		0.065		0.01

Compound (Comp.) Identifification

1 1-HO-2-Propanone
2 3-Octanol
3 4-Methyl-1-(1-methylethyl)cyclohexene
4 Pulegone
5 Dodecanol (isomer 1)
6 Dodecanol (isomer 2)
7 3-Phenyl-2-propenal
8 Dodecanol (isomer 3)
9 Eugenol

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The invention has been described in detail with particular reference to preferred embodiments thereof, but it will be understood that variations and modifications can be effected within the spirit and scope of the invention. Moreover, all patents, patent applications (published and unpublished, foreign or domestic), literature references or other publications noted above are incorporated herein by reference for any disclosure pertinent to the practice of this invention.

CLAIMS

We claim:

1. A molded object prepared from a copolyester having an inherent viscosity of 0.4 to 1.1 dL/g,

wherein the acid component comprises repeat units from 90 to 40 mole % terephthalic acid and from 10 to 60 mole % of one or more additional dibasic acids selected from the group consisting of isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid, diphenyldicarboxylic acid, and stilbenedicarboxylic acid;

wherein the glycol component comprises repeat units from 1,4—cyclohexanedimethanol.

2. The molded object of Claim 1 wherein said acid component comprises repeat units of 85 to 52 mole % terephthalic acid and 15 to 48 mole % of one or more of said additional dibasic acids.

3. The molded object of Claim 2 wherein said acid component comprises repeat units of 83 to 52 mole % terephthalic acid and 17 to 48 mole % of one or more of said additional dibasic acids.

4. The molded object of Claim 1 wherein said one or more of said additional dibasic acids comprises isophthalic acid, cyclohexanedicarboxylic acid, naphthalenedicarboxylic acid.

5. The molded object of Claim 4 wherein one or more of said additional dibasic acids comprises isophthalic acid.

6. The molded object of Claim 4 wherein one or more of said additional dibasic acids comprises 1,3-cyclohexanedicarboxylic acid.

7. The molded object of Claim 4 wherein one or more of said additional dibasic acids comprises 1,4-cyclohexanedicarboxylic acid.

8. The molded object of Claim 4 wherein one or more said additional dibasic acids comprises naphthalenedicarboxylic acid.

9. The molded object of Claim 8 wherein said naphthalenedicarboxylic acid is selected from the group consisting of 2,6-naphthalenedicarboxylic acid, 2,7-naphthalenedicarboxylic acid, 1,4-naphthalenedicarboxylic acid, and 1,5-naphthalenedicarboxylic acid.

10. The molded object of Claim 1 comprising up to 10 mole % of even further additional dibasic acids.

11. The molded object of Claim 10 wherein said even further additional dibasic acids are selected from one or more of the group consisting aromatic dicarboxylic acids preferably having 8 to 14 carbon atoms, aliphatic dicarboxylic acids preferably having 4 to 12 carbon atoms, and cycloaliphatic dicarboxylic acids preferably having 8 to 12 carbon atoms.

12. The molded object of Claim 11 wherein said even further additional dibasic acids are selected from one or more of the group consisting of phthalic acid, cyclohexanediacetic acid, succinic acid,

glutaric acid, adipic acid, azelaic acid and sebacic acid.

13. The molded object of Claim 1 wherein said glycol component comprises 70 to 100 mole % 1,4-cyclohexanedimethanol.

14. The molded object of Claim 13 wherein said glycol component comprises 80 to 100 mole % 1,4-cyclohexanedimethanol.

15. The molded object of Claim 14 wherein said glycol component comprises 85 to 100 mole % 1,4-cyclohexanedimethanol.

16. The molded object of Claim 15 wherein said glycol component comprises 90 to 100 mole % 1,4-cyclohexanedimethanol.

17. The molded object of Claim 16 wherein said glycol component comprises 95 to 100 mole % 1,4-cyclohexanedimethanol.

18. The molded object of Claim 13 wherein said glycol component contains up to 30 mole % of one or more additional aliphatic or alicyclic glycols.

19. The molded object of Claim 18 wherein said one or more additional glycols is selected from the group consisting of ethylene glycol, diethylene glycol, triethylene glycol, propanediol, butanediol, pentanediol, hexanediol, neopentyl glycol and tetramethylcyclobutanediol.

20. The molded object of Claim 19 wherein said one or more additional glycols comprises ethylene glycol.

21. The molded object of Claim 1 having a crystallization haze half-time of greater than 1 minute.

22. The molded object of Claim 1 having a crystallization haze half-time of greater than 3 minutes.

23. The molded object of Claim 21 which is visually clear for portions of said object having a thickness of from 1 to 11.5 mm.

24. The molded object of Claim 22 having a crystallization haze half-time of greater than 5 minutes.

25. The molded object of Claim 23 which is visually clear for portions of said object having a thickness of from 5 to 11.5 mm.

26. The molded object of Claim 1 prepared from said copolyester having a diffuse transmittance value of less than about 60% as determined by ASTM Method D1003.

27. The molded object of Claim 1 having improved stress cracking resistance as determined for test specimens which are 0.32 centimeters thick under a flexural load with 2.7% strain.

28. The molded object of Claim 27 wherein said molded object has improved stress cracking resistance as

determined for test specimens which are 0.32 centimeters thick under a flexural load with 2.7% strain.

29. The molded object of Claim 26 wherein said molded object has improved stress cracking resistance as determined for test specimens which are 0.32 centimeters thick under a flexural load with 2.7% strain and which are contacted with toothpaste solution comprising 0.6 weight % flavorant as determined by gas chromatography.

30. The molded object of Claim 29 wherein said toothpaste solution comprises:

(a) water and

(b) a toothpaste comprising 0.6 weight % mint oil.

31. The molded object of Claim 30 wherein said molded object is contacted with said toothpaste solution for 18 to 186 hours.

32. The molded object of Claim 29 wherein said molded object is contacted with said flavorant for 1 to 118 hours.

33. The molded object of Claim 32 wherein said molded object is contacted with flavorant for 1 to 6 hours.

34. The molded object of Claim 29 wherein said flavorant is selected from the group consisting of peppermint oil, spearmint oil, curly mint oil, anise oil, Japanese anise oil, caraway oil, eucalyptus oil, fennel oil, cinnamon oil, clove

oil, geranium oil, sage oil, pimento oil, thyme oil, and majoram oil.

35. The molded object of Claim 34 wherein said flavorant is selected from mint oil.

36. The molded object of Claim 35 wherein said mint oil comprises a component selected from the group consisting of limonene, cineole, menthone, menthol, and carvone.

37. The molded object of Claim 35 wherein said mint oil comprises peppermint oil.

38. The molded object of Claim 29 wherein said flavorant contains synthetic ingredients.

39. The molded object of Claim 38 wherein said synthetic ingredient is menthol.

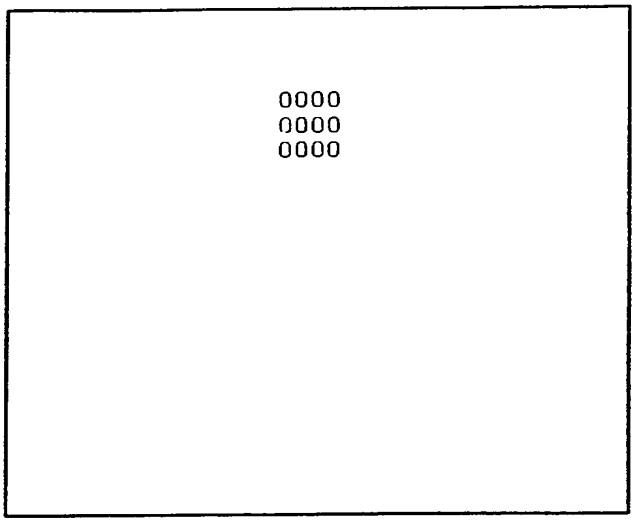


FIG. 1

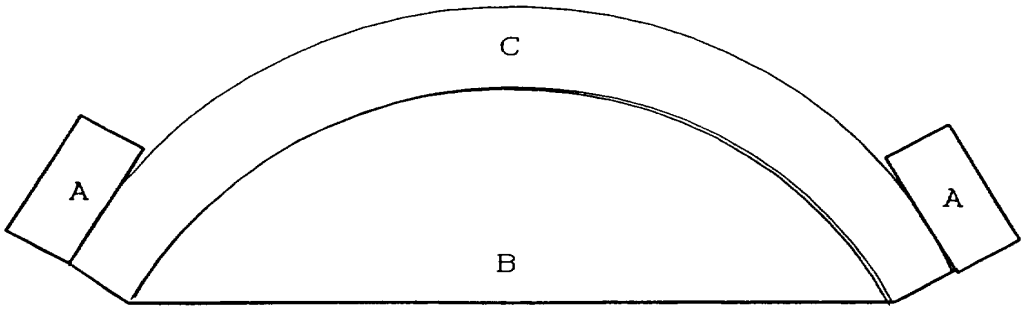


FIG. 2

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PC1/US 96/14873

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C08G63/199

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)
IPC 6 C08G

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 9421 Derwent Publications Ltd., London, GB; AN 94-173316 XP002022433 & JP 06 115 028 A (TORAY IND INC) , 26 April 1994 see abstract ---	1-5, 13-17
X	RESEARCH DISCLOSURE, vol. 313, no. 10, May 1990, HAVANT GB, page 368 XP000114814 ANONYMOUSLY: "Oriented polyester film" see the whole document ---	1-5, 13-17
X	US 5 207 967 A (SMALL, JR. ET AL.) 4 May 1993 see claim 1 --- -/--	1-5, 13-17

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"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

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"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

1

Date of the actual completion of the international search	Date of mailing of the international search report
10 January 1997	24. 01. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Decocker, L

Form PCT/ISA/210 (second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

Inte[illegible]onal Application No
PCT/US 96/14873

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	RESEARCH DISCLOSURE, vol. 284, no. 42, December 1987, HAVANT GB, pages 779-782, XP002022432 ANONYMOUSLY: "Terephthalate-co-napthalenedicarboxylate copolyesters" see examples 6,7 ---	1-4,8,9, 13-17
A	US 5 319 039 A (MOSES ET AL.) 7 June 1994 see column 2, line 22 - line 49; claims 1,6,7 -----	1,29-39

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

nformation on patent family members

Inter onal Application No
PC1/US 96/14873

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5207967	04-05-93	CA-A-	2130907	16-09-93
		EP-A-	0629220	21-12-94
		JP-T-	7509009	05-10-95
		WO-A-	9318089	16-09-93
US-A-5319039	07-06-94	CA-A-	2133582	11-11-93
		EP-A-	0638109	15-02-95
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(54) Title: MONOLITHIC THERMOPLASTIC ETHER POLYURETHANE HAVING HIGH WATER VAPOR TRANSMISSION

(57) Abstract: A thermoplastic polyurethane comprising a tetrahydrofuran based polyether diol intermediate chain extended with selective types of diols has good water vapor transmission but is resistant to liquid water through put, has good dimensional stability, good softness and elasticity, good tensile set and is non blocking. The thermoplastic polyurethane can be made by either a one shot process as in an extruder or by a prepolymer route and can be formed into a monolithic sheet or film for such uses as a roofing membrane, house wrapping, tubing, fiber, wound dressing, and the like.

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MONOLITHIC THERMOPLASTIC ETHER POLYURETHANE HAVING HIGH WATER VAPOR TRANSMISSION

FIELD OF INVENTION

The present invention relates to a polyether thermoplastic polyurethane extrudable at high speeds into sheets or films having good water vapor transmission but is resistant to liquid water penetration. The thermoplastic polyurethane displays a unique combination of properties such as softness, elasticity, crystallinity, and good dimensional stability.

BACKGROUND OF THE INVENTION

Heretofore, various polymers having micropores formed therein have been used as moisture vapor transmitting membranes. Such polymers are alleged as being resistant to liquid water throughput but permit water vapor to pass therethrough. These micropore structures are generally not suitable for wraps because they tend to leak liquid water.

European patent application 708,212 A1 relates to an underlayment, particularly for inclined, heat-insulated roofs with a nonwoven fabric layer that is permeable to water vapor, but resistant to liquid water; and to a reinforcing layer that is arranged on and bonded to the fabric layer and is also permeable to water vapor, but impermeable to liquid water.

SUMMARY OF THE INVENTION

The thermoplastic polyurethane of the present invention is preferably derived from a tetrahydrofuran polyether intermediate reacted with a diisocyanate and low amounts of selective chain extenders to form a non-perforated, solid, crystalline sheet or film. In addition to high water vapor transmission but good resistance to liquid water throughput, the

polyurethane has several favorable properties such as high speed extrusion, low Shore A hardness (softness), good elasticity (Tg of minus -30°C or less), suitable crystallinity for rapid extrusion and non-blocking, good dimensional stability in water at 24 hours, and the like.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graph showing the moisture vapor transmission of the composition of Example 1;

FIG. 2 is a graph showing DCS scans of the composition of Example 1;

FIG. 3 is a graph showing the moisture vapor transmission of the composition of Example 3;

FIG. 4 is a graph showing DCS scans of the composition of Example 4;

FIG. 5 is a graph showing the moisture vapor transmission of the composition of Example 4; and

FIG. 6 is a graph showing DCS scans of the composition of Example 5.

DETAILED DESCRIPTION

The thermoplastic polyurethanes having a unique combination of properties contain a polyether intermediate derived from tetrahydrofuran monomers so that tetramethylene oxide repeat units are present in the intermediate which also has terminal hydroxyl groups. Optionally, selective types of other alkylene oxide monomers can be utilized in addition to the tetrahydrofuran monomers to form ether copolymers such as propylene oxide or a mixture of propylene oxide with ethylene oxide since other types of monomers generally yield poor dimensional stability. The ether intermediate generally has a number average molecular weight of from about 500 to

about 4,000, desirably from about 1,000 to about 2,500, and preferably from about 1,500 to about 2,200 as determined by hydroxyl end groups. The amount of the one or more optional comonomers is generally from about 15 to about 75 and desirably from about 20 to about 30 parts by weight per 100 total parts by weight of the tetrahydrofuran monomers. The amount of the ethylene oxide monomers, when utilized, is generally from about 15% to about 50% and desirably from about 20% to about 30% based upon the total weight of the propylene oxide and ethylene oxide monomers.

The polyether intermediate is one of three main ingredients forming the thermoplastic urethanes of the present invention and the amount thereof is generally from about 60% to about 80%, desirably from about 65% to about 75%, and preferably from about 67% to about 73% by weight based upon the total weight of the polyether intermediate, a polyisocyanate, and a chain extender. The amount of polyisocyanate is generally from about 20% to about 30% and desirably from about 22% to about 28% by weight, and the amount of the chain extender is from 1% to about 10% and desirably from about 2% to about 8% by weight, based upon the total weight of the polyether intermediate, the polyisocyanate, and the chain extender.

The polyisocyanates of the present invention generally have the formula $R(NCO)_n$ where n is generally from 2 to 4 with 2 being highly preferred inasmuch as the composition is a thermoplastic. Thus, polyisocyanates having a functionality of 3 or 4 are utilized in very small amounts, for example less than 5% and desirably less than 2% by weight based upon the total weight of all polyisocyanates, inasmuch as they cause crosslinking. R can be aromatic, cycloaliphatic, and aliphatic, or combinations thereof generally having a total of from 2 to about 20 carbon atoms. Examples of suitable aromatic diisocyanates include diphenyl methane-4, 4'-diisocyanate (MDI), H_{12} MDI, m-xylylene diisocyanate (XDI), m-tetramethyl xylylene diisocyanate (TMXDI), phenylene-1,4-diisocyanate (PPDI), 1,5-naphthalene diisocyanate (NDI), and diphenylmethane-3,3'-

dimethoxy-4,4'-diisocyanate (TODI). Examples of suitable aliphatic diisocyanates include isophorone diisocyanate (IPDI), 1,4-cyclohexyl diisocyanate (CHDI), hexamethylene diisocyanate (HDI), 1,6-diisocyanato-2,2,4,4-tetramethyl hexane (TMDI), 1,10-decane diisocyanate, and trans-dicyclohexylmethane diisocyanate (HMDI). A highly preferred diisocyanate is MDI containing less than about 3% by weight of ortho-para (2,4) isomer.

Generally any conventional catalyst can be utilized to react the diisocyanate with the polyether intermediate or the chain extender and the same is well known to the art and to the literature. Examples of suitable catalysts include the various alkyl ethers or alkyl thiol ethers of bismuth or tin wherein the alkyl portion has from 1 to about 20 carbon atoms with specific examples including bismuth octoate, bismuth laurate, and the like. Preferred catalysts include the various tin catalysts such as stannous octoate, dibutyltin dioctoate, dibutyltin dilaurate, and the like. The amount of such catalyst is generally small such as from about 20 to about 200 parts per million based upon the total weight of the polyurethane forming monomers.

In addition to the selective types of polyether intermediates utilized, it is an important aspect of the present invention to use selective types of chain extenders in order to achieve the unique combination of physical properties of the thermoplastic polyurethanes of the present invention. While butane diol is preferred, ethylene glycol, hexane diol, dipropylene diol, ethoxylated hydroquionone and 1,4-cyclohexylydiene diol can also be utilized. Low amounts of the chain extender are utilized in order to keep the number of hard segments of the polyurethane low and thus to produce a soft, elastic, resilient, but high moisture vapor transmissible polyurethane.

Thermoplastic polyurethanes of the present invention are preferably made via a "one shot" process wherein all the components are added together simultaneously or substantially simultaneously to a heated extruder and reacted to form the polyurethane. The equivalent ratio of the

diisocyanate to the total equivalents of the hydroxyl terminated polyether intermediate and the diol chain extender is generally from about 0.95 to about 1.10, desirably from about 0.98 to about 1.05, and preferably from about 0.99 to about 1.03. The equivalent ratio of the hydroxyl terminated polyether to the hydroxyl terminated chain extender is generally from 0.5 to about 1.5 and preferably from about 0.70 to about 1. Reaction temperatures utilizing urethane catalyst are generally from about 175°C to about 245°C and preferably from about 180°C to about 220°C. The number average molecular weight of the thermoplastic polyurethane is generally from about 10,000 to about 150,000 and desirably from about 50,000 to about 100,000 as measured by GPC relative to polystyrene standards.

The thermoplastic polyurethanes can also be prepared utilizing a prepolymer process. In the prepolymer route, the hydroxyl terminated tetramethylene oxide based polyether intermediate is reacted with generally an equivalent excess of one or more polyisocyanates to form a prepolymer solution having free or unreacted polyisocyanate therein. Reaction is generally carried out at temperatures of from about 80°C to about 220°C and preferably from about 150°C to about 200°C in the presence of a suitable urethane catalyst. Subsequently, a selective type of chain extender as noted above is added in an equivalent amount generally equal to the isocyanate end groups as well as to any free or unreacted diisocyanate compounds. The overall equivalent ratio of the total diisocyanate to the total equivalent of the hydroxyl terminated polyether and the chain extender is thus from about 0.95 to about 1.10, desirably from about 0.98 to about 1.05 and preferably from about 0.99 to about 1.03. The equivalent ratio of the hydroxyl terminated polyether to the chain extender is generally from about 0.5 to about 1.5 and desirably from about 0.7 to about 1. The chain extension reaction temperature is generally from about 180°C to about 250°C with from about 200°C to about 240°C being preferred. Typically the

prepolymer route can be carried out in any conventional device with an extruder being preferred. Thus, the polyether intermediate is reacted with an equivalent excess of a diisocyanate in a first portion of the extruder to form a prepolymer solution and subsequently the chain extender is added at a downstream portion and reacted with the prepolymer solution. Any conventional extruder can be utilized, with extruders equipped with barrier screws having a length to diameter ratio of at least 20 and preferably at least 25.

Useful additives can be utilized in suitable amounts and include opacifying pigments, colorants, mineral fillers, stabilizers, lubricants, UV absorbers, processing aids, and other additives as desired. Useful opacifying pigments include titanium dioxide, zinc oxide, and titanate yellow, while useful tinting pigments include carbon black, yellow oxides, brown oxides, raw and burnt sienna or umber, chromium oxide green, cadmium pigments, chromium pigments, and other mixed metal oxide and organic pigments. Useful fillers include diatomaceous earth (superfloss) clay, silica, talc, mica, wallostonite, barium sulfate, and calcium carbonate. If desired, useful stabilizers such as antioxidants can be used and include phenolic antioxidants, while useful photostabilizers include organic phosphates, and organotin thiolates (mercaptides). Useful lubricants include metal stearates, paraffin oils and amide waxes. Useful UV absorbers include 2-(2'-hydroxyphenol)benzotriazoles and 2-hydroxybenzophenones.

Plasticizer additives can also be utilized advantageously to reduce hardness without affecting properties.

The thermoplastic ether polyurethanes of the present invention made utilizing selective monomers as set forth hereinabove have unexpectedly been found to yield a unique combination of properties which render the polyurethane suitable for numerous end uses set forth herein below. The thermoplastic polyurethane has a high crystalinity such as from about 3 J/g to about 10 J/g and desirably from about 4 J/g to about 8 J/g as measured

by a differential scanning colorimeter. Such crystallinity permits extrusion of films and sheets at high speeds such as at least 25 meters per minute, desirably from about 30 to about 60 meters per minute and preferably from about 40 to about 50 meters per minute on a 120 millimeter extruder fitted with a 120 centimeter slit die set at a gap of 4 mils. Such extrusion rates are faster than conventional polyurethanes of similar hardness and lower crystallinity. The conventional, prior art products with lower crystallinity contain high level of lubricants and antiblocking agents which reduce the moisture vapor transmission rates. Crystallinity also imparts good non-blocking properties so the sheets or films can be rolled upon itself without sticking. Yet, the thermoplastic ether polyurethane is generally soft and elastic.

The ASTM D-2240 Shore A hardness is generally about 80 or less, desirably from about 68 to about 78, and preferably from about 70 to about 75. The polyurethanes of the present invention are very elastic due in part to the low Tg thereof which is generally less than about minus 30°C, desirably less than about minus 40°C, and preferably from about minus 40°C to about minus 75°C as measured by differential scanning calorimeter, 10°C/min temperature program. The resilience or elasticity is somewhat similar to rubber in that the polymer can be elongated generally from about 50% to about 300% or 500% and desirably from about 100% to about 200% with ready retraction to its original length.

Another desirable attribute of the thermoplastic polyurethanes of the present invention is that they have excellent dimensional stability of less than 10%, desirably less than 5% and preferably less than about 3% or about 1.5% weight gain after being immersed in water for 24 hours, ASTM D-471-98.

A notable property of the thermoplastic polyurethane is its excellent water vapor transmission as measured by a Mocon Permatran-W model

instrument at a thickness of 1 to 4 mils, (25 to 100 microns) at 38°C and 100% relative humidity which is at least 1,500, desirably from about 1,500 to about 2,500, and preferably from about 1,700 to about 2,000 grams per square meter per 24 hours at atmospheric pressure. The upright cup moisture vapor transmission at a 1 mil thickness at 23°C and 50% relative humidity and atmospheric pressure is at least 200, desirably from about 250 to about 450 and preferably from about 275 to about 350 grams per square meter per 24 hours, ASTM E-96.

The mechanical properties of the thermoplastic polyurethane are good in that tensile strengths according to ASTM D-412/D-638 is generally at least about 20 or 30, and preferably from about 35 to about 60 MPa. Tensile set at 200% elongation according to ASTM D-412 is generally less than 15%, desirably less than 10%, and preferably less than about 8%.

Inasmuch as the thermoplastic elastomer when sheeted or formed into film, cast or blown films, etc. is a solid, that is a monolithic barrier free of any perforations, it can be used in any application where high water vapor transmission is desired such as building wrap as for a house, a roofing membrane as in roofing material, as a wound dressing layer for application to a person or animal, for waterproof textiles, and the like. Other applications include tubing for pneumatics or peristaltic pumps, elastic fibers as for Spandex ® applications, gaskets, hose jacketing, and the like. Molded articles can also be made such as shoe straps, overmolding over rigid plastics and metals for soft touch handles and covers. Further, laminates of the thermoplastic ether polyurethane elastomers of the present invention can be made wherein the backing layer can be woven or non-woven polyester, polypropylene, paper, polyvinyl chloride, nylon, and the like.

Since the various article, layers, sheets, films, etc, formed from the polyurethanes of the invetnion are solid, they are substantially free of pin holes, perforations and the like. In other words, they contain a perforated area of less than 1%, less than 0.5%, 0.01%, or 0.005%. To test the

presence of pin holes membranes were attached to frames set at 45° angle and soaked with shower heads placed above the frames to simulate rain for at least a few hours. The presence of pin holes show up as wet circles on the reverse side of membranes. They are counted per unit area of (m^2) membrane and membranes showing pinholes (measured as leak spots) in number above 0.001/m^2 are not used.

The present invention will be better understood by reference to the following examples which serve to illustrate, but not to limit the invention.

EXAMPLES

Example 1 (One Shot)

Polyether polyol PTMEG of molecular weight 2000 Daltons is charged into a heated (90°C) and agitated tank blended with based on 100 points by weight of the final polymer weight, with 0.3% by weight antioxidant and 0.3% by weight uv stabilizer. A second preheated tank was charged with the chain extender, 1,4-butanedio,l and kept at 50°C. A third preheated agitated tank contained 4,4'-methylenebisphenylisocyanate (MDI). The ingredients of three tanks were metered accurately into throat of a 40mm co-rotating twin-screw extruder reactor made by Werner & Pfleiderer Corp., Ramsay, NJ. The extruder had 11 barrel sections which were heated between 190°C to 205°C. The end of the extruder was coupled to an under-water pelletizer after a six hole die equipped with screen packs. The following formulation was run continuously by metering 25.07 pts of MDI, 5.82 pts of 1,-4-butanediol and 68.5 pts of polyol (PTMEG). Extruder throughput was adjusted to 150 lbs/hr while from a separate small tank 50ppm (based on polymer) of stannous octoate catalyst was injected into polyol stream. The product was underwater pelletized and collected in a heated silo at 105°C to dry the product for three hours. The product

produced in this way was extruded into 2 mils thick void free films with a single screw extruder fitted with a flat film die. Extruder speed can be varied from 30 to 70 without causing any tackiness and very little rise in melt temperature. The properties of the film was measured and listed in Table 1 and the moisture vapor transmission and the DCS scans are set forth respectively in FIGS. 1 and 2.

Table 1
Film Properties of Polymer of Example 1:

Typical Properties	*Test Method*	Typical Values	
		SI Units	English Units
PHYSICAL			
Specific Gravity	ASTM D-792	1.13	1.13
Shore Hardness (after 5 sec)	ASTM D-2240	72A	72A
MECHANICAL			
Tensile Strength	ASTM D-412/D-638	52.4 MPa	7600 psi
Stress @	ASTM D-412/D-638		
100% Elongation		5.7 MPa	820 psi
300% Elongation		10.2 MPa	1480 psi
Ultimate Elongation	ASTM D-412/D-638	660%	660%
Tensile Set @ 200% Elongation	ASTM D-412	6%	6%
Tear Strength	ASTM D-624, Die C	67.6 kN/m	386 lb/in
Split Tear Resistance	ASTM D-470	17.2 kN/m	98 lb/in
THERMAL			
Glass Transition Temperature	DSC		
Pellets		-67°C	-89°F
Film (1.2 mil)		-69°C	-92°F
Melt Temperature			
Pellets		167°C	333°F
Film (1.2 mil)		170°C	338°F
Crystallization Temperature			
Pellets		97°C	207°F
Film (1.2 mil)		90°C	194°F
Kofler Melt Point	Kofler	155°C	311°F
OTHER RELEVANT DATA			
Moisture Vapor Transmission			
Mocon (38°C/100% RH)	ASTM D 6701	1880g/m^2 • 24h	1880g/m^2 • 24h
Upright Cup (23°C/50% RH)	ASTM E-96	310g/m^2 • 24h	310g/m^2 • 24h

Example 2 (One Shot)

Polyether polyol PTMEG of molecular weight 2000 Daltons and dipropylene glycol (DPG) chain extender are charged into a heated (90°C) and agitated tank in at a ratio of 68.04:1.34 by weight and blended based

on the final polymer weight, with 0.3% by weight antioxidant and 0.3% by weight uv stabilizer. A second preheated tank was charged with the chain extender 1,4-butanediol and kept at 50°C. A third preheated agitated tank contained 4,4'-methylenebisphenylisocyanate (MDI). The ingredients of three tanks were metered accurately into throat of a 40mm co-rotating twin-screw extruder reactor made by Werner & Pfleiderer Corp., Ramsay, NJ. The extruder had 11 barrel sections which were heated between 190°C to 205°C. The end of the extruder was coupled to an under-water pelletizer after a six hole die equipped with screen packs. The following formulation was run continuously by metering 25.07 pts of MDI, 4.94 pts of 1,-4-butanediol and 69.4 pts of polyol (PTMEG)/(DPG) mixture from the first tank. PTMEG/DPG blend and BDO was combined and passed through a static mixer forming a single stream which was fed with the MDI stream into a heated pre-reactor which discharged the partially reacted mixture continuously into the extruder throat. Extruder throughput was adjusted to 150 lbs/hr while from a separate small tank 50ppm (based on polymer) of stannous octoate catalyst was injected into polyol stream. The product was underwater pelletized and collected in a heated silo at 105°C to dry the product for three hours. Melt flow index (MFI) of the pelletized product was measured to be 15.6 at 200°C/3800gm. The product was extruded into 2 mils thick void free films with a single screw extruder fitted with a flat film die. Extruder speed can be varied from 30 to 70 RPM without causing any tackiness and very little rise in melt temperature.

Example 3 (One Shot)

Polyether polyol PTMEG of molecular weight 1450 Daltons is charged into a heated (90°C) and agitated tank blended, based on the final polymer weight, with 0.3% by weight antioxidant and 0.3% by weight uv stabilizer. A second preheated tank was charged with the chain extender 1,4-butanediol

and kept at 50°C. A third preheated tank agitated tank contained 4,4'-methylene bisphenyl isocyanate (MDI). The ingredients of the three tanks were metered accurately into throat of a 40mm co-rotating twin-screw extruder reactor made by Werner & Pfleiderer Corp., Ramsay, NJ. The extruder had 11 barrel sections which were heated between 190°C to 205°C. The end of the extruder was coupled to an under-water pelletizer after a six hole die equipped with screen packs. The following formulation was run continuously by metering 25.07 pts of MDI, 4.52 pts of 1,-4-butanediol and 69.8 pts of polyol (PTMEG). PTMEG and BDO was combined and passed through a static mixer forming a single stream which was fed with the MDI stream into a heated pre-reactor which discharged the partially reacted mixture continuously into the extruder throat. Extruder throughput was adjusted to 150 lbs/hr while from a separate small tank 50ppm (based on polymer) of stannous octoate catalyst was injected into the polyol stream. The product was underwater pelletized and collected in a heated silo at 105°C to dry the product for three hours. Melt flow index (MFI) of the palletized product was measured to be 6.2 at 200°C/3800gm. The product produced was extruded into 1 to 4 mils thick void free films with a single screw extruder fitted with a flat film die. Extruder speed can be varied from 30 to 70 without causing any tackiness and very little rise in melt temperature. Moisture vapor transmission rates (MVT) are plotted in Figure 3 and extrapolated to a value of 2800gms.m^2/day measured with the Mocon Permatran-W Model instrument made by Mocon Company, Minneapolis, MN at 38°C and 100% relative humidity.

Example 4: (One Shot)

Polyether polyol PTMEG of molecular weight 2000 Daltons is charged into a heated (90°C) and agitated tank blended based on the final polymer weight, with 0.3% by weight antioxidant and 0.3% by weight uv stabilizer. A

second preheated tank was charged with the chain extender 1,4-butanediol and kept at 50°C. A third preheated agitated tank contained 4,4'-methylenebisphenylisocyanate (MDI). The ingredients of three tanks were metered accurately into throat of a 40mm co-rotating twin-screw extruder reactor made by Werner & Pfleiderer Corp., Ramsay, NJ. The extruder had 11 barrel sections which were heated between 190°C to 205°C. The end of the extruder was coupled to an under-water pelletizer after a six hole die equipped with screen packs. The following formulation was run continuously by metering 25.07 pts of MDI, 4.52 pts of 1,-4-butanediol and 69.8 pts of polyol (PTMEG). PTMEG and BDO was combined and passed through a static mixer forming a single stream which was fed with the MDI stream into a heated pre-reactor which discharged the partially reacted mixture continuously into the extruder throat. Extruder throughput was adjusted to 150 lbs/hr while from a separate small tank 50ppm (based on polymer) of stannous octoate catalyst was injected into polyol stream. 2% based on the polymer of diatomecous earth (superfloss) was also introduced into the extruder at barrel section 2 as a non blocking filler. The product was underwater pelletized and collected in a heated silo at 105°C to dry the product for three hours. Melt flow index (MFI) of the pelletized product was measured to be 6.2 at 200°C/3800gm. The product produced was extruded into 1 to 4 mils thick void free films with a single screw extruder fitted with a flat film die. Extruder speed can be varied from 30 to 70 without causing any tackiness and very little rise in melt temperature. The properties of the film was measured and listed in Table 2 and the extrusion outputs are set forth in Tables 3 and 4. DCS scans are set forth in FIG. 4 and moisture vapor transmission rates (MVT) is plotted in Figure 5 and extrapolates to a value of 3200gms.m^2/day measured with the Mocon Permatran-W Model instrument made by Mocon Company, Minneapolis, MN at 38°C and 100% relative humidity.

Table 2

Properties of Product of example 4

Typical Properties	*Test Method*	Typical Values	
		SI Unit	English Units
PHYSICAL			
Specific Gravity	ASTM D-792	1.08	1.08
Shore Hardness (after 5 sec)	ASTM D-2240	72A	72A
MECHANICAL			
Tensile Strength	ASTM D-412/D-638	52.4 MPa	7600 psi
Stress @	ASTM D-412/D-638		
100% Elongation		5.7 MPa	820 psi
300% Elongation		10.2 MPa	1480 psi
Ultimate Elongation	ASTM D-412/D-638	660%	660%
Tensile Set @ 200% Elongation	ASTM D-412	6%	6%
Tear Strength	ASTM D-624, Die C	67.6 kN/m	386 lb/in
Split Tear Resistance	ASTM D-470	17.2 kN/m	98 lb/in
THERMAL			
Glass Transition Temperature	DSC		
Pellets		-67°C	-89°F
Film (1.2 mil)		-69°C	-92°F
Melt Temperature			
Pellets		167°C	333°F
Film (1.2 mil)		170°C	338°F
Crystallization Temperature			
Pellets		97°C	207°F
Film (1.2 mil)		90°C	194°F
Kofler Melt Point	Kofler	155°C	311°F
Compression Set			
@ 23 °C		20%	20%
@ 70 °C		29%	29%
OTHER RELEVANT DATA			
Moisture Vapor Transmission			
Mocon (38°C/100% RH)	ASTM D 6701	1880g/m^2 • 24h	1880g/m^2 • 24h
Upright Cup (23°C/50% RH)	ASTM E-96	310g/m^2 • 24h	310g/m^2 • 24h
DIMENSIONAL STABILITY			
Immersion Results in Water	ASTM D471-98		
Time 24 hrs	Volume Change %	0.96	0.96
	Mass Change %	1.03	1.03

Extrusion Output study on polymer of Example 4

Table 3
1 ½" Akron Extruder 32:1 barrier screw Saxton Mixer, 12" wide die
Temperature settings 355 °F 365 °F 375 °F, die 375 °F

product	speed rpm	pressure psi	current amps	melt T °F	rate (lb/h) (ave of 3)
Polymer of Example 4	30	1900	8	397	16.2
	50	1800	9	416	27.6
	70	1500	9	438	39.6

Table 4
2 ½" Killion Extruder 24:1 barrier screw Saxton Mixer, 18" wide die
Temperature settings 355 °F 365 °F 375 °F, die 375 °F

product	speed rpm	pressure psi	current amps	melt T °F	rate (lb/h) (ave of 3)
Polymer of Example 4	30	1600	42	402	76.8
	50	1600	43	424	120.0

Example 5 (Two Step)

22.75 pts of MDI, 72.27 pts of PTMEG (2000 Daltons) and 0.004 pts of stannous octoate were blended and reacted by vigorous stirring in a 500 ml steel beaker at 200°C for 2 minutes. 4.97 pts of 1,4-butanediol was then quickly added to this partially reacted prepolymer and stirring continued for additional 2 minutes. The polymer melt was poured to a teflon coated pan and cured for 2 hours at 105°C. The MFI index of this polymer was found to be 4.4 measured at 200°C under 3800 gm load. The weight average Mw GPC molecular weight was 229956 and number average Mn molecular weight was 66630 indicating high molecular weight product. The crystallinity was deter mined by DSC and shown in Figure 6 below.

Integrated peaks at 8°C and 138°C indicate the material is sufficiently crystalline to be considered non-tacky for membrane extrusion purposes.

While in accordance with the Patent Statutes the best mode and preferred embodiment have been set forth, the scope of the invention is not limited thereto but rather by the scope of the attached claims.

WHAT IS CLAIMED IS:

1. A thermoplastic polyurethane composition, comprising:

the reaction product of a polyether intermediate having at least a tetramethylene oxide repeat unit, and optionally a repeat unit derived from propylene oxide or from propylene oxide and ethylene oxide; a diisocyanate; and a chain extender comprising ethylene glycol, butane diol, hexane diol, dipropylene diol, ethoxylated hydroquinone, or cyclohexylydiene diol, or combinations thereof;

said composition having a water vapor transmission of at least 1,500 grams per square meter per 24 hours at atmospheric pressure and 38°C, and 100% relative humidity at a thickness of 1 to 4 mils.

2. A thermoplastic polyurethane composition according to claim 1, wherein said polyether intermediate has a number average molecular weight of from about 500 to about 4,000, wherein said diisocyanate has the formula $R(NCO)_2$ wherein R is an aliphatic, an aromatic, an cycloaliphatic, or combinations thereof having a total of from 2 to about 20 carbon atoms, wherein said composition has a dimensional stability of less than 10% weight gain according to ASTM D-471-98, and a crystallinity of from about 3J/g to about 10J/g.

3. A thermoplastic polyurethane composition according to claim 2, wherein said composition has a Shore A hardness of less than 80.

4. A thermoplastic polyurethane composition according to claim 3, wherein the amount of said polyether intermediate is from about 60% to about 80% by weight, wherein the amount of said diisocyanate is from about 20% to about 30% by weight, and wherein the amount of said chain extender is from about 1% to about 10% by weight based upon the total

weight of said polyether intermediate, said diisocyanate, and said chain extender, and wherein said composition has a Tg of less than about minus 30°C.

5. A thermoplastic polyurethane composition according to claim 4, wherein said molecular weight of said polyether intermediate is from about 1,000 to about 2,500, wherein said dimensional stability is about 5% or less, and wherein said water vapor transmission is from about 1,500 to about 2,500.

6. A thermoplastic polyurethane composition according to claim 5, wherein said diisocyanate is diphenyl methane diisocyanate (MDI), wherein said diol is butane diol, wherein said thermoplastic polyurethane has a number average molecular weight of from about 50,000 to about 100,000, wherein said Tg is less than about minus 40°C, and wherein said Shore A hardness is from about 68 to about 78.

7. A thermoplastic polyurethane composition according to claim 1, wherein said composition is in the form of a sheet, said sheet being substantially free of perforations.

8. A thermoplastic polyurethane composition according to claim 4, wherein said composition is in the form of a sheet, and wherein said sheet has less than 0.5% of perforated area.

9. A thermoplastic polyurethane composition according to claim 6, wherein said composition is in the form of a sheet, and wherein said sheet has less than 0.01% of perforated area.

10. A thermoplastic polyurethane composition according to claim 1, wherein said composition is a building wrap, a roofing membrane, a wound dressing, a waterproof textile, or an elastic fiber.

11. A thermoplastic polyurethane composition according to claim 4, wherein said composition is a building wrap, a roofing membrane, a wound dressing, a waterproof textile, or an elastic fiber.

12. A thermoplastic polyurethane composition according to claim 6, wherein said composition is a building wrap, a roofing membrane, a wound dressing, a waterproof textile, or an elastic fiber.

13. A thermoplastic polyurethane composition according to claim 8, wherein said composition is a building wrap, a roofing membrane, a wound dressing, a waterproof textile, or an elastic fiber.

14. A thermoplastic polyurethane, comprising:

a polymer having repeat units derived from tetrahydrofuran, a chain extender, and a diisocyanate, wherein said chain extender comprises ethylene glycol, butane diol, hexane diol, dipropylene diol, ethoxylated hydroquinone, or cyclohexylydiene diol, or combinations thereof, wherein said diisocyanate has the formula $R(NCO)_2$ wherein R is an aliphatic, an aromatic, an cycloaliphatic, or combinations thereof having a total of from 2 to about 20 carbon atoms, wherein said polymer has a crystallinity of from about 3J/g to about 10J/g and a Tg of less than about minus 30°C.

15. A thermoplastic polyurethane according to claim 14, wherein the number average molecular weight of said thermoplastic polyurethane is from about 10,000 to about 150,000, wherein said thermoplastic urethane has a dimensional stability of less than about 5% weight gain according to

ASTM D-471-98 and a vapor transmission of at least 1,500 grams per square meter at 38°C and 100% relative humidity over a 24 hours period at a thickness from 1 to 4 mils.

16. A thermoplastic polyurethane according to claim 15, wherein said polymer has a polyether intermediate derived said tetrahydrofuran, wherein said polyether intermediate has a number average molecular weight of from about 1,000 to about 2,500, wherein said thermoplastic polyurethane polymer has a number average molecular weight of from about 50,000 to about 100,000, a Shore A hardness of from about 70 to about 75, and a dimensional stability of less than about 1.5% weight gain.

17. A thermoplastic polyurethane according to claim 16, wherein said diisocyanate is MDI, wherein said chain extender is butane diol or dipropylene glycol or combinations thereof, wherein said Tg is from about minus 40°C to about minus 75°C, and wherein said water vapor transmission is from about 1,700 to about 2,000.

18. A thermoplastic polyurethane according to claim 16, wherein said polyurethane is in the form of a sheet, and wherein said sheet has less than 0.1% of perforated area.

19. A thermoplastic polyurethane according to claim 14, wherein said polyurethane is a building wrap, a roofing membrane, a wound dressing, a waterproof textile, or an elastic fiber.

20. A thermoplastic polyurethane according to claim 17, wherein said polyurethane is a building wrap, a roofing membrane, a wound dressing, a waterproof textile, or an elastic fiber.

21. A process for forming a thermoplastic polyurethane, comprising the steps of:

reacting a polyether intermediate comprising a tetramethylene oxide repeat unit, and optionally a repeat unit derived from propylene oxide or a mixture of propylene oxide and ethylene oxide; a diisocyanate; and a chain extender comprising ethylene glycol, butane diol, hexane diol, dipropylene diol, ethoxylated hydroquinone, or cyclohexylydiene diol, or combinations thereof, and

forming a solid sheet, said thermoplastic polyurethane having a Shore A hardness of less than 80.

22. A process according to claim 21, wherein all of said components are reacted in a single step, wherein the number average molecular weight of said polyether intermediate is from about 500 to about 4,000, wherein the number average molecular weight of said thermoplastic polyurethane is from about 10,000 to about 150,000, wherein said diisocyanate has the formula $R(NCO)_2$ wherein R is an aliphatic, an aromatic, an cycloaliphatic, or combinations thereof having a total of from 2 to about 20 carbon atoms, wherein said thermoplastic polyurethane has a water vapor transmission at a 1 to 4 mil thickness at 38°C and 100% humidity of at least 1,500 grams per square meter per 24 hours, and wherein said thermoplastic polyurethane has a Tg of less than about minus 40°C.

23. A process according to claim 22, wherein said diisocyanate is MDI, wherein said diol is butane diol or dipropylene diol, or combinations thereof, wherein said Shore A hardness is from about 68 to about 78, and wherein said thermoplastic polyurethane has a dimensional stability of less than 3% weight gain according to ASTM D-471-98.

24. A process according to claim 23, wherein the number average molecular weight of said polyether intermediate is from about 1,500 to about 2,200, wherein the number average molecular weight of said thermoplastic polyurethane is from about 50,000 to about 100,000, wherein said water vapor rate transmission is from about 1,700 to about 2,000, wherein said Tg is from about minus 40°C to about minus 75°C, and wherein said thermoplastic polyurethane has a crystallinity of from about 4J/g to about 8J/g.

25. A process according to claim 21, wherein initially said polyether intermediate is reacted with an excess of a diisocyanate to form a prepolymer solution, and subsequently reacting said prepolymer solution with said chain extender to form said thermoplastic polyurethane.

26. A process according to claim 25, wherein said thermoplastic polyurethane has a water vapor transmission at a 1 to 4 mil thickness at 38°C and 100% humidity of at least 1,500 grams per square meter per 24 hours, and wherein said thermoplastic polyurethane has a Tg of less than about minus 40°C.

27. A process according to claim 26, wherein said diisocyanate is MDI, wherein said diol is butane diol or dipropylene diol, or combinations thereof, wherein said Shore A hardness is from about 68 to about 78, and wherein said thermoplastic polyurethane has a dimensional stability of less than 3% weight gain according to ASTM D-471-98.

28. A process according to claim 27, wherein the number average molecular weight of said polyether intermediate is from about 1,500 to about 2,200, wherein the number average molecular weight of said

thermoplastic polyurethane is from about 50,000 to about 100,000, wherein said water vapor rate transmission is from about 1,700 to about 2,000, wherein said Tg is from about minus 40°C to about minus 75°C, and wherein said thermoplastic polyurethane has a crystallinity of from about 4J/g to about 8J/g.

FIG. 1

Moisture Vapor Transmission (MVT) of Example 1

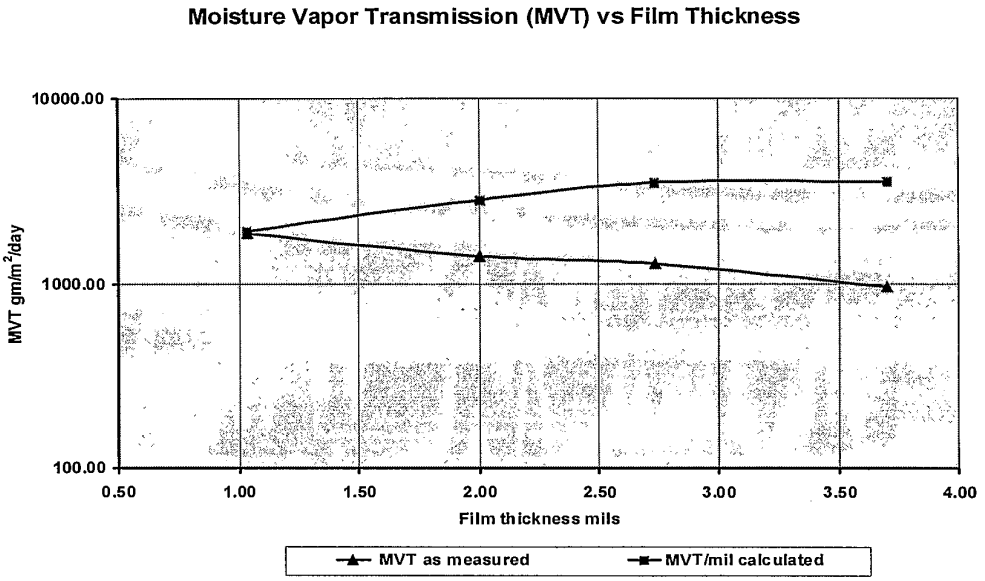


FIG. 2

DCS Scans for Example 1

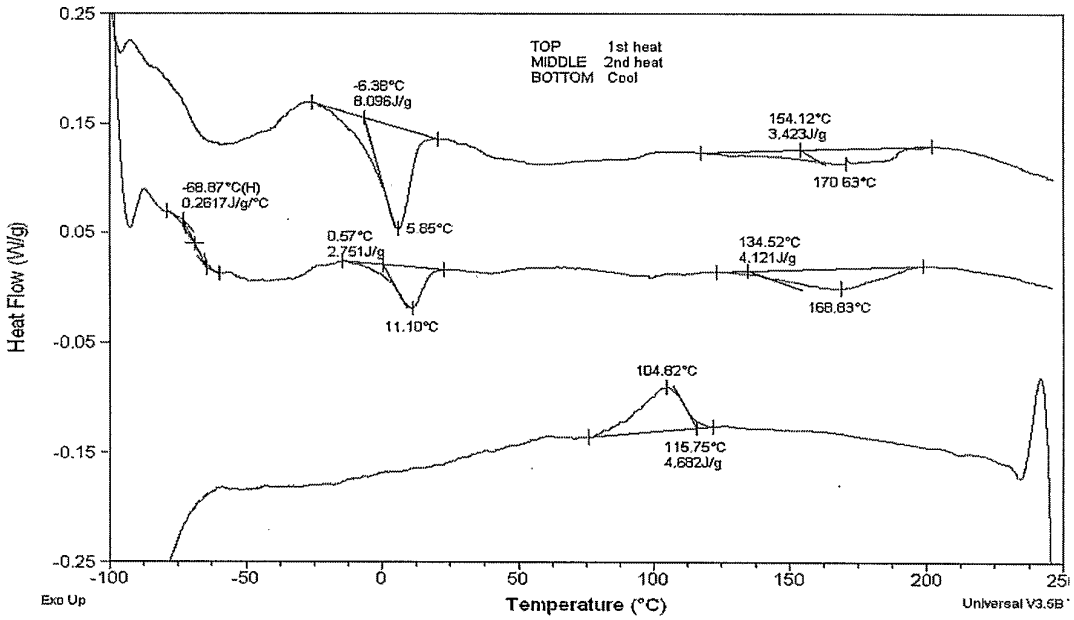


FIG. 3

Moisture Vapor Transmission (MVT) of Example 3

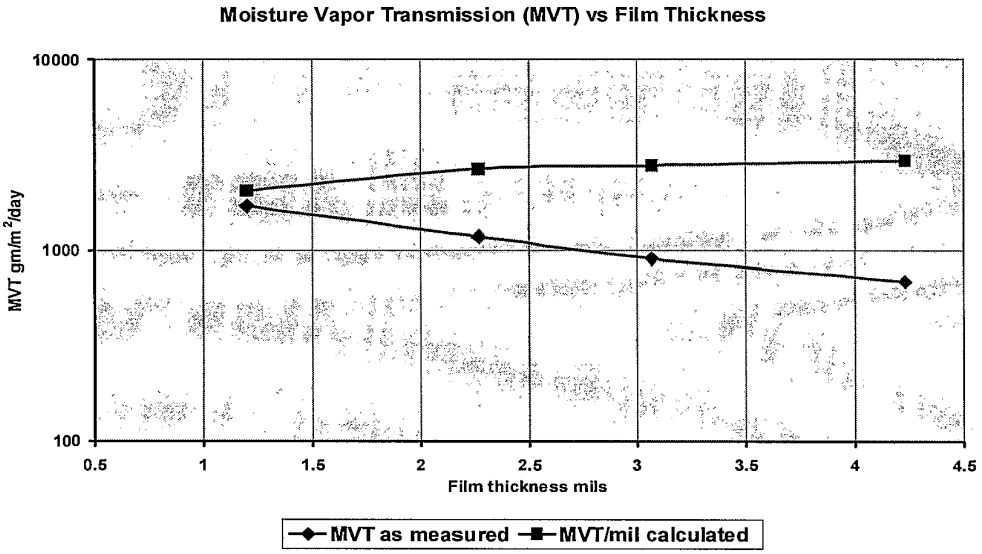


FIG. 4

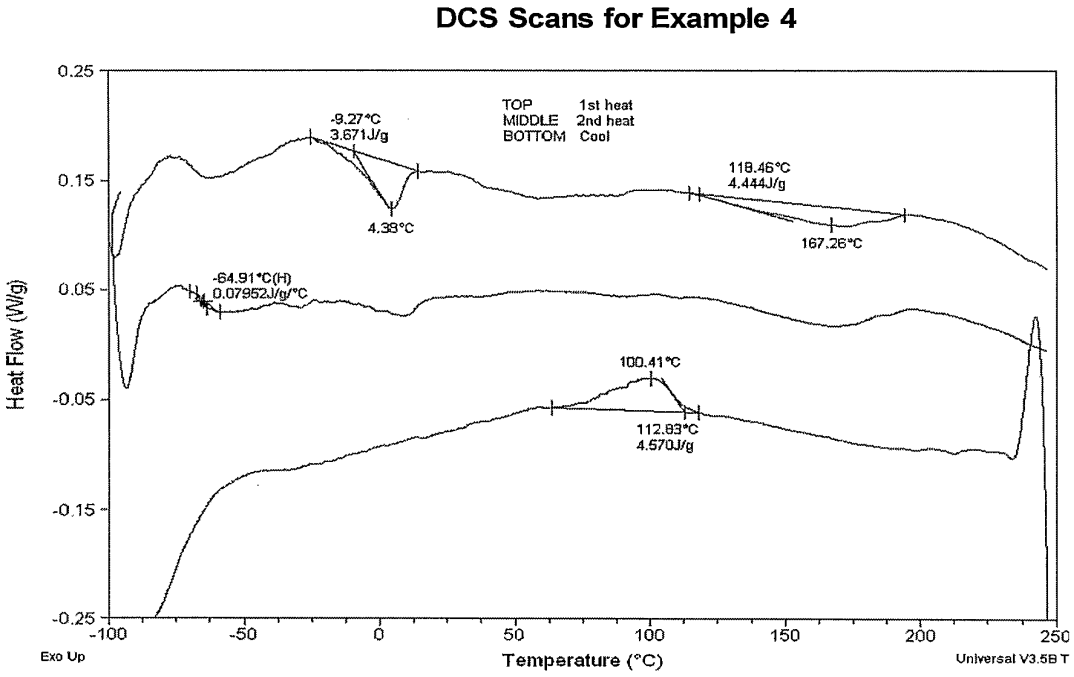

DCS Scans for Example 4
TOP 1st heat
MIDDLE 2nd heat
BOTTOM Cool
-9.27°C
3.671J/g
4.39°C
118.46°C
4.444J/g
167.26°C
-64.91°C(H)
0.07952J/g/°C
100.41°C
112.83°C
4.570J/g
Heat Flow (W/g)
0.25
0.15
0.05
-0.05
-0.15
-0.25
-100
-50
0
50
100
150
200
250
Exo Up
Temperature (°C)
Universal V3.5B T

FIG. 5

Moisture Vapor Transmission (MVT) of Example 4

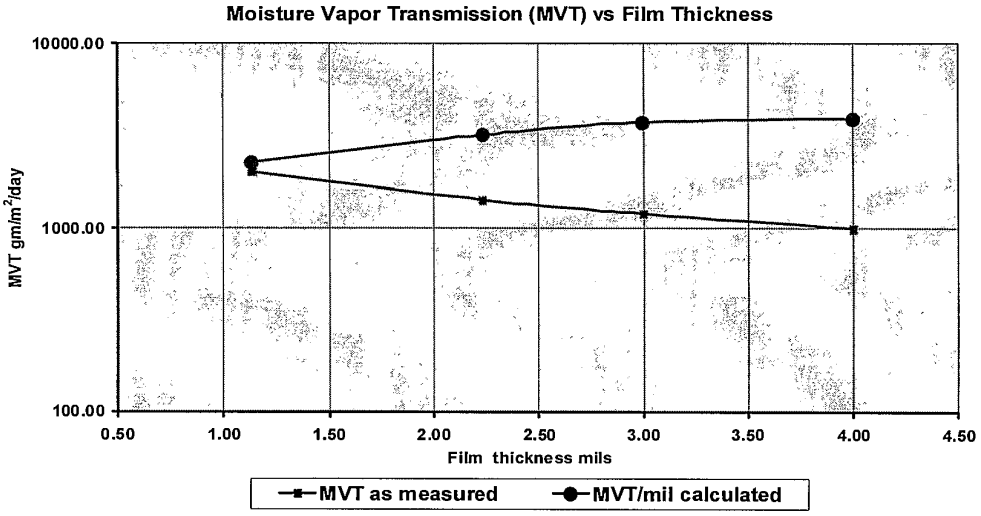
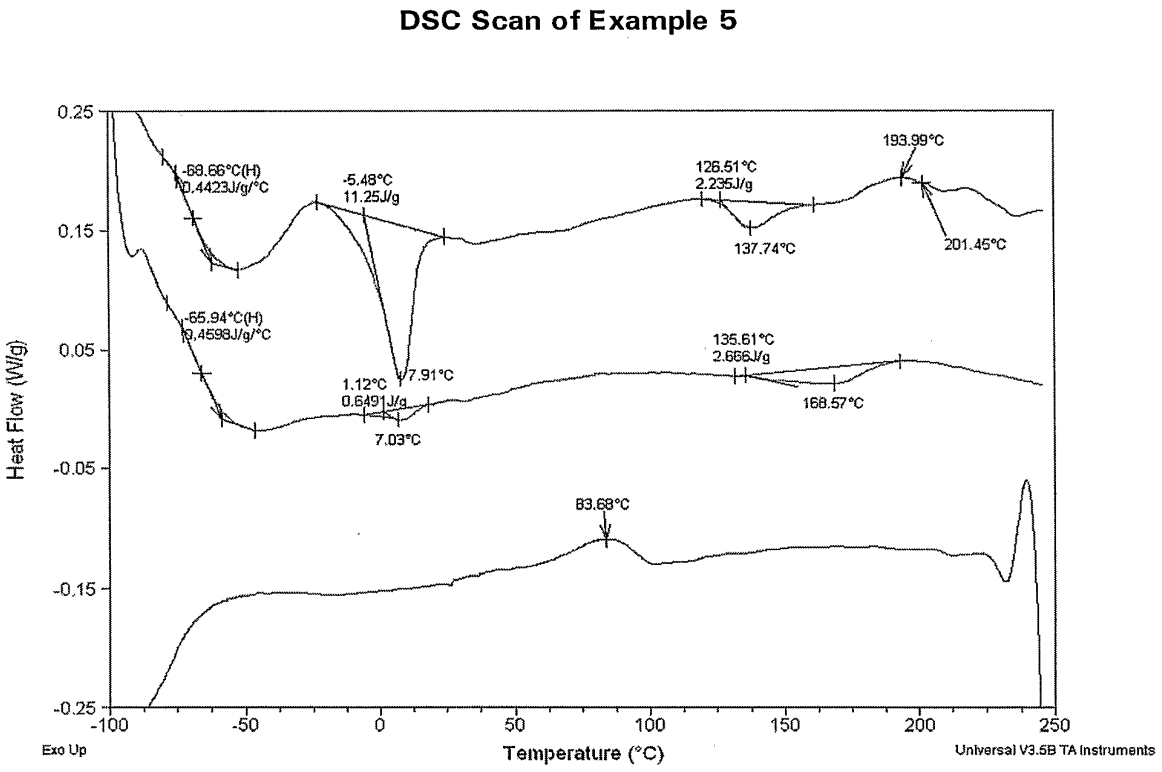


FIG. 6


DSC Scan of Example 5
0.25
0.15
0.05
-0.05
-0.15
-0.25
Heat Flow (W/g)
-69.66°C(H)
0.4423J/g/°C
-5.48°C
11.25J/g
126.51°C
2.235J/g
137.74°C
193.99°C
201.45°C
-65.94°C(H)
0.4598J/g/°C
1.12°C
0.6491J/g
7.91°C
7.03°C
135.61°C
2.666J/g
168.57°C
83.68°C
-100
-50
0
50
100
150
200
250
Temperature (°C)
Exo Up
Universal V3.5B TA Instruments

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/31980

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C08G18/48 C08J5/18

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)
IPC 7 C08G C08J

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 practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 371 736 A (MITSUBISHI KASHEI) 6 June 1990 (1990-06-06) page 2, line 37 - page 3, line 36; claims 1-5; example 13; tables 3-5	1-5
X	EP 0 714 950 A (WOLFF WALSRODE) 5 June 1996 (1996-06-05) page 2, line 23 - page 4, line 58 page 6, line 17 - line 20 page 7, line 7; claims 1,6	1
A	EP 0 534 295 A (BASF) 31 March 1993 (1993-03-31) page 3, line 19 - page 4, line 52; claims 1,2; examples	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 February 2004	12/02/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bourgonje, A

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/31980

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0371736 A	06-06-1990	JP 1971094 C	27-09-1995
		JP 2147062 A	06-06-1990
		JP 6104116 B	21-12-1994
		DE 68914604 D1	19-05-1994
		DE 68914604 T2	04-08-1994
		EP 0371736 A2	06-06-1990
		US 5035893 A	30-07-1991
EP 0714950 A	05-06-1996	DE 4442380 A1	30-05-1996
		AT 201708 T	15-06-2001
		CA 2163722 A1	30-05-1996
		DE 59509303 D1	05-07-2001
		EP 0714950 A2	05-06-1996
		ES 2158030 T3	01-09-2001
		US 5840812 A	24-11-1998
EP 0534295 A	31-03-1993	DE 4132015 A1	01-04-1993
		AT 146196 T	15-12-1996
		CA 2079245 A1	27-03-1993
		DE 59207659 D1	23-01-1997
		DK 534295 T3	30-12-1996
		EP 0534295 A2	31-03-1993
		ES 2095377 T3	16-02-1997
		JP 5255471 A	05-10-1993
		US 5247049 A	21-09-1993

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11/074,300	7 March 2005 (07.03.2005)	US
11/074,301	7 March 2005 (07.03.2005)	US
11/107,584	15 April 2005 (15.04.2005)	US
60/676,100	29 April 2005 (29.04.2005)	US

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Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: VARIATIONS OF DENTAL ALIGNERS

(57) Abstract: Dental appliances for producing corrective movement in a subject's teeth include dental aligners which may be worn on a subject's teeth, gingiva or other region of the oral cavity. Described herein are dental appliances that include features that enhance the performance and comfort of the appliance, including features for preventing damage or wear on the appliance. Described herein are fluid-permeable aligners, wrinkled aligners, modular aligners, aligners of varying thickness, aligners of varying stiffness, snap-on aligners, textured aligners, aligners having multiple layers, and lateral correction aligners. Methods of making and using such aligners are also described.

WO 2006/096558 A2

VARIATIONS OF DENTAL ALIGNERS

Inventors: Huafeng Wen and Frank Zhenhuan Liu

TECHNICAL FIELD

[0001] This application generally relates to the field of dental care, and more particularly to the field of orthodontics.

CROSS-REFERENCES TO RELATED INVENTIONS

[0002] The present invention claims priority to US patent applications: U.S. Patent Application Serial No. 11/074,301, titled "Dental Aligner for Providing Accurate Dental Treatment" by Wen et. al.; U.S. Patent Application Serial No. 11/074,297, titled "Producing Wrinkled Dental Aligner for Dental Treatment" by Wen et al.; U.S. Patent Application Serial No. 11/074,300, titled "Fluid Permeable Dental Aligner" by Huafeng Wen; U.S. Patent Application Serial No. 11/107,584, titled "Dental Aligner Devices Having Snap-On Connectors" by Wen et al.; U.S. Patent Application Serial No. 11/074,298, titled "Disposable Dental Aligner" by Huafeng Wen; and U.S. Provisional Patent Application Serial No. 60/676,100, titled "Nonuniform Dental Aligner and Methods" by Huafeng Wen. Each of these applications is herein incorporated by reference in its entirety.

[0003] Refer also to commonly assigned U.S. Patent applications: U.S. Provisional Patent Application Serial No. 60/676,546, titled "Digitization of Dental Arch Model Components" by Huafeng Wen; U.S. Provisional Patent Application 60/673,970, titled "System for Digitizing and Registering a Subject's Upper and Lower Dental Arches" by Wen et. al.; and U.S. Patent Application 11/205,496, titled "System for Organizing Dental Aligners" by Huafeng Wen. Each of these applications is herein incorporated by reference in its entirety.

[0004] Refer also to U.S. Patent Application Serial No. 11/074,301, titled "Dental aligner for providing accurate dental treatment" by Liu et al, filed 3/7/2005, U.S. Patent Application Serial No. 11/074,297, titled "Producing wrinkled dental aligner for dental treatment" by Liu et al, filed 3/7/2005, U.S. Patent Application Serial No. 11/074,300,

titled "Fluid permeable dental aligner" by Huafeng Wen, filed 3/7/2005, U.S. Patent Application Serial No. 11/074,298, titled "Disposable dental aligner by Huafeng Wen, filed 3/7/2005, and U.S. Patent Application Serial No. 11/050,051, titled "Storage system for dental devices" by Huafeng Wen, filed 2/3/2005. Each of these applications is herein incorporated by reference in its entirety.

[0005] Refer also to U.S. Patent Application Serial No. 10/979,823, titled "Method and apparatus for manufacturing and constructing a physical dental arch model" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application Serial No. 10/979,497, titled "Method and apparatus for manufacturing and constructing a dental aligner" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application Serial No. 10/979,504, titled "Producing an adjustable physical dental arch model" by Huafeng Wen, filed 11/2/2004, and U.S. Patent Application Serial No. 10/979,824, titled "Producing a base for physical dental arch model" by Huafeng Wen, filed 11/2/2004. Each of these applications is herein incorporated by reference in its entirety.

[0006] Refer also to U.S. Patent Application Serial No. 11/013,152, titled "A base for physical dental arch model" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/012,924, titled "Accurately producing a base for physical dental arch model" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,145, titled "Fabricating a base compatible with physical dental tooth models" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,156, titled "Producing non-interfering tooth models on a base" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,160, titled "System and methods for casting physical tooth model" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,159, titled "Producing a base for accurately receiving dental tooth models" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,157, titled "Producing accurate base for dental arch model" by Huafeng Wen, filed 12/14/2004. Each of these applications is herein incorporated by reference in its entirety.

BACKGROUND

[0007] Orthodontics is the practice of manipulating a subject's teeth to provide better function and appearance. In general, brackets are bonded to a subject's teeth and coupled together with an arched wire. The combination of the brackets and wire provide a force on the teeth causing them to move. Once the teeth have moved to a desired location

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and are held in a place for a certain period of time, the body adapts bone and tissue to maintain the teeth in the desired location. To further assist in retaining the teeth in the desired location, a subject may be fitted with a retainer.

[0008] To achieve tooth movement, orthodontists utilize their expertise to first determine a three-dimensional mental image of the subject's physical orthodontic structure and a three-dimensional mental image of a desired physical orthodontic structure for the subject, which may be assisted through the use of x-rays and/or models. Based on these mental images, the orthodontist further relies on his/her expertise to place the brackets and/or bands on the teeth and to manually bend (i.e., shape) wire, such that a force is asserted on the teeth to reposition the teeth into the desired physical orthodontic structure. As the teeth move towards the desired location, the orthodontist makes continual judgments as to the progress of the treatment, the next step in the treatment (e.g., new bend in the wire, reposition or replace brackets, is head gear required, etc.), and the success of the previous step.

[0009] In general, the orthodontist makes manual adjustments to the wire and/or replaces or repositions brackets based on his or her expert opinion. Unfortunately, in the oral environment, it is difficult for a human being to accurately develop a visual three-dimensional image of an orthodontic structure due to the limitations of human sight and the physical structure of a human mouth. In addition, it is difficult (if not impossible) to accurately estimate three-dimensional wire bends (with accuracy within a few degrees) and to manually apply such bends to a wire. Further, it is difficult (or impossible) to determine an ideal bracket location to achieve the desired orthodontic structure based on the mental images. It is also extremely difficult to manually place brackets in what is estimated to be the ideal location. Accordingly, orthodontic treatment is an iterative process requiring multiple wire changes, with the success and speed of the process being dependent on the orthodontist's motor skills and diagnostic expertise. As a result of multiple wire changes, cost and subject discomfort is increased. The quality of care may also vary greatly from orthodontist to orthodontist, as does the time to treat a subject.

[0010] The practice of orthodontic is very much an art, relying on the expert opinions and judgments of the orthodontist. In an effort to shift the practice of orthodontic from an art to a science, many innovations have been developed. For example, U.S. Pat. No. 5,518,397 issued to Andreiko, et. al. provides a method of forming an orthodontic brace. Such a method includes obtaining a model of the teeth of a patient's mouth and a

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prescription of desired positioning of such teeth. The contour of the teeth of the patient's mouth is determined, from the model. Calculations of the contour and the desired positioning of the patient's teeth are then made to determine the geometry (e.g., grooves or slots) to be provided. Custom brackets including a special geometry are then created for receiving an arch wire to form an orthodontic brace system. Such geometry is intended to provide for the disposition of the arched wire on the bracket in a progressive curvature in a horizontal plane and a substantially linear configuration in a vertical plane. The geometry of the brackets is altered, (e.g., by cutting grooves into the brackets at individual positions and angles and with particular depth) in accordance with such calculations of the bracket geometry. In such a system, the brackets are customized to provide three-dimensional movement of the teeth, once the wire, which has a two dimensional shape (i.e., linear shape in the vertical plane and curvature in the horizontal plane), is applied to the brackets.

[0011] Other innovations relating to bracket and bracket placements have also been described. For example, such patent innovations are disclosed in U.S. Pat. No. 5,618,716 entitled "Orthodontic Bracket and Ligature," which describes a method of ligating arch wires to brackets, U.S. Pat. No. 5,011,405 "Entitled Method for Determining Orthodontic Bracket Placement," U.S. Pat. No. 5,395,238 entitled "Method of Forming Orthodontic Brace," and U.S. Pat. No. 5,533,895 entitled "Orthodontic Appliance and Group Standardize Brackets therefore and methods of making, assembling and using appliance to straighten teeth".

[0012] Kuroda et al. (1996) Am. J. Orthodontics 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Pat. No. 5,605,459. U.S. Pat. Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, which describe methods for manipulating digital images of teeth for designing orthodontic appliances.

[0013] U.S. Pat. No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Pat. No. 5,338,198. U.S. Pat. No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Pat. Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the arch is described in U.S. Pat. Nos. 5,342,202 and 5,340,309.

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[0014] Other patents of interest include U.S. Pat. Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

[0015] Efficiency in treatment and maximum quality in results may depend on a realistic simulation of the treatment process. Plaster models of the upper and lower arch may be made, the model may be cut into single tooth models and these tooth models can be stuck into a wax bed, in a desired position, to create a "set-up." This approach allows modeling of a perfect occlusion without any guessing. The next step is to bond a bracket at every tooth model. This would tell the orthodontist the geometry of the wire to run through the bracket slots to receive exactly this result. Then the bracket position may be transferred to the original malocclusion model. To make sure that the brackets will be bonded at exactly this position at the real patient's teeth, small templates for every tooth would have to be fabricated that fit over the bracket and a relevant part of the tooth and allow for reliable placement of the bracket on the patient's teeth. To increase efficiency of the bonding process, another option would be to place each single bracket onto a model of the malocclusion and then fabricate one single transfer tray per arch that covers all brackets and relevant portions of every tooth. Using such a transfer tray guarantees a very quick and yet precise bonding using indirect bonding.

[0016] U.S. Pat. No. 5,431,562 to Andreiko et al. describes a computerized, appliance-driven approach to orthodontics. In this method, first certain shape information of teeth is acquired. A uniplanar target archform is calculated from the shape information. The shape of customized bracket slots, the bracket base, and the shape of the orthodontic archwire, are calculated in accordance with a mathematically-derived target archform. The goal of the Andreiko et al. method is to give more predictability, standardization, and certainty to orthodontics by replacing the human element in orthodontic appliance design with a deterministic, mathematical computation of a target archform and appliance design. Hence the '562 patent teaches away from an interactive, computer-based system in which the orthodontist remains fully involved in patient diagnosis, appliance design, and treatment planning and monitoring.

[0017] Align Technologies recently began offering transparent, removable aligning devices as a new treatment modality in orthodontics. In this system, an impression model of the dentition of the patient is obtained by the orthodontist and shipped to a remote appliance-manufacturing center, where it is scanned with a CT scanner. A computer model

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of the dentition in a target situation is generated at the appliance-manufacturing center and made available for viewing to the orthodontist over the Internet. The orthodontist indicates changes they wish to make to individual tooth positions. Later, another virtual model is provided over the Internet and the orthodontist reviews the revised model, and indicates any further changes. After several such iterations, the target situation is agreed upon. A series of removable aligning devices or shells are manufactured and delivered to the orthodontist. The shells, in theory, will move the patient's teeth to the desired or target position.

[0018] US Patent 6,699,037 by Align Technologies describes an improved methods and systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance. The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

[0019] The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, some of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply

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sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

[0020] The fabrication of aligners by Align Technologies utilizes stereo lithography process as disclosed in US patents 6471,511 and 6,682,346. Several drawbacks exist however with the stereo lithography process. The materials used by stereo lithography process may be toxic and harmful to human health. Stereo lithography process builds the aligner layer by layer by layer, which may create room to hide germs and bacteria while it is worn by a patient. Furthermore, stereo lithography process used by Align Technology also requires a different aligner mold at each stage of the treatment, which produces a lot of waste and is environmental unfriendly. There is therefore a long felt need for practical, effective and efficient methods to produce a dental aligner.

[0021] Another challenge for orthodontic treatment using removable dental aligning devices is that dental aligners often deform or otherwise loose their shape with age, use and/or environment. For example, a dental aligner (e.g., a "shell") may be deformed by chewing, biting, and hot beverages during wearing by the patient. The deformation can affect the proper function of the removable dental aligning device, because the ability of the aligner to effectively move teeth may depend upon the contact that the aligner makes with the teeth.

[0022] Furthermore, dental aligners may become relaxed and open up after repeated usage by a patient, which causes a loss of corrective forces applied by the aligner to the patient's teeth. This results in insufficient or inaccurate teeth movement and costly corrective measures in the orthodontic treatment.

[0023] Another difficulty with the current removable dental aligning devices is that the narrow tolerance for the removable dental aligning devices to fit to the patient's teeth. The removable dental aligning devices have to be produced very close to the surface profiles of the patient's teeth. Mismatch between the removable dental aligning devices and patient's teeth often produce discomfort in wearing the removable dental aligning devices.

[0024] Existing aligner have not adequately addresses these problems. For example, U.S. Patent 4,793,803 by Martz discloses separate appliances insertable in and removable from the upper and lower jaws of the subject to correct minor malocclusions. Martz describes: (a) a fairly rigid portion which mates with or securely grips the tooth surface, (b) a rigid portion to provide the base and shape, and (c) an intermediate, flexible resilient portion interposed between (a) and (b) which biases the teeth into the desired

position. The rigidity of the rigid portion may vary depending on the condition of an individual case. In some instances the rigid portion need only be somewhat flexible, thereby performing the function of the intermediate portion as well.

[0025] US Patent 6,309,215 by Phan et al. describes systems and methods for removably attaching a dental positioning appliance to the teeth of a subject during orthodontic treatment. Such removable dental positioning appliances are often preferred over conventional braces for tooth repositioning due to comfort, appearance and ease of use. These appliances apply force to specific surfaces of the teeth to cause directed movement. However, the type of movement and amount of force applied is usually dependent on the surface characteristics and positions of connection to the teeth. The appliances or connection between the appliance and the teeth may not provide sufficient anchoring to impart a desired force on the teeth to be repositioned. Thus, such systems may require the use of one or more attachment devices that may be positioned on the teeth to provide the appropriate physical features. Appliances may attach to a subject's teeth by interactions with a pit or dimple on the dental aligning devices are often not secure enough, especially when large teeth movements are required. Furthermore, over a period of usage by a subject, an aligner can also become relaxed and open up. Dental aligning devices that attach to the subject's teeth by dimples may slip over the attachment, which can result in inaccurate teeth movement and costly corrective measures in the orthodontic treatment. However, specific design and location of these attachment devices may provide more effective repositioning forces, anchoring ability and appliance retention.

[0026] Another issue with most commercially available removable aligning devices (e.g., the devices manufactured by Align Technologies) is that the aligning devices do not allow oxygen to pass through them. A typical treatment takes about 18 to 24 months, and during this interval the cervical lines of the patient wearing such appliances typically remain covered for the major part of the day without letting air to pass through them. Oxygen cannot reach the cells of the cervical lines, and air trapped inside the aligning appliances cannot readily escape. Anaerobic bacteria such as Fusobacterium and Actinomyces often thrive in an oxygen-deprived environment and may produce volatile sulfur compounds (VSC) as byproducts, which can result in bad breath (halitosis) and hygiene problems in the patient's mouth.

[0027] In addition to the problems identified above, many aligners are also limited in their ability to effect corrections requiring lateral expansion of the palate. Most

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presently available aligners move only the teeth, with only minimal impact on the motion of the palate. Further, traditional devices for expanding the palate are difficult to manufacture, and are incapable of correcting the entire upper dental arch. For example, US Patent application Serial Number 10/636,313 to McSurdy (herein incorporated by reference in its entirety) describes a palatal expansion device. Thus, it would be desirable to provide an economical, easily fabricated aligner capable of reforming the entire upper dental arch, including the palate.

[0028] The devices, systems, and methods described herein illustrate removable dental aligners having one or more features addressing at least some of the problems described above. In particular described herein are variations of dental aligners including dental aligners having through-holes through which connectors securable to a subject's teeth may pass and be secured, dental aligners including controllably deformable regions or textured surfaces (e.g., wrinkled aligners), non-uniform and/or multilayer dental aligners, and dental aligners which are fluid and/or gas permeable. Any or all of these features may be combined to form a dental aligner, as described more fully below.

SUMMARY OF THE INVENTION

[0029] Described herein are systems, methods and devices to correct or modify the position of a subject's teeth. Methods of manufacturing such apparatuses are also described. In particular dental appliances are described. Any of the variations of dental appliances, as well as methods of designing, fabricating, and using them are illustrated. Dental appliances may be any appropriate dental device, including dental aligners. The term dental aligner may also generally refer to any appropriate dental appliance.

[0030] Any of the features described (e.g., snap-on dental aligners, textured, fluid- and/or gas- permeable, wrinkled, modular, or varying thickness, stiffness or other properties) may be incorporated as part of a dental aligner, individually or in any reasonable combination. For purposes of descriptive convenience only, individual dental aligners are described or illustrated to emphasize only one or a few features. This arrangement is not intended to be limiting or to imply that the aligners, system, and methods of making or using these aligners are restricted to the examples shown or described.

[0031] Dental aligners may incorporate features that assist in securing the dental aligner to a subject's teeth, for helping the aligner maintain its conformation or resisting

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wear and relaxation, and for improving the comfort and effectiveness of the aligner. For example, the dental aligner may be a "snap-on" dental aligner (which may be secured to connectors on a subject's teeth). The dental aligners may be fluid permeable. The dental aligners may be non-uniform and/or may be multi-layered dental aligners. The dental aligners may be textured or shaped to permit a predictable expansion or contraction of the dental aligner. For example, the dental aligner may be a wrinkled aligner.

[0032] Snap-on dental aligners may include one or more of the following.

[0033] Snap-on dental aligners may produce corrective movement in a subject's teeth, and may include a dental aligner (or shell) configured to be worn on a subject's teeth, and one or more through-holes passing through the device. The aligner device includes a shell portion having an outer surface and an inner surface, wherein at least a portion of the inner surface is configured to contact the subject's tooth. Thus, the thorough-holes extend from the outer surface to the inner surface of the shell portion of the dental device. The through-hole is configured to mate with a connector.

[0034] A system for producing corrective movement in a subject's teeth may includes a dental aligner device having one or more through-holes, configured to be worn on the subject's teeth, and one or more connectors that are configured to be fixed to the subject's teeth. The connectors are configured to engage with the through-holes when the dental aligner is worn on the subject's teeth.

[0035] A system for producing a snap-on dental aligner for dental treatment may include a guide to indicate the location where through-holes (corresponding to connectors on the subject) are to be formed on a dental aligner, and a positioner (a positioning device) to position a hole-maker with respect to the dental aligner based on the information provided by the guide. In some variations, the system also includes a hole-maker to produce through-holes in the dental aligner at the positions indicated by the guide to produce the snap-on dental aligner.

[0036] A method for moving a subject's teeth in a dental treatment may comprise fabricating a dental aligner to be worn on the subject's teeth, producing one or more through-holes in the dental aligner, fixing one or more connectors on the subject's teeth to engage the through-holes, and engaging the one or more connectors on the subject's teeth with the through-holes of the dental aligner to secure the dental aligner on the subject's teeth.

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[0037] Embodiments described herein may provide practical methods and systems for making dental aligners (e.g., snap-on dental aligners) and associated receiving connectors on the subject's teeth. The aligners can be attached onto the subject's teeth and assure the dental aligner to be in precise registration as designed throughout the period of wearing by the subject. The aligners may also overcome the aligner relaxation problem due to repeated uses, which is common in prior art dental aligners. The snap-on dental aligner therefore can ensure that the aligner produces the correct force to achieve a desirable movement in the subject's teeth, which improves the accuracy and effectiveness of the orthodontic treatment by the aligner.

[0038] One disclosed mechanisms in the dental aligners described include through-holes in the dental aligners and connectors fixed on a subject's teeth to receive the through-holes. The disclosed mechanisms allow the dental aligners to be effectively locked into intended positions during wearing by the subject. The registration and holding capability may thus be significantly enhanced.

[0039] The snap-on dental aligners may also lengthen the usage lifetime of an aligner by sustaining corrective forces for a longer period of time. As a result, the number of visits to the dentist office may be reduced. The material and manufacture costs of the aligners for an orthodontic treatment may be decreased. The need for corrective rework due to aligner deformation may also be significantly reduced, which may further reduce costs of the orthodontic treatment.

[0040] Snap-on dental aligners may allow a thinner dental aligner while still engaging that subject's teeth and providing sustainable forces to cause teeth movement. Thinner and lower profiled removable dental aligners are less intrusive to subject's mouth and often more comfortable for the subject to wear. Snap-on dental aligners may be applicable to class II bite corrections in dental treatment.

[0041] The properties of the snap-on aligners may also be simulated and optimized in the design process. The performance of the snap-on aligners can be optimized by varying parameters such as the number, the locations, and the density of the snap-on connectors, and the sizes and locations of the through-holes in the snap-on mechanisms, etc. The snap-on dental aligners can be manufactured by cost-effective processes such as vacuum forming, cutting by a cutter, etching by a laser beam or thermal applier, and CNC based manufacturing.

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[0042] Dental appliances may have properties that differ in various portions of the appliance. Properties that may differ in various regions of the appliance may include one or more of the following: color, texture, flexural strength, tensile modulus, flexural modulus, hardness, thermal conductivity, heat capacity, compression modulus, and toughness. Thus, regions of the appliance may differ from one another by one or more of the properties listed above. Examples of appliances having regions of different properties (as well method of designing, manufacturing and using such appliances) are described herein.

[0043] The difference in properties of the appliance (e.g., a dental aligner) may be introduced by incorporating two or more polymers into an appliance. The polymers may be the same type (e.g. thermoplastic or thermoset) or may be of different types. The polymers may be different chemical compositions (e.g. polyurethane and silicone polymer), or they may be the same chemical composition (e.g. acrylic polymer) that has been formed under different conditions to provide polymers of distinctive properties. The polymers may be homopolymers or copolymers in which the ratio of monomers in regions differs or is the same. The polymers may also be one or more polymer blends or alloys.

[0044] The appliances may be made by e.g. utilizing different polymer sheets in molds to provide an appliance in which layers of polymer in one or more regions or in the entire appliance differ from an adjacent layer or layers, or the appliances may be made by treating a polymer to different processing conditions during appliance manufacturing to provide a continuous polymeric construction across borders of the regions but in which properties differ from region to region across the appliance.

[0045] For example, a method for making a multi-layer dental aligner may comprise placing a first layer of a first aligner-making material over one or more physical tooth models, conforming the first layer of the first aligner-making material to the surfaces of the one or more physical tooth models, placing a second layer of a second aligner-making material over the first layer of the first aligner-making material, and conforming the second layer of the second aligner-making material to the surfaces of the first layer of the first aligner-making material over the one or more physical tooth models to produce the multi-layer dental aligner.

[0046] In some variations, a method for making a multi-layer dental aligner comprises heating a first layer of the first aligner-making material, holding the first layer of the first aligner-making material against one or more physical tooth models by vacuum

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suction, cutting the first layer of the first aligner-making material along the gingival lines of the physical tooth models, heating a second layer of the second aligner-making material, holding the second layer of the second aligner-making material against the first layer of the first aligner-making material over the physical tooth models by vacuum suction, and cutting the second layer of the second aligner-making material along the gingival lines of the physical tooth models to produce the multi-layer dental aligner.

[0047] In some variations, a multi-layer dental aligner may comprise a first layer of a first aligner-making material and a second layer of a second aligner-making material, wherein at least one of the first layer and the second layer is formed by heating a layer of an aligner-making material and holding the layer of the aligner-making material against one or more physical tooth models.

[0048] Another method for making a non-uniform dental aligner comprises non-uniformly heating the sheet of aligner-making material, and holding the sheet of aligner-making material against one or more physical tooth models to produce the non-uniform dental aligner.

[0049] Additionally, a method for making a non-uniform dental aligner may comprise heating a first section of a sheet of aligner-making material at a first temperature for a first period of time, heating a second section of the sheet of aligner-making material at a second temperature for a second period of time, holding the sheet of aligner-making material against the one or more physical tooth models to produce the non-uniform dental aligner by vacuum suction; and cutting the sheet of aligner-making material along the gingival lines of the physical tooth models to produce the non-uniform dental aligner.

[0050] Dental appliances may also be fluid permeable. For example, a dental aligner may be fluid permeable while still supplying adequate strength and structure necessary to move the teeth in the desired manner. "Fluid permeable" may refer to permeability to both liquids (e.g., water, saliva, etc.) and/or gasses (e.g., oxygen). A dental appliance may be fluid permeable because it comprises a fluid permeable material, or because it has been permeabilized by the addition of pores, passages or holes of any appropriate size or shape.

[0051] For example, a shell-shaped dental aligner for producing predetermined movement in a patient's tooth may comprise a shell portion comprising a fluid-permeable material; an outer surface of the shell portion; and an inner surface of the shell portion, the inner surface to be in contact with the patient's tooth, wherein the fluid-permeable material

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can allow fluid to communicate between the patient's tooth and the vicinity of the outer surface.

[0052] A method for treating a patient's teeth may therefore comprising determining an initial configuration of the patient's teeth, determining a final configuration of the patient's teeth, designing a movement path for at least one of the patient's teeth from the initial configuration to the final configuration, dividing the movement path into a plurality of successive treatment steps (each having a target configuration for the patient's teeth) and producing a dental aligner comprising a fluid-permeable material to move the patient's teeth to the target configuration associated with a treatment step. A system for treating a patient's teeth may comprising a computer configured to determine a target configuration for the patient's teeth and an apparatus configured to produce a dental aligner comprising a shell portion that comprises a fluid-permeable material, an outer surface, and an inner surface to be in contact with one of the patient's teeth. The fluid-permeable material can allow fluid to communicate between the one of the patient's teeth and the vicinity of the outer surface and the dental aligner is configured to move the patient's teeth to the target configuration.

[0053] Fluid permeable dental aligning devices may readily allow oxygen to pass through to the patient's teeth and cervical lines in the arch. Permitting an increased oxygen concentration under the dental aligning devices can overcome problems related to bacterial growth under the aligner device (which may be a problem for conventional aligner systems). Porous channels may also allow saliva to pass through the dental aligners. Saliva plays a critical role in controlling halitosis and bacterial growth. Saliva contains proteins, carbohydrates, and immunoglobulins that interfere with bacterial metabolism and bacterial adherence to oral surfaces. Saliva is also a solvent that can control mouth odor in the oral chemical environment. Thus, oral hygiene and odor associated with the mouth of a patient wearing a fluid permeable dental aligner may be improved, particularly in comparison with non-permeable or less-permeable appliances. Further, the ability to pass oxygen and saliva not only improves the patient's oral hygiene but may also allow the patient to clean the aligner less frequently, enhancing convenience. The less frequent removal (because of extended wearing) can also lengthen the usage lifetime and the effectiveness of the dental aligning devices.

[0054] The appliances described herein may also be disposable. Thus, a method for treating a patient's teeth with a disposable aligner may include using more than one

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appliance (e.g., 2, 3, 4, etc.) that are otherwise identical for each step of the treatment. For example, one method of treating a patients teeth using disposable aligners includes: determining an initial configuration of the patient's teeth, determining a final configuration of the patient's teeth, designing a movement path for at least one of the patient's teeth from the initial configuration to the final configuration, dividing the movement path into a plurality of successive treatment steps, each having a target configuration for the patient's teeth, and producing two or more dental aligners of substantially identical shape for at least one of the treatment steps in accordance with the target configuration. Aligners having substantially identical shape are generally aligners that would produce the same movement of the teeth if either aligner were placed on an identical (e.g., initial) dental arch.

[0055] A method for treating a patient's teeth may also comprise: determining a target configuration for the patient's teeth, producing two dental aligners having substantially identical shape, and using the two dental aligners to move the patient's teeth to the target configuration.

[0056] Disposable aligner may be used for each step of the treatment process, or may be used for only some (e.g., steps requiring the same shaped aligner to be worn for an extended period) treatment steps. In some variations, a disposable aligner may be provided for pre-determined increments of time (e.g., for each day, each week, each month, etc.). Thus, a system for treating a patient's teeth may comprise: a computer configured to determine a target configuration for the patient's teeth; and an apparatus configured to produce two dental aligners configured to move the patient's teeth to the target configuration, wherein the two dental aligners have substantially identical shape.

[0057] Disposable aligners may provide convenient dental aligning devices for patients. The dental aligners. As used herein the term "disposable" aligners refers may refer to redundant dental aligners provided to the patient at each treatment step so that a "new" aligner having the same shape can be used during one or more of the treatment steps. Thus, if a dental aligner is lost or damaged, the patient does not have to request another aligner and wait for it to be made and sent to her. This may make treatment and storage of the aligners easier for the patient, as special care (to prevent damage, loss or wear) does not need to be taken. The disclosed disposable dental aligners are therefore more convenient for patients to use. The costs may also be reduced for re-ordering and remaking lost or damaged dental aligners.

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[0058] Disposable aligners may also provide more accurate and effective dental treatment for the patients. Conventional dental aligners often relax over the use of a period of time and lose their strength to exert intended forces on the patients' teeth, which results in ineffective and inaccurate movements for the dental treatment. When multiple dental aligners are provided at each treatment step, dental aligners can be disposed before they become relaxed. The accuracy and effectiveness of the dental treatment are therefore improved. As a result, the overall treatment time and cost can be reduced.

[0059] Furthermore, disposable aligners may also improves a patient's oral hygiene by allowing the patient to frequently replace the dental aligner worn by a short period of time by new dental aligner.

[0060] The dental appliances described herein may also be configured or fabricated so that they prevent deformation of the appliance. For example, a dental aligner may be configured to allow some flexion or expansion of the appliance in predetermined regions. For example, the appliance may include "wrinkles" over at least a region of their length. A wrinkled aligner typically has one or more surfaces (or regions) that are furrowed, ridged, or creased rather than normally smooth. For example, the wrinkles in the aligner surface may appear crumpled, folded, or curved. The wrinkles may allow the appliance to bend or expand to a greater degree than an otherwise unwrinkled aligner, thereby preventing material stresses that may damage the appliance.

[0061] A method for manufacturing wrinkled dental aligner for a patient's tooth may comprise: developing a digital dental aligner model specifying at least one wrinkled surface on a dental aligner, and producing a dental aligner having the wrinkled surface in accordance with digital dental aligner model.

[0062] In some variations, a method for manufacturing wrinkled dental aligner for a patient's arch, comprises: developing a digital dental arch model based the patient's arch, developing a digital dental aligner model based on the digital dental arch model, wherein the digital dental aligner model specifies one or more wrinkles on a surface, and producing a wrinkled dental aligner in accordance with the digital dental aligner model. A system for manufacturing a wrinkled dental aligner for a patient may comprise: a computer configured to store a digital dental aligner model specifying at least one wrinkled surface on the wrinkled dental aligner, and an apparatus configured to produce the wrinkled dental aligner in accordance with digital dental aligner model.

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[0063] Wrinkled appliances may provide advantages over non-wrinkled appliances. For example, a wrinkled aligner prevents the relaxation of the dental aligner after repeated uses, which is common in prior art systems. The wrinkled dental aligner therefore can ensure the aligner to produce the correct force to produce desirable movement in the patient's teeth, which improves the accuracy and effectiveness of the orthodontic treatment by the aligner. The reduction or elimination of the relaxation and force loss that are problems associated with conventional dental aligners may also lengthen the lifetime of the aligner. As a result, the number of visits to the dentist office is reduced. The material and manufacture costs of the aligners for an orthodontic treatment are decreased. Additionally, corrective rework due to aligner deformation may be significantly reduced, further reducing costs of the orthodontic treatment.

[0064] The properties of the wrinkled aligners can be simulated and optimized in the design process. The performance of the wrinkled aligners can be optimized by simulating and varying wrinkle parameters such as wrinkle depth, wrinkle location and orientation, and wrinkle density. The wrinkled dental aligner can be manufactured by cost-effective processes such as vacuum forming, cutting by a cutter, etching by a laser beam or thermal applier, or CNC based manufacturing.

[0065] Also described herein are aligners that are capable of lateral corrections, including expanding the upper palate. Such aligners may be referred to as "lateral correction aligners" and are for the upper dental arch. Lateral correction aligners typically include a shell region that covers the teeth and contacts at least a portion of the upper pallet. The aligner design encourages movement of the upper palate by modeling the target position of the upper palate and generating one or more incremental steps (as described herein with respect to movements of the teeth). This allows lateral corrections to be made on the teeth and upper pallet.

[0066] Typically, aligners configured for laterally correcting the teeth and/or remodeling the upper palate include a palate-spanning region. In order to provide later force on the teeth and pallet by the aligner, the palate-spanning region may include a support piece for maintaining and/or applying force against the palate and/or teeth. Support pieces may include any material having structural strength (e.g., metals, ceramics, etc.), but in particular, may comprise materials capable of applying force to remodel the upper dental arch. For example, the support piece may be a spring or other expandable member. The support piece may be included (e.g., sandwiched) within the palate region of the aligner.

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This may make the aligner more comfortable, and prevent damage to either the tongue or palate region.

[0067] The lateral correction aligners may be configured either to expand or contract the palate. Further lateral correction aligners may be formed by any of the methods described herein. For example, the lateral correction aligners may be formed using a model of the upper dental arch (e.g., by vacuum-forming one or more layers of material) or may be formed from a digital model (e.g., by CNC, lithography, etc.).

[0068] Thus, lateral correction dental aligners for remodeling a subject's upper dental arch (including the palate region) may include a shell having an outer surface and an inner surface, and a palate-spanning region, wherein the palate-spanning region is configured to contact the subject's upper palate and provide force to remodel the subject's upper arch. The shell region typically comprises a tooth contacting region configured to contact the teeth of the subject's upper arch. As described herein, the shell region typically contacts both sides of the subject's teeth (front and back). The shell region of the lateral correction aligner typically contacts all of the subject's teeth that are present (e.g., including the incisors, canines, bicuspids, molars). The palate-spanning region generally covers at least a portion of the subject's palate when the subject wears the aligner. For example, the palate-spanning region may correspond to a substantial portion of the subject's hard palate. The palate-spanning region may correspond to the front of the subject's hard palate (near the incisors) as well as the back of the subject's hard palate region (e.g., near the molars).

[0069] In some variations, the palate-spanning region further comprises a support piece configured to provide structural support to the palate-spanning region. The support piece may span the entire palate-spanning region, or it may be a portion of the palate-spanning region. The palate-spanning region may be made of a fluid-permeable material as described above, including materials that have been permeablized by adding passages through them (e.g., by laser perforation, etc.).

[0070] Also described herein is a method for reshaping a patient's dental palate, comprising: determining an initial configuration of the patient's teeth and upper palate region (e.g., by modeling or by direct measurement), determining a final configuration of the patient's teeth and upper palate region, designing a movement path for at least a portion of the upper palate region from the initial configuration to the final configuration, dividing the movement path into a plurality of successive treatment steps, and producing a plurality

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of dental aligners including a palate-spanning region to remodel the upper palate region to the target configuration.

[0071] The details of one or more embodiments of these dental aligners are set forth in the accompanying drawing and in the description below. Other features, objects, and advantages of the invention will become apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0072] The accompanying drawings, which are incorporated in and form a part of this specification, illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention:

[0073] Figure 1A-1F show cross-sectional profiles of various through-holes as described herein.

[0074] Figure 2A-2E show cross-sectional profiles of various connectors as described herein.

[0075] Figure 3 illustrates an arrangement of fabricating a snap-on dental aligner.

[0076] Figure 4 illustrates a system diagram for fabricating a snap-on dental aligner.

[0077] Figure 5 is a flow chart for fabricating a set of connected dental aligners for a dental treatment in accordance with the present invention.

[0078] Figure 6 illustrates the side view of a conventional dental aligner newly worn on a subject's tooth.

[0079] Figure 7 shows the side view of a conventional dental aligner worn on a subject's tooth after a period of usage.

[0080] Figure 8 illustrates the top views of a conventional dental aligner when it is newly worn and after it is worn for a period of time.

[0081] Figure 9 illustrates a cross-sectional view of a snap-on dental aligner.

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[0082] Figure 10 is a flow chart for providing orthodontic treatment using a removable multi-layer dental aligner.

[0083] Figure 11 illustrates a tooth model having registration features.

[0084] Figure 12 is a top view of a dental base comprising a plurality of sockets for receiving pins affixed on the physical tooth models.

[0085] Figure 13 illustrates the fabrication of the first layer of a multi-layer dental aligner.

[0086] Figure 14 illustrates the fabrication of the second layer of a multi-layer dental aligner.

[0087] Figure 15 is a top view of a multi-layer dental aligner.

[0088] Figure 16 is a view of another aligner.

[0089] Figure 17 is a cross-sectional view of a multi-layer or non-uniform dental aligner worn on a patient's tooth.

[0090] Figure 18 illustrates an orthodontic process for using a dental aligner comprising a fluid-permeable material.

[0091] Figure 19a illustrates the side view of a new conventional dental aligner worn a patient's tooth.

[0092] Figure 19b shows the side view of a conventional dental aligner worn after a period of usage.

[0093] Figure 20 illustrates the top views of a conventional dental aligner when it is newly worn and after it is worn for a period of time.

[0094] Figure 21 illustrates a process for producing a disposable dental aligner.

[0095] Figure 22 is a flow chart for producing a physical aligner in accordance with the present invention.

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[0096] Figure 23 illustrates the smoothening of the digital aligner model in preparation for a CNC based manufacturing of physical aligner in accordance with the present invention.

[0097] Figure 24 illustrates the segmentation of digital aligner model into segmented components suitable for CNC based manufacturing in accordance with the present invention.

[0098] Figures 25a-25d illustrate the segmentation of an inter-proximal region by removing a space around the inter-proximal region and replacing it by a wedge.

[0099] Figures 26a-26d illustrates aligner components comprising features that allow them to assemble to form an aligner.

[00100] Figure 27 illustrates an aligner assembled from a plurality of aligner components each comprising features that assist the assembling.

[00101] Figure 28 illustrates an arrangement of the wrinkles on aligners.

[00102] Figure 29 illustrates the fabrication of a wrinkled aligner from a sheet of aligner material.

[00103] Figure 30 illustrates the process of designing and fabrication of the wrinkled dental aligners.

[00104] Figure 31a shows a cross-section of one variation of a lateral correction aligner on a dental arch. The same dental aligner is shown in Figure 31b without the dental arch.

[00105] Figure 32a shows a perspective view of one variation of a lateral correction aligner as described herein on a dental arch. Figure 32b shows another perspective view of a lateral correction aligner.

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[00106] Figure 33a shows a cross section of one variation of a lateral dental aligner. Figure 33b shows an expanded view of a region of the lateral dental aligner shown in Figure 33a.

DESCRIPTION OF INVENTION

[00107] Dental appliances are described herein. In general, dental appliances (e.g., dental aligners) are devices which may be worn on a subject's teeth, gingiva or other region of the oral cavity. Dental appliances are typically used to treat malocclusion. Dental appliances may include features which enhance the performance of the appliance. The dental appliances described herein may include features for preventing damage or wear on the appliance (e.g., fluid-permeability, wrinkled structure, modular construction, and varying thickness, stiffness, etc.). The dental appliance may also include features for enhancing the fit of the appliance, (e.g., snap-on features, through-holes, textured surfaces, etc.).

[00108] The following description is presented to enable any person of ordinary skill in the art to make and use the invention. Descriptions of specific materials, techniques, and applications are provided only as examples. Various modifications to the examples described herein will be readily apparent to those of ordinary skill in the art, and the general principles defined herein may be applied to other examples and applications without departing from the spirit and scope of the invention. Thus, the present invention is not intended to be limited to the examples described and shown, but is to be accorded a scope consistent with the appended claims.

[00109] As used herein, the term "dental aligner" refers to a dental device or appliance for rendering corrective teeth movement or for correcting malocclusion. An orthodontic treatment usually includes plurality of treatment steps. One or more dental aligners can be worn on the subject's teeth at each treatment step. The orthodontist first determines the initial configurations of the subject's teeth and decides target final configurations for the subject's teeth at the end of the treatment. One or more dental aligners can then be produced so that a subject wearing the dental aligners will gradually have his or her teeth repositioned by the dental aligner "pushing" (or pulling) against the teeth, or gums (gingiva).

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[00110] As used herein a "subject" may be any subject who may benefit from the use of a snap-on aligner, including orthodontic patients.

[00111] Individual dental aligner appliances generally cover some (or all) of a subject's teeth and may extend to the gums (or other regions of the oral cavity, including the roof of the mouth). In some variations, a dental aligner may comprise a polymeric shell having a teeth-receiving cavity formed therein. The dental aligner may be formed by molding. Each individual appliance may be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the subject, certain of the teeth will be misaligned relative to an un-deformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and may apply sufficient resilient force against such misaligned teeth to reposition the teeth to the intermediate or end arrangement desired for that treatment step. Examples of dental aligners, as well as additional description, may be found in the figures described below, as well as in the incorporated references.

[00112] The portion of the dental aligner covering the teeth may be referred to as the shell region of the dental aligner. The shell region typically has an inner (e.g., teeth-contacting) surface and an outer surface (opposite to the inner surface). The dental aligner may also be considered to have a tip region (e.g., near the crown of the teeth on which the aligner is worn) and a bottom portion, which may sit near the gums (or gingival) when the aligner is worn on the teeth. Side regions may be identified between the tip region and the bottom region (e.g., and inner side region facing the tongue, and an outer side region facing the lips).

[00113] The dental aligners described herein may further include any or all of the features described below (e.g., snap-on dental aligners, textured, fluid- and/or gas-permeable, wrinkled, modular, or varying thickness, stiffness or other properties) which may be incorporated as part of a dental aligner, individually or in any reasonable combination. For purposes of descriptive convenience only, individual dental aligners are described or illustrated to in the sections that follow to individually emphasize features or aspects of the dental aligners described herein. This arrangement is not intended to be limiting or to imply that the aligners, system, and methods of making or using these aligners are restricted to the examples shown or described.

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[00114] Dental aligners may incorporate features that assist in securing the dental aligner to a subject's teeth, including connectors and through-holes and textured contact surfaces.

Manufacturing a Dental Aligner

[00115] Dental aligners may be fabricated from a digital or actual (e.g., physical) model of a subject's dental arch. The subject's current dental arch is modified to represent a target dental arch (or a series of target dental arches) my incrementally moving the teeth from their current position towards the intended position. Typically, a dental aligner is made by forming an aligner to fit the model of the dental arch that is incrementally different from the current dental arch. Thus, the dental aligner provides force to help correct malocclusions of teeth. In forming the aligner from the model of the dental arch (either digital or actual), it may be beneficial to smooth the model of the teeth, so that the aligner accurately conforms to the dental arch, but does not include surfaces corresponding to sharp edges or spaces which may interfere with the comfort and effectiveness of the aligner.

[00116] Figure 22 illustrates one variation of a process of producing a dental aligner as described herein. First, a three dimensional (3D) digital dental arch model is acquired from a patient's arch in step 4110. The digital dental arch model can be obtained by 3D scanning of a cast produced from the patient's arch. The digital model includes a mesh of points in three dimensions that define the surfaces of an entire or a large portion of an upper or lower arch. Details of obtaining a digital model of an arch are disclosed in above referenced US Patent Application titled "Producing a base for a physical dental arch model" by Huafeng Wen, filed 12/14/2004, the content of which is incorporated herein by reference.

[00117] Next, in step 4120, the digital dental arch model is smoothened by computer processing using computer software. One or more criteria for the degree of smoothness can also be provided by a user. Undesirable features such as sharp edges, gaps, and divots are removed from the digital dental arch model. When a physical model alone is used, the edges may be manually smoothed, and gaps may be filled in (e.g., using wax, etc.).

[00118] The degree of smoothness that is required may depend upon the specific dental application. For example, plastic aligners cannot reach into the gaps between the teeth, and therefore these gaps may be filled in when forming the aligner. In addition, it is also undesirable to have aligner to have fine features inside the gaps because that could

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potentially create resistance to desired tooth movement in an orthodontics treatment procedure.

[00119] The criteria for the degree of smoothness can also be determined by the type of tools used to manufacture the aligner components, as described below. For example, Computer Numerical Control (CNC) based manufacturing refers to the automated and computer controlled machining. A CNC machine typically provides automatic, precise, and consistent motion control. All forms of CNC equipment have two or more directions of motion, called axes. These axes can be precisely and automatically positioned along their lengths of travel. The two most common axis types are linear (driven along a straight path) and rotary (driven along a circular path). Instead of causing motion by manually turning cranks and hand wheels as is required on conventional machine tools, CNC machines allow motions to be actuated by servomotors under control of the CNC, and guided by the part program. Generally speaking, the motion type (rapid, linear, and circular), the axes to move, the amount of motion and the motion rate (feed rate) are programmable with almost all CNC machine tools. In the present invention, in addition to CNC based milling, the CNC based manufacturing is also compatible with other computer numerical controlled manufacturing processes such as stereolithography, laser machining, molding as well as other types of CNC based machining.

[00120] For manufacturing a physical dental arch model, however, the drill bit in CNC based milling is usually too big to reach into the gaps and holes in a dental arch model. CNC milling is usually around one axis, which makes it difficult to machine the complex shapes within the gaps between teeth. CNC based milling also has limitations in accuracy and repeatability between different stages of milling.

[00121] Several techniques may be used to remove the gaps in the digital dental arch model to produce a smoothened digital dental arch model. These techniques include:

[00122] (1.) Boolean union with primitive 3D objects. Graphics Constructive Solid Geometry primitives or self developed predefined geometries can be inserted into the gaps in the digital dental arch model and then combine with the original 3D digital mesh.

[00123] (2.) Extrusion. The surfaces near the gaps are extruded to fill the gaps in the original 3D digital mesh.

[00124] (3.) Geometry modification by moving vertices. Sharp gaps can be closed by specifying the desired boundaries and modifying the mesh to the desired boundaries in the problem regions.

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[00125] (4.) Subdivision of surfaces and movement. Similar to Technique 3, the dental arch surfaces are subdivided in the regions of surface modification for greater smoothness and continuity.

[00126] (5.) Convex hull creation of sub parts to be used as filling objects in the gaps. The gap regions are first located and the points defining edges of the sharp gaps are identified. A convex hull is computed based on these points. The convex hull is joined with the original mesh to fill the gaps using Boolean union.

[00127] (6.) Using parametric surfaces to model fill objects that will be used fit in the gaps.

[00128] Figure 23 illustrates the smoothening effects of the gap filling by comparing the surfaces 4210 of before gap fillings and the surfaces 4220 after the gap fillings.

[00129] A simulation can be conducted using the smoothened the digital dental arch model as input to check and verify the smoothness of the digital dental arch model. The simulation can be run using simulator software in response to the smoothness criteria required by the manufacturing process such as CNC based milling or the dental applications. Refinement ad smoothening iterations may be called for if the smoothness criteria are not completely satisfied.

[00130] Once the dental arch model is smoothed, an aligner model may be developed based on the smoothed dental arch model (e.g., a digital arch model). For example a smoothed digital arch model may be used to develop a digital aligner model, as shown in Fig. 22, Step 4130. The digital aligner model typically comprises an inner surface and an outer surface. Since the inner surface(s) of the aligner will be in contact with the outer surface of the patient's teeth (and sometimes gingiva), the inner surfaces of the digital aligner model may approximately follow the contours of the outer surface of the digital dental arch model, so that the dental aligner will fit (e.g., snap) onto the arch. Moreover, the inner and outer surfaces of digital aligner may be designed to various shapes and thickness that may apply the desired forces in order to achieve the movement of the teeth in accordance with a treatment plan.

[00131] In the method outlined in Figure 22, the digital aligner is next divided into smaller components that may be easily manufactured (e.g., by CNC techniques) and reassembled to form a final aligner. In Step 4140, the digital aligner model is segmented into digital aligner components suitable for CNC manufacturing. A typical aligner in the digital aligner model includes an upper or lower aligner respectively for the upper and

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lower arch or a portion of an arch comprising a plurality of teeth. An aligner 4300 is shown in Figure 24. The aligner components 4310, 4320 can correspond to a portion or region of a dental arch model (e.g., a portion of a tooth, a whole individual tooth, or sometimes a segment of arch including several teeth).

[00132] The criteria for the size, location, and the number of aligner components are based on both orthodontic needs and manufacturing requirements. The orthodontic criteria require the tracking of how the original locations of the aligner components and which components can be moved together as a group, which aligner components must be moved independently, and which teeth cannot be moved.

[00133] The manufacturing requirements relate mainly to the manufacturability of the digital aligner components, which usually supersedes the orthodontic criteria. For example, a single tooth can be divided into multiple components to make its model manufacturable. The segmented digital components can be evaluated by a simulation software to verify their manufacturability by a specific manufacture process such as CNC based milling, which may suggest refinement in the size, location, and numbers of the segmentation. The simulation can also include an evaluation and estimation of the physical strength after the assembly, as described below, to determine if the assembled aligner components are strong enough to withstand the physical forces in a pressure forming process.

[00134] In one variation, a digital aligner model can be smoothened during the segmentation. Different segmented digital components may receive different types or degree of smoothening so that the smoothening is tailored to the segments and manufacturing requirements.

[00135] By the method described in Figure 22, an aligner model can be segmented to small, manufacturable aligner components that can be manufactured by automated, precise numerical manufacturing techniques. The manufacturability of the digital components may be simulated, verified and refined if necessary prior to manufacturing. As a result, complex aligner shapes that cannot be made can now be practically manufactured. Waste and cycle times are reduced in the process from design, testing, pilot, to production.

[00136] After designing the segmented aligner and manufacturing the segments, the segments may be assembled to form a complete aligner. For example, in step 4150, one or more features are added to the aligner components to assist the assembling of the aligner components to form an aligner. These features may include a pin, a registration slot, a

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notch, a protrusion, a hole, an interlocking mechanism, a socket, a jig, and a pluggable or an attachable feature. The adjacent manufactured aligner components may include matching male (e.g. mushroom, push pins) and female features (e.g. hole, notches etc.) for attachment. The male and female features can be fabricated for example by casting mold that include female and male matching features in the mold, each responsible for making respective male and female features. The adjacent aligner components can be attached together by simply pushing male feature into the female feature, for example, by pressing a pushpin into a receiving hole. In some variations, the segments may be secured together by an additional step (e.g., by an adhesive, sintering, etc.)

[00137] Special care may be applied to the inter-proximal regions when segmenting the arch into digital components. For example, the inter-proximal regions may involve complexity and details so that CNC based manufacturing techniques (such as cutting or milling) can result in losing details. As shown in Figures 25a and 25b, an inter-proximal region 4440 may be removed between a tooth model 4410 and a tooth model 4420 along the lines 4430. This can be achieved by data processing over the digital dental arch model. A thin gap 4450 may be formed between tooth model 4410 and tooth model 4420. A wedge 4460, shown in Figure 25c, can then be made using CNC based manufacturing technique similar to other manufacturable digital components. The wedge 4470 can be inserted into the gap 4450 to complete the digital tooth arch model. The wedge making and insertion can take into account of the movement of the tooth models 4410, 4420 during the orthodontic treatment. As shown Figure 25d, the wedge 4480 may be made to be slightly sheared. The wedge 4490 inserted between the tooth models 4410, 4420 can therefore induce a relative movement between the tooth models 4410, 4420. In general the relative movement can include translational and directional adjustment in different degrees of freedoms. The resulted tooth arch model can then be used to made dental aligners.

[00138] Figures 26a, 26b, 26c and 26d illustrate examples of the features 4515, 4525, 4535, 4545 in the aligner components 4510, 4520, 4530, 4540 that may allow the aligner components 4510, 4520, 4530, 4540 to be attached to each other to form a whole or part of a physical aligner. Figure 26a shows a feature 4515 having a cubic base for an aligner component 4510. Figure 26b shows a feature 4525 having a star-shaped base for an aligner component 4520. The star-shaped base defines unique orientation when aligner component 4520 is assembled with another aligner component. Figures 26c and 26d show features 4535 and 4545 respectively comprising two and three pins in the aligner

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components 4530 and 4540. The two pins ensure uniquely defined orientation when aligner component 4530 is assembled with another aligner component. Similarly, the three pins in feature 4545 ensure unique configuration when aligner component 4540 is assembled with another aligner component.

[00139] The aligner components 4310, 4320 are manufactured in Step 4160 using CNC based manufacturing techniques. The segmented digital aligner components are provided to as CNC objects input to a CNC machine. The aligner components 4310, 4320 are manufactured individually. In the disclosed methods and systems, the precision and yield of the CNC based manufacturing are high because manufacturability has been considered and verified as part of the designs of the aligner components. Common materials for the aligner components include polymers, urethane, epoxy, plastics, plaster, stone, clay, acrylic, metals, wood, paper, ceramics, and porcelain. A mechanism may be required to hold the components in place during the milling process.

[00140] As described in more detail below, the digital dental aligner model can include wrinkle features to be produced on the aligner components and finally formed on the surfaces of the physical dental aligner. The wrinkle features can be pre-designed and simulated to reduce the relaxation of the aligner after repeated use. The wrinkled aligner or aligner components can be fabricated in accordance with the digital dental aligner model.

[00141] The physical aligner model 4600 is assembled in Step 4170 by assembling the aligner components. Figure 27 illustrates one example of how aligner components 4610, 4520, 4530 can be assembled to form a whole or a portion of a physical aligner model 4600. The different aligner components 4610, 4620, 4630 can be attached or plugged into each other at joining features 650 that can be pins, registration slot, a notch, etc.

[00142] The physical aligners can be used in different dental applications such as dental crown, dental bridge, dental retainer, mouth guard and teeth whitening. For aligner fabrication, for example, each stage of the teeth treatment may correspond to a unique physical aligner model. Aligners can be fabricated based on the digital dental arch model as the teeth movement progresses during the treatment. At each stage of the treatment, the desirable teeth positions for the next stage are calculated. A physical aligner model is fabricated using the process described above for modifying teeth positions in Step 4180.

[00143] The methods and system for forming an aligner described herein may allow variable shape and thickness in the aligner designs as compared to other systems.

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Moreover, the disclosed methods and system provides a wider range of aligner material selections. Analyses over aligner shape can be conducted done to ensure the optimal shape of aligner to be produced to achieve the desired movements at each stage of the orthodontic treatment. In addition, aligners having optimized shapes can achieve certain movements that the prior art cannot achieve. Thus, aligners can be made thinner and more cosmetic, allowing more comfort in wearing. The manufacturing process may be easier and more consistent.

[00144] Aligner components can also be labeled with unique identification marks, and be assembled and detached in predetermined sequences. The assembling and detachment can also be readily automated (for example by a robotic arm under the control of a computer) in accordance with the predetermined sequences.

[00145] The aligner components may also be assembled by pressure forming. The aligner components may be hollow, and have outer surfaces that match the digital aligner components to allow proper union of the aligner components. The aligner components may also be pre-fabricated to interlock (e.g., similar to LEGO™ blocks). The surfaces of the aligner components may include standard registration and attaching features for them to join together. The interlocking aligner components could also be assembled automatically by robotic arms under computer control. The aligner components can be separated and repaired after the assembly. The attaching features between aligner components allow the components to be detached in a sequence. Broken components could be removed, repaired or replaced, followed by re-assembling.

Snap-on Dental Aligners

[00146] In general, Snap-on dental aligners comprise one or more through-holes (or passages) through a wall of the dental aligner so that the dental aligner may be secured to the teeth of a user. For convenience, the snap-on dental aligners described herein may be referred to as aligners (or dental aligners).

[00147] Generally, the snap-on dental aligners described herein also comprise one or more through-holes for a connector to pass through, to secure the aligner to a subject's teeth, to help maintain the shape of the aligner, or to direct force against a subject's teeth. Various types of through-holes and connectors may be used. In addition to serving as attachment sites, through-holes may also allow the gums to "breath" by providing passages in the aligner though which gases and fluids can be exchanged.

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Through-holes

[00148] Any appropriate dental aligner may be used as a snap-on dental aligner, having one or more through-holes for mating with one or more connectors. Furthermore, the through-hole may be any appropriate through-hole that is adequate to secure the aligner to a subject's teeth, or to help maintain the shape of the aligner, or to direct forces to realign a subject's teeth. Through-holes may form passages extending the thickness of a dental aligner (e.g., from the inner surface of the dental aligner to the outer surface of the dental aligner). Through-holes may be engaged by a connector. A through-hole may also be referred to as a "window" or a passage. Thus, the through-hole forms a window or passage through the aligner, potentially providing access to the teeth and gingiva.

[00149] Any number of through-holes may be formed in an individual aligner. One or more through-holes may be used. In some variations, only one through-hole is used. In some variations, one through-hole is used per tooth covered by the aligner. The number of through-holes may be chosen or selected based on individual subject criterion (e.g., based on the force to be applied to move the teeth, the shape of the subject's teeth, and/or the arrangement of the subject's teeth). An orthodontist or other health profession may select the number of holes to be formed on an individual aligner. The number of holes may also depend upon the material used to form the aligner. More through-holes may be formed when the material is more likely to deform with use or age. In some variations, more than one through-hole may be formed for individual teeth covered by the aligner. For example, a pair of symmetrically-located through-holes may be formed on the aligner.

[00150] The number of through-holes may correspond to the number of connectors. Generally, for each connector to be attached to a subject's tooth, there is a corresponding through-hole on the subject-specific aligner. However, an aligner may have more through-holes than connectors. Thus, there may be redundant through-holes, in the event that a connector becomes disengaged, removed, or never used.

[00151] In general, through-holes may be located anywhere on the aligner. For example, through-holes may be located on the bottom region (on either or both sides of a tooth), or may be located on the sides of the aligner, or may be located on the tip region of the aligner. The location may be chosen so that the aligner applies a desired force to the subject's teeth. Thus, through-holes may be more closely located together when the aligner is more likely to slide or become dislodged because of the forces between the teeth and the

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aligner. Similarly, it may be beneficial to have through-holes near the ends of an aligner to aid in securing the aligner to the teeth.

[00152] Thorough-holes may be of any configuration to effectively engage connectors attached to the teeth. Thus, through-holes may have a diameter that is complementary to the shape and size of the connectors to which the aligner with mate. In some variations, the through-holes are sized differently from the connectors for ease of use. For example, all, or a portion, of a through-hole may be larger in diameter than the diameter of a connector so that the connector can easily engage the through-hole. The through-hole may have a constant diameter, or a variable diameter. In one variation, the through-hole may have a wide opening that tapers in to a smaller diameter as it passes from the inner surface to the outer surface of the aligner. In one variation, the through-hole has a larger diameter within the middle of the passage or at the outer portion of the passage. A thorough-hole may also have a smaller diameter than a connector. In some variations, when the connector engages a through-hole having a smaller diameter, the through-hole may expand, and help hold the connector engaged.

[00153] The through-hole may have any appropriate profile. For example, the cross-sectional profile (transecting between the inner and outer surfaces of the device), may be round, polygonal (e.g., triangular, square, asymmetric, etc.). In one variation, the through-hole is a slit cut through the aligner which remains closed until a connector is inserted. The longitudinal profile of the through-hole may also be any appropriate shape. For example, the longitudinal profile may conform to the longitudinal shape of the connector. Thus, if the connector has a knobbed region, the longitudinal profile may include a cavity into which the knob may fit.

[00154] The through-hole may also be formed so as to secure the connector. Thus, the through-hole may be (or may have a region that is) slightly smaller than the profile of the connector. In some variations, the through-hole has a longitudinal profile that is jagged, or edged. For example, the through-hole may have an accordion-type profile. Such edges may mate with edges on the connector. The through-hole may have directional surfaces, such as edges which point in a direction (e.g., from the inner surface to the outer surface) so that a connector may easily engage a through-hole, but less easily withdraw. In one variation, the through-hole includes a rim having a narrower diameter than a region of the connector. Thus, when the connector must "snap" past the rim within the through-hole, and may be locked into position.

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[00155] An additional locking or securing device may be accommodated within the through-hole. For example, the through-hole may accommodate a pin, washer, gasket, or other locking or securing device for holding the connector within the through-hole.

[00156] The through-hole may also be reinforced. Thus, the through-hole may include additional structures to prevent damage to the through-hole, aligner or connector. For example, the through-hole may include a rim or edge where it exits the outer surface of the aligner.

[00157] As described, the through-hole may be any appropriate size. For example, the through-hole may have a diameter that is between 0.005 and 1 mm, or between 0.01 mm and 0.5 mm or between 0.1 mm and 1 mm, or between .001 mm and 0.1 mm.

[00158] Figure 1 illustrates additional profiles of through-holes that may be used. Fig. 1A shows a cross-section of a through-hole having a circular profile with a uniform diameter through the length of the through-hole. In all of Figures 1A-1F, the inner surface 101 is shown at the top of the profile and the outer surface 103 is shown at the bottom of the profile. Generally, a connector attached to a tooth enters the through-hole from the inner surface (closest to the teeth). Figure 1B shows a through-hole that with a large opening at the inner surface 101, which gradually tapers into a narrower opening. Figure 1C shows a through-hole with a smaller opening on the inner surface 101 that gradually enlarges to a larger opening on the outer surface 103. In Figure 1D, the through-hole also narrows from a large opening on the inner surface 101 to a small opening in a non-linear fashion. Alternatively, the through-hole may also expand from a narrow opening to a larger opening in a non-linear way (not shown). In any of embodiment of the through-hole, the change from the outer or inner surface may be gradual, rather than sharp. For example, the edges may be rounded or smoothed, which may prevent irritation, and may aid in engaging the connector.

[00159] Figure 1E shows one variation of a locking through-hole, having multiple ridges 107 which may engage one or more surfaces of the connector to inhibit withdrawal of the connector once it has engaged the through-hole. In Fig. 1E, the ridges 107 are directed from the inner surface 101 towards the outer surface 103. Although four ridges are shown in Figure 1E, any number of ridges (include a single ridge) of any shape or size may be used. Furthermore, "spikes" or pins may also be used, rather than symmetric ridges (or asymmetric ridges). Figure 1F shows a through-hole reinforced with a lip or rim 110, as described above.

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[00160] The through-hole may also comprise additional materials. For example, the through-hole may be coated or lined in order to enhance the interaction (e.g., contact) with a connector, or to provide therapeutic benefit. In one variation, the through-hole is reinforced with another material (e.g., a stiff material such as a polymer, metal, ceramic, or some combination thereof). In one variation, the through-hole is coated or filled with a material to help secure the connector. For example, the through-hole may be coated with an adhesive. In one variation, the through-hole is filled with a material to maintain the shape of the through-hole until the connector is engaged with the through-hole. For example, the through-hole may have a "plug" that is pushed from the through-hole by the connector when the connector engages the through-hole. In some variations, the through-hole is coated with a lubricant.

[00161] Although Figure 1 shows through-holes having profiles that are perpendicular to the inner and outer surfaces, the through-hole may be present in any appropriate angle to the inner and/or outer surfaces. For example, the through-hole may be angled so that the exit from the outer side of the aligner is offset from the entrance into the through-hole on the inner side of the aligner. Angled through-holes may also help secure the connector within the through-hole, and may further facilitate the application of force against the teeth by the aligner. In one variation, the through-hole is angled between about 30° and 60°. In one variation, the through-hole is angled approximately 45°.

[00162] The through-holes may also be configured to apply force to the connectors, and therefore to a tooth or teeth. For example, the walls of the through-hole may provide asymmetric force against the connector, which may in turn push or pull the tooth that the connector is attached to.

[00163] Different through-holes on the same aligner may be different shapes, sizes and/or orientations. The different shapes and sizes of the through-holes may also affect the strength of the attachment of the aligner to the teeth by the connector, as well as the force applied by the connector to a tooth. For example, through-holes located at the ends of the aligner may be configured to secure the aligner to the teeth, while through-holes located elsewhere on the aligner may be configured to help the aligner apply force to the teeth, or to a single tooth.

Connectors

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[00164] Any appropriate connector may be used for connecting a snap-on aligner to a subject's teeth. Connectors are generally attached to the teeth of a subject so that the aligner may be secured to the subject's teeth by engaging the through-holes on the aligner. Typical connectors may be pre-formed (e.g., shaped before being secured to the subject's teeth) or formed at the time that they are connected to the subject. Although all of the examples described below concern connectors that are attached to the subject's teeth, connectors may be attached to any appropriate region of the subject's oral cavity, including the subject's gingiva.

[00165] A connector may be any appropriate shape for engaging with through-holes in the aligner. For example, the connector may be a post, a button, a bump, a nodule, a node, a protrusion, or the like. The connector may be shaped or sized to complement or conform to the through-holes as described above. The connector may be ridged, tubular, bulbous, or irregularly shaped. In some variations, the connector is asymmetrically shaped. In some variations, the connector comprises an orientation, so that it engages the through-hole in a particular orientation, which may prevent undesirable movement (e.g., loosening or shifting) of the connector within the through-hole. The connector may comprise any appropriate profile. For example, the cross-sectional profile may be round, polygonal (e.g., triangular, square, asymmetric, etc.), etc.

[00166] Figure 2 illustrates profiles of different connectors. In Figure 2A, the connector profile is a peg or box shape. In Figures 2A-2E the connector is shown attached to a subject's tooth 201. Figure 2B shows a profile of a connector that is a smooth "bump" or node. The connector generally projects from the surface of the tooth, and may project far enough so that it extends beyond the outer surface of the aligner (or is flush with the outer surface of the aligner) when it is engaged with the through-hole of the aligner. In one variation, the connector extends past the outer surface of the aligner so that an edge of the connector rest on the outer edge of the aligner. In one variation, the connector does not extend out of the through-hole.

[00167] Figure 2C shows a connector with a bulbous end (e.g., a button shaped end). The connector protrudes from the tooth on a base that is slightly narrower than the upper portion of the connector. As described for the through-holes, the connectors may also be angled in any appropriate fashion. For example, a connector may project from the surface of a tooth at a 30° angle, a 40° angle, a 45° angle, a 50° angle, a 60° angle, or an angle

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between 30° and 60°. Figure 2D shows a connector that is angled at approximately 45° from the surface of the tooth 201.

[00168] Connectors may also comprise hooks, or other anchors. For example, the sides or the end of a connector may include a hook (or ridge) for securing within the through-hole of the aligner, as shown in Figure 2E. In many instances it may be beneficial to have connectors that do not irritate or harm the subject to which the connectors are attached. Thus, the connector may be blunt (or blunted). In some variations, the end of the connector is blunt.

[00169] Connectors may also comprise additional sites for connection to anchors or to devices that may otherwise assist in moving or applying force to the teeth. For example, an elastic, rubber band, or other tensioning device may attached the connector and/or to another connector or to the aligner. A tensioning device such as an elastic band could be attached to a connector for bicuspid extraction and class II correction, for example. Thus, the tensioning device would provide additional force to move the teeth. In one variation, an anchor may also be applied to a connector after it has passed through the through-hole of the aligner to secure the aligner into position. For example, as gasket (e.g., a rubber band) may also be used as an anchor (or part of an anchor). A rubber band may be linked between two connectors on two different teeth to act both as a tensioning device (applying force to move the teeth) and as an anchor. Any appropriate anchor or tensioning device may be used. In some variations, the dental aligner may include buttons that are part of the aligner but not attached directly to the teeth. These buttons may be used to attach tensioning devices (e.g., rubber bands, etc.) on the same aligner or between an upper and lower aligner.

[00170] A connector may be any appropriate size or diameter for engaging with a though-hole. For example, the connector may have a diameter that is between 0.005 and 1 mm, or between 0.01 mm and 0.5 mm or between 0.1 mm and 1 mm, or between .001 mm and 0.1 mm. Furthermore, any appropriate number of connectors may be used to connect to an aligner, and thus may be secured to (or fixed to) the subject's teeth. For example, the subject may have one, two, or more connectors secured to his or her teeth to engage the through-holes of an aligner.

[00171] Connectors may be positioned on the teeth in any appropriate location or locations to engage an aligner. In some variations, the location of the connectors on the subject's teeth may be determined by an orthodontist or physician. For example, the

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orthodontist may determine how the connectors should be located to best secure the aligner, and/or to best apply force to the teeth. The connectors may be secured to the subject's teeth before or after the through-holes have been formed in the aligner.

[00172] Any appropriate material may be used to form the connector. For example, the connector may comprise a resin, an epoxy, a cement, a polymer, a metal, a ceramic, or any combination thereof. The connector may be formed of a biocompatible material, or a bio-inert material. The connector may also comprise a material which is similar in color and/or texture to a subject's dental enamel. In one variation, the connector is secured to the subject's teeth using the same material that forms the connector itself. For example, the connector may comprise a UV cross-linkable material that may be molded into the shape of a connector and hardened (polymerized) using UV light to form the connector as part of the same step that the connector is attached to the subject's teeth. The connectors may also be attached as part of a separate step. Mechanical or chemical attachments may be used. For example, the connectors may be attached by screws, cements, etc. The shape of the connector may be adapted to help secure the connector to the teeth. For example, the connector may have a rough edge surface for bonding to the surface of a tooth.

[00173] As described above, connectors may be pre-formed, or formed at the time of attachment. In one variation, a template is used to position and form the connectors on the subject's teeth. A template may be similar to an aligner (and may be produced by a similar process, as described in the incorporated references). In one version, the template is a snap-on aligner, having through-holes. The template fits onto the patients teeth, and may include gaps or openings (negative spaces) where the connectors are to be located. The negative spaces may also be shaped like the connectors. A cross-linkable material (e.g., polymer) may be loaded into these negative spaces. The template containing the cross-linkable material may them be treated so that the material in the negative spaces is cured (cross-linked), forming the connectors, and simultaneously, bonding them to the surface of the teeth. For example, the cross-linkable material may comprise a UV cross-linkable polymer.

Making or Manufacturing a Snap-On Aligner

[00174] A snap-on aligner as described herein may be fabricated by making holes in a dental aligner that may correspond to connectors on the subject's teeth. Any appropriate method of fabricating the snap-on aligner (including making the holes) may be used.

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[00175] In general, a guide is used to indicate where on an aligner the through-hole(s) should be positioned. The guide may be created by the orthodontist or doctor to indicate where to position the through-holes and/or connectors. The guide may be a manual guide (e.g., a diagram), or a computerized guide (e.g., a computer or computerized device for storing the locations). The guide may indicate the location based on a relative coordinate system. For example, the guide may indicate position based on fiduciary marks that correspond to positions of the aligner. Thus, the guide may comprise a computer to store the desired positions of the through-holes on the aligner. In some variations, the computer may be used to control the process of making the guide holes as well (e.g., by controlling a hole driller, and/or a positioner). In some variations, the computer may be used to calculate the desired number and/or position of the through-holes or connectors. computer may also be used to assist an orthodontist and/or physician in locating the through-holes and/or connectors. For example, the computer may draw, plot, or calculate the result of different positions of through-holes/connectors on the teeth.

[00176] Figure 3 illustrates an exemplified method of fabricating a snap-on dental aligner. A sheet 310 of aligner-making material is attached to a sheet holder and then lifted up near a heating element. The sheet can be made of uniform distribution of a single material or comprise multiple layers of different materials. After the aligner-making material is heated by a specified time, the sheet holder is pressed on the subject's dental arch model on the base plate. A vacuum pump removes air at the bottom of the base plate to cause the softened aligner making material to relax and fittingly form around the surface the subject's dental arch model. This process of aligner making is referred to as the vacuum forming.

[00177] In one embodiment, the subject's dental arch model includes registration marks that can be copied onto the sheet 310 of aligner-making material during vacuum forming. The copied registration marks 320 are formed on the aligner 350. A digital arch model captures the shape information of the subject's tooth models and the information about the registration marks. The digital arch model further specifies the location of the connectors to be produced on the subject teeth to receive the through-holes. A digital dental aligner model is developed based on the digital arch model for moving the subject's teeth at a particular treatment step. The digital dental aligner model specifies the locations and the sizes of the through-holes 330 in the dental aligner 350 at locations that are in registration with the connectors (e.g. protrusions 530, 540) on the subject's teeth 520.

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[00178] Figure 4 shows a block diagram of a system 400 for fabricating a snap-on dental aligner. An aligner 410 is held to a stage 415. A computer 420 stores the digital aligner model and the information about the through-holes 330 to be made on the aligner 410. A drilling device 430 is mounted on a two-dimensional or three-dimensional positioning system 440. The positioning system 440 first locates the copied registration marks 320 on the sheet 310 under the control of the computer 420. The positioning system 440 defines a coordinate system in reference to the copied registration marks 320. The positional system 440 then moves the drilling device 430 to the intended locations for the through-holes 330 in accordance with the digital aligner model. The through-holes 330 can then be drilled by any appropriate method, including a mechanical drill bit or a high-power laser beam. The sheet 310 of the aligner making material is then cut out along the gingival line 340 to obtain a snap-on aligner 350 that can fit to the subject teeth.

[00179] In another embodiment, the aligner 410 is mounted on a positioner rather than the drilling device 430. The positioner is capable of producing the similar relative movement between the aligner and the drilling device 430. A coordinate system is first developed using the copied registration marks. The aligner 410 is then moved to positions to allow through-holes to be drilled at the intended locations.

[00180] In one aspect, the system 400 described above can a Computer Numerical Controlled (CNC) based manufacturing system. In still another embodiment, aligner components are fabricated by CNC based manufacturing in accordance with a digital dental aligner model. Through-holes are produced also in accordance with the digital dental aligner model. The dental aligner components are subsequently assembled to produce the snap-on dental aligner.

[00181] As mentioned previously, the aligner may be fabricated with the through-holes present in the device (including fabricating by molding , CNC methods, etc.). In addition, since a subject's treatment may be re-evaluated or modified during the course of treatment, the location of the connectors (and/or through holes) may also be modified during the course of treatment.

Using a Snap-On Dental Aligner

[00182] Figure 5 illustrates an example of a process of using a snap-on dental aligner in accordance with the present invention. Dental aligners are designed for each treatment step in step 510. The dental aligner device is fabricated in step 520. The fabrication techniques can include vacuum forming, milling, stereo lithography, laser machining,

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molding, and so on. In accordance with the present invention, through-holes are then made in the dental aligner in the dental aligner in step 530. For example, the through-holes can be drilled with a mechanical drill bit or a laser beam. Connectors are next produced on the subject's teeth to be snapped into (e.g., engaged with) the through-holes in the dental aligner in step 540. For example, the connectors can include a pre-made component that is glued to the subject's teeth by adhesives and/or UV assisted polymerization. The dental aligner having the through-holes is then fittingly placed on the subject's teeth as described in step 550. The connectors on the subject's teeth at locations are in registration with the through-holes in the dental aligner. The dental aligner is then pressed the subject's teeth the snap the connectors into the through-holes in step 560.

[00183] The disclosed snap-on dental aligners may help overcome the above-described aligner relaxation problem. Figure 6 illustrates a side view of a dental aligner 610 that is newly worn on a subject's tooth 620. The aligner is typically in a shell shape, comprises a shell portion, a tip portion, and a bottom portion. The inner surface of the shell portion is to be in contact with the subject's teeth. The dental aligner 610 fits properly at the bottom of the tooth where the gingival separates the tooth from the root. The newly worn aligner 610 can provide proper and effective force for the tooth movement in the orthodontic treatment.

[00184] Figure 7 shows the side view of the aligner 710 that has been worn on the subject's tooth 720 after a period of usage such as a few days or a week. The lower part 715 of the dental aligner 710 is relaxed and opened up, which prevents the dental aligner 710 to exert proper stress on the bottom of the tooth. The dental aligner 710 thus can no longer produce effective and accurate tooth movement. Different parts of the dental aligner can relax similarly to different extent.

[00185] Figure 8 illustrates the top view of a conventional dental aligner 800 that is newly worn on a subject's tooth 810. After it is worn for a period of time, the same dental aligner 820 is relaxed and loose. It can no longer apply effective forces to the tooth 810 to render tooth movement required by the treatment.

[00186] Figure 9 illustrates a cross-sectional view of a snap-on dental aligner 910. The snap-on dental aligner 910 includes a shell portion 911, a tip portion 912, and a bottom portion 913. The snap-on dental aligner 910 also includes through-holes 935 and 945. Connectors 930 and 940 are produced on the subject's tooth 920 in registration with the through-holes 935 and 945. The connectors 930 and 940 can be formed by pre-made

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components glued to the subject's tooth 920 by adhesives and/or UV assisted polymerization, for example. The connectors 930 and 940 are shown as posts.

[00187] One or more connectors 930 and 940 can be fixed of a subject's tooth. Connectors 930 and 940 can be fixed to any or more than one of the shell portion 911, the tip portion 912, and the bottom portion 913. For example, connectors 930 and 940 and through-holes 935 and 945 can be produced near the bottom portion 913 to prevent the relaxation or the opening up of the dental aligner 910 near the gingival line.

[00188] The connectors 930 and 940 can be snapped into the through-holes 935 and 945 when the dental aligner 910 is pressed against the tooth 920. The dental aligner 910 is pulled toward the tooth 920 by the snap-on mechanism to come to contact with the subject's tooth 920.

Non-Uniform Dental Aligners

[00189] Dental aligners may also be made having multiple layers (e.g., 2 or more layers). Multiple layers may allow the aligner to resist wear, and to be more comfortably (and accurately) worn by a user. Each layer may comprise a material (or a region of material) having different properties, (e.g., such as stiffness, elasticity, hardness, surface friction, hydrophobicity, etc.). Examples of aligners having such different layers are described below.

[00190] Figure 10 illustrates a process for providing accurate orthodontic treatment for a patient and is one example of how a non-uniform or multi-layer dental appliance may be formed. In this process, the initial configurations of the patient's teeth are measured in step 1010. The initial configurations of the patient's teeth can include the positions and the orientations of the patient's teeth before the treatment begins. The measurement can include making dental impressions of the patient's upper and/or lower arches. The surface locations of the dental impressions are then measured to determine the positions and the orientations of the patient's teeth. Details of conducting measurement on dental impressions are disclosed in the above referenced U.S. Patent Application Serial No. 11/013,159, titled "Producing a base for accurately receiving dental tooth models" by Huafeng Wen, filed 12/14/2004 and U.S. Patent Application Serial No. 11/013,157, titled "Producing accurate base for dental arch model" by Huafeng Wen, filed 12/14/2004. Any appropriate method may be used to fabricate a non-uniform or multi-layered aligner, including those described in the examples herein.

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[00191] An orthodontist determines the final configuration for the patient's teeth in step 120. With or without the assistance of computer software, the orthodontist designs a treatment plan that specifies movement paths for the patient's teeth in step 1030. The teeth movement should avoid teeth collision into each other. The movement paths are divided into a plurality of successive treatment steps in step 1040. For example, there could be ten to forty steps.

[00192] Multi-layer or non-uniform dental aligners can be fabricated with the assistance of physical tooth models. The physical tooth models can be produced in step 1050 and may include registration features for them to be assembled together or to a dental base. The physical dental arch model can be formed on a dental base having receiving features to receive the physical tooth models in step 1060. The physical tooth models of the patient's teeth can be fabricated and used for one or more treatment steps. The dental base can include a plurality of receiving features for receiving the tooth models. The tooth models can comprise registration features compatible with the receiving features. The dental base can include different configurations each corresponding to one or more treatment steps. Dental aligners can be conveniently and inexpensively fabricated using the physical arch models at different treatment steps. The shared use of physical tooth models and the dental base between treatment steps significantly reduces the treatment time and cost. Various steps of the disclosed treatment system and methods are disclosed in the above referenced and commonly assigned U.S. Patent Applications.

[00193] Physical tooth models can be fabricated before the first treatment step or produced again in any of the subsequent steps if any of the tooth models are worn or damaged. A plurality of tooth models can also be fabricated at once to save set-up time and handling cost. In one example, the physical tooth models can be molded using the negative impression in a casting chamber. The casting chamber can be filled with a malleable casting material. The casting chamber can be sealed. The casting material is solidified with the assistance of heating, pressure, and/or UV irradiation. A physical arch model of the patient's arch can then be obtained by removing the solidified casting material. The physical arch model can then be separated into a plurality of tooth models. The one or more reference marks can be simultaneously molded on the physical arch model such that the surface points on the physical arch model can be accurately translated back to the original coordinates for the negative arch impression. Details of molding physical arch models are disclosed in the above referenced and commonly assigned U.S. Patent Application Serial

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No. 11/013,160, titled "System and methods for casting physical tooth model" by Huafeng Wen, filed 12/14/2004 and U.S. Patent Application Serial No. 10/979,823, titled "Method and apparatus for manufacturing and constructing a physical dental arch model" by Huafeng Wen, filed 11/2/2004.

[00194] The physical tooth model 1200 shown in Figure 11 can include a tooth model body 1220 and one or more registration features 1210. The registration features can include a pin, a protrusion, a stud, a socket, a slot, a hole, and other features that can be attached to the receiving features on the dental base 1300 as shown in Figure 12. The registration features can be simultaneously produced in the molding process by molding them into the malleable casting materials. For examples, pins can be inserted into the malleable casting material before it is solidified. Alternatively, the registration features 1210 can be produced in the physical tooth model 1200 after the making of the physical arch model and before the physical arch model is separated into the physical tooth models 1200. For example, the registration features 1210 can include sockets that can be drilled by a drilling system on the physical arch model. Details of obtaining a physical dental arch model having registration features and 3D reference positions are disclosed in above referenced US Patent Application titled "Producing a base for accurately receiving dental tooth models" by Huafeng Wen, filed 12/14/2004.

[00195] Figure 12 is a top view of a dental base 1300 comprising a plurality of sockets 1310, 1320 for receiving the studs of a plurality of tooth models. The positions of the sockets 1310, 1320 are determined by either initial tooth positions in a patient's arch or the tooth positions during the orthodontic treatment process. The base 1300 can be in the form of a plate as shown in Figure 12, comprising a plurality of pairs of sockets 1310, 1320. Each pair of sockets 1310, 1320 is adapted to receive two pins associated with a physical tooth model. Each pair of sockets includes a socket 1310 on the inside of the tooth arch model and a socket 1320 on the outside of the tooth arch model.

[00196] The sockets 1310, 1320 on the dental base 1300 are complimentary to and compatible with the registration features 1210 on the tooth models 1200. The sockets can be drilled by a device under the control of a computer. The locations of the sockets can be translated to the reference marks in the dental impression. In general, the receiving features and the registration features can include one or more of pins, protrusions, studs, sockets, slots, and holes. The physical tooth models 1200 are attached to the dental base 1300 to form a dental arch model in step 1060. The dental arch model can be a model for a whole

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upper arch or a lower arch of the patient, or a portion of the upper or lower arch of the patient.

[00197] A multi-layer dental aligner can be fabricated by vacuum forming or thermal forming the aligner. The multi-layer dental aligner can comprise two or more layers that are formed in two or more steps. The different layers can be made of different dental-aligner materials of different properties. For example, the outer layer can have higher hardness than the inner layer(s) to provide durability against chewing, biting, etc. during usage. The outer layer can also comprise a material less sensitive to elevated temperature such that it will not deform or relax when the patient drinks hot fluids and eats hot food. The outer layer can have substantially the same color as and similar texture to the patient's teeth to make it more aesthetically appealing.

[00198] The outer layer may be softer than the inner layer(s). The softer outer layer can help the fitting between the teeth of the patient's upper arch and the lower arch. For example, the outer layer may comprise a biocompatible material (e.g., polymer such as polyfluorocarbons such as the various PTFEs and expanded PTFE, polypropylene, polyethylene, polyoxymethylene, polycarbonate, polyesters including polyamides such as the Nylons, polyphenylene oxide, and polyurethane or elastomeric polymers including Silicones, natural rubber, butadiene-styrene rubber, carboxylic butadiene-styrene, butadiene-acrylonitrile rubber, carboxylic butadiene-acrylonitrile rubber, chlorobutadiene rubber, polybutadiene rubber, silicone rubbers, and acrylate rubbers, perhaps vulcanized, and other elastomeric materials). Other soft materials may include foamed polymers (e.g., foamed polyurethane, foamed polystyrene, foamed polypropylene, etc.).

[00199] The inner layer may have a different color from the outer layer. The inner layer(s) can be softer than the outer layer to make the multi-layer dental aligner more comfortable for the patient to wear. The softer inner layer may also allow wider contact area to the patient's teeth, making it easier to fit to the patient's teeth. The inner layer may have different surface properties than the outer layer(s). For example, the inner layer may be textured, or may comprise a material that more readily sticks to structures in the oral cavity (e.g., the teeth). The fit of a softer inner layer may also relax tolerance on the precision of the aligner manufacturing.

[00200] The deformation of the dental aligners with use can theoretically be overcome by using a single layer of a harder dental aligner material. But a harder aligner is usually less comfortable for a patient to wear. The harder aligner also provides less contact

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areas to the patient's teeth. The combination of different dental aligner layers of different properties in the disclosed system can overcome the aligner deformation problem without creating discomfort to the patient.

[00201] Any appropriate biocompatible (e.g., non-toxic, etc.) material may be used for the hard material comprising an aligner, including polymers (e.g., polyfluorocarbons, polypropylene, polyethylene, polyoxymethylene, polycarbonate, polyesters, and polyurethanes, etc.), metals, ceramics, and composites of any of these. Of course "hardness" and "softness" of the different layers of an aligner are relative terms, which may reflect comparative measure of the surface hardness, structural hardness, elasticity and/or stiffness of a material. Furthermore, relatively hard and relatively soft versions of the same material may be used as different layers (or different regions of the same layer) in the aligners described herein.

[00202] A non-uniform dental aligner may comprise one or more layers of polymeric material in which regions of a polymer layer are continuous in structure with adjoining regions (compared to discontinuous regions or interfaces as may be formed by bonding two distinct films to one another) but differ in properties from one another. The different areas or regions have different physical properties as enumerated above. For example, the outer section can have higher hardness than the inner section to provide durability against chewing, biting, etc. during usage. The outer section can also comprise a material less sensitive to elevated temperature such that it will not deform or relax when the patient drinks hot fluids and eats hot food. Alternatively, the outer sections can be softer than inner section to provide better fitting between the teeth of the patient's upper arch and lower arches. The outer section can have substantially the same color as and similar texture to the patient's teeth to make it more aesthetically appealing.

[00203] The inner section can be softer than the outer section to make the non-uniform dental aligner more comfortable for the patient to wear. The softer inner sections may provide flexibility to the dental aligner and allow better contact to the patient's teeth, making it easier to fit to the patient's teeth. Furthermore, the easier fitting enabled by the flexibility of softer inner sections relaxes tolerance on the precision of the aligner manufacturing.

[00204] A first non-uniform dental aligner is formed in step 1070 as shown in Figure 10. The patient wears the first non-uniform dental aligner to move teeth into target configurations at a treatment step in step 1080. A second non-uniform dental aligner is

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formed in step 1090 in a similar process. The patient wears the second non-uniform dental aligner to move teeth into target configurations at the next treatment step in step 1095. The patient can wear one or a plurality of the non-uniform dental aligners at each treatment step. Each of the aligners can be worn for a period of time such as a few hours to a few weeks. The treatment process is completed by iterating through the treatment steps to move the patient's teeth to the final configuration. The teeth movement caused by the non-uniform dental aligner may not be as designed by the treatment plan. The teeth movement caused by one or more non-uniform aligners can be measured. The measurement can serve as a feedback to the adjustment of the treatment plan.

[00205] A first dental aligner layer of a multi-layer dental aligner is formed as shown in Figure 13. A sheet 1410 of a first aligner-making material can be attached to a sheet holder and then lifted up near a heating element. After the sheet 1410 is heated for a specified time, the sheet holder is pressed or held against a patient's physical tooth models on the dental base 1300. In this case, the upper and lower arch models are both present so that the upper and lower aligners may be formed simultaneously. A vacuum pump removes air at the bottom of the dental base 1300 through suction holes in the dental base 1300. The air suction causes the softened first aligner-making material to conform to the physical tooth models. The sheet 1410 thus fittingly forms around the surface the dental arch model around the gingival lines 1420 of the physical tooth models. The sheet 1410 is then cooled and hardened, and holes are formed through sheet 1410.

[00206] A second dental aligner layer of a multi-layer dental aligner may be formed in step 1075 as illustrated in Figure 14. A sheet 1510 of a second aligner-making material can be attached to a sheet holder and then lifted up near a heating element. After the sheet 1510 is heated sufficiently, the sheet holder is held on the sheet 1410 over the patient's physical tooth models on the dental base 1300. A vacuum pump removes air at the bottom of the dental base 1300 and through the holes formed in sheet 1410 to cause the softened second aligner-making material to conform to the surface of sheet 1410.

[00207] After the sheet 1510 is cooled and hardened, the sheet 1410 and the sheet 1510 can then be cut along gingival lines 1420 to form a multi-layer dental aligner layer 1530. Figure 15 is a top view of a multi-layer dental aligner 1610 comprising a first aligner layer 1620 and a second aligner layer 1630. The individual arch-shaped aligners may be separated from one another. In some variations, the second layer is formed by a different method than the first layer. For example, the second layer maybe formed by extruding,

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dipping. coating, depositing, etc. onto the pre-formed first layer. In some variations, the first and second layer may be combined prior to forming over the tooth model and then (together) formed over the tooth model as described.

[00208] The different layers (e.g., first and second layers) may be attached to each other directly, or an adhesive may be used to connect the different layers.

[00209] In another arrangement, each of the dental aligner layers can be separately cut. The sheet 1410 can be cut along the gingival lines 1420 after the sheet 1410 conforms to the physical tooth models to obtain a first aligner layer 1430. The sheet 1510 is then heated and held against the first aligner layer 1430 over the physical tooth models. After cool down, the sheet 1510 can then be cut along gingival lines 1420 to form a multi-layer dental aligner 1610 comprising the first aligner layer 1620 and the second aligner layer 1630.

[00210] In another arrangement, two or more polymer sheets may be laminated to one another to form a single sheet that is heated and vacuum-formed over the arch models to provide multi-layer dental aligners.

[00211] Figure 16 is a cross-sectional view of a multi-layer dental aligner 1700 worn on a patient's tooth 1710. The multi-layer dental aligner 1700 comprises an inner aligner layer 1720 in contact with the tooth 1710 and an outer aligner layer 1730. The outer aligner layer 1730 can provide strength and durability, which helps to prevent deformation and relaxation of the aligner especially along the gingival lines. The inner layer can be made of softer material that enables better contact with the patient tooth 1710. The multilayer structure of the multi-layer dental aligner 1700 can therefore improve aligner's performance and extend usage time. Manufacturing robustness and aligner costs are also reduced.

[00212] The different dental-aligner layers in the multi-layer dental aligner 1700 can also comprise the same material. That is, rather than forming a dental aligner by a thick layer of the same aligner-making material, the aligner is formed by a plurality of thinner layers of aligner-making material using vacuum forming. The thinner layers can be more easily conformed to the physical tooth models than a single thick layer.

[00213] Further, a wider array of polymers may be utilized where thinner layers are used to form an appliance. Polymers of disparate properties may delaminate from one another where thicker films are used. Thinner films allow more intimate contact between polymer sheets and therefore help bond the films to one another.

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[00214] A dental aligner may also be formed so that it has sections or portions of different properties. The non-uniform dental aligner 1710 of Figure 16 is formed from a polymer sheet having sections of different properties. The different sections can be formed using different thermal profiles in the vacuum forming process, for instance. Some sections of the non-uniform dental aligner 1710 can be heated at higher temperature and/or for a longer period of time than e.g. section 1720. A temperature distribution for the polymer sheet can be designed using software on a computer to produce desired distribution of properties. Alternatively or additionally, the different sections can be formed through a different pressure profiles generated by vacuum suction. The size and density of holes in the dental base can be fabricated to achieve a pressure distribution such that the polymer sheet of aligner making material can be subjected to different degrees of holding force during vacuum forming.

[00215] Figure 17 is a cross-sectional view of a non-uniform dental aligner 1800 worn on a patient's tooth 1810. The non-uniform dental aligner 1800 can comprise inner sections 1820 and outer sections 1830. The inner sections 1820 and the outer sections 1830 are characterized as having different values of one or more physical properties. For example, they can have different compressional, bending, or torsional elastic constants. They may also have during thermal properties.

[00216] In one arrangement, the outer sections 1830 can provide strength and durability to sustain chewing and biting. The inner sections can be made of softer material that enables better contact with the patient tooth 1810 and prevents deformation and relaxation of the aligner especially along the gingival lines. The non-uniform dental aligner 1800 therefore can improve aligner's performance and extend usage time. Manufacturing robustness and aligner costs can also be reduced.

[00217] Particular examples of materials for dental aligners include polymers of acrylic, methacrylic, acrylate, methacrylate, carbonate, urethane, urea, epoxy, and other polymeric materials. The material selections of the inner and outer aligner layers or the different sections can include different materials or the same material family but different compositions (e.g. different degrees of polymerizations). The aligner materials may possess the following general properties: the ease to be vacuum-formed or molded, the capability to be extruded into films or filament, enough hardness to prevent breakage, flexibility, relatively high melting temperature to stand mild heat, strong enough to resist deformation, pliability, and food-grade that is safe for oral use. Preferably, the material is transparent or

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close to the colors of the patient's teeth. Other common materials available for the aligner making include those already described, including polymers, plaster, stone, clay, metals, wood, paper, ceramics, and porcelain.

[00218] The aligner-making materials can also include porous materials to allow air and liquid to pass through to reduce bacteria growth and odor in the patient's mouth. Passages or channels may also be included in the aligner (e.g., formed or later cut or drilled). As described further below, the surface or structure of the multi-layer dental aligners can also be wrinkled to further improve durability and reduce the deformation and relaxation over usage. Details of fabricating dental aligners of different properties in various arrangements are also disclosed in the above referenced U.S. Patent Application Serial No. 10/979,497, titled "Method and apparatus for manufacturing and constructing a dental aligner" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application No. 11/074,301, titled "Dental aligner for providing accurate dental treatment" by Liu et al, filed 3/7/2005, U.S. Patent Application No. 11/074,297, titled "Producing wrinkled dental aligner for dental treatment" by Liu et al, filed 3/7/2005, U.S. Patent Application No. 11/074,300, titled "Fluid permeable dental aligner" by Huafeng Wen, filed 3/7/2005, and U.S. Patent Application Serial No. 11/074,298, titled "Disposable dental aligner by Huafeng Wen, filed 3/7/2005.

[00219] The patient can wear one or a plurality of the multi-layer dental aligners at a treatment step in step 1080 of Figure 10. Each of the aligners can be worn for a period of time such as a few hours to a few weeks. After a treatment step is completed, one or more multi-layer or non-uniform dental aligners can be produced for the next treatment step in step 1090 for the patient to wear in step 1095. The teeth movement caused by the multi-layer dental aligner may not be as designed by the treatment plan. The teeth movement caused by one or more multi-layer or non-uniform aligners can be measured. The measurement can serve as a feedback to the adjustment of the treatment plan.

[00220] Properties that may differ in regions of an appliance include color, texture, flexural strength, tensile modulus, flexural modulus, hardness, thermal conductivity, heat capacity, compression modulus, and toughness. Regions differ from one another by one or more of the properties listed above.

[00221] For instance, a first portion of an appliance that contacts or is near the gum may have a lower flexural strength than does a second portion of an appliance in contact with a tooth. The lower flexural strength permits the first portion to conform better to the

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gum, providing a more comfortable appliance. Similarly, the flexural modulus of a portion of the appliance contacting or near the gum may be lower than the flexural modulus of another portion of the appliance contacting the tooth.

[00222] The thermal conductivity of the outer portion of an appliance may be lower than the thermal conductivity of an inner portion. The lower thermal conductivity of the outer polymeric material insulates the tooth from temperatures that may aggravate teeth and nerves that are already sensitized by tooth movement. Similarly, a material on the outer surface of an appliance may have a higher heat capacity than a polymer on the inner surface so that the outer surface absorbs heat without elevating the temperature to an uncomfortable level.

[00223] Compression modulus may differ in regions of an appliance. For instance, regions of an appliance subjected to tooth grinding forces or forces imparted by a clenched jaw may have a lower compression modulus than e.g. portions along a tooth sidewall to allow the polymer to yield somewhat to aid in comfort.

[00224] Color and texture of the appliance may be set to enhance comfort and/or appearance. Color may differ in different sections of an appliance. Portions of an appliance that contact gingival tissue may be pinkish, whereas portions of the appliance that contact the tooth may be whitish. Likewise, texture may differ to better match gingival tissue and teeth in various regions of the appliance.

[00225] The disclosed systems, devices, and method may include one or more of the following advantages. The disclosed system and methods may provide durable dental aligners for moving patient's teeth. The dental aligners can be formed of a plurality of layers with a hard outer layer and one or more relatively softer inner layers. A harder outer (or inner) layer may assure that the dental aligner sustains the mechanical and thermal impacts during the dental aligner's usage. The dental aligners may avoid the deforming and relaxation problems in the current dental aligning devices, and can maintain corrective force to the teeth movement during the intended treatment step.

[00226] Another advantage of a disclosed system is that the dental aligners can be more comfortable for the patient to wear over teeth. The dental aligners can include a relatively softer inner layer in contact with the patient's teeth. The softer inner layer assures large contact areas for transmitting forces from the aligners to patient's teeth. The softer inner layer also provides wider tolerance in the aligner manufacturing because the fitting of

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the aligners on the patient's teeth are less sensitive to the exact shapes of the outer layer of the dental aligner. Manufacturing and rework costs are therefore reduced.

[00227] The disclosed system and methods may provide durable dental aligners for moving patient's teeth. The dental aligners can include a layer or region of non-uniformly distributed aligner-making material. The aligner-making material can be harder in the contact areas between the patient's teeth in upper arch and the teeth in the lower arch, which assures the non-uniform dental aligner to sustain the mechanical and thermal impact during the non-uniform dental aligner's usage such as chewing, biting, etc.

[00228] The aligner-making material in certain sections of the aligner layer may be softer in some areas to allow flexibility and better contact to the patient's teeth. A softer and more elastic material may allow the non-uniform dental aligner to be more tightly wrapped around the gingival lines of the patient's teeth. The deformation and relaxation problems in the current dental aligning devices can be prevented. The non-uniform dental aligner can thus maintain corrective force to the teeth movement during the intended treatment step. The softer areas of the aligner-making material assure larger contact areas for transmitting forces by the non-uniform aligners to patient's teeth.

[00229] The non-uniform dental aligner may also provide wider tolerance in the aligner manufacturing because of the built-in flexibility in the non-uniform dental aligner. The fitting of the non-uniform dental aligner on the patient's teeth may be less sensitive to the exact shapes of the dental aligner. Manufacturing and rework costs are therefore reduced. The non-uniform dental aligner may also be more comfortable for the patient to wear because it is more easily fit to the patient's teeth.

[00230] The appliances and methods herein are not those disclosed in U.S. Pat. No. 6,183,248 and 6,524,101, which patents are incorporated by reference in their entirety as if put forth in full below.

[00231] In addition to aligners having different layers, the aligners described herein may also comprise a single layer that has regions of different material properties. For example, the material (e.g.,. the polymer) forming an aligner may be treated differently (by heat, light, chemical treatment, etc.). For example, the inner region of the aligner may be heat treated to further polymerize the aligner material, resulting in a harder inner surface. In another variation, the inner surface of the aligner is treated so that it has a surface that is roughened compared to the outer surface.

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Fluid Permeable Aligners

[00232] As described briefly above, an appliance may be fluid permeable. For example, removal dental aligners may be fabricated using a fluid-permeable material to allow fluid to communicate between the outer surface and the inner surface of the dental aligner, or a removable dental aligner may be treated to make it fluid permeable. Thus, a fluid-permeable appliance may comprises pores or micro-channels to allow air and liquid to permeate through to the patient's teeth, which suppresses the growth of the VSC producing bacteria in the patient's mount and improves the patient's oral hygiene. Air trapped in the dental aligner can also be circulated out continuously, which also helps to suppress the unnatural growth of anaerobic bacteria and associated halitosis. Oxygenated saliva liquid passing through the permeable material to the cervical line of the patient's teeth may reduce the amount of bacterial VSCs, which reduces the risks for halitosis.

[00233] Fluid-permeable appliances may be permeable to any fluid (e.g., liquids and gas, particularly water or saliva). The pores may correspond to channels, passages or openings in the appliances. As described further below, any appropriate size pore (or range of sizes) may be used. In some variations, only a region of the appliance is fluid permeable.

[00234] Figure 18 illustrates a process for producing a dental aligner made of a fluid permeable material. Although Fig. 18 describes one method of forming a fluid-permeable dental aligner, any appropriate method may be used. In an orthodontic treatment, an initial configuration of the patient's arch is first determined in step 2810. The patient's arch can include one or more teeth in the upper jaw and lower jaw. The configuration includes positions and orientations of the patient's teeth. The initial configuration can be obtained by first producing a negative impression of the patient's arch and then scanning the surfaces of the negative impression by 3D positional measurement devices. The dentist may analyze the initial configuration of the patient's teeth and determines the final configuration of the patient's teeth in step 2820. The final configuration comprises the positions and the orientations of the patient's teeth after the corrective treatment process.

[00235] The dentist will then design a movement path for each of the teeth involved in step 2830. A typical orthodontic treatment is usually divided into a plurality of successive treatment steps in step 2840. One or more specifically designed disposable dental aligners are used to move the patient's teeth to a pre-designed target configuration. The treatment at the step is intended to produce incremental amounts of changes in

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positions or orientations that are within the comfort tolerance of the patient as well as the performance of the dental aligner.

[00236] The removable dental aligner is typically shell shaped and can be worn by a patient over his or her dental arch to produce corrective movement in a patient's teeth. As described above, a dental aligner typically includes a shell portion, an outer surface of the shell portion, and an inner surface of the shell portion. The inner surface will be in contact with the patient's teeth. The shell-shaped dental aligner can further include a bottom portion to be placed near the gingival of the patient's tooth and a tip portion on the opposite side of the bottom portion.

[00237] Fluid-permeable dental aligners allow air or liquid to communicate between the patient's tooth and the vicinity of the outer surface. Dental aligners are fabricated to achieve the same incremental teeth movement at that particular step 2850. The dental aligners can be molded using fluid-permeable material materials in a casting chamber. The mold can be a negative impression produced by a physical dental arch model that comprises the patient's tooth models that are configured in the target configuration for the specific treatment step. The dental aligners can also be fabricated by a CNC based machine in response to a digital aligner model.

[00238] Details of producing physical dental arch model and associated base are disclosed in the above referenced and commonly assigned U.S. Patent Application Serial No. 10/979,823, titled "Method and apparatus for manufacturing and constructing a physical dental arch model" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application Serial No. 10/979,497, titled "Method and apparatus for manufacturing and constructing a dental aligner" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application Serial No. 10/979,504, titled "Producing an adjustable physical dental arch model" by Huafeng Wen, filed 11/2/2004, and U.S. Patent Application Serial No. 10/979,824, titled "Producing a base for physical dental arch model" by Huafeng Wen, filed 11/2/2004. The disclosure of these related applications are incorporated herein by reference.

[00239] The effects of the dental aligners having permeable materials can be simulated by computer modeling. The progressive teeth configurations in an orthodontic treatment can be represented by a digital dental arch model. The disposable aligners can be simulated by a digital aligner model. The computer simulation helps to determine the number of steps needed for each treatment, the material properties of the dental aligners. In particular, the properties of the permeable materials can be simulated to predict and

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optimize the fluid permeation function of the dental aligner. The fluid permeability of the dental aligner can be optimized by varying the diameters and the density of the pores. The preferred material properties and structures are predicted. Materials and fabrication processes can be experimented and selected to achieve the desired properties and structures in the dental aligners.

[00240] The pore density and diameters can be of uniform or non-uniform distribution across the dental aligners. For example, the pore density can be higher at the portion of the shell-shaped dental aligner along cervical lines to allow extra air and liquid communication to the cervical lines of the patient's teeth to prevent bacteria growth. The hardness of the dental aligners can also be varied depending on the intended length of use of a particular dental aligner. In addition, the fluid permeation properties can also depend on the patient life style, his or her use pattern of the dental aligner, and the climate in which he or she wears the dental aligning devices. These optimized properties may improve the patient comfort and convenience in using the dental aligner having fluid-permeable material for corrective orthodontic treatment in step 2860.

[00241] The dental aligners can include wrinkled surfaces to enhance the strength and sustainability of the dental aligner. Details of wrinkled dental aligners and the fabrications are described in more detail below.

[00242] The dental aligners comprising fluid-permeable material can also be disposable. A plurality of disposable dental aligners having substantially identical shape can be produced for a single step of the treatment. The use of multiple disposable dental aligners allows a disposal dental aligner to be replaced before it is relaxed and deforms. This assures the uniform application of force the patient's teeth over time and improves the accuracy of the treatment. Because of their effectiveness, the disposal dental aligners can shorten the overall treatment time. The disposal dental aligners is also more comfortable for the patient to wear because of the smaller granular movements induced by each disposal dental aligner. Details of the manufacturing of disposable dental aligners are also described in more detail below.

[00243] A variety of fluid-permeable materials are compatible with the disclosed methods and system. The fluid-permeable materials can include polymeric materials prepared by copolymerizing styrene and divinylbenzene (DVB). Very small pores or 'micropores' can be formed in such process as a result of DVB tying together linear chains of styrene at various points. The "degree of cross-linking" is determined by the percentage

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of DVB present. The "degree of cross-linking" in turn determines the size of the pores. A 10% cross-linked polymer contains 10% DVB and has somewhat smaller pores than a 2% cross-linked polymer since the additional DVB creates additional linkage points making the average distance between those points smaller. However, as cross-linking is reduced pore size increases, the physical stability of the polymer decreases. Fluid permeability and strength therefore need to be co-optimized in designing dental aligners. Pore sizes are typically less than 30 Å in diameter and fairly uniform distributed.

[00244] Another type of porous polymer was independently developed in the late 1950s by scientists at The Dow Chemical Company and at Rohm and Haas. These materials have come to be called "macroporous polymers", and pores are formed independently of cross-linking. Polymerization takes place in the presence of "porogens". Porogens are substances that are soluble in monomers, but insoluble in formed polymers. Thus, as polymerization proceeds, pores are formed in the spaces where porogens are found. Pore diameters are typically greater than 50 Å, with some polymers having pore diameters as great as 2000 to 4000 Å. Most polymers, however, contain pores in the 100 Å to 300 Å range. Pore size distributions tend to be somewhat broad, particularly in polymers having large average pore sizes. These materials are characterized by irregular shaped pores that terminate within the polymer body. Macroporous polymers are usually prepared with a high degree of cross-linking (typically 30% or greater) to lend greater physical stability to the resulting material and to yield polymers that do not swell in solvents. The discovery of this route to synthesizing polymers led to materials with much larger pore size and much higher porosity than preceding microporous materials; however total porosity rarely exceeds 50%. Details of this type of porous polymers are disclosed in U.S. Patent 3,322,695 titled "Preparation of Porous Structures" by Alfrey et al., and U.S. Patent 4,224,415 titled "Polymerization Processes and Products Therefrom" by Meitzner et al., the disclosure of these U.S. Patents are incorporated herein by reference.

[00245] Other porous materials include porous polymer structures known as "high internal phase emulsions" ("HIPE") that are disclosed in US Patent 4,522,953 "Low Density Porous Cross-linked Polymeric Materials and their Preparation and Use as Carriers for Included Liquids" by Barby et al. and US Patent 5,583,162 titled "Polymeric Microbeads and Method of Preparation" by Li et al. The disclosures of these U.S. Patents are incorporated herein by reference.

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[00246] Another approach of making fluid permeable dental aligners is to mix a base sheet material with small granules of a low-density compound (usually a form of plastic). The low-density compound has a lower sublimation point than the base material. The sheet of material mixture is then placed in a heated container over a mould. Air is pumped out. The appliance is separated from the mould and is subjected to high temperature and/or pressure, which results in the sublimation of the granular low-density material. The molecules of the material are converted to gaseous forms (in case of plastic, formaldehyde) and leave behind pores large enough to let gas and/or liquid molecules pass through.

[00247] Pores can also be made in the dental aligner. For example, a laser may be used (e.g., particularly a power-stable laser). The diameter of the pores or holes can be controlled, for example, in the range between 40 - 400 μm at a perforation speed as high as 500,000 holes per second. The density and pore sizes can be directly controlled by a computer in response to a dental aligner model.

Disposable Aligners

[00248] The appliances described herein may also be disposable. In general, disposable aligners include "redundant" aligners, wherein multiple aligners having the same basic shape (e.g., the same treatment effect) are provided to be used within the same treatment step. Disposable aligners may help overcome the aforementioned problem with relaxation or loss of shape which occurs as aligners are worn or age. For example, aligners can become relaxed and "open up" after repeated usage by a patient, or the patient can bite the aligner to cause aligner to bend outwards. Further, each time the patient takes off the aligner during eating, drinking, or before sleep, the bottom part of the aligner tend to open up and relax. Material relaxation at bottom of the aligner over usage time can render ineffective application of force at the bottom of the teeth. Relaxation of an aligner can occur after only a few days of usage. The loss of corrective force applied by the aligner to the patient's teeth results in insufficient or inaccurate teeth movement, requiring reordering of the same aligners and delay in the orthodontic treatment, which are costly for the patients.

[00249] To illustrate the above described problem, Figure 19a illustrates a side view of a new aligner 3100 worn a patient's tooth 3110. The aligner is typically in a shell shape, comprising shell portion, a tip portion, and a bottom portion. The inner surface of the shell portion is to be in contact with the patient's teeth. The aligner fits properly at the bottom of

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the tooth where the gingival separates the tooth from the root. The newly worn aligner 3100 provides proper and effective force for the tooth movement in the orthodontic treatment. Figure 19b shows the side view of the aligner 3150 that has been worn on the patient's tooth 3160 after a period of usage such as a few days or a week. The lower part 3155 of the dental aligner 3150 is relaxed and opened up, which prevents the dental aligner 3150 to exert proper stress on the bottom of the tooth. The dental aligner 3150 thus can no longer produce effective and accurate tooth movement. Figure 20 illustrates the top view of a conventional dental aligner 220 that is newly worn on a patient's tooth 3210. After it is worn for a period of time, the dental aligner 3230 is relaxed and loose. It can no longer apply effective forces to the tooth 3210.

[00250] Figure 21 illustrates a process for producing a disposable dental aligner. In an orthodontic treatment, an initial configuration of the patient's arch is first determined in step 3310. The patient's arch can include one or more teeth in the upper jaw and lower jaw. The configuration includes positions and orientations of the patient's teeth. The initial configuration can be obtained by first producing a negative impression of the patient's arch and then scanning the surfaces of the negative impression by 3D positional measurement devices. The dentist analyzes the initial configuration of the patient's teeth and determines the final configuration of the patient's teeth in step 3320. The final configuration comprises the positions and the orientations of the patient's teeth after the corrective treatment.

[00251] The dentist will then design a movement path for each of the teeth involved in step 3330. A typical orthodontic treatment is usually divided into a plurality of successive treatment steps in step 3340. One or more specifically designed disposable dental aligners are used to move the patient's teeth to a pre-designed target configuration. The treatment at the step is intended to produce incremental amounts of changes in positions or orientations that are within the comfort tolerance of the patient as well as the performance of the dental aligner.

[00252] Once the movement path is determined and divided into steps, the dentist, orthodontist, or other practitioner may determine how long each step of the treatment step. Generally, the length of time that a given treatment path may be estimated by the expertise of the practitioner. In some variations, the time for each treatment path may be calculated (e.g., manually or via computer program) based on information about the subject's dental arch. For example, the estimate of how long a treatment step will take may be based upon comparison with how long a similar treatment step took in similar dental arches in other

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patients (historical data), or based upon the patient's age and dental health, the type of teeth being moved, the amount and type of movement being made (e.g., rotation versus linear translation), and the type and shape of the aligner.

[00253] A plurality of disposable dental aligners may be designed for each step of the treatment. The plurality of disposable dental aligners has substantially identical shape designed to achieve the same incremental teeth movement at that particular step. The patient will receive the set of disposable dental aligner at once without visiting the dentist office he or she switches from one disposal dental aligner to the other.

[00254] The disposal dental aligners are designed to be worn by the patient for a shorter period of time than conventional dental aligners. A patient can change disposable dental aligner every week, every three days, every day, or even in a matter of hours or minutes. For example, the patient can wear a disposal aligner just for having dinner.

[00255] An optimal wearing interval may be determined for an aligner. The optimal wearing interval may be based upon the aligner's structure (e.g., material, size, etc.), or may be based upon predicted use. The frequency of change of the disposal dental aligner (e.g., optimal wearing interval) may depend on the patient's profile or lifestyle. The number of disposal dental aligners for each treatment step is determined in step 3350, which can depend on factors such as the number of meals, the sleeping pattern, and dental hygiene of the particular patient. For example, if a person is a heavy smoker, he will be advised to change the disposable aligners more frequently that someone who is very strict about his oral hygiene. The number of disposal dental aligners for each treatment step can also depend on the relative magnitude of the incremental movement designed in that treatment step. For example, the optimal wearing interval may be twelve hours, one day, two days, three days, four days, a week, two weeks, or a month.

[00256] The effect of the disposable dental aligners can be simulated by computer modeling. The progressive teeth configurations in an orthodontic treatment can be represented by a digital dental arch model. The disposable aligners can be simulated by a digital aligner model. The effects of the multiple disposal dental aligners on the patient's teeth can be simulated at each treatment step. The computer simulation helps to determine the number of steps needed for each treatment, the material properties of the disposal dental aligners as well as the number of dental aligners of substantially identical shape for each step.

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[00257] The use of multiple disposable dental aligners allows a disposal dental aligner to be replaced before it is relaxed and deforms. This assures the uniform application of force the patient's teeth over time and improves the accuracy of the treatment. Because of their effectiveness, the disposal dental aligners can shorten the overall treatment time. The disposal dental aligners is also more comfortable for the patient to wear because of the smaller granular movements induced by each disposal dental aligner.

[00258] The disposable aligners are produced in step 3360 for each treatment step. Any appropriate fabrication method may be used. It is worth noting that (because they are disposable), the disposable aligners may be more easily fabricated, or may be fabricated more inexpensively, because less durable material may be used. For example, thinner material, or material having less strength than other materials used for traditional aligners. Further, in fabricating the disposable dental aligners, identical aligners can be fabricated in parallel or in series using the same molds, etc.

[00259] For example, two or more disposal dental aligners can be molded using the same mold in a casting chamber. The mold can be a negative impression produced by a physical dental arch model that comprises the patient's tooth models that are configured in the target configuration for the specific treatment step. The disposable dental aligners can also be fabricated by a CNC based machine that receives a digital aligner model as input. Details of producing physical dental arch model and associated base are disclosed above, as well as in the above referenced patents and applications previously incorporated by reference.

[00260] It may be desirable to produce all of the aligners needed for a particular treatment step at one time. The number of disposable dental aligners made per treatment step may be determined from the amount of time the treatment step will take and the estimate of the optimal wearing interval. For example, if it will take three weeks for a treatment step to be complete, and the optimal wearing interval (e.g., recommended wearing interval) is two days, then it will take at least 11 aligners to complete the treatment step using the optimal wearing interval.

[00261] The disposal dental aligners produced by the above processes therefore have substantially the same shape. As described above, different materials however can be used for the different molding events to mold disposable aligners of different hardness. The surface of the positive impression can include features for molding wrinkled surfaces to produce the wrinkled disposable aligners, as described further below.

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[00262] The mold for making a disposal aligner can be kept at the orthodontist's office. Additional disposable aligners can be easily made whenever more copies are needed. The mold could also be sent to the clinic or to the patient's home where the disposable dental aligners can be made conveniently without the intervention of the orthodontist.

[00263] As described above, the disposable aligners can be made of materials that possess the following general properties: the ease to be molded, the capability to be extruded into films or filament, enough hardness to prevent breakage, flexibility, relatively high melting temperature to stand mild heat, strong enough to resist deformation, pliability, and food-grade that is safe for oral use. Preferably, the material is transparent. Examples of materials for disposable dental aligners include acrylic and polycarbonate.

[00264] Conventional aligners are usually worn for a period of approximately two weeks, and thus the material properties are optimized to allow it to last for two weeks without breaking. The material properties of the disposal aligner may be optimized to be just hard enough to last for just one or two days before it is discarded.

[00265] In another variation, the disposal dental aligners for a treatment step can comprise slightly different materials. The disposable aligner to be worn at the earlier time of a treatment step can be made of relatively softer material so that the patient can more comfortably wear them (e.g., without feeling much pressure to initiate the teeth movement at the particular treatment step). For instance, the patient may wear the first disposable dental aligner for two days and switch to another disposable dental aligner with increasing hardness. The latter aligners can help to reinforce and solidify the initial movement achieved until the desired full-step movement is achieved.

Wrinkled Aligners

[00266] Dental appliances may also be designed and fabricated to include structures or regions which may flex to relieve stress on the aligner, preventing deformation of the aligner. For example, the aligner may be a "wrinkled" aligner in which at leas a portion of the aligner has one or more surfaces (or regions) that are furrowed, ridged, or creased. For example, the wrinkles in the aligner surface may appear crumpled, folded, or curved. The wrinkles may allow the appliance to bend or expand to a greater degree than an otherwise unwrinkled aligner, thereby preventing material stresses that may damage the appliance.

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[00267] Wrinkled aligners may prevent the aligner from using its shape. Aligners are typically made of plastic materials and can become relaxed and open up after repeated usage by a patient, as described above. The material relaxation of the aligner with usage can prevent the effective application of force on the teeth. Relaxation of the aligner can occur in as short a period as a few days of usage. The loss of corrective force applied by the aligner to the patient's teeth results in insufficient or inaccurate teeth movement. The corrective measures can include reordering of the same aligners and delay in the orthodontic treatment, which are costly for the patients.

[00268] Wrinkled aligners may overcome the loss of force caused by the relaxation of the aligners. Wrinkled aligners can include different designs. As shown in Figure 28, a wrinkled aligner 4900 can include a shell portion 4910 that has an inner surface to be in contact with the patient's teeth, an outer surface 4920, a tip portion 4930, a bottom portion 4940 along the base line 4950 of the shell portion 4910. The shell portion 4910 can have varying thicknesses in different areas. The shell portion 4910 can also comprise a plurality of layers of the same or different materials.

[00269] The dental aligner 4900 is worn over the patient teeth over gum 4960. Wrinkles 4970 can be produced on one of or both the outer surface 4920 (i.e. the buccal side) and the inner surface (i.e. lingual side) of the wrinkled aligner 4900. The wrinkles 4970 can be aligned from tip portion 4930 to the bottom portion 4940 of the wrinkled aligner 4900 at a predetermined spacing between the adjacent wrinkles. The wrinkles 4970 allow the wrinkled aligner 4900 to relax when it receives stresses during patient's biting, or when the aligner is taken off and put on. The wrinkled shape can automatically restore when the stresses are removed. The wrinkled aligner 4900 therefore is free of the relaxation problems in the prior art aligners. In other words, the wrinkled aligners 4900 include robust structure designs that can tolerate stresses and maintain functional shape under stresses.

[00270] The wrinkles can be formed in different orientations and locations of the shell-shaped dental aligners. The wrinkle can also be made in parallel to the base line 4950 of the wrinkled aligner 4900 (i.e. across the direction from the tip portion 4930 to the bottom portion 4940), which helps to prevent the wrinkled aligner to open near the base. The wrinkles can also be produced in both horizontal (parallel to the base line 4950 of the aligner) and vertical (from the tip portion to the bottom portion) directions. In another arrangement, a corrugated structure or "wrinkles" can be produced along the on the base line 4950 of the wrinkled aligner 4900. The corrugated structure along the base line 4950

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can generate elastic shrinking stress over the tooth, which can overcome the above described relaxation problem and extends the life of the wrinkled aligner 4900. Various wrinkle arrangements can be applied singularly or in combination for optimize performance.

[00271] Wrinkled aligners can be fabricated by a variety of manufacturing methods. In one arrangement of aligner manufacturing, a patient's dental arch model is placed on a base plate of a vacuum former machine. The digital dental aligner model specifies a shell portion including an outer surface and an inner surface to be in contact with the patient's tooth, a bottom portion to be placed near the gingival of the patient's tooth, and a tip portion on the opposite side of the bottom portion. The digital dental aligner model also defines one or more wrinkles formed over at least one of the outer surface of the shell portion, the inner surface of the shell portion, and the bottom portion. An apparatus produces a physical dental aligner having a wrinkled surface in accordance with the digital dental aligner model.

[00272] As shown in Figure 29, a sheet 4010 of aligner-making material is attached to a sheet holder and then lifted up near a heating element. The sheet can be made of uniform distribution of a single material or comprise multiple layers of different materials. After the aligner-making material is heated by a specified time, the sheet holder is pressed on the patient's dental arch model on the base plate. A vacuum pump removes air at the bottom of the base plate to cause the softened aligner making material to relax and fittingly form around the surface the patient's dental arch model. The sheet of the aligner making material is then cut out along the gingival line 4040 to produce an aligner 4050 that can perfectly fit to the patient teeth. This process of aligner making is referred to as the vacuum forming.

[00273] In one method of wrinkle making, some material is extruded on other tooth surfaces of the patient's dental arch model that is fixed on to the base plate. The protrusions formed by the extruded material are distributed (e.g. the locations and the density of the wrinkles, the width and the depth of the wrinkles, etc.) to compatible with the wrinkles to be formed over the aligner. The extruded material is subsequently hardened over the surfaces of the arch model. When the soft sheet of aligner making material is pressed over the arch model, the protrusions formed by the extruded material produce the wrinkles 4030 on the sheet of the aligner making material. A wrinkled aligner 4050 is obtained after the cutting of the sheet.

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[00274] In a variation of the above method of manufacturing wrinkled aligners, a high-tension material is placed at the locations of the dental arch model where the wrinkles are to be formed. The high strength material is absorbed and become embedded into the aligner material after the sheet of aligner making material is heated and pressed over the arch model. The distribution of high strength material creates an uneven elasticity distribution over the aligner surface that produces the wrinkles 4030.

[00275] In yet another variation, a high-tension material is placed in parallel stripes over the sheet of aligner making material before it is placed in the sheet holder. The subsequent heating causes the high-tension material to penetrate and embed in the sheet, which produces wrinkles 4030 in the wrinkled aligner 4050.

[00276] A physical dental aligner without wrinkles may be first produced by the above described vacuum forming process. The physical dental aligner can then subsequently be softened by heating. A thermal applier such as a stylus is then pressed against the physical dental aligner. The thermal applier moves across the surface to etch off materials to the wrinkles at the desired locations. Alternatively, wrinkles can be cut over the surface of the aligner by a position-controlled cutter or a laser beam.

[00277] In still another variation, aligner components are fabricated by CNC based manufacturing as described above in accordance with a digital dental aligner model. The digital dental aligner model includes wrinkle features over the surfaces of the dental aligner. The aligner components are fabricated in accordance with the digital dental aligner model having the wrinkle features. The dental aligner components are subsequently assembled to produce the physical dental aligner.

[00278] The wrinkled aligner may be milled out of a plastic block in accordance with digital aligner model. The milled out portion can be a portion of a tooth or a group of teeth. The inner hollow portion of the partially milled plastic block is then filled up with a soft holding material under heating. The holding material is soft at elevated temperatures and is hardened at room temperature. The holding material forms a handle after it cools off to room temperature. The partially milled plastic block can be held from outside while it is milled by CNC based manufacturing. An aligner having wrinkled surfaces can be produced after machining. The holding material may then subsequently be removed by heating. The holding material can be wax, silicon, Epoxy or other kind of removable glue.

[00279] In yet another variation, a special clamp can also be used to hold the partially milled aligner parts in place while the rest of the aligner is milled using the CNC

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machine. The aligner components may be assembled to form an aligner having one or more wrinkled surface. The aligner components include physical features to permit the aligner components to be assembled into the physical dental aligner having at least one wrinkled surface. The CNC based manufacturing can include one or more of milling, stereo lithography, laser machining, molding, and casting.

[00280] Figure 30 illustrates a process of designing and fabrication of a wrinkled dental aligner. A dental aligner model is first obtained using CAD software (step 4111). In general, the features of the wrinkles can be co-optimized with the properties of the aligners. For example, the wrinkle design may take into account the aligner material (e.g., stiffer materials may require larger wrinkles), the geometric parameters (curvature, thickness of the aligner), and the intended degree of teeth movement the aligner is to generate. These parameters may be set in step 4112. A predetermined set of wrinkle features can then be added to the surface of the digital aligner model in step 4103. The feature can include the locations, the orientations, and the density of the wrinkles, the width and the depth of the wrinkles, as well as the embedded materials that are used to produce the wrinkles.

[00281] The properties of the aligner and the features of the wrinkles on the aligners are next simulated for the optimal orthodontic performance and pre-stored in the digital aligner model in step 4114. The responses of the wrinkled aligners to various conditions during the patient's use of the wrinkled aligner are simulated using Finite Element Analysis (FEA). The conditions can include stresses applied by the patient during the biting, the wearing, and the removal of the aligner. The conditions can also include temperature changes when the patient has hot drinks or ice cream. Using Virtual Prototyping Software (a component of CAD software), the properties and performance of the wrinkled aligner can be analyzed under various simulated mechanical loads. The wrinkle features and the aligner properties can be varied in iterations for optimized performance in step 4115. Finally, the optimized wrinkle configurations are stored in a computer and used to control the fabrication of the wrinkled aligner in step 4116.

Lateral Correction Aligners

[00282] Dental appliances may also be designed and fabricated for altering the palate of the upper dental arch. These aligners may be referred to as lateral correction aligners. Lateral correction aligners typically apply force to the palate and/or the teeth to help remodel the dental arch. For example, a lateral correction aligner may help either expand

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(or contract) a subject's palate. Described herein are appliances (e.g., lateral correction aligners) comprising a shell having a palate-spanning region. As previously described, the shell typically includes an outer surface and an inner surface, and at least a portion of the inner surface is configured to contact a subject's teeth. Lateral correction aligners typically include one or more regions that span at least a portion of a subject's palate (e.g., a palate-spanning region).. This palate-spanning region may contact the anterior portion of the palate, such as the hard palate region.

[00283] Figure 31a and 31b show a cross-section through a lateral correction aligner. In Figure 31a, the aligner 3107 is worn on the upper dental arch. In Fig. 31A this could be a subject's actual dental arch, or a model of the dental arch which includes both the teeth 3105 and anterior palate region 3101. This lateral correction aligner 3107 includes a palate-spanning region 3109 that connects region of the shell 3107 that contact the teeth. Figure 31b shows the lateral correction aligner (in cross-section) of Figure 31a without the upper dental arch.

[00284] When the lateral correction dental aligner is worn, as shown in Figure 31a, the palate-spanning region 3107 applies force to remodel the palate region of the upper dental arch. In some variations, the palate-spanning region may also provide additional support for the other region of the shell to enhance remodeling of the teeth 3015. In some variations, the palate-spanning region may push against the palate at one or more contact sites (or over the entire surface) of the palate-spanning region. Thus, the palate-spanning region may substantially conform to the palate or engage the palate. The palate-spanning region may engage the grooves (e.g., the longitudinal palatine grooves and canals).

[00285] As described previously for other types of dental aligners, the lateral correction dental aligner may be designed to remodel the palate in a series of steps in which the subject wears (for an appropriate treatment time) each of a series of aligners that proceed towards a final configuration. A practitioner (e.g., an orthodontist) determines the final configuration for the patient's dental arch (including teeth and palate). The practitioner designs a treatment plan that specifies movement paths for the patient's teeth and arch with our without the use of a computer, and the movement paths are divided into a plurality of successive treatment steps in step (e.g., three to forty treatment steps). Each step may correspond to one or more dental aligners to be worn.

[00286] In designing the treatment steps, as well as the final configuration, the practitioner may be guided by an awareness (or a model) of how the dental arch itself may

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move. For example, as would be known by one of skill in the art, different regions of the palate may be more easily modified by treatment than other regions. In general, the more lateral regions of the hard palate may be more easily moved than the upper (e.g., central) region of the hard palate. Thus, a lateral correction dental aligner may be configured to expand the palate from the regions closer to the teeth than the more central region. Treatment steps may be planned using empirical information about remodeling the palate. For example, predictions about how any particular subject's palate may be remodeled may be based on comparing information about the subject (e.g., age, gender, size of the palate, etc.) with measurements or treatments performed on other, similar subjects. Treatment may also be based on models for the expansion (or contraction) of the palate based on published data. For example, see Carmen M, Marcella P, Giuseppe C, Roberto A., "Periodontal evaluation in patients undergoing maxillary expansion" (J Craniofac Surg. 2000 Sep;11(5):491-4); Ramieri GA, Spada MC, Austa M, Bianchi SD, Berrone S., "Transverse maxillary distraction with a bone-anchored appliance: dento-periodontal effects and clinical and radiological results" (Int J Oral Maxillofac Surg. 2005 Jun;34(4):357-63. Epub 2005 Jan 24); Davidovitch M, Efstathiou S, Sarne O, Vardimon AD., "Skeletal and dental response to rapid maxillary expansion with 2- versus 4-band appliances" (Am J Orthod Dentofacial Orthop. 2005 Apr;127(4):483-92); and Ferrario VF, Garattini G, Colombo A, Filippi V, Pozzoli S, Sforza C., "Quantitative effects of a nickel-titanium palatal expander on skeletal and dental structures in the primary and mixed dentition: a preliminary study" (Eur J Orthod. 2003 Aug;25(4):401-10). Each of these articles is herein incorporated in its entirety.

[00287] Treatment plans and the design of lateral correction aligners may be generated either manually or automatically. For example, software may be used to suggest treatment plans (and aligner designs), or it may be used to design the aligners used for treatment. As described above, software may be used to digitally model the dental arch (including the upper palate), as well as to manipulate the position of the teeth and upper palate. The software may include constraints on the remodeling of the upper palate, consistent with either empirical data using similar aligners or appliances, or based on models of a generic upper palate. In some variations, the software may derive a model for remodeling the upper palate based on data taken from the individual patient, such as X-ray or other scanning data, as well as molds or casts made of the hard palate region (and/or other regions of the subject's head and mouth).

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[00288] Figures 32a and 32b show views of one variation of a lateral correction aligner as described herein. In Figure 32a, the lateral correction aligner 3207 is shown positioned on a subject's upper dental arch. The shell portion of the dental aligner contacts the subject's teeth, while the palate-spanning region 3205 contacts a portion of the subject's hard palate 3203. As described above, the palate-spanning region may be a single piece that connects to the teeth-contacting region of the shell, or it may be multiple pieces, (e.g., leaving one or more holes or gaps) exposing regions of the palate. The palate-spanning region may be a strip or a plurality of strips spanning the palate from any two or more points on the perimeter of the dental arch, where the palate-spanning region attaches to the tooth/gum-contacting region of the aligner.

[00289] In operation, the lateral correction aligner may be used to remodel the palate by applying force to both the teeth. It may be beneficial to distribute the force applied by the palate-spanning region over the entire dental arch (e.g., by including a palate-spanning region with a shell that covers most or all of the upper teeth). The force applied by the palate-spanning region may contribute to the movement of the teeth as well as the palate, just as the force applied by the shell against the teeth may contribute to the remodeling of the palate. In addition, the palate may be remodeled in any appropriate direction by a lateral correction aligner, including the anterior/posterior direction (e.g., from the front of the mouth to the back of the mouth) and the left/right direction. A lateral correction aligner may also remodel the dental arch by distalization of the teeth.

[00290] A lateral correction dental aligner may be used even it is not necessary or desirable to remodel the subject's palate. The lateral correction aligner may add support to the region of the aligner shell contacting (e.g., moving) the teeth. One or more steps of a treatment series may include a lateral correction aligner (other steps in the treatment may include aligners that do not have a palate-spanning region). In general, different types of aligners described herein (or aligners with different features, e.g., wrinkled aligners, aligners having palate-spanning regions, etc.) may be used at different steps of a treatment. In some variations, it may be desirable to use a lateral correction dental aligner in the same step as an aligner that does not include a palate-spanning region. For example, a subject may wear a dental aligner without a palate-spanning region during the day and a lateral alignment dental aligner when sleeping. The shell regions of both aligners may be identical except for the presence or absence of the palate-spanning region.

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[00291] The palate-spanning region of the aligner may provide force against the teeth as well as the palate. Thus the palate-spanning region may comprise a material capable of providing sufficient force to effect movement of the palate and/or teeth. For example, the palate-spanning region may comprise a support piece or brace. The support piece typically gives structural support to the aligner, permitting it to maintain force against the palate and/or teeth.

[00292] A support piece may comprise any material having sufficient strength, stiffness (or elasticity), and durability. For example, the support piece may comprise a metal (including alloys such as nickel titanium alloys), ceramic, polymer (e.g., polypropylenes, polycarbonates, etc.), or some combination thereof. The shape of the support pieces may also provide support. For example, the support piece may be a spring (e.g., coiled spring, leaf spring, etc.), or may be layered to provide additional support. In some variations, the palate-spanning region does not include an additional support piece, because the material from which the palate-spanning region is made has sufficient strength to remodel the dental arch (e.g., .teeth and/or palate) as desired.

[00293] The entire palate-spanning region of the shell may include a support piece, or the support piece may be included in only a portion of the palate-spanning region. In some variations, the palate-spanning region comprises only a support piece. The support piece may be attached to the upper or lower portions of the palate-spanning region, or it may be embedded within the palate-spanning region. More than one support piece may be used.

[00294] Figure 33a and 33b shows one example of a palate-spanning region of an aligner 3107 in which the support piece 3307 is sandwiched between an inner 3303 and outer 3305 shell layer of the aligner. As described above, a lateral-correction aligner may be fabricated using any of the methods described herein. For example, the aligner may be fabricated as a multi-layered aligner in which the layers (including the support piece) are vacuum-formed onto a model of the upper dental arch. A lateral correction aligner may include any of the features previously described, including fluid permeable features, snap-on features, wrinkles, etc.

[00295] The palate-spanning region (including the support piece) may be configured to minimize discomfort. For example, the palate-spanning region may comprise a coating to smooth the palate-spanning region, particularly the portion of the aligner that may contact the tongue. Coatings may smooth the surface of the aligner, and may have

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additional beneficial effects. Coatings may include wetting coatings (e.g., silicones, etc.), hygienic coatings (e.g., antibacterial coatings, etc.), friction-reducing coatings (e.g., waxes, lubricious coatings), odor-absorbent coatings (e.g., containing activated charcoal, etc.), or the like.

[00296] As described, the plate spanning region (including the support piece) may be made of any appropriate material. For example, the plate-spanning region may be made of any of the layered materials described herein. In some variations, the plate-spanning region comprises a fluid (e.g., water or gas) permeable material, and may include one or more passages. Aligners with plate spanning regions may be more comfortable for a user when at least a portion of the plate spanning region comprises a permeable material.

[00297] The above detailed description is provided to illustrate exemplary embodiments and is not intended to be limiting. For example, any of the features of an embodiment may be combined with some or all of the features of other embodiments. It will be apparent to those skilled in the art that numerous modifications and variations within the scope of the present invention are possible. Throughout this description, particular examples have been discussed, including descriptions of how these examples may address certain disadvantages in related art. However, this discussion is not meant to restrict the various examples to methods and/or systems that actually address or solve the disadvantages. Accordingly, the present invention is defined by the appended claims and should not be limited by the description herein.

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CLAIMS

What is claimed is:

1. A device for producing corrective movement in a subject's teeth, the device comprising:
   a dental aligner configured to be worn on a subject's teeth, the dental aligner comprising:
      a shell portion having an outer surface and an inner surface, wherein at least a portion of the inner surface is configured to contact the subject's tooth; and
      one or more through-holes passing from the outer surface to the inner surface of the shell portion of the dental device.

2. The device of claim 1, wherein the through-hole is configured to mate with a connector.

3. A system for producing corrective movement in a subject's teeth, comprising:
   a dental aligner device having one or more through-holes, wherein the dental aligner device is configured to be worn on the subject's teeth; and
   one or more connectors, wherein the connector is configured to engage the through-hole when the dental aligner is worn on the subject's teeth.

4. The system of claim 3, wherein the one or more connectors include one or more of posts, nodules, and bumps.

5. The system of claim 3, wherein the dental aligner contacts the subject's teeth when the connector is engaged with the through-hole in the dental aligner.

6. The system of claim 3, wherein the dental aligner is fabricated by one or more of vacuum forming, milling, stereo lithography, laser machining, molding, and CNC based manufacturing.

7. The system of claim 3, wherein the dental aligner comprises:

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a shell portion having an outer surface and an inner surface to be in contact with the subject's tooth;

a bottom portion to be placed near the gingival line of the subject's tooth; and

a tip portion on the opposite side of the bottom portion.

8. The system of claim 7, wherein the through-hole of the dental aligner device passes through the bottom portion or the tip portion.

9. The system of claim 3, wherein the connector is configured to be secured to a subject's tooth.

10. A system for producing a snap-on dental aligner for dental treatment, comprising:

a guide to indicate the locations of through-holes to be formed in a dental aligner;

a positioner to position a hole-maker with respect to the dental aligner based on the indication of the guide; and

a hole-maker to produce through-holes in the dental aligner at the positions indicated by the guide to produce the snap-on dental aligner.

11. The system of claim 10, wherein the guide comprises a computer to store the locations of through-holes to be formed in a dental aligner.

12. The system of claim 11, wherein the computer is further configured to store locations of one or more connectors to be secured to the subject's teeth, so that the one or more connectors engage the through-holes when the dental aligner is worn on the subject's teeth.

13. The system of claim 10, wherein the hole-maker is configured to drill through-holes in the dental aligner.

14. The system of claim 10, wherein the hole-maker comprises a mechanical drill bit or a laser.

15. A method for moving a subject's teeth in a dental treatment, comprising:

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fabricating a dental aligner to be worn on the subject's teeth;

producing one or more through-holes in the dental aligner;

fixing one or more connectors on the subject's teeth to engage the through-holes; and

engaging the one or more connectors on the subject's teeth with the through-holes of the dental aligner to secure the dental aligner on the subject's teeth.

16. The method of claims 15, further comprising fixing the one or more connectors on the subject's teeth at locations in registration with the through-holes when the dental aligner is worn on the subject's teeth.

17. The method of claim 16, wherein the connector comprises a pre-formed connector.

18. The method of claim 16, wherein the connector comprises an adhesive or a UV cross-linkable polymer.

19. The method of claim 16, wherein the one or more connectors include one or more of protrusions, nodules, and bumps.

20. The method of claim 15, further comprising securing the dental aligner against the subject's teeth to engage the connectors secured on the subject's teeth into the through-holes of the dental aligner.

21. The method of claim 15, further comprising fabricating the dental aligner device by one or more of vacuum forming, milling, stereo lithography, laser machining, and molding.

22. The method of claim 15, further comprising drilling the one or more through-holes in the dental aligners.

23. A shell-shaped dental aligner for producing predetermined movement in a patient's tooth, comprising:

a shell portion comprising a fluid-permeable material;

an outer surface of the shell portion; and

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an inner surface of the shell portion, the inner surface to be in contact with the patient's tooth, wherein the fluid-permeable material can allow fluid to communicate between the patient's tooth and the vicinity of the outer surface.

24. The shell-shaped dental aligner of claim 23, wherein the fluid-permeable material allows air and liquid to communicate between the patient's tooth and the vicinity of the outer surface.

24. The shell-shaped dental aligner of claim 23, wherein the fluid-permeable material allows the permeation of oxygen from the vicinity of the outer surface to the patient's tooth.

25. The shell-shaped dental aligner of claim 23, wherein the fluid-permeable material allows the permeation of saliva between the outer surface and the inner surface.

26. The shell-shaped dental aligner of claim 23, further comprising:
a bottom portion to be placed near the gingival of the patient's tooth; and
a tip portion on the opposite side of the bottom portion.

27. The shell-shaped dental aligner of claim 23, wherein the fluid-permeable material comprises a porous polymeric material.

28. The shell-shaped dental aligner of claim 23, wherein the fluid-permeable material comprises pores that are drilled by a laser beam.

29. The shell-shaped dental aligner of claim 23, wherein the fluid-permeable material comprises micro-channels or pore having diameters in the range of 50 Å to 400 μM.

30. A method for treating a patient's teeth, comprising
determining an initial configuration of the patient's teeth;
determining a final configuration of the patient's teeth;
designing a movement path for at least one of the patient's teeth from the initial configuration to the final configuration;

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dividing the movement path into a plurality of successive treatment steps, each having a target configuration for the patient's teeth; and

producing a dental aligner comprising a fluid-permeable material to move the patient's teeth to the target configuration associated with a treatment step.

31. The method of claim 30, wherein the fluid-permeable material comprises a porous polymeric material.

32. The method of claim 30, further comprising drilling holes by a laser beam in a dental-aligner material to form a fluid-permeable dental aligner.

33. The method of claim 31, wherein the target configuration comprises the target positions and the target orientations of one or more of the patient's teeth.

34. The method of claim 31, further comprising molding the dental aligner having the fluid-permeable material using in a casting chamber.

35. The method of claim 31, further comprising producing two dental aligners comprising the fluid-permeable material and having substantially identical shape.

36. The method of claim 31, wherein the fluid-permeable material comprises pores are formed by subliming a low density granular compound by pressure and/or elevated temperature in a base material.

37. A system for treating a patient's teeth, comprising:

a computer configured to determine a target configuration for the patient's teeth; and

an apparatus configured to produce a dental aligner comprising a shell portion that comprises a fluid-permeable material, an outer surface, and an inner surface to be in contact with one of the patient's teeth, wherein the fluid-permeable material can allow fluid to communicate between the one of the patient's teeth and the vicinity of the outer surface and the dental aligner is configured to move the patient's teeth to the target configuration.

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38. The system of claim 37, wherein the fluid-permeable material comprises a porous polymeric material.

39. The system of claim 37, wherein the apparatus is configured to drill holes by a laser beam in a dental-aligner material to form a fluid-permeable dental aligner.

40. The system of claim 37, wherein the apparatus is configured to mold the dental aligner having the fluid-permeable material using in a casting chamber.

41. The system of claim 37, wherein the apparatus is configured to produce fluid-permeable dental aligner comprising micro-channels or pore having diameters in the range of 50 Å to 400 μM.

42. A method for making a multi-layer dental aligner, comprising:

placing a first layer of a first aligner-making material over one or more physical tooth models;

conforming the first layer of the first aligner-making material to the surfaces of the one or more physical tooth models;

placing a second layer of a second aligner-making material over the first layer of the first aligner-making material; and

conforming the second layer of the second aligner-making material to the surfaces of the first layer of the first aligner-making material over the one or more physical tooth models to produce the multi-layer dental aligner.

43. The method of claim 42, further comprising:

heating the first layer of the first aligner-making material;

holding the first layer of the first aligner-making material against the one or more physical tooth models;

heating the second layer of the second aligner-making material; and

holding the second layer of the second aligner-making material against the first layer of the first aligner-making material over the one or more physical tooth models to produce the multi-layer dental aligner.

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44. The method of claim 43, further comprising:

holding the first layer of the first aligner-making material or the second layer of the second aligner-making material against the one or more physical tooth models by vacuum suction.

45. The method of claim 42, further comprising:

cutting the first layer of the first aligner-making material and/or the second layer of the second aligner-making material along the gingival lines of the physical tooth models to produce the multi-layer dental aligner.

46. The method of claim 42, further comprising:

cutting the first layer of the first aligner-making material along the gingival lines of the physical tooth models before placing the second layer of the second aligner-making material over the first layer of the first aligner-making material; and

cutting the second layer of the second aligner-making material along the gingival lines of the physical tooth models to produce the multi-layer dental aligner.

47. The method of claim 42, wherein the first layer of the first aligner-making material has a higher hardness than the second layer of the second aligner-making material.

48. The method of claim 42, wherein the first aligner-making material or the second aligner-making material comprises one or more of acrylic, polycarbonate, urethane, and epoxy.

49. The method of claim 42, wherein the first aligner-making material is the same as the second aligner-making material.

50. The method of claim 42, wherein the second layer of the second aligner-making material has substantially the same color as the patient's teeth.

51. The method of claim 42, wherein the one or more tooth models are assembled to form a physical arch model.

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52. The method of claim 51, wherein the one or more tooth models are attached to a dental base to form the physical arch model.

53. A method for making a multi-layer dental aligner, comprising:

heating a first layer of the first aligner-making material;

holding the first layer of the first aligner-making material against one or more physical tooth models by vacuum suction;

cutting the first layer of the first aligner-making material along the gingival lines of the physical tooth models;

heating a second layer of the second aligner-making material;

holding the second layer of the second aligner-making material against the first layer of the first aligner-making material over the physical tooth models by vacuum suction; and

cutting the second layer of the second aligner-making material along the gingival lines of the physical tooth models to produce the multi-layer dental aligner.

54. The method of claim 53, wherein the first aligner-making material has a higher hardness than the second aligner-making material.

55. The method of claim 53, wherein the first aligner-making material or the second aligner-making material comprises one or more of acrylic, polycarbonate, urethane, and epoxy.

56. The method of claim 53, wherein the first aligner-making material is the same as the second aligner-making material.

57. A multi-layer dental aligner, comprising:

a first layer of a first aligner-making material; and

a second layer of a second aligner-making material, wherein at least one of the first layer and the second layer is formed by heating a layer of an aligner-making material and holding the layer of the aligner-making material against one or more physical tooth models.

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58. The multi-layer dental aligner of claim 57, wherein the first layer is formed by heating and holding the first layer of the first aligner-making material against one or more physical tooth models by vacuum suction.

59. The multi-layer dental aligner of claim 57, wherein the second layer is formed by heating and holding the second layer of the first aligner-making material against the first layer of the first aligner-making material over the physical tooth models by vacuum suction.

60. The multi-layer dental aligner of claim 57, wherein the first layer has a higher hardness than the second layer.

61. The multi-layer dental aligner of claim 57, wherein the first aligner-making material is the same as the second aligner-making material.

62. A method for making a non-uniform dental aligner, comprising:
non-uniformly heating the sheet of aligner-making material; and
holding the sheet of aligner-making material against one or more physical tooth models to produce the non-uniform dental aligner.

63. The method of claim 62, further comprising:
heating a first section of the sheet of aligner-making material at a higher temperature than a second section of the sheet of aligner-making material.

64. The method of claim 62, further comprising:
heating a first section of the sheet of aligner-making material for a longer period of time than a second section of the sheet of aligner-making material.

65. The method of claim 62, wherein one or more elastic properties of the aligner-making material vary as a function of the temperature or the length of the heating.

66. The method of claim 62, further comprising:

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holding the sheet of aligner-making material against the one or more physical tooth models by vacuum suction.

67. The method of claim 66, further comprising:

holding the sheet of aligner-making material against the one or more physical tooth models by a non-uniform distribution of vacuum suction.

68. The method of claim 62, further comprising:

cutting the sheet of aligner-making material along the gingival lines of the physical tooth models to produce the non-uniform dental aligner.

69. The method of claim 62, wherein a first section of the sheet of aligner-making material has a higher hardness than a second section of the sheet of aligner-making material.

70. The method of claim 62, wherein the aligner-making material comprises one or more of acrylic, polycarbonate, urethane, and epoxy.

71. The method of claim 62, wherein the one or more tooth models are assembled to form a physical arch model.

72. The method of claim 71, wherein the one or more tooth models are attached to a dental base to form the physical arch model.

73. A method for making a non-uniform dental aligner, comprising:

heating a first section of a sheet of aligner-making material at a first temperature for a first period of time;

heating a second section of the sheet of aligner-making material at a second temperature for a second period of time;

holding the sheet of aligner-making material against the one or more physical tooth models to produce the non-uniform dental aligner by vacuum suction; and

cutting the sheet of aligner-making material along the gingival lines of the physical tooth models to produce the non-uniform dental aligner.

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74. The method of claim 73, wherein one or more elastic properties of the aligner-making material vary as a function of the temperature or the length of the heating.

75. The method of claim 73, wherein the first section of a sheet of aligner-making material has one or more different elastic constants different from the second section of a sheet of aligner-making material.

76. The method of claim 73, further comprising:

holding the sheet of aligner-making material against the one or more physical tooth models by a non-uniform distribution of vacuum suction.

77. The method of claim 73, wherein the aligner-making material comprises one or more of acrylic, polycarbonate, urethane, and epoxy.

78. A non-uniform dental aligner, comprising:

a layer of aligner-making material shaped to fit on a patient's teeth, wherein the layer of aligner-making material comprise a first section characterized by a first elastic constant and a second section characterized by a second elastic constant.

79. A non-uniform dental aligner of claim 78, wherein the layer of aligner-making material is shaped to fit a patient's teeth by non-uniformly heating a sheet of aligner-making material and holding the sheet of aligner-making material against the one or more physical tooth models by vacuum suction.

80. The non-uniform dental aligner of claim 78, wherein the aligner-making material in the first section has a higher hardness than the aligner-making material in the second section.

81. The non-uniform dental aligner of claim 78, wherein the aligner-making material comprises one or more of acrylic, polycarbonate, urethane, and epoxy.

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82. A dental aligner for producing predetermined movement in a patient's tooth, comprising:

a shell-shaped portion including an outer surface and an inner surface to be in contact with the patient's tooth;

a bottom portion to be placed near the gingival of the patient's tooth;

a tip portion on the opposite side of the bottom portion; and

one or more wrinkles formed over at least one of the outer surface, the inner surface, and the bottom portion.

83. The dental aligner of claim 82, wherein the wrinkles are formed over the outer surface or the inner surface of the shell portion and aligned substantially from the tip portion to the bottom portion.

84. The dental aligner of claim 82, wherein the wrinkles are aligned substantially across the direction from the tip portion to the bottom portion.

85. The dental aligner of claim 82, wherein the wrinkles include a corrugated structure over the bottom portion.

86. The dental aligner of claim 82, wherein the wrinkles are formed by a material that is different from the material in the shell portion.

87. The dental aligner of claim 82, wherein the shell portion comprises a material selected from the group consisting of plastics, polymers, urethane, epoxy, plaster, stone, clay, acrylic, metals, wood, paper, ceramics, and porcelain.

88. The dental aligner of claim 82, wherein the shell portion comprises varying thicknesses in different areas.

89. The dental aligner of claim 82, wherein the shell portion comprises a plurality of layers each comprising the same or different materials.

90. A method for manufacturing wrinkled dental aligner for a patient's arch, comprising:

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producing a physical dental aligner for the patient's arch, wherein the physical dental aligner comprises substantially smooth surfaces; and

producing at least one wrinkle over one of the substantially smooth surfaces on the physical dental aligner to form a wrinkled surface on the dental aligner.

91. The method of claim 90, further comprising: simultaneously producing the physical dental aligner and the wrinkled surface on the physical dental aligner.

92. The method of claim 90, further comprising: producing the wrinkled surface on the physical dental aligner by one or more of vacuum forming, cutting, milling, etching by a thermal applier, a laser, and CNC based manufacturing.

93. A system for manufacturing shell-shaped dental aligner for producing predetermined movement in a patient's tooth, comprising:

a computer configured to store a digital dental aligner model that specifies a shell portion including an outer surface and an inner surface to be in contact with the patient's tooth, a bottom portion to be placed near the gingival of the patient's tooth, a tip portion on the opposite side of the bottom portion, and one or more wrinkles formed over at least one of the outer surface of the shell portion, the inner surface of the shell portion, and the bottom portion; and

an apparatus configured to produce a physical dental aligner having a wrinkled surface in accordance with the digital dental aligner model.

94. The system of claim 93, wherein the computer is configured to simulate the physical dental aligner having a wrinkled surface using the digital dental aligner model to optimize the properties of the one or more wrinkles.

95. The system of claim 94, wherein the properties of the wrinkles include one or more of the locations and orientations of the wrinkles, the spacing between adjacent wrinkles, and the depths of the wrinkles.

96. The system of claim 93, wherein the apparatus configured to produce the wrinkled surface on the physical dental aligner by one or more of vacuum forming, cutting,

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milling, etching by a thermal applier, cutting by a laser beam, and CNC based manufacturing.

97. The system of claim 93, wherein the wrinkles are formed over the outer surface or the inner surface of the shell portion and aligned substantially from the tip portion to the bottom portion.

98. The system of claim 93, wherein the wrinkles are aligned substantially across the direction from the tip portion to the bottom portion.

99. The system of claim 93, wherein the wrinkles include a corrugated structure over the bottom portion.

100. The system of claim 93, wherein the shell portion comprises varying thicknesses in different areas.

101. The system of claim 93, wherein the shell portion comprises a plurality of layers.

102. A method for manufacturing wrinkled dental aligner for a patient's tooth, comprising:

developing a digital dental aligner model specifying at least one wrinkled surface on a dental aligner; and

producing a dental aligner having the wrinkled surface in accordance with digital dental aligner model.

103. The method of claim 102, further comprising: producing the physical dental aligner having the wrinkled surface by vacuum forming over a dental arch model of the patient, wherein at least one surface of the dental arch model includes features to produce wrinkled surface on the dental aligner.

104. The method of claim 102, further comprising: producing the wrinkled surface on the physical dental aligner by embedding a high-tension material under the surface of the physical dental aligner.

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105. The method of claim 102, further comprising: producing the wrinkled surface on the physical dental aligner by cutting the surface of a physical dental aligner.

106. The method of claim 102, further comprising: producing the wrinkled surface on the physical dental aligner etching the surface of the physical dental aligner by a thermal applier or a laser beam.

107. The method of claim 102, further comprising:

fabricating aligner components using CNC based manufacturing in accordance with the digital dental aligner model; and

producing the physical dental aligner having the wrinkled surface by assembling the aligner components.

108. The method of claim 107, wherein the CNC based manufacturing includes one or more of milling, stereo lithography, laser machining, molding, and casting.

109. The method of claim 107, further comprising: producing physical features on the aligner components to permit the aligner components to be assembled into the physical dental aligner having at least one wrinkled surface.

110. The method of claim 102, further comprising:

simulating the dental aligner having the wrinkled surface using the digital dental aligner model; and

optimizing the properties of the wrinkles on the wrinkled surface.

111. The method of claim 110, wherein the properties of the wrinkles include one or more of the locations of the wrinkles, the orientations of the wrinkles, the spacing between adjacent wrinkles, and the depths of the wrinkles.

112. The method of claim 102, further comprising: developing the digital dental aligner model based on a digital dental arch model.

113. A method for manufacturing wrinkled dental aligner for a patient's arch, comprising:

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developing a digital dental arch model based the patient's arch;

developing a digital dental aligner model based on the digital dental arch model, wherein the digital dental aligner model specifies one or more wrinkles on a surface; and

producing a wrinkled dental aligner in accordance with the digital dental aligner model.

114. The method of claims 113, further comprising:

segmenting the digital dental aligner model into a plurality of manufacturable digital aligner components;

producing physical aligner components using Computer Numerical Control (CNC) based manufacturing in accordance with the digital aligner components; and

assembling the physical aligner components to form the wrinkled dental aligner.

115. The method of claim 114, wherein the CNC based manufacturing includes one or more of milling, stereo lithography, laser machining, molding, and casting.

116. The method of claim 114, further comprising: producing physical features on the aligner components to permit the aligner components to be assembled into the physical dental aligner having at least one wrinkled surface.

117. A system for manufacturing a wrinkled dental aligner for a patient, comprising:

a computer configured to store a digital dental aligner model specifying at least one wrinkled surface on the wrinkled dental aligner; and

an apparatus configured to produce the wrinkled dental aligner in accordance with digital dental aligner model.

118. The system of claim 117, wherein the computer is configured to simulate the wrinkled dental aligner using the digital dental aligner model and to optimize the properties of the wrinkled surface.

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119. The system of claim 118, wherein the properties of the wrinkled surface include one or more of the locations of the wrinkles, the orientations of the wrinkles, the spacing between adjacent wrinkles, and the depths of the wrinkles.

120. The system of claim 117, wherein the apparatus is configured to produce the wrinkled dental aligner by one or more of vacuum forming, cutting, etching by a thermal applier, cutting by a laser beam, and CNC based manufacturing.

121. A method for treating a patient's teeth, comprising

determining an initial configuration of the patient's teeth;

determining a final configuration of the patient's teeth;

designing a movement path for at least one of the patient's teeth from the initial configuration to the final configuration;

dividing the movement path into a plurality of successive treatment steps, each having a target configuration for the one of the patient's teeth; and

producing two or more dental aligners of substantially identical shape to move the one of the patient's teeth to the target configuration.

122. The method of claim 121, further comprising

estimating the amount of time a treatment step will take; and

estimating an optimal wearing interval for the dental aligners.

123. The method of claim 122, wherein the step of producing two or more dental aligners of substantially identical shape comprises producing the number of dental aligners needed for the treatment step based on the estimated amount of time the treatment step will take and the estimate of the optimal wearing interval.

124. The method of claim 121, further comprising:

simulating the dental aligners of substantially identical shape needed for the target configuration at the treatment steps using a digital aligner model; and

producing two or more dental aligners of substantially identical shape in accordance with the digital aligner model.

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125. A method for treating a patient's teeth, comprising
determining a target configuration for the patient's teeth;
producing at least two dental aligners having substantially identical shape; and
using the two dental aligners to move the patient's teeth to the target configuration.

126. The method of claim 125, wherein the two dental aligners comprise different material compositions.

127. The method of claim 125, wherein each dental aligner is used for not longer than three days.

128. A lateral correction dental aligner for remodeling a subject's upper dental arch including the palate, the aligner comprising:
a shell having an outer surface and an inner surface, the shell comprising:
a tooth contacting region configured to contact the teeth of the subject's upper arch; and
a palate-spanning region, wherein the palate-spanning region is configured to contact the subject's upper palate and provide force to remodel the subject's upper arch.

129. The lateral correction dental aligner of claim 128, wherein the palate-spanning region further comprises a support piece configured to provide structural support to the palate-spanning region.

130. The lateral correction dental aligner of claim 128, wherein the palate-spanning region comprises a fluid-permeable material.

131. The lateral correction dental aligner of claim 128, wherein the palate-spanning region spans the majority of the hard palate.

130. A method for reshaping a patient's dental palate, comprising
determining an initial configuration of the patient's teeth and upper palate region;
determining a final configuration of the patient's teeth and upper palate region;

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designing a movement path for at least a portion of the upper palate region from the initial configuration to the final configuration;

dividing the movement path into a plurality of successive treatment steps; and

producing a plurality of dental aligners including a palate-spanning region to remodel the upper palate region to the target configuration.

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Figure 1A

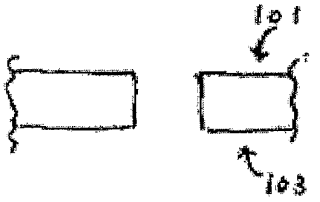


Figure 1B

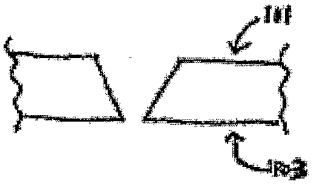


Figure 1C

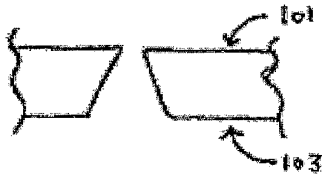


Figure 1D

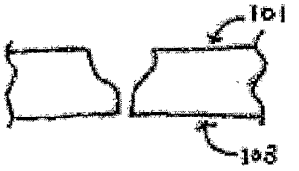


Figure 1E

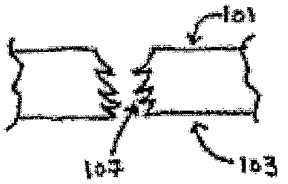


Figure 1F

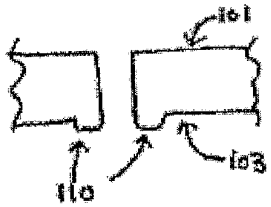


Figure 2A



Figure 2B



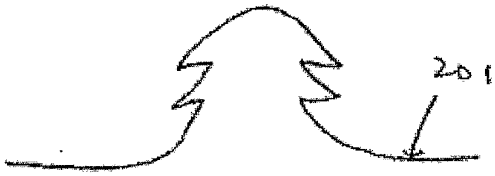
Figure 2C



Figure 2D



Figure 2E



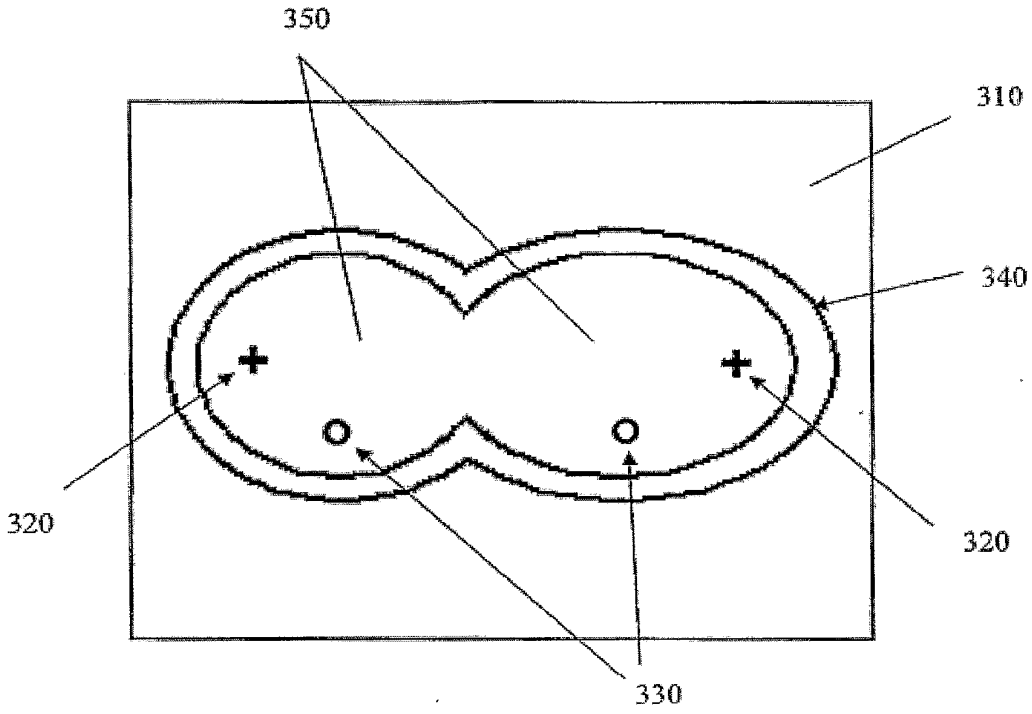


Figure 3

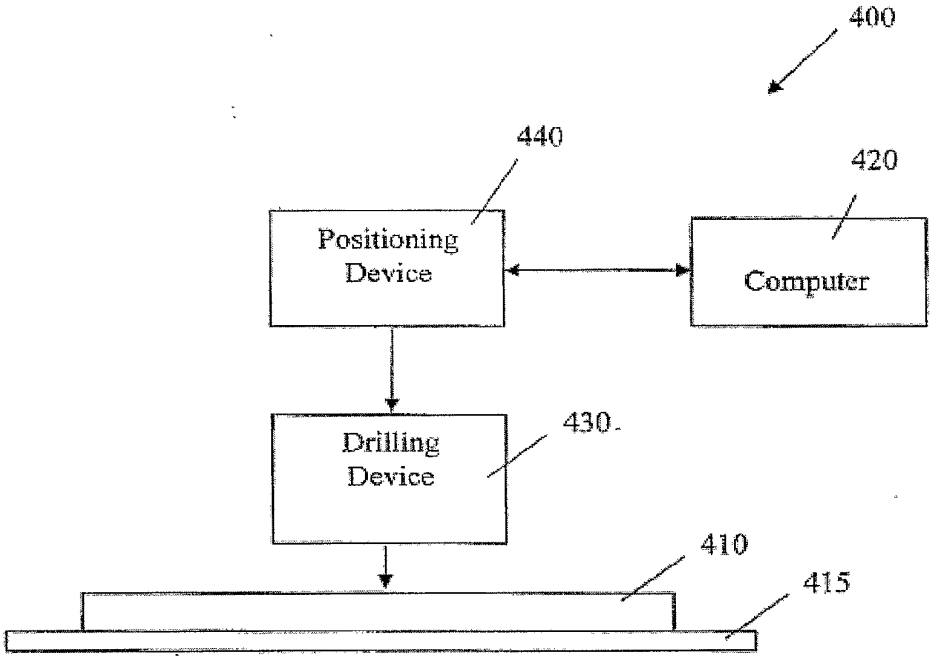

400
440
420
Positioning Device
Computer
Drilling Device
430
410
415

Figure 4

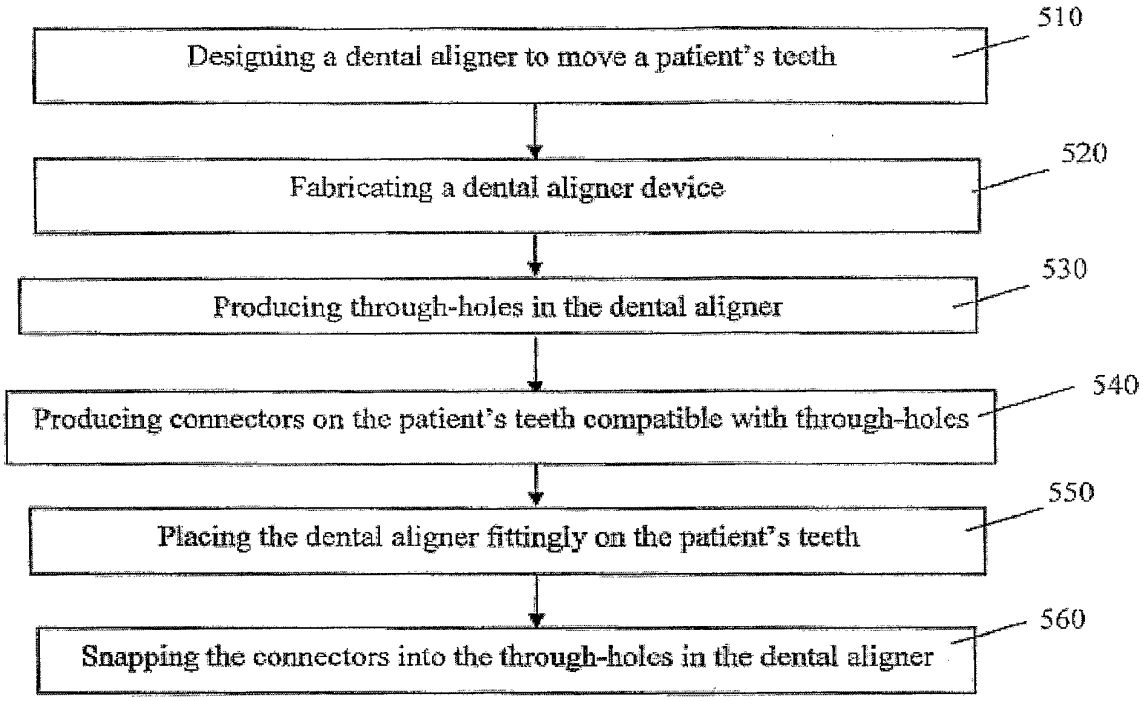

Designing a dental aligner to move a patient's teeth
510
Fabricating a dental aligner device
520
Producing through-holes in the dental aligner
530
Producing connectors on the patient's teeth compatible with through-holes
540
Placing the dental aligner fittingly on the patient's teeth
550
Snapping the connectors into the through-holes in the dental aligner
560

Figure 5

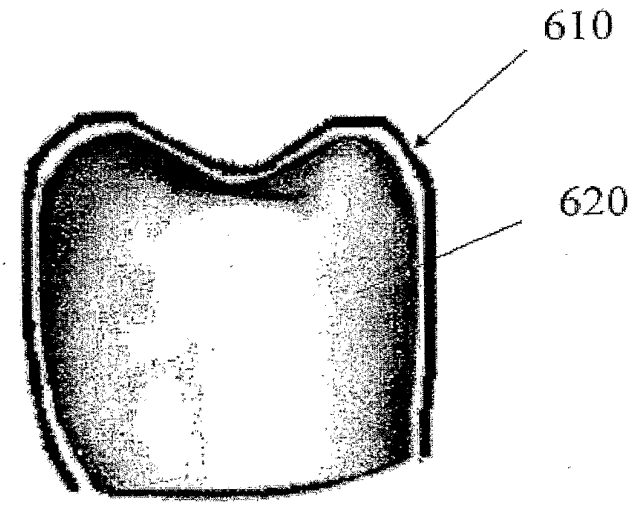


Figure 6

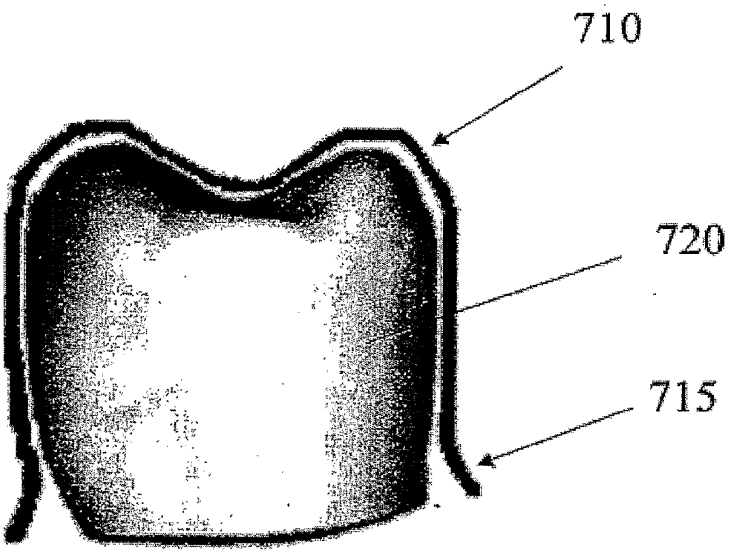


Figure 7

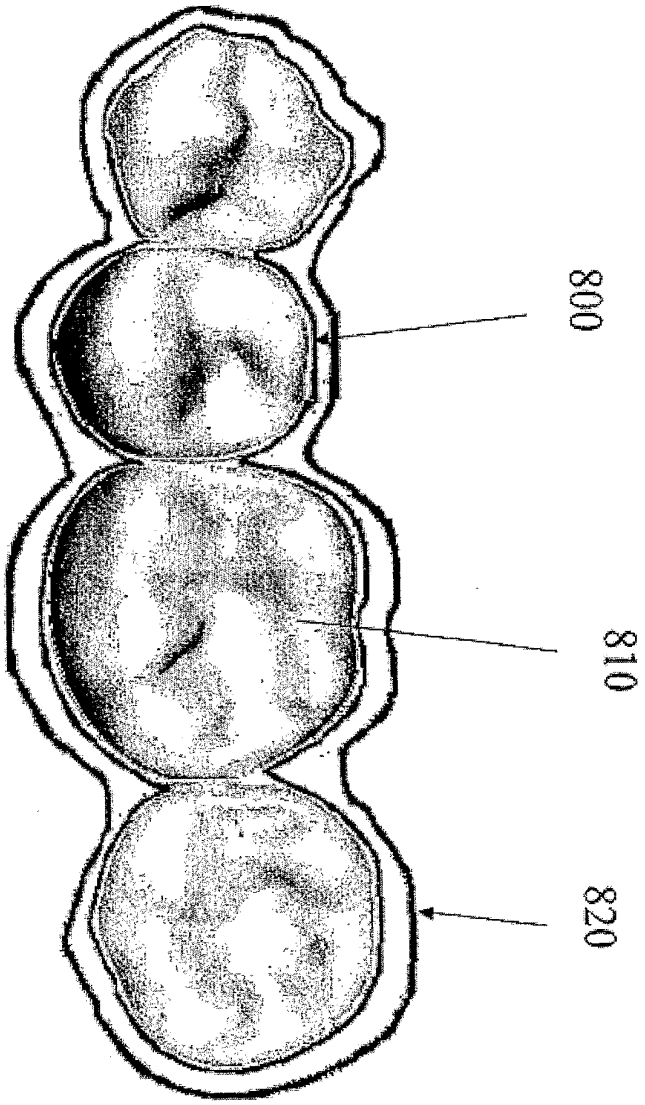


Figure 8

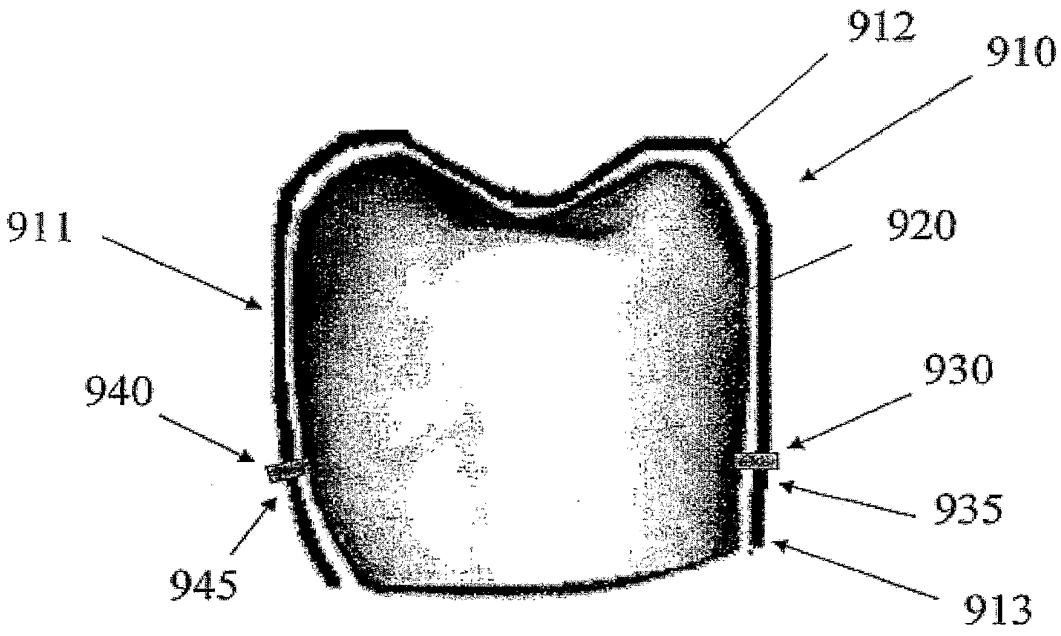
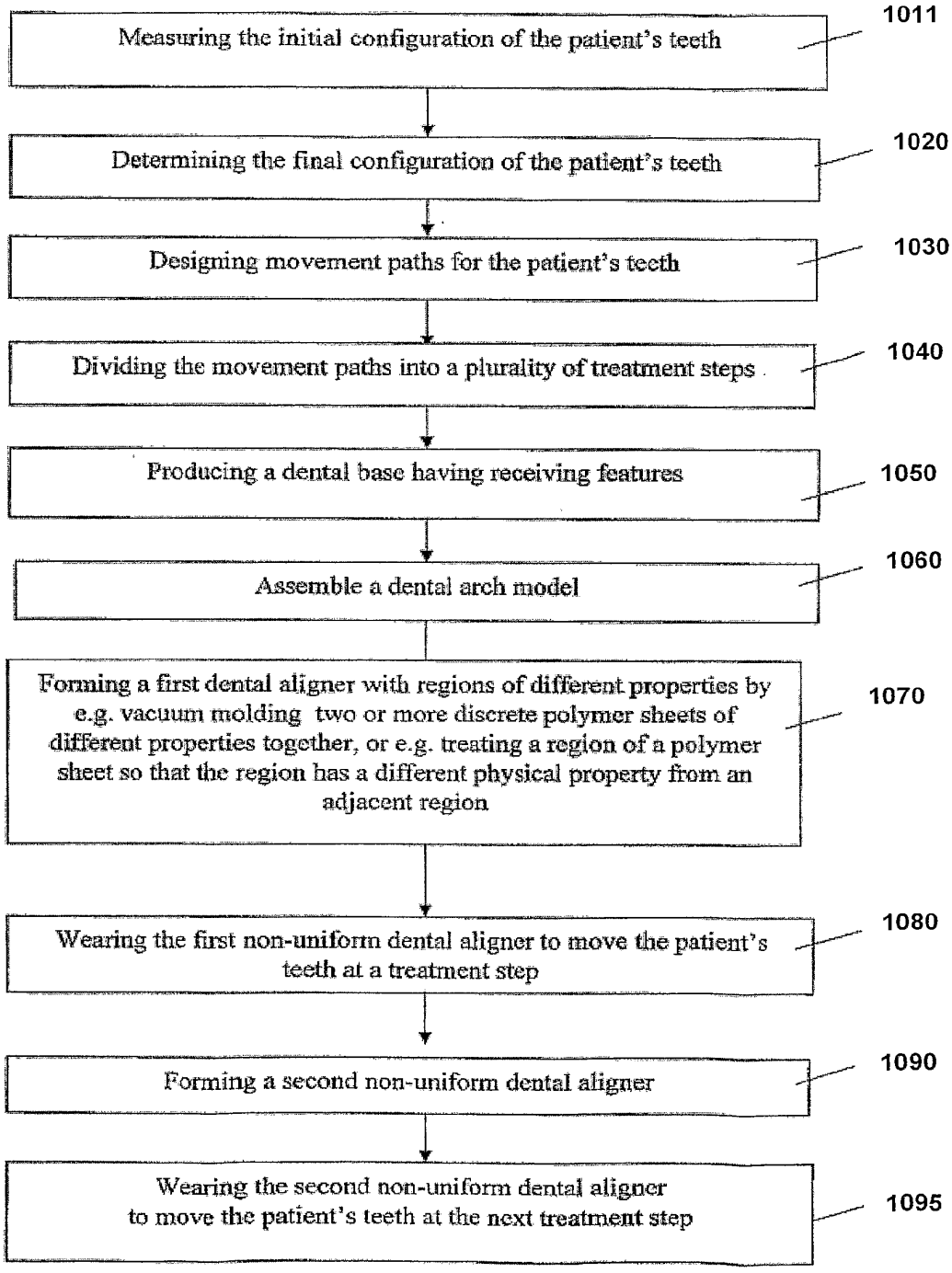


Figure 9

Figure 10


Measuring the initial configuration of the patient's teeth
1011
Determining the final configuration of the patient's teeth
1020
Designing movement paths for the patient's teeth
1030
Dividing the movement paths into a plurality of treatment steps
1040
Producing a dental base having receiving features
1050
Assemble a dental arch model
1060
Forming a first dental aligner with regions of different properties by e.g. vacuum molding two or more discrete polymer sheets of different properties together, or e.g. treating a region of a polymer sheet so that the region has a different physical property from an adjacent region
1070
Wearing the first non-uniform dental aligner to move the patient's teeth at a treatment step
1080
Forming a second non-uniform dental aligner
1090
Wearing the second non-uniform dental aligner to move the patient's teeth at the next treatment step
1095

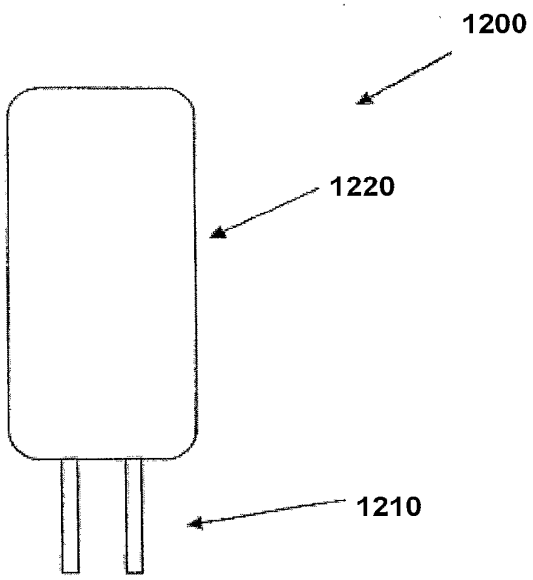


Figure 11

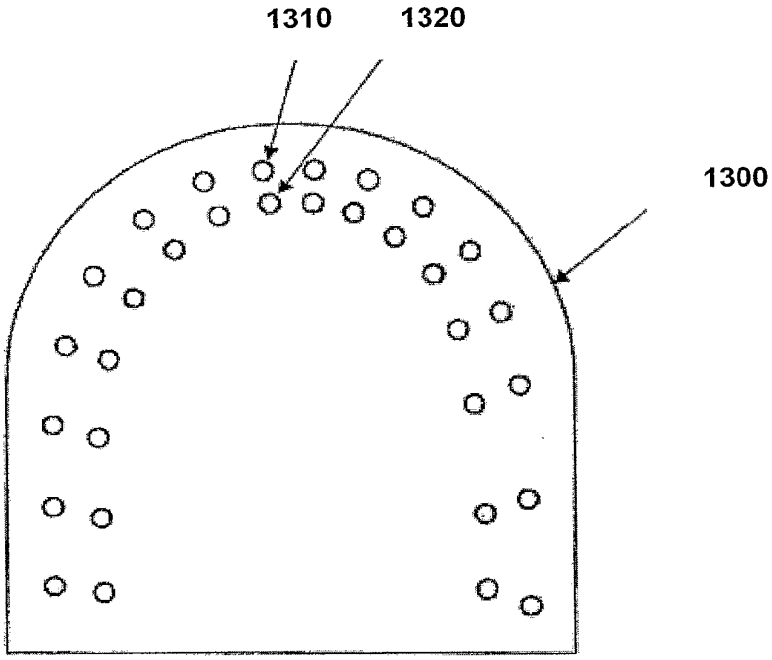


Figure 12

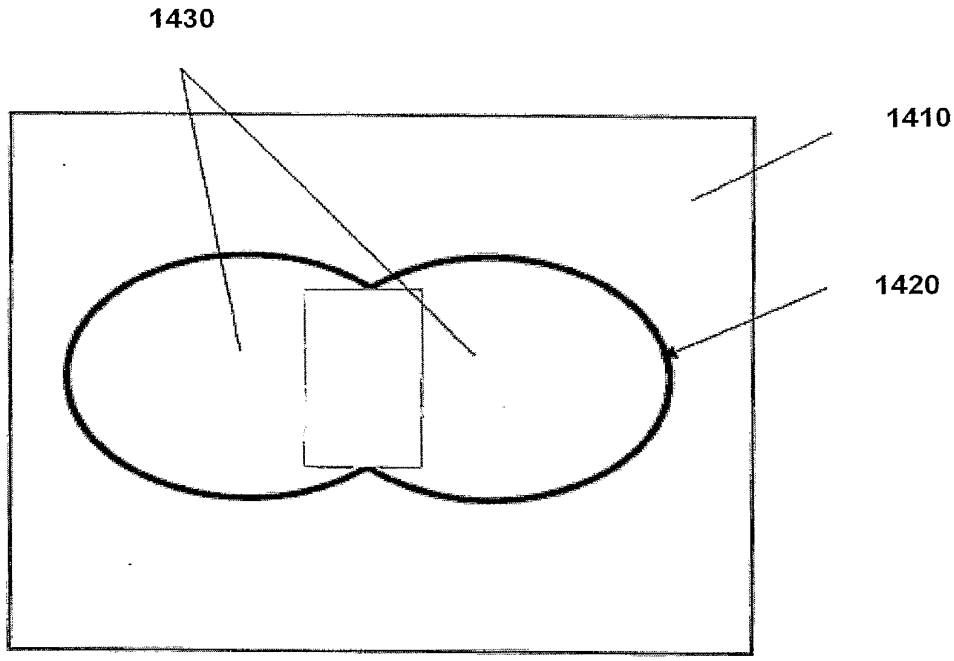


Figure 13

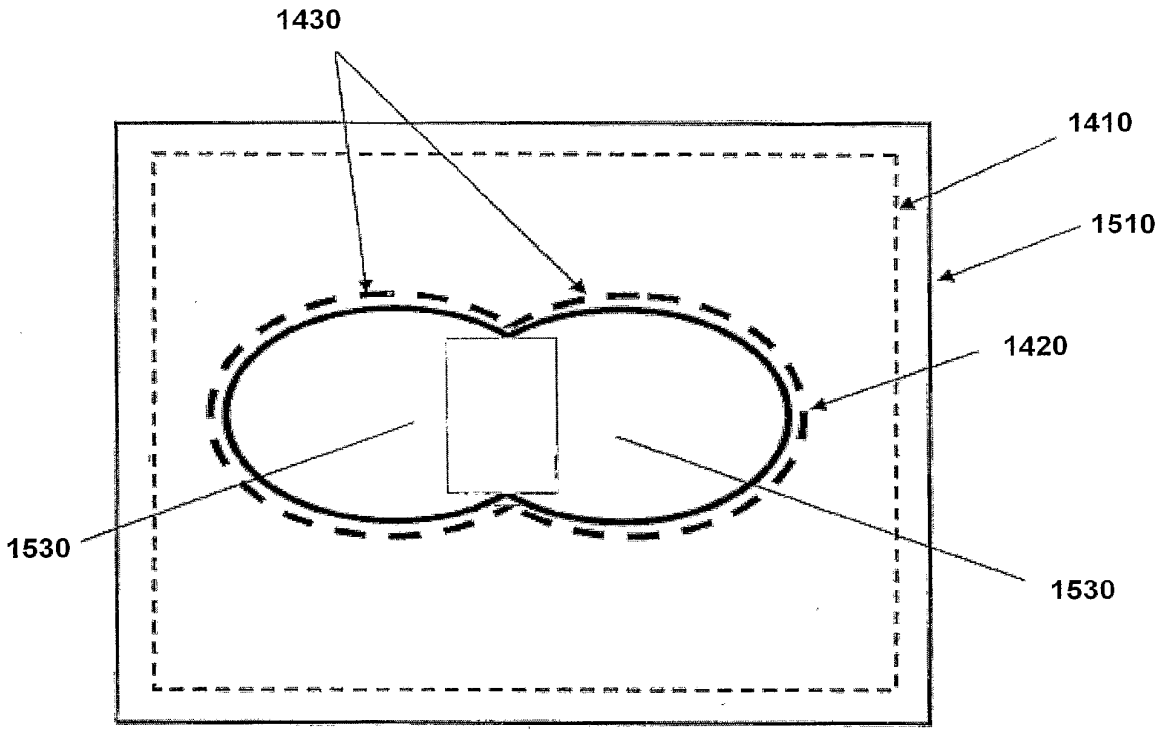


Figure 14

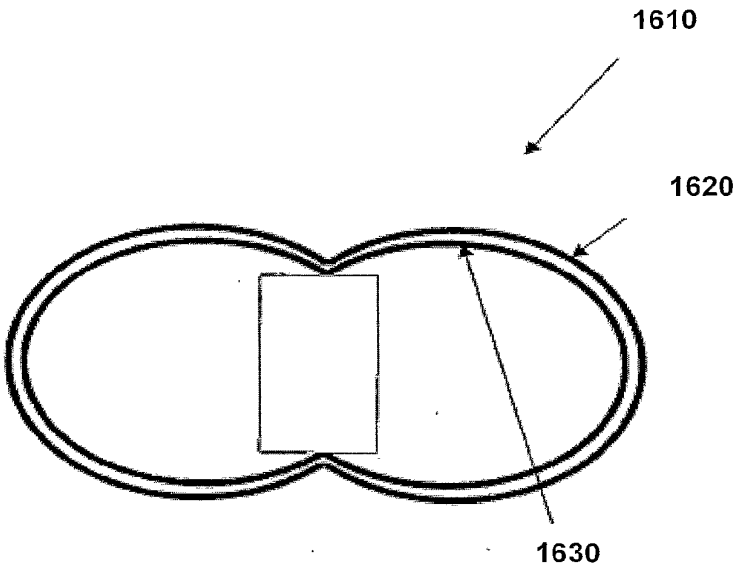


Figure 15

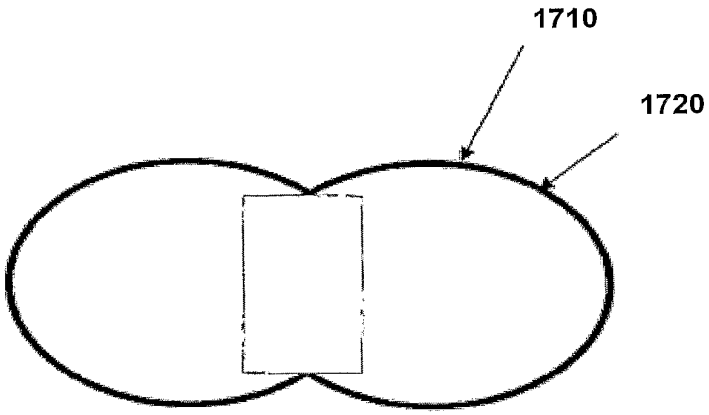


Figure 16

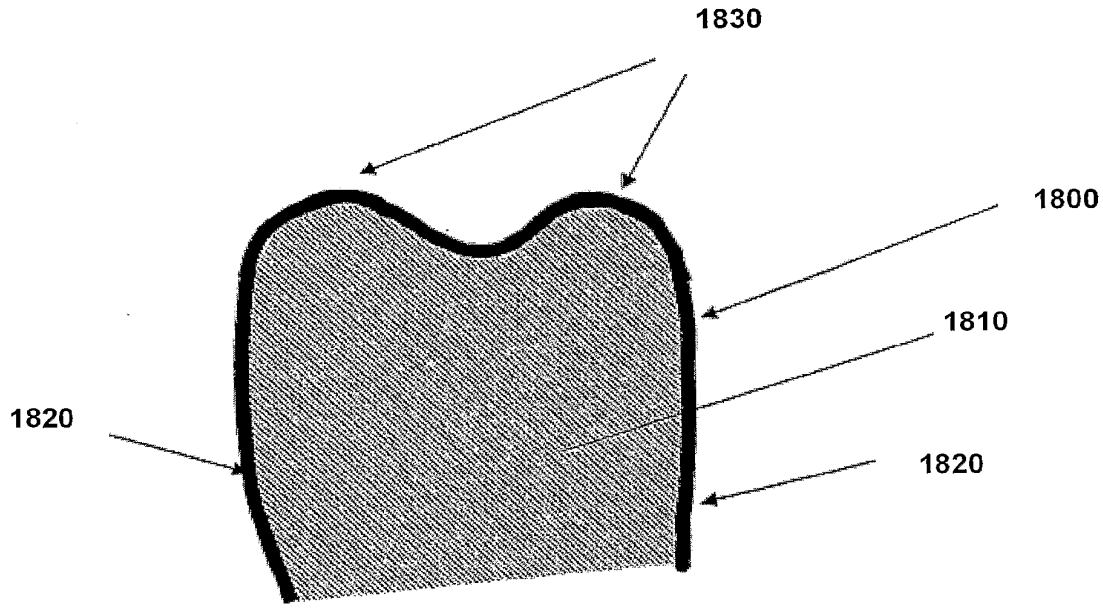


Figure 17

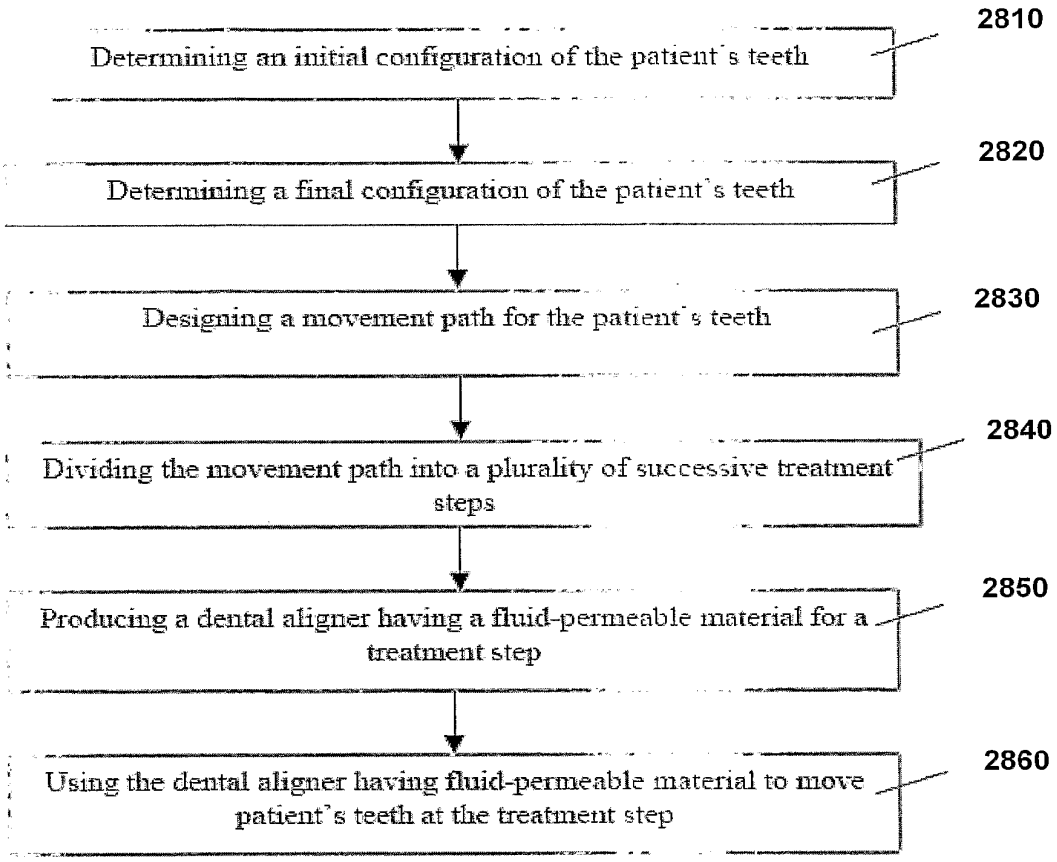

Determining an initial configuration of the patient's teeth
2810
Determining a final configuration of the patient's teeth
2820
Designing a movement path for the patient's teeth
2830
Dividing the movement path into a plurality of successive treatment steps
2840
Producing a dental aligner having a fluid-permeable material for a treatment step
2850
Using the dental aligner having fluid-permeable material to move patient's teeth at the treatment step
2860

Figure 18

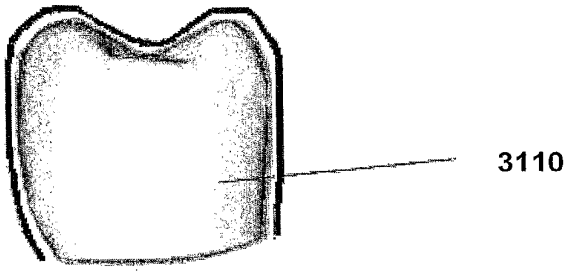


Figure 19a

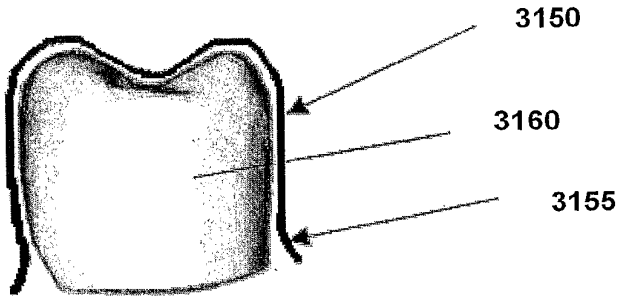


Figure 19b

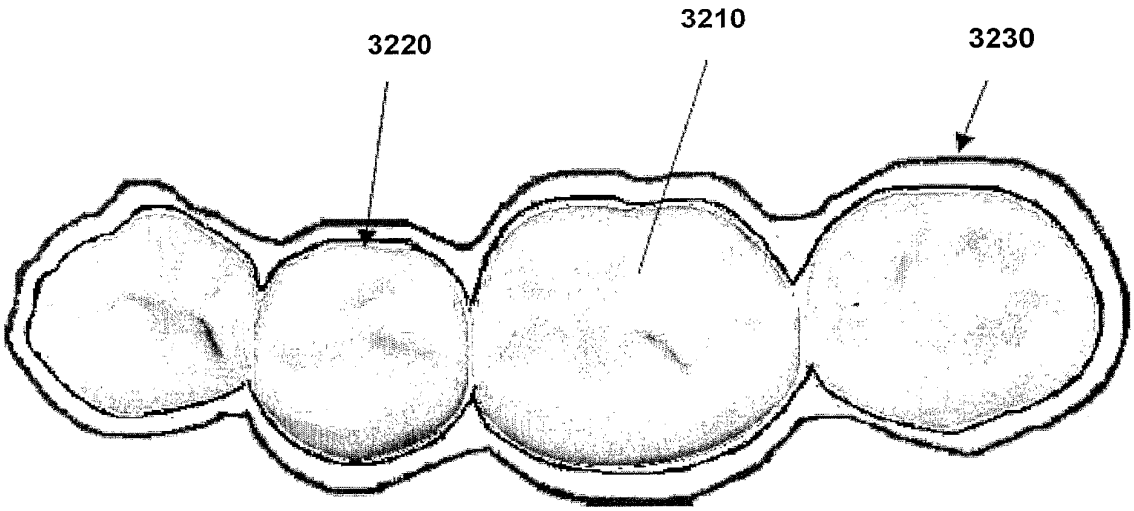


Figure 20

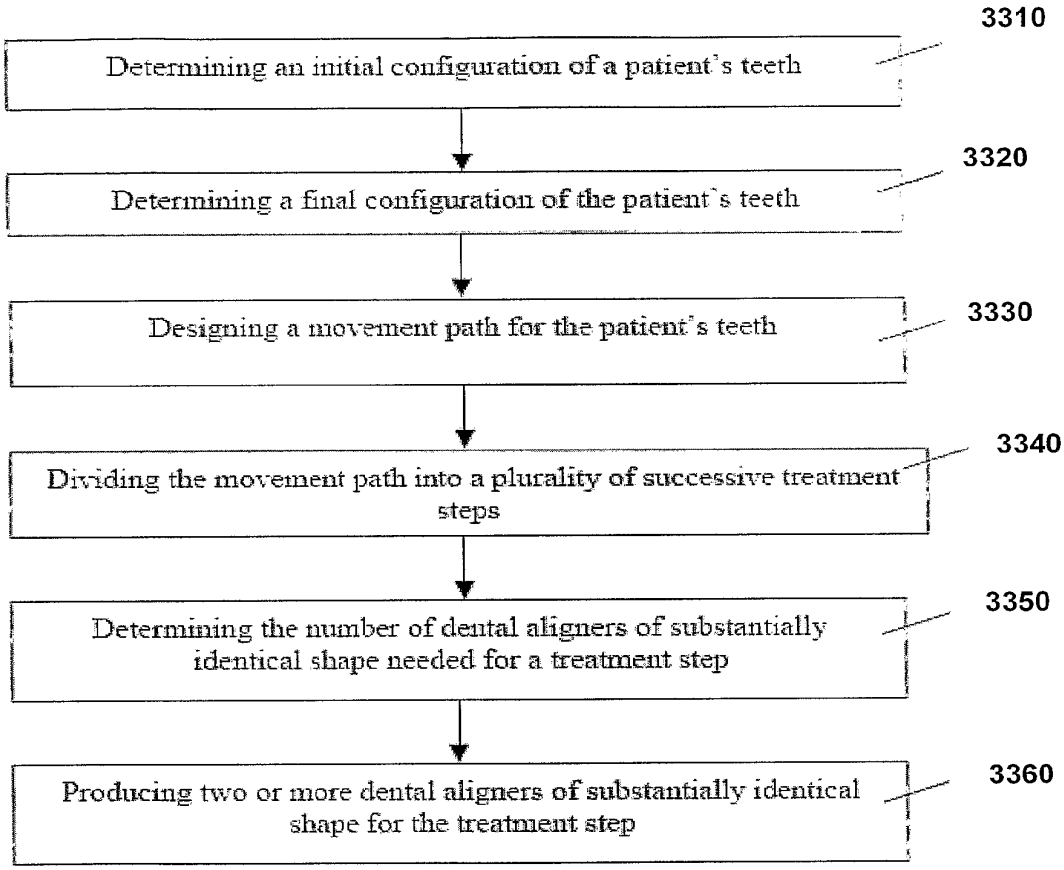

3310
Determining an initial configuration of a patient's teeth
3320
Determining a final configuration of the patient's teeth
3330
Designing a movement path for the patient's teeth
3340
Dividing the movement path into a plurality of successive treatment steps
3350
Determining the number of dental aligners of substantially identical shape needed for a treatment step
3360
Producing two or more dental aligners of substantially identical shape for the treatment step

Figure 21

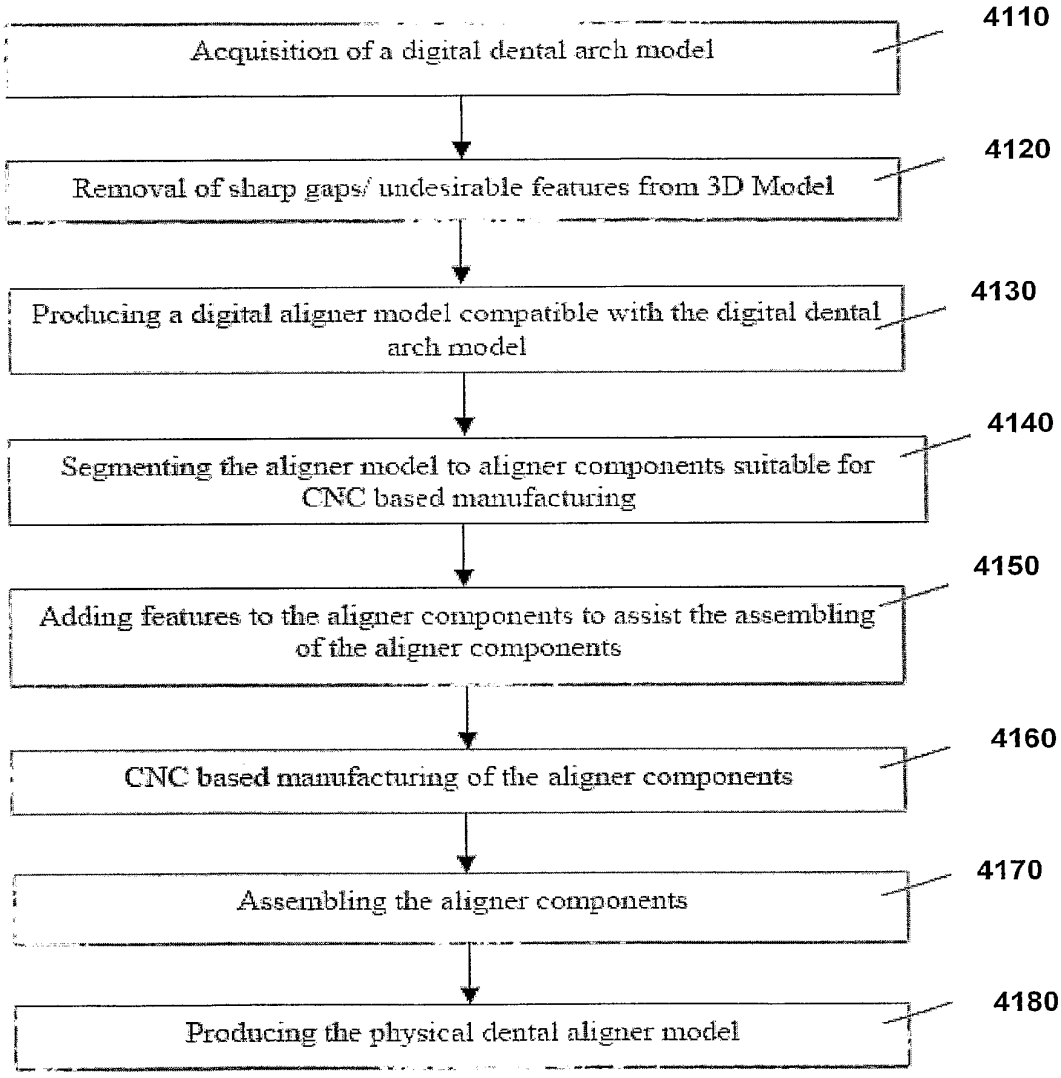

Acquisition of a digital dental arch model
4110
Removal of sharp gaps/ undesirable features from 3D Model
4120
Producing a digital aligner model compatible with the digital dental arch model
4130
Segmenting the aligner model to aligner components suitable for CNC based manufacturing
4140
Adding features to the aligner components to assist the assembling of the aligner components
4150
CNC based manufacturing of the aligner components
4160
Assembling the aligner components
4170
Producing the physical dental aligner model
4180

Figure 22

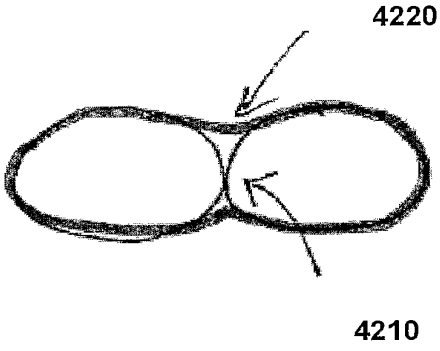


Figure 23

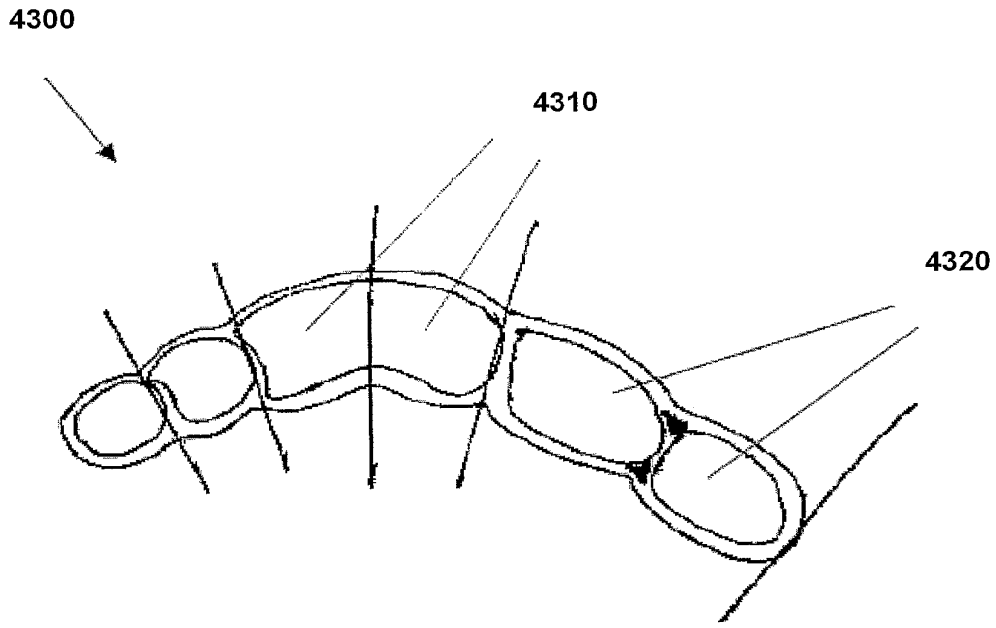


Figure 24

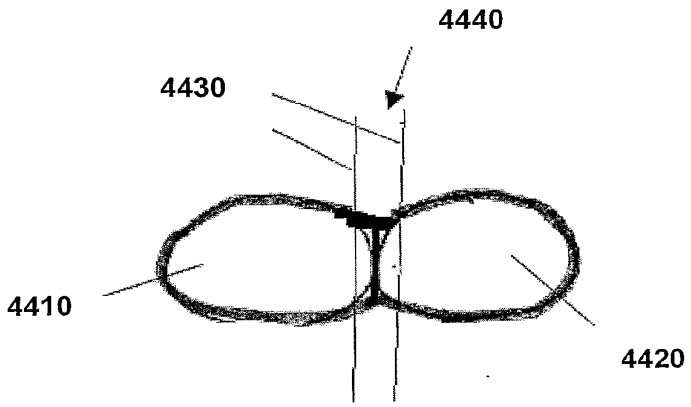


Figure 25a

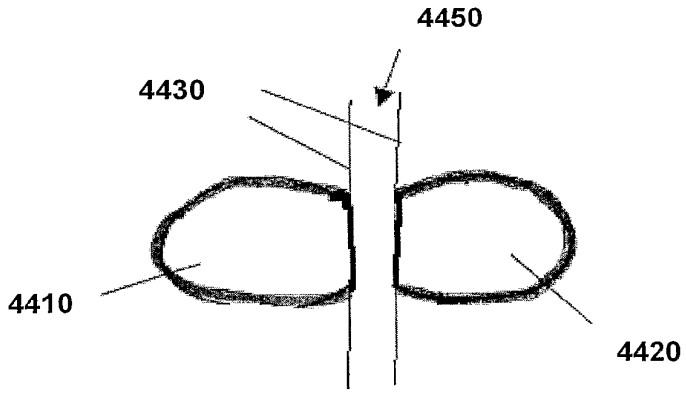


Figure 25b

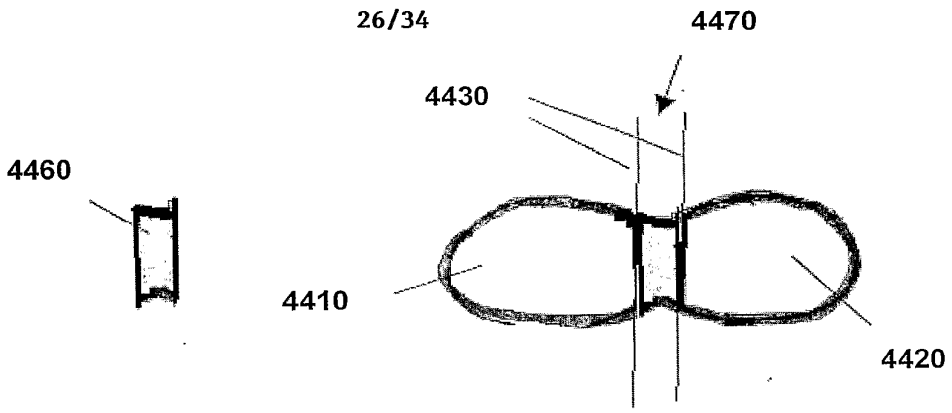


Figure 25c

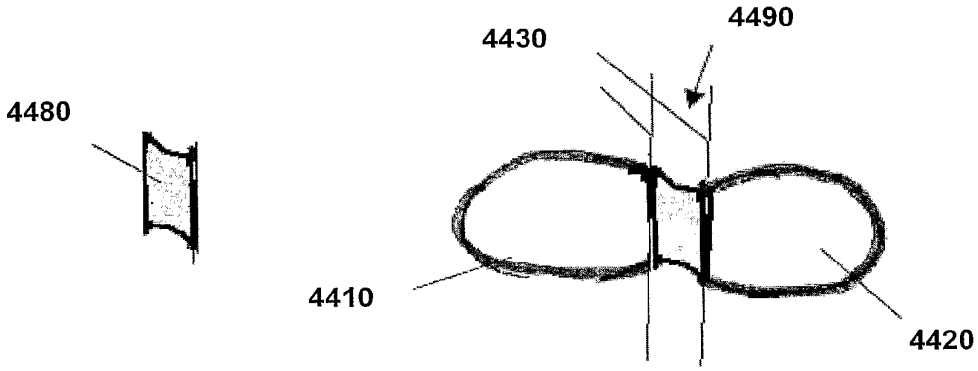


Figure 25d

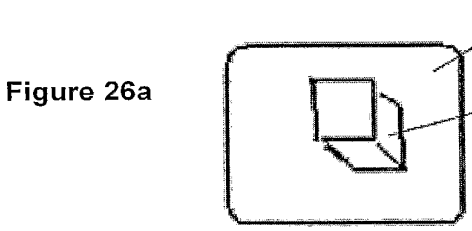


Figure 26a

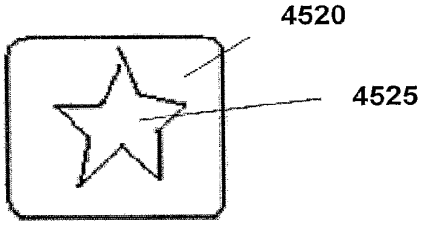


Figure 26b

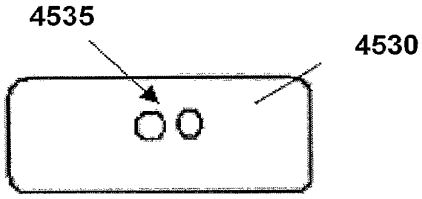


Figure 26c

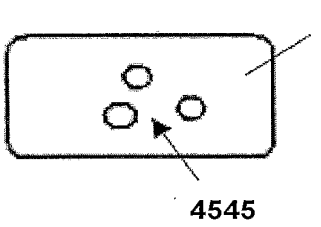


Figure 26d

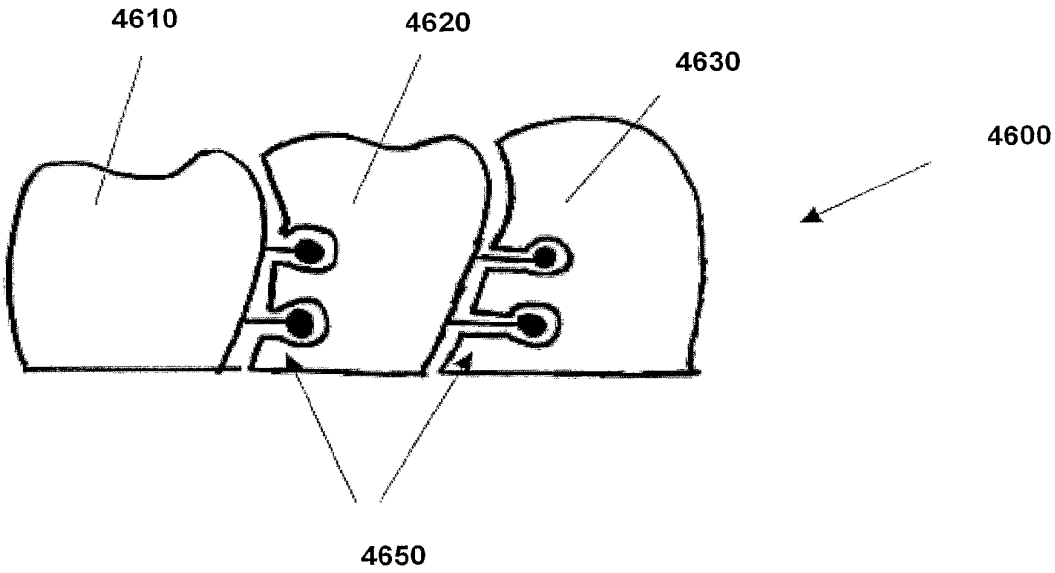


Figure 27

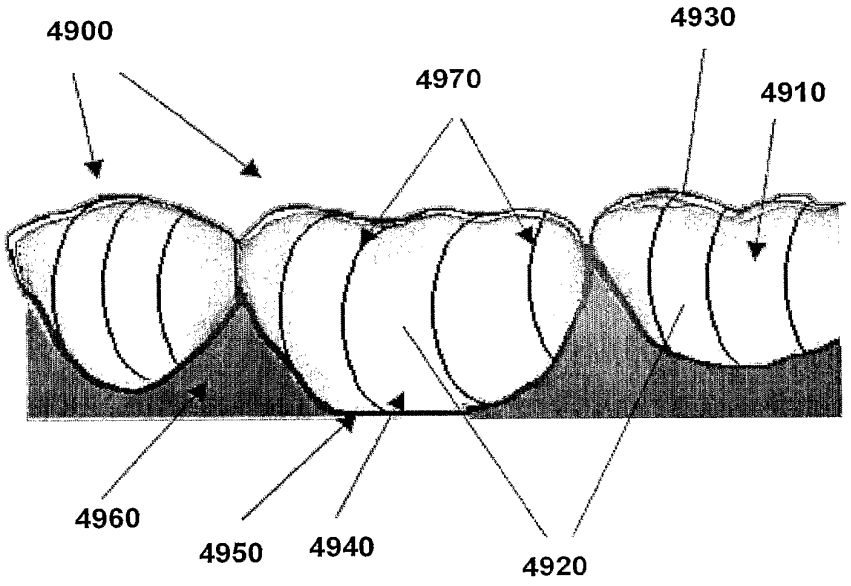


Figure 28

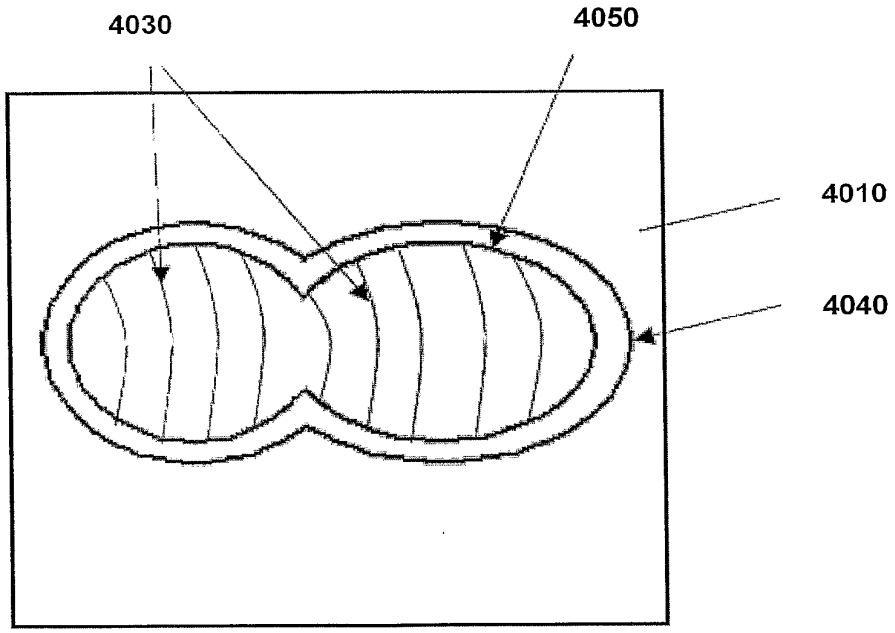


Figure 29

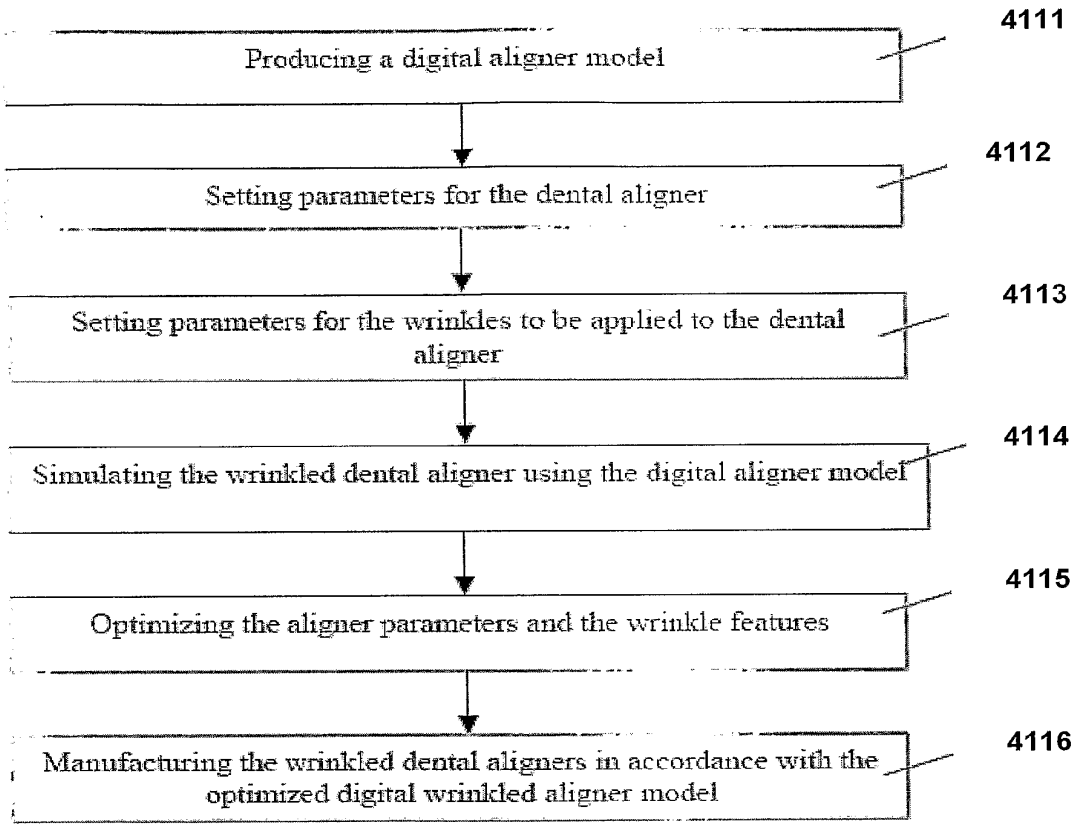

Producing a digital aligner model
4111
Setting parameters for the dental aligner
4112
Setting parameters for the wrinkles to be applied to the dental aligner
4113
Simulating the wrinkled dental aligner using the digital aligner model
4114
Optimizing the aligner parameters and the wrinkle features
4115
Manufacturing the wrinkled dental aligners in accordance with the optimized digital wrinkled aligner model
4116

Figure 30

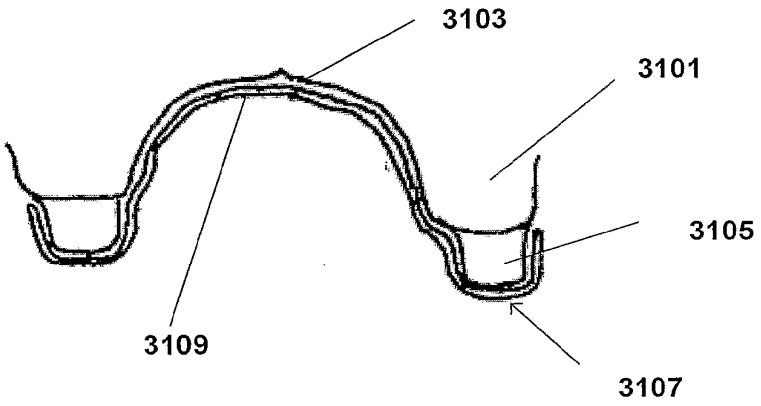


Figure 31a

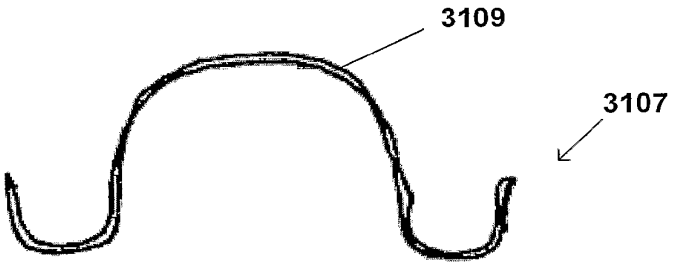


Figure 31b

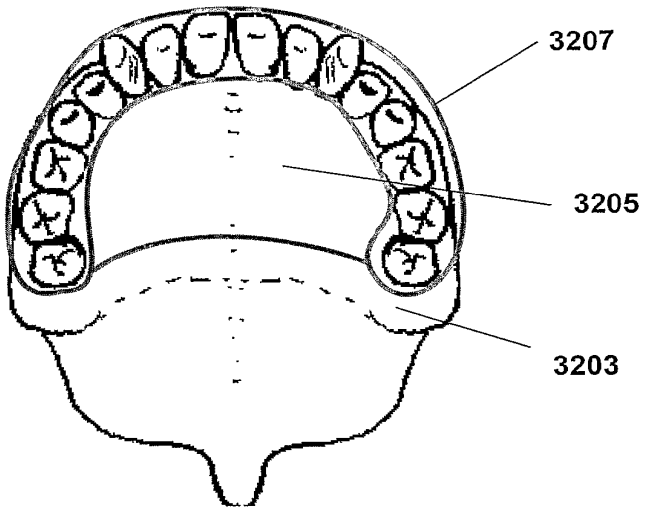


Figure 32a

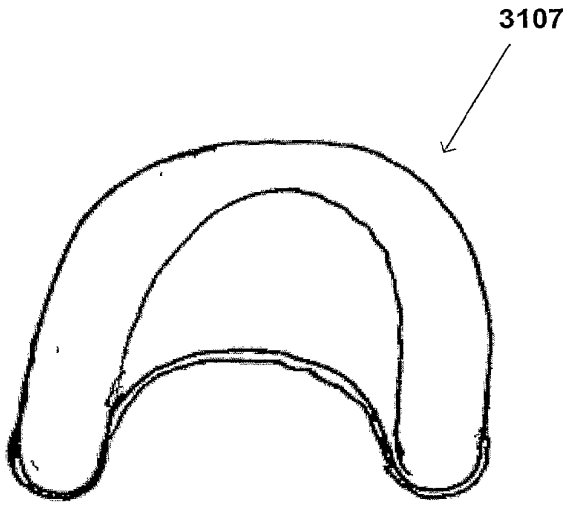


Figure 32b

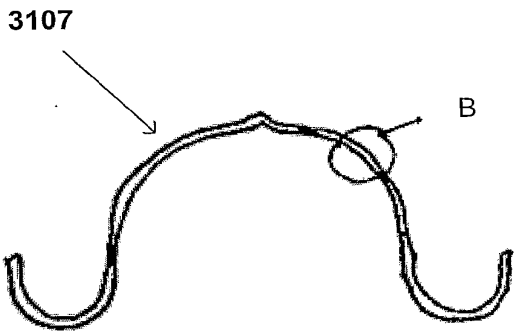


Figure 33a

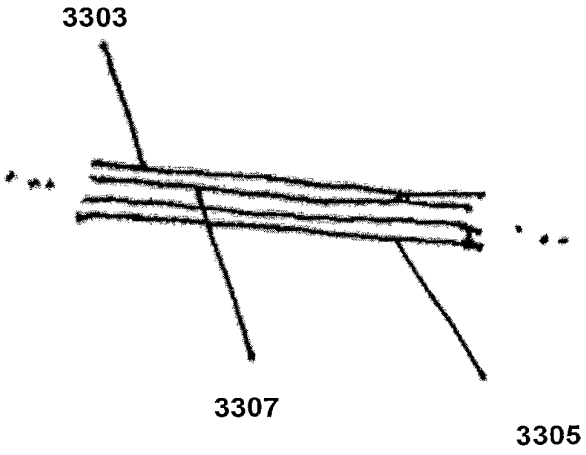


Figure 33b

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(54) Title: CYCLIC BLOCK COMPOLYMER COMPOSITIONS AND ARTICLES OF MANUFACTURE FABRICATED THEREFROM

(57) Abstract: Convert cyclic block copolymer compositions into mono-layer sheets or multi-layer sheets that have at least one cyclic block copolymer composition layer and transform the sheets into articles of manufacture such as orthodontic appliances.

CYCLIC BLOCK COMPOLYMER COMPOSITIONS AND ARTICLES OF MANUFACTURE FABRICATED THEREFROM

This application is a non-provisional application claiming priority from the U.S. Provisional Patent Application No. 61/122,931, filed on December 16, 2008, entitled "CYCLIC BLOCK COPOLYMER COMPOSITIONS AND ARTICLES OF MANUFACTURE FABRICATED THEREFROM," the teachings of which are incorporated by reference herein, as if reproduced in full hereinbelow.

This invention relates to cyclic block copolymer (CBC) compositions, mono-layer sheets fabricated from such compositions, multi-layer sheets having at least one layer fabricated from such compositions, and articles of manufacture (e.g. an orthodontic appliance) fabricated, at least in part, from a mono-layer sheet, a multi-layer sheet or both a mono-layer sheet and a multi-layer sheet.

A growing trend exists that focuses on use of clear, transparent plastic orthodontic devices to align human teeth. Growth stems, at least in part, from ease of use and relative aesthetic beauty relative to conventional orthodontic braces or devices based upon metal.

Manufacturers of plastic orthodontic devices desire a plastic material that allows for or promotes movement of human teeth in a controlled, uniform and safe manner for as large a portion of the human population as possible. In attempts to satisfy this desire, manufacturers currently use transparent, thermoplastic resins or materials such as rigid, thermoplastic polyurethane (TPU), polycarbonate (PC) or saturated polyester. Devices fabricated from PC resins tend to undergo environmental stress cracking when exposed to human saliva. Devices fabricated from rigid TPU or polyester resins often show undesirable levels of creep when exposed to human saliva, possibly due in part to a tendency of such resins toward plasticization when immersed in water.

United States Patent (US) 6,964,564 (Phan et al.) discloses improved devices, systems and methods for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The system comprises a series of polymeric shell appliances configured to receive teeth and incrementally reposition individual teeth in a series of incremental steps. See also related USP 6,454,565 (Phan et al.) and USP 6, 424,101 (Phan et al.).

United States Patent Application Publication (USPAP) 2006/0078841 (DeSimone et al.) teaches forming a polymeric shell of a removable dental positioning appliance from transparent polymeric materials having a tensile strength at yield of greater than 6,000

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pounds per square inch (psi), an elongation at yield of greater than 4%, an elongation at break of greater than 80%, a tensile modulus greater than 200,000 psi, a flexural modulus greater than 200,000 psi, stress relaxation over time of not more than 50%, and a transmissivity of light between 400 nm and 800 nm greater than 75%.

In some aspects, this invention is a CBC composition, the composition comprising a CBC that is a substantially fully hydrogenated vinyl aromatic-conjugated diene block copolymer, said substantially fully hydrogenated block copolymer having an elongation strain at break of more than 30% and a modulus that is within a range of from greater than or equal to 150,000 pounds per square inch (psi) (1034 megapascals (MPa) to less than 270,000 psi (1862 MPa). Determine both elongation strain at break and modulus in accord with American Society for Testing and Materials (ASTM) Test D638-02a.

In some aspects, the CBC is a functionalized CBC. Examples include but not restricted to, silane-grafted CBCs, maleic anhydride grafted CBCs, acrylate-grafted CBCs, methacrylate-grafted CBCs and siloxanes-grafted CBCs. Silane-grafted CBCs employ a grafting moiety such as vinyl trimethoxy silane (VTMS) or vinyl triethoxy silane (VTES) which crosslinks upon hydrolysis. Siloxane grafted CBCs employ a grafting moiety such as a vinyl terminated polydimethyl siloxane that does not undergo crosslinking upon hydrolysis.

In some aspects, the aforementioned CBC composition further comprises an amount of at least one other polymer or copolymer selected from a group consisting of a non-hydrogenated vinyl aromatic-conjugated diene block copolymer or random copolymer, a hydrogenated vinyl aromatic homopolymer, a cyclic olefin polymer, or a cyclic olefin copolymer.

The CBC compositions disclosed above have utility in that they may readily be formed (e.g. extruded, or injection molded) into a sheet, either mono-layer or multi-layer. The sheet, in turn, has utility in that it can be thermoformed into a shaped article such as an orthodontic appliance. In view of these utilities, additional aspects follow in succeeding paragraphs.

In some aspects, this invention is a multi-layer, thermoformable, polymeric sheet, the sheet comprising at least one hard layer and at least one soft layer, the hard layer comprising the CBC composition described in the immediately preceding two paragraphs and the soft layer comprising an elastomeric, substantially fully hydrogenated CBC composition, the

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elastomeric CBC composition comprising a substantially fully hydrogenated vinyl aromatic-conjugated diene block copolymer composition, said composition having a prehydrogenated vinyl aromatic content of less than 50 percent by weight (wt%), based upon total vinyl aromatic-conjugated diene block copolymer weight prior to hydrogenation, and a number average molecular weight (Mn) within a range of from 30,000 grams per mole (g/M) to 250,000 g/M.

In some aspects, this invention is a multi-layer, thermoformable, polymeric sheet having a hard layer as described above, but with a soft layer that comprises a polymer composition other than the elastomeric CBC composition, such other polymer composition comprising at least one of a cyclic vinyl aromatic-conjugated diene block copolymer in which only the diene block is substantially fully hydrogenated and the vinyl aromatic block is substantially free of hydrogenation (e.g. styrene-ethylene-propylene-styrene (SEPS) or styrene-ethylene-butylene-styrene (SEBS)), an olefin elastomer and a thermoplastic polyurethane (TPU).

In some aspects, this invention is a mono-layer sheet, preferably an extruded mono-layer sheet or an injection molded sheet comprising the CBC composition described hereinabove. A "mono-layer sheet" has a thickness of at least 20 mils (0.51 millimeters (mm)). The thickness preferably lies within a range of from 20 mils (0.5 mm) to 60 mils (1.5 mm) and more preferably within a range of from 25 mils (0.6 mm) to 40 mils (1 mm).

In some aspects, this invention is a process for preparing a thermoformed sheet, the process comprising subjecting a sheet selected from the multi-layer sheet and the mono-layer sheet, each of which is described hereinabove, to thermoforming conditions, the thermoforming conditions including use of a thermoforming device, and a thermoforming temperature within a range of from the cyclic block copolymer composition's glass transition temperature (Tg) to a temperature 100 degrees centigrade (^{0}C) in excess of the Tg, preferably within a range of from Tg + 5 ^{0}C to Tg + 50 ^{0}C. The thermoforming conditions preferably include a pressure sufficient to effect, in conjunction with the thermoforming device and the thermoforming temperature, a change in shape from sheet form to a desired shape, e.g. that of an orthodontic appliance when the thermoforming device includes a die that facilitates forming the desired shape.

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When ranges are stated herein, as in a range of from 2 to 10, both end points of the range (e.g. 2 and 10) and each numerical value, whether such value is a rational number or an irrational number, are included within the range unless otherwise specifically excluded.

Expressions of temperature may be in terms either of degrees Fahrenheit (^{0}F) together with its equivalent in ^{0}C or, more typically, simply in ^{0}C.

Unless stated to the contrary, implicit from the context, or customary in the art, all parts and percents are based on weight.

A thermoformed sheet in a form such as an orthodontic appliance has certain property advantages relative to a thermoformed sheet fabricated solely from rigid TPU. The advantages include an improved creep resistance and a slightly lower modulus, both relative to rigid TPU.

The CBC compositions of various aspects of this invention have certain processing advantages over rigid TPU compositions, especially when such compositions are destined for use in an orthodontic appliance. One may, for example, feed CBC composition pellets to an extruder as is when forming a sheet without resort to a drying step commonly required for rigid TPU pellets. A CBC sheet similarly need not be dried before thermoforming into a device such as an orthodontic appliance. A rigid TPU sheet typically requires a drying step at an elevated temperature (e.g., 80°C) for at least 12 hrs. Elimination of drying steps translates to energy savings and reduction in manufacturing costs.

The CBC is a substantially fully hydrogenated vinyl aromatic-conjugated diene block copolymer with an elongation strain at break, determined in accordance with American Society for Testing and Materials (ASTM) D638 that is preferably at least (>) 30%, more preferably ≥ 50%, and even more preferably at least 100%. The cyclic block copolymer also preferably has a modulus, determined in accord with ASTM D638, that is ≥ 150,000 psi (1034 MPa) but less than (<) 270,000 psi (1862 MPa).

"Substantially fully hydrogenated" means that at least 90 percent (%) of vinyl aromatic double bonds and at least 95% of conjugated diene double bonds are hydrogenated.

The substantially fully hydrogenated vinyl aromatic-conjugated diene block copolymers preferably have, prior to hydrogenation, a pentablock architecture with alternating styrene (S) blocks and either butadiene (B) blocks or isoprene (I) blocks. Representative prehydrogenation pentablock copolymers include SBSBS pentablock copolymers and SISIS pentablock copolymers. The styrene (S) blocks may, but need not be

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of equal length. Similarly, the butadiene (B) blocks and isoprene (I) blocks may, but need not be of equal length.

The SBSBS-based and SISIS-based CBC pentablock copolymers have a pre-hydrogenation styrene content that is preferably greater than 50 percent by weight (wt%) to less than 70 wt%, more preferably within a range of from 55 wt% to 65 wt%, each wt% being based upon total pentablock copolymer weight prior to hydrogenation. The pentablock copolymers have a pre-hydrogenation Mn that is preferably within a range of from 40,000 g/M to 150,000 g/M, more preferably within a range of from 50,000 g/M to 120,000 g/M, and even more preferably within a range of from 60,000 g/M to 90,000 g/M. Following hydrogenation, at least 90 percent (%) of vinyl aromatic (e.g. styrene) unsaturation (double bonds) present prior to hydrogenation and at least 90 % of conjugated diene (e.g. butadiene or isoprene) unsaturation (double bonds) present prior to hydrogenation are hydrogenated or converted to saturated bonds. The percentage more preferably equals or exceeds 95 %.

While sequentially polymerized pentablock copolymers may be preferred, satisfactory results also occur with use of triblock, multi-armed or coupled block copolymers. The multi-armed and coupled block copolymers contain a residue from a coupling agent. Such coupled block copolymers may be represented as, for example, $X(BS)_n$ where n is $\geq$ 1 and X represents a chain coupling agent. The coupled block copolymers preferably have the same styrene content and hydrogenation percentage as the sequential SBSBS and SISIS pentablock copolymers but a broader Mn range that is preferably from 40,000 g/M to 250,000 g/M, more preferably from 50,000 g/M to 200,000 g/M and even more preferably from 60,000 g/M to 160,000 g/M.

The CBC compositions of at least some aspects of this invention may be modified by one or more procedures, one of which is silane-grafting. USP 5,266,627 and USPAP 20060 1999 14Al teach suitable procedures for silane grafting using a silane compound such as vinyltrimethoxysilane and a catalyst such as 2,5-di-tert-butylperoxy-2,5-dimethylhexane.

See Patrice Lucas and Jean-Jacques Robin, "Silicone-Based Polymer Blends: An Overview of the Materials and Processes", Advanced Polymer Science (2007), volume 209, pages 111-147, for a discussion of siloxane and silane technology in general and blending and grafting in particular.

See Kuk Young Cho et al., "Grafting of Glycidyl Methacrylate onto High-Density

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Polyethylene with Reaction Time in the Batch Mixer", Journal of Applied Polymer Science, Volume 108, pages 1093-1099 (2008), for general teachings relative to methacrylate grafting. *See also* Shenglong Ding et al., "The Study of Melt Grafting Mechanism of Acrylic Acid and Butyl Acrylate onto Low Density Polyethylene and Its Application as Internal Plasticizer", Journal of Applied Polymer Science, Volume 108, pages 423-430 (2008) for general teachings relative to acrylate grafting. In addition, *see* K. E. Russell, "Free radical graft polymerization and copolymerization at higher temperatures", Progress in Polymer Science, Volume 27 (2002), pages 1007-1038, for teachings relative to graft addition of vinyl monomers to polyolefins.

The CBC compositions of at least some aspects of this invention yield optically transparent, thermoformable sheets or films. Optical transparency makes such sheets and the compositions that form the sheets very desirable from an aesthetic point of view in orthodontic appliances, especially those used for tooth alignment (otherwise known as "braces").

While orthodontic appliances represent a preferred end use application for CBC compositions of some aspects of this invention and thermoformable sheets of other aspects of this invention, the compositions and sheets have utility in other end use applications. Such other end use applications include, but are not limited to, display films, signage sheets, and medical/pharmaceutical vials and bottles.

The CBC compositions of at least some aspects of this invention further comprise any one or more members of three groups of polymers. The groups are: a) hydrogenated vinyl aromatic-conjugated diene block copolymers; b) hydrogenated random vinyl aromatic-conjugated diene copolymers; c) hydrogenated vinyl aromatic homopolymers; d) cyclic olefin polymers; e) and cyclic olefin copolymers.; f) non-hydrogenated vinyl aromatic-conjugated diene block copolymers; and g) non-hydrogenated random vinyl aromatic-conjugated diene copolymers.

Conversion of CBC compositions of some aspects of this invention into thermoformable sheets of other aspects of this invention employs conventional processes. Such conventional processes include extrusion, injection molding and compression molding. Any of these processes readily forms a plaque suitable for thermoforming into an article of manufacture, such as an orthodontic appliance of some aspects of this invention.

Compositions of some aspects of this invention have utility as a layer of a multi-

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layer structure, especially as a hard outer layer of a multi-layer structure such as a coextruded multi-layer structure. The hard outer layer provides creep resistance. A softer, relative to the hard outer layer, inner layer provides a degree of wearer comfort in an orthodontic appliance wherein the inner layer is in contact with the wearer's teeth and the hard outer layer is spaced apart from the wearer's teeth by the inner layer. Materials suitable for use in fabricating the inner or soft layer include, but are not limited to, styrene-ethylene-butylene-styrene copolymers, styrene-ethylene-propylene-styrene copolymers, olefin elastomers, and thermoplastic polyurethanes.

Extruded sheets, either mono-layer or multi-layer, of some aspects of this invention lend themselves to thermoforming into various structures, one of which is an orthodontic appliance. Suitable thermoforming temperatures satisfy a relationship wherein thermoforming temperature (T) lies within a range that has a lower limit established by glass transition temperature (Tg) of CBCs of some aspects of this invention and an upper limit of 100° C greater than the Tg. The range is preferably from Tg + 5°C to Tg + 50^{0}C.

Compositions of some aspects of this invention may include one or more conventional additives. Illustrative additives include antioxidants, mold release agents, ultraviolet light stabilizers, processing aids, lubricants, anti-static agents, antimicrobial agents (e.g. ALPHASAN™ RC2000 or MICROBAN™), colorants, coloring agents, and dyes.

Examples

The following examples illustrate, but do not limit, the present invention. All parts and percentages are based upon weight, unless otherwise stated. All temperatures are in ^{0}C. Examples (Ex) of the present invention are designated by Arabic numerals and Comparative Examples (Comp Ex or CEx) are designated by capital alphabetic letters. Unless otherwise stated herein, "room temperature" and "ambient temperature" are nominally 25^{0}C.

Table 1 below lists three pentablock (SBSBS-based) CBCs (CBC-I, CBC-2 and CBC-3), and one TPU (ISOPLAST™ 2530, commercially available from The Dow Chemical Company). For the CBCs, Table 1 includes their respective Mn, wt% styrene (based on total CBC weight before hydrogenation) and wt% 1,2-vinyl (based on total butadiene (B) content before hydrogenation) content . Table 1 also includes physical performance data in terms of strain at break and modulus (thousand psi or kpsi and MPa), both determined in accord with ASTM D638.

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Table 1

Material	Mn (g/M)	Styrene content (wt%)	1,2-vinyl content (wt%)	Strain@break (%)	Modulus (kpsi/MPa)
CBC-1	72,800	60	8	240	220/1517
CBC-2	69,000	55	8	300	155/1069
CBC-3	70,500	70	11	20	244/1682
TPU	N/A	N/A	N/A	160	270/1862

Determine T_g of hydrogenated vinyl aromatic block copolymers by dynamic mechanical analysis using a rheometer (e.g., ARES rheometer manufactured by TA Instruments). Define Tg by its tan δ peak measured from a solid state temperature ramp of linear viscoelastic spectrum data (storage modulus G', loss modulus G" and tanδ = G'VG') between room temperature and 160°C at a temperature ramp rate of 3°C/min and an oscillatory frequency of 1 radian per second (rad/s). Use a solid rectangular shaped specimen of approximate 45 millimeter (mm) length, 12.5 mm width and 3.2 mm thickness for testing. Compression mold test specimens at a temperature of 250°C and a pressure of approximately 500 pounds per square inch (psi) (3447 kilopascals (KPa) using a standard compression molder (e.g., Tetrahedron™ 1401 from Tetrahedron Associates Inc., San Diego, CA).

Conduct molecular weight analysis of a hydrogenated vinyl aromatic-conjugated diene block copolymer by subjecting the block copolymer, prior to its hydrogenation, to gel permeation chromatography (GPC) using tetrahydrofuran (THF) as a solvent for the block copolymer. Calibrate GPC columns using narrow molecular weight polystyrene standards from Polymer Labs, Inc. The Mn of the standards ranges from 580 g/M to 3,900,000 g/M. Prepare six standard cocktails that have three or four standards per cocktail, each standard in the cocktail differing in molecular weight from others in the cocktail by a factor of approximately ten. Determine peak elution volume of each standard and generate a column calibration of molecular weight versus elution volume by fitting the narrow standard data with a 5th order polynomial fit. Report Mn of pre-hydrogenated block copolymers as polystyrene-equivalent values.

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Test Methods

A. Determination of Resistance to Stress Cracking

Use ASTM D638 Type IV (dog bone type) microtensile test specimens and a clamp equipped with a strain jig that applies a five percent (5%) strain deformation to each specimen for stress crack testing. Place a clamped specimen into a container that holds a volume of water sufficient to allow complete sample immersion and fully immerse the clamped specimen in the water for one week at a set point temperature of 37°C.

Following the one week immersion, remove each clamped specimen from the water and then remove each specimen from the strain jig, then pat the sample specimen dry using paper towels before subjecting it to tensile testing.

Prescreen specimens for tensile testing by inspecting each dried specimen for visual defects such as craze lines, stress marks and breakage. Set aside any test specimens that contain a visual defect. Mount each specimen that lacks visual defects in an Instron machine and subject it to ASTM D638 tensile testing. Record strain at break for each tested specimen and compare it to an untreated sample (no strain or immersion in water).

A reduction in elongation strain at break, relative to the untreated sample, of less than 25% merits a pass rating, with values that approach a reduction of 0% being very desirable.

B. Determination of Creep Resistance

Using test specimens measuring 4 inches (in) (10.2 centimeter (cm)) x 0.5 in (1.3 cm) x 0.030 in (0.08 cm), conduct a three point bending test to characterize a material's resistance to creep. Die cut the test specimens from compression molded plaques that measure five (5) inches (in.) (12.7 centimeters (cm)) x 5 in. (12.7 cm) x 0.030 in. (0.08 cm). Before loading a test specimen onto the testing fixture of an Instron machine, soak the specimen in the water for 30 minutes and then pat the specimen dry using paper towels.

Place each dried test specimen on the Instron machine's two lower loading noses with a support span of 16 millimeters (mm). Quickly (no more than six (6) seconds between zero strain and 5% strain deformation) apply a 5% strain deformation to the test specimen, then allow it to relax over time and record stress relaxation over time. As between two materials, one with a faster stress decay also has a poorer creep resistance. A slower decaying rate of stress relaxation is desirable for the application.

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Analyze the stress relaxation data to obtain both initial stress decay rate (τi) and long term stress decay rate (τ_2). As a first step, normalize stress versus time data based upon measured maximum stress value applied to a test specimen. The stress value typically reaches a maximum some three to six seconds after starting the stress relaxation test. Fit the normalized stress (σ) versus time (t) (in seconds) data in a second order exponential decay function:

$$\sigma = A_0 + A_1 \exp(-\frac{t}{T_1}) + A_2 \exp(-\frac{t}{T_2})$$

Where, σ is the normalized stress value from 0 to 1, Ao, *Ai*, A_2,Ti and T_2 are data fitting parameters,

$$\tau_1 = \frac{T_1}{60},$$

$$\tau_2 = \frac{T_2}{3600}$$

Increasing values for τi and τ_2 indicate slowing rates of applied stress decay.

Ex 1

Compression mold CBC-I at a temperature of 250^{0}C into plaques measuring 5 in (12.7 cm) x 5 in (12.7 cm) and having a thickness of 0.030 in 0.08 cm). Die cut test specimens from the plaques. Measure tensile properties of this material with and without the water immersion described above for determining resistance to stress cracking. Measure elongation strain at break and stress relaxation in accord with procedures detailed above and summarize measurements in Table 2 below.

Ex 2

Replicate Ex 1 but use CBC-2 rather than CBC-I. Summarize measurements in Table 2 below

CEx A

Replicate Ex 1 but use TPU rather than CBC-I. Summarize measurements in Table 2 below

CEx B

Replicate Ex 1 but use CBC-3 rather than CBC-I. Summarize measurements in Table 2 below

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Table 2

Ex/CEx	Strain at Break (no immersion/treatment) (%)	Strain at Break (with immersion/treatment) (%)	Initial Stress Decay rate (minutes)	Long term Stress Decay Rate (hours)
1	240	213	6.7	2.2
2	300	300	nm	nm
A	160	187	4.2	1.5
B	20	10	1.7	1.5

"nm" means not measured

The results in Table 2 show that both initial and long term stress decay rates are more than 50% slower for CBC-I than for CEx A (TPU). The results also show that not all CBCs perform equally well in that CEx B (CBC-3, 70 wt% styrene content) with a much lower elongation strain at break than either CBC-I (Ex 1) or CBC-2 (Ex 2) at 20% versus, respectively, 240% and 300%, has a very low strain at break (10%) relative to Ex 1 (240 %) and a much more rapid initial stress decay rate at 1.7 minutes than either TPU (4.2 minuets) or CBC-I (6.7 minutes). The long term stress decay rate of CBC-3 is also more rapid than CBC-I at 1.5 hours versus 2.2 hours. CBC-I shows an improvement over TPU in terms of strain at break (before and after immersion) and both initial and long term stress decay rates while CBC-3 performs worse than TPU in the same properties. On that basis, CBC-I represents a viable candidate for use in orthodontic applications, but CBC-3 does not. CBC-2 should also be a viable candidate based on its higher, relative to CBC-I, strain at break.

Based on information and belief, human saliva exposure, especially over extended periods of time, increases magnitude of performance differences between TPU and CBC.

Ex 3. Silane modified CBC material

In a container, mix three (3) parts by weight (pbw) of liquid vinyltrimethoxysilane (VTMS) (Dow Corning Z-3600, CAS number 2768-02-7) and 0.08 pbw of liquid 2,5-Di-tert-butylperoxy-2,5-dimethylhexane (LUPEROX™ 101, Aldrich, CAS number 78-63-7) to 100 pbw CBC-2 resin. Allow the liquids to diffuse and imbibe into the CBC-2 resin at room temperature (nominally 25 degrees centigrade (^{0}C) overnight (at least 12 hours).

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Feed the container contents into an 18 millimeter (mm) Leistritz ZSE-18 twin screw extruder (Leistritz Corporation, Somerville, NJ) equipped with a pelletizer to effect reactive extrusion compounding of the container contents. The extruder operates at a set point temperature of 220°C with an extruder output of 5 pounds per hour (lbs/hr) (11 kilograms per hour (kg/hr)).

Place the pellets in a vacuum oven operating at a set point temperature of 90°C overnight (at least 12 hours) to remove ungrafted silane (VTMS).

Compression mold the compounded, pelletized container contents (also known as "silane-grafted CBC material" into plaques as in Ex 1, but use a mold temperature of 220°C rather than 250°C.

Prepare the plaques for physical property testing by immersing them in an aqueous dodecylbenzenesulfonic acid solution (10 wt% dodecylbenzenesulfonic acid, based on total solution weight) heated to a set point temperature of 80°C for 72 hours in an effort to promote siloxanes crosslinking.

The plaques have a tensile modulus of 168,000 pounds per square inch (psi) (1158 kilopascals (kPa)) and an average elongation strain at break (with immersion) of 92%. The plaques have an initial stress decay rate (also known as "short term decay rate") of 6.5 minutes and a long term stress decay rate of 2.1 hours.

Ex 3 demonstrates that functionalized CBC polymers are also suitable for the use in orthodontic applications.

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WHAT IS CLAIMED IS:

1. A cyclic block copolymer composition, the composition comprising a cyclic block copolymer that is a substantially fully hydrogenated vinyl aromatic-conjugated diene block copolymer, said substantially fully hydrogenated block copolymer having an elongation strain at break of more than 30% and a modulus that is within a range of from greater than or equal to 150,000 psi (1034 MPa) to less than 270,000 psi (1862 MPa), both elongation strain at break and modulus being determined in accord with American Society for Testing and Materials (ASTM) Test D638-02a.

2. The cyclic block copolymer composition of Claim 1, wherein the elongation strain at break is at least 50%.

3. The cyclic block copolymer composition of Claim 1 or Claim 2, wherein the block copolymer is selected from a group consisting of a sequentially-polymerized pentablock copolymer, a sequentially-polymerized triblock copolymer, a multi-armed block copolymer, or a coupled block copolymer.

4. The cyclic block copolymer composition of any of Claims 1 through 3, wherein the composition further comprises an amount of at least one other polymer or copolymer selected from a group consisting of a) hydrogenated vinyl aromatic-conjugated diene block copolymers; b) hydrogenated random vinyl aromatic-conjugated diene copolymers; c) hydrogenated vinyl aromatic homopolymers; d) cyclic olefin polymers; e) and cyclic olefin copolymers.; f) non-hydrogenated vinyl aromatic-conjugated diene block copolymers; and g) non-hydrogenated random vinyl aromatic-conjugated diene copolymers.

5. The cyclic block copolymer composition of any of Claims 1 through 4, wherein the cyclic block copolymer is a functionalized cyclic block copolymer selected from silane-grafted cyclic block copolymers, maleic anhydride grafted cyclic block copolymers, acrylate-grafted cyclic block copolymers, methacrylate-grafted cyclic block copolymers, and siloxane grafted cyclic block copolymers.

6. A multi-layer, thermoformable, polymeric sheet, the sheet comprising at least one hard layer and at least one soft layer, the hard layer comprising the cyclic block copolymer composition of any of Claims 1 through 5, and the soft layer comprising an elastomeric, substantially fully hydrogenated cyclic block copolymer composition, the elastomeric cyclic block copolymer composition comprising a substantially fully hydrogenated vinyl aromatic-conjugated diene block copolymer composition, said

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composition having a prehydrogenated vinyl aromatic content of less than 50 percent by weight based upon total vinyl aromatic-conjugated diene block copolymer weight prior to hydrogenation, and a number average molecular weight within a range of from 30,000 grams per mole to 250,000 grams per mole.

7. A multi-layer, thermoformable, polymeric sheet, the sheet comprising at least one hard layer and at least one soft layer, the hard layer comprising the cyclic block copolymer composition of any of Claims 1 through 5, and the soft layer comprising at least one of a cyclic vinyl aromatic-conjugated diene block copolymer in which only the diene block is substantially fully hydrogenated and the vinyl aromatic block is substantially free of hydrogenation, an olefin elastomer, and a thermoplastic polyurethane.

8. A mono-layer sheet, the mono-layer sheet comprising the cyclic block copolymer composition of any of Claims 1 through 5, the mono-layer sheet having a thickness of at least 20 mils (0.51 millimeters (mm)).

9. A process for preparing a thermoformed sheet, the process comprising subjecting a sheet selected from the multi-layer sheet of Claim 6 or Claim 7 and the mono-layer sheet of Claim 8 to thermoforming conditions, the thermoforming conditions including use of a thermoforming device, a thermoforming temperature within a range of from the cyclic block copolymer composition's glass transition temperature (Tg) to a temperature 100 degrees centigrade (^{0}C) in excess of the Tg, and a pressure sufficient to effect, in conjunction with the thermoforming device and the thermoforming temperature, a change in shape from sheet form to a desired shape.

10. The process of Claim 9, wherein the desired shape is an orthodontic appliance.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/059537

A. CLASSIFICATION OF SUBJECT MATTER
INV. C08L51/00 C08L53/00 C08L53/02 C08F8/04 B32B7/02
B32B25/16

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)
C08L C08F 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 practical, search terms used)
EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropnate, of the relevant passages	Relevant to claim No
X	US 6 632 890 B1 (BATES FRANK S [US] ET AL) 14 October 2003 (2003-10-14)	1-3
Y	column 2, line 38 - column 4, line 47 column 7, line 62 - column 8, line 35; example 2; table II	5
X	WO 01/44315 A1 (DOW CHEMICAL CO [US]) 21 June 2001 (2001-06-21) page 4, line 9 - line 29 page 5, line 30 - page 6, line 13 page 8, line 1 - line 25 page 9, line 12 - page 10, line 6 page 12, line 20	1-4,6-7

-/--

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

' Special categones of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority cla im(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 prtonty date claimed

"T" later document published after the international filing date or prionty date and not in conflict with the application but cited to understand the pnnciple or theory underlying the invention

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"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 docu¬ments, 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	Date of mailing of the international search report
26 January 2010	01/02/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040, Fax (+31-70) 340-3016	Gi ani , Elena

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/059537

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	WO 00/77095 A1 (DOW CHEMICAL CO [US]) 21 December 2000 (2000-12-21)	1-4,6-9
Y	page 2, line 7 - line 35 page 4, line 14 - page 6, line 16 page 11, line 1 - line 15 page 30, line 21 - line 26 page 31, line 14 - line 16 page 34, line 3 - line 16 page 35, line 1 - line 3	10
Y	US 4 578 429 A (GERGEN WILLIAM P [US] ET AL) 25 March 1986 (1986-03-25) column 5, line 14 - column 6, line 9	5
Y	US 2006/078841 A1 (DESIMONE JOSEPH M [US] ET AL) 13 April 2006 (2006-04-13) cited in the application paragraph [0021]	10

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/059537

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6632890 B1	14-10-2003	NONE	
WO 0144315 A1	21-06-2001	AT 305482 T	15-10-2005
		AU 1924701 A	25-06-2001
		DE 60022904 T2	13-07-2006
		EP 1242474 A1	25-09-2002
		JP 2003517055 T	20-05-2003
		TW 266788 B	21-11-2006
WO 0077095 A1	21-12-2000	AT 265497 T	15-05-2004
		AU 5588100 A	02-01-2001
		BR 0012087 A	02-04-2002
		CN 1355827 A	26-06-2002
		DE 60010260 D1	03-06-2004
		DE 60010260 T2	07-07-2005
		EP 1189988 A1	27-03-2002
		JP 2003502471 T	21-01-2003
US 4578429 A	25-03-1986	NONE	
US 2006078841 A1	13-04-2006	EP 1804759 A1	11-07-2007
		JP 2008515590 T	15-05-2008
		JP 2008264583 A	06-11-2008
		US 2008248438 A1	09-10-2008
		WO 2006044014 A1	27-04-2006

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Application Number:	15476655
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First Named Inventor/Applicant Name:	Chunhua LI
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS22773-826-401-03-12-2019.pdf	328517 e0e17806bef61f9b43cb01497c880e6626f0927f	yes	9

	Multipart Description/PDF files in .zip description				
	Document Description	**Start**	**End**		
	Information Disclosure Statement (IDS) Form (SB08)	5	9		
	Transmittal Letter	1	4		
Warnings:					
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2	Non Patent Literature	ISR-WO-06-28-13-PCTEP2013059701.PDF	192906 48fd8ce5f662677c7380d6192d81b145e82117ef	no	6
Warnings:					
Information:					
3	Foreign Reference	JP2011079284A_EFS.PDF	2558771 444beb306e80852e276e4bbcef255e666708 9b779	no	56
Warnings:					
Information:					
4	Foreign Reference	JPH08508174A-W-ENG-ABST. PDF	585058 f049ae1233ae477e41bd618c01d182fcaa7a 7f24	no	5
Warnings:					
Information:					
5	Foreign Reference	RU2201944C2_EFS.PDF	920110 8d630f90990707b620c4283d38a0c9c74cfd 3bd2	no	18
Warnings:					
Information:					
6	Foreign Reference	RU2008137623A_EFS.PDF	278362 fcfa3de1ba096098c81cde1e400f99693d70 d836	no	5
Warnings:					
Information:					
7	Non Patent Literature	US16043065.PDF	1286522 7fd5c431085abe565fc9b6d4e172a42a8fa4 0d12	no	31
Warnings:					

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8	Non Patent Literature	US16264420.PDF	1127666 0fa1c7157eb7e347708a72b05c5ee00881b29d5e	no	30
Warnings:					
Information:					
9	Non Patent Literature	WO9711106A1_EFS.PDF	1425748 4c2181de96a4fe8dff73b11628de2a1ea4005a7f	no	47
Warnings:					
Information:					
10	Non Patent Literature	WO2004041898A1_EFS.PDF	1209167 cb45a0b0c1d72eaf04ff15f351b6396675698a66	no	33
Warnings:					
Information:					
11	Non Patent Literature	WO2006096558A2_EFS.PDF	6393550 5236d5b2fe15f7629511abee6bf7d63218e022214	no	123
Warnings:					
Information:					
12	Non Patent Literature	WO2010074789A1.PDF	450767 95abe92c62673e72e40aa81d4abfb558c9bbb1f9	no	19
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New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 03/14/2019

WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER
MONTIEL, CAROLINE

ART UNIT	PAPER NUMBER
1748	

NOTIFICATION DATE	DELIVERY MODE
03/14/2019	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):

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Office Action Summary	**Application No.** 15/476,655	**Applicant(s)** LI et al.	
	Examiner Caroline Montiel	**Art Unit** 1748	**AIA (FITF) Status** No

-- 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 4/3/2017.

☐ 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) 20-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 20-30 is/are rejected.

8) ☐ Claim(s) _____ 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 _____ 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: _____.

DETAILED ACTION

1. The communication dated 4/3/2017 has been entered and fully considered.

2. Claims 20-30 are pending.

3. The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 103

4. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

5. The following is a quotation of pre-AIA 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, 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 negatived by the manner in which the invention was made.

6. Claims 20-25 and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen et al. (U.S. PGPUB 2009/0246724), hereinafter CHEN, and DeSimone et al. (U.S. 7,641,828), hereinafter DESIMONE (CHEN and DESIMONE are provided in the IDS of 3/31/2017).

7. Regarding **claim 20**, CHEN teaches: *A method of making a dental appliance for positioning a patient's teeth, the method comprising* (CHEN teaches a method of making a dental appliance [0014-0017])*: providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer* (CHEN teaches an appliance (100) with a hard inner polymer layer (132) having a hard polymer layer elastic modulus [Fig. 4C; 0032;0036]. CHEN further teaches a first and second soft outer

polymer layer (134), each having soft polymer elastic modulus less than the hard polymer layer elastic modulus [Fig. 4C; 0003; 0032; 0036]).

8. CHEN is silent as to providing a positive model of the patient's teach in a target position and fabricating an appliance as a negative of the positive model. In the same field of endeavor, dental appliances, DESIMONE teaches positive tooth models of a patient's teeth using intermediate and final data sets, examiner is interpreting the intermediate and final data sets as target positions [Col. 3, lines 53-67-Col. 4, lines 1-7]. DESIMONE further teaches fabricating positioning appliances with a molding machine that produces shells of dental appliances from a thermoformable material [Col. 4, lines 3-12, examiner is interpreting the shells as negatives of the positive models]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify CHEN by providing a positive model of the patient's teach in a target position and fabricating an appliance as a negative of the positive model, as suggested by DESIMONE, in order to progressively reposition teeth from a first initial arrangement to a final tooth arrangement in the patient's mouth (Col. 3, lines 36-51).

9. Regarding **claim 21**, CHEN teaches: *wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof* (CHEN teaches a hard polymer layer being a polycarbonate ([0036], examiner is interpreting inner layers (150) as hard polymer layer)).

10. Regarding **claim 22**, CHEN teaches: *wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a*

polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate (CHEN teaches the hard polymer layer comprises of at least two layers (Figs. 4A-4D; 5; [0031-0033; 0035-0036], examiner is interpreting inner layers (132,150) as hard polymer layer). CHEN teaches a hard polymer layer being a polycarbonate ([0036], examiner is interpreting inner layers (150) as hard polymer layer)).

11. Regarding **claim 23**, CHEN teaches: *wherein each of the first soft polymer layer and the second soft polymer layer independently comprises a layer of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof* (CHEN teaches the soft polymer can be a copolymer blend of thermoplastics ([0036], examiner is interpreting outer layer (152) as soft polymer layer)).

12. Regarding **claim 24**, CHEN teaches: *wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer* (CHEN teaches having at least two soft layers [Figs. 4A-4D; 0030-0031].

CHEN further teaches the soft polymer can be a copolymer blend of thermoplastics ([0036], examiner is interpreting outer layer (152) as soft polymer layer)).

13. Regarding **claim 25**, DESIMONE further teaches: *wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet environment, and a light transmission between 400 nm and 800 nm of greater than about 75%* (DESIMONE teaches a transparent polymeric material preferably having a tensile strength at yield of greater than 6,000 psi, which overlaps with the claimed tensile strength at yield of between about 4000 psi and 6500 psi [Col. 7, lines 42-44, examiner is interpreting transparent polymeric material as a hard polymer layer as DESIMONE states thermoplastic polyurethanes can be used]). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN by having a tensile strength at yield of about 4000 psi and 6500 psi, as suggested by DESIMONE, in order for making dental appliances with improved material properties [Col. 4, lines 13-16].

14. In the alternative, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the materials of DESIMONE to form the hard polymer layer in CHEN since DESIMONE teaches that such materials for the intended use of such hard layers with predictable results and/or reasonable expectation of success

15. Regarding **claim 27**, DESIMONE further teaches: *further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth* (DESIMONE teaches fabricating a plurality of appliances based on different arrangements of the

patient's teeth [Col. 3, 53-67-Col. 4, lines 1-7]). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN by fabricating a plurality of appliances of different arrangements of the patient's teeth, as suggested by DESIMONE, in order to progressively reposition teeth from a first initial arrangement to a final tooth arrangement in the patient's mouth (Col. 3, lines 36-51).

16. Regarding **claim 28**, DESIMONE further teaches: *wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models* (DESIMONE teaches digitally staging a plurality of digital models of the patient's teeth [Col. 3, lines 53-67] and fabricating a plurality of appliances [Col. 4, lines 7-8]). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN by fabricating a plurality of digital models of the patient's teeth, as suggested by DESIMONE, in order to obtain the polymeric shells of dental positioning appliances for a patient (Col. 3, lines 53-56).

17. Regarding **claim 29**, CHEN teaches a sheet comprising a hard polymer layer between a first and second soft polymer layer (CHEN teaches an appliance (100) with a hard inner polymer layer (132) having a hard polymer layer elastic modulus [Fig. 4C; 0032; 0036]. CHEN further teaches a first and second soft outer polymer layer (134), each having soft polymer elastic modulus less than the hard polymer layer elastic modulus [Fig. 4C; 0003; 0032; 0036]), but is silent as to making a plurality of appliances. In the same field of endeavor, dental appliances, DESIMONE teaches a plurality of appliances [Col. 4, lines 7-12]). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN by having a plurality of appliances, as suggested by DESIMONE, in order to progressively reposition teeth

from a first initial arrangement to a final tooth arrangement in the patient's mouth (Col. 3, lines 36-51).

18. Regarding **claim 30**, DESIMONE further teaches: *wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers* (DESIMONE teaches polycarbonate-based laminates (Col. 7, lines 30-35)). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN by having laminated polymer layers, as suggested by DESIMONE, in order for making dental appliances with improved material properties [Col. 4, lines 13-16].

19. In the alternative, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the materials of DESIMONE to form the hard polymer layer in CHEN since DESIMONE teaches that such materials for the intended use of such hard layers with predictable results and/or reasonable expectation of success.

20. Claim 26 rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen et al. (U.S. PGPUB 2009/0246724), hereinafter CHEN, and DeSimone et al. (U.S. 7,641,828), hereinafter DESIMONE, as applied to claim 20 above, and further in view of Hostettler (U.S. 4,791,156), hereinafter HOSTETTLER (HOSTETTLER is provided in the IDS of 3/31/2017).

21. Regarding **claim 26**, CHEN and DESIMONE teach all of the limitations of the invention as stated above, but are silent as to soft layer having a hardness of about 60A to about 85D. In the same field of endeavor, dental appliances, HOSTETTLER teaches a soft polyurethane elastomer having a hardness not greater than about 65A (Col. 2, lines 36-44) which overlaps with the claimed range of hardness of about 60A to about 85D. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN and

DESIMONE by having a soft layer with a hardness not greater than 65A, as suggested by HOSTETTLER, in order to provide a soft layer which provides tissue relief, is inexpensive, trouble-free, and easy to keep clean (Col. 1, lines 40-41, 50-59).

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caroline Montiel whose telephone number is (571)272-2529. The examiner can normally be reached on Monday - Friday 8:30 A.M. - 5:00 P.M.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alison Hindenlang can be reached on (571) 270-7001. 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). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.M./
Examiner, Art Unit 1748

/Anthony Calandra/
Primary Examiner, Art Unit 1748

Notice of References Cited	Application/Control No. 15/476,655	Applicant(s)/Patent Under Reexamination LI et al.	
	Examiner Caroline Montiel	Art Unit 1748	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-4791156-A	12-1988	Hostettler; Fritz	C08G18/42	433/199.1
*	B	US-20090246724-A1	10-2009	Chen; Yan	A61C7/08	433/6
*	C	US-20110062609-A1	03-2011	DeSimone; Joseph M.	A61C7/08	264/16
	D					
	E					
	F					
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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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	**Art Unit**
	Caroline Montiel	1748

✓	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	03/06/2019								
	20	✓								
	21	✓								
	22	✓								
	23	✓								
	24	✓								
	25	✓								
	26	✓								
	27	✓								
	28	✓								
	29	✓								
	30	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	Caroline Montiel	1748

CPC - Searched*		
Symbol	Date	Examiner

/C.M./ Examiner, Art Unit 1748	

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	Caroline Montiel	1748

A61C 7/08	03/07/2019	CM
B32B 7/02	03/07/2019	CM
B29C 51/14	03/07/2019	CM
B32B 27/40	03/07/2019	CM
B32B 25/08	03/07/2019	CM
B32B 25/20	03/07/2019	CM
B32B 27/08	03/07/2019	CM
B32B 27/281	03/07/2019	CM
B32B 27/286	03/07/2019	CM
B32B 27/308	03/07/2019	CM
B32B 27/32	03/07/2019	CM
B32B 27/34	03/07/2019	CM
B32B 27/36	03/07/2019	CM
B32B 27/365	03/07/2019	CM
B29K 2995/0077	03/07/2019	CM
B32B 2250/24	03/07/2019	CM
B29L 2031/753	03/07/2019	CM
B29K 2067/00	03/07/2019	CM
B29K 2075/00	03/07/2019	CM
B29K 2995/0026	03/07/2019	CM
B29K 2995/007	03/07/2019	CM
B29K 2995/0082	03/07/2019	CM
B32B 2307/54	03/07/2019	CM
B32B 2250/03	03/07/2019	CM
B32B 2274/00	03/07/2019	CM
B32B 2307/412	03/07/2019	CM
B32B 2307/536	03/07/2019	CM
B32B 2535/00	03/07/2019	CM
B32B 2307/546	03/07/2019	CM

/C.M./ Examiner, Art Unit 1748	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	Caroline Montiel	1748

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
See EAST search history	03/07/2019	CM
See EAST inventor search	03/07/2019	CM

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

/C.M./ Examiner, Art Unit 1748	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	172	("20010041320" | "20020006597" | "20030009252" | "20030139834" | "20030224311" | "20040128010" | "20040146670" | "20050055118" | "20070148608" | "20080299507" | "20090087808" | "20090239188" | "20090246724" | "20100055639" | "20150140300" | "20160228215" | "2467432" | "3407500" | "3600808" | "3660900" | "3683502" | "3738005" | "3860803" | "3916526" | "3922786" | "3950851" | "3983628" | "4014096" | "4195046" | "4253828" | "4324546" | "4324547" | "4348178" | "4478580" | "4500294" | "4504225" | "4505673" | "4526540" | "4575330" | "4575805" | "4591341" | "4609349" | "4611288" | "4656860" | "4663720" | "4664626" | "4676747" | "4742464" | "4755139" | "4763791" | "4791156" | "4793803" | "4798534" | "4836778" | "4837732" | "4850864" | "4850865" | "4856991" | "4877398" | "4880380" | "4889238" | "4890608" | "4935635" | "4936862" | "4937928" | "4941826" | "4964770" | "4975052" | "4983334" | "5011405" | "5017133" | "5024790" | "5027281" | "5035613" | "5055039" | "5059118" | "5100316" | "5121333" | "5125832" | "5128870" | "5130064" | "5131843" | "5131844" | "5139419" | "5145364" | "5176517" | "5184306" | "5186623" | "5257203" | "5273429" | "5278756" | "5328362" | "5338198" | "5340309" | "5342202" | "5368478" | "5382164" | "5395238" | "5431562" | "5440326" | "5440496" | "5447432" | "5452219" | "5454717" | "5456600" | "5474448" | "5518397" | "5528735" | "5533895" | "5542842" | "5549476" | "5562448" | "5587912" | "5605459" | "5607305" | "5614075" | "5621648" | "5645420" | "5645421" | "5655653" | "5683243" | "5692894" | "5725376" | "5725378" | "5733126" | "5740267" | "5742700" | "5799100" | "5800174" | "5823778" | "5848115" | "5857853" | "5866058" | "5879158" | "5880961" | "5880962" | "5934288" | "5957686" | "5964587" | "5971754" | "5975893" | "6015289" | "6044309" | "6049743" | "6062861" | "6068482" | "6099314" | "6123544" | "6152731" | "6183248" | "6190165" |	US-PGPUB; USPAT	OR	ON	2019/03/07 09:13

		"6217325" | "6217334" | "6244861" | "6309215" | "6315553" | "6322359" | "6350120" | "6382975" | "6398548" | "6402707" | "6482298" | "6524101" | "6554611" | "6572372" | "6629840" | "6705863" | "6722880" | "7641828" | "8235713" | "8496473" | "RE35169").PN.				
S1	437	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/02/14 10:59
S2	939	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/02/14 10:59
S3	2184	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:26
S4	108400	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S5	2363	S4 and dental	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S6	4722	S4 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:37
S7	2	13/470,681.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/14 11:42
S8	4	("2009/0246724").URPN.	USPAT	OR	ON	2019/02/19 10:41
S9	108672	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:42

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		B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.				
S11	121	(dental teeth) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:43
S12	50	(dental teeth) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:45
S13	53	dental and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:47
S14	98	(oral dental) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:00
S15	40	(dental oral) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:01
S16	2480	(oral dental) and (braces retainers) and polymeric adj material	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:03
S17	18	(oral dental) and (braces retainers) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:04
S18	3542	(A61C7/00).IPCR.	US-PGPUB; USPAT	OR	OFF	2019/02/19 13:53
S19	124	S18 and layers and polymeric near5 material and (hardness hard durometer stiff stiffness) and sheet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 13:55
S20	821	S18 and (polyester co-polyester polycarbonate "thermoplastic polyurethane" polypropylene polyethylene polypropylene "polyethylene copolymer" acrylic "cyclic block copolymer" polyetheretherketone polyamide "polyethylene terephthalate" "polybutylene terephthalate" polyetherimide polyethersulfone "polytrimethylene terephthalate")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:17
S21	201	S18 and ((styrenic adj1 block adj1 copolymer "SBC") "silicone rubber" "elastomeric alloy" (thermoplastic adj1 elastomer "TPE") (thermoplastic adj1	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2019/02/19 14:19

		vulcanizate adj1 elastomer "TPV" adj1 elastomer) "polyurethane elastomer" "block copolymer elastomer" "polyolefin blend elastomer" "thermoplastic co-polyester elastomer" "thermoplastic polyamide elastomer")	EPO; JPO; DERWENT; IBM_TDB			
S22	125	S21 and S20	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:20
S23	81	soft adj1 polymer adj1 layer and hard adj1 polymer adj1 layer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/21 15:43

EAST Search History (Interference)

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3/ 7/ 2019 10:04:01 AM
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-RE35169	03-05-1996	LEMCHEN; Marc S. et al.	
	002	US-2467432	04-19-1949	KESLING; Harold D.	
	003	US-3407500	10-29-1968	KESLING; Peter C.	
	004	US-3600808	08-24-1971	JAMES; Jackson Reeve	
	005	US-3660900	05-09-1972	LAWRENCE; F. Andrews	
	006	US-3683502	08-15-1972	MELVIN; Wallshein	
	007	US-3738005	06-12-1973	COHEN; Mus et al.	
	008	US-3860803	01-14-1975	LEVINE; Richard Carl	
	009	US-3916526	11-04-1975	SCHUDY; Fred Frank	
	010	US-3922786	12-02-1975	LAVIN; Joseph L.	
	011	US-3950851	04-20-1976	BERGERSEN; Earl O.	
	012	US-3983628	10-05-1976	ACEVEDO; Raul	
	013	US-4014096	03-29-1977	DELLINGER; Eugene L.	
	014	US-4195046	03-25-1980	KESLING; Peter C.	
	015	US-4253828	03-03-1981	COLES; Donna C. et al.	
	016	US-4324546	04-13-1982	HEITLINGER; Paul et al.	
	017	US-4324547	04-13-1982	ARCAN; Mircea et al.	
	018	US-4348178	09-07-1982	KURZ; Craven H.	
	019	US-4478580	10-23-1984	BARRUT; Luc P.	
	020	US-4500294	02-19-1985	LEWIS; William D.	
	021	US-4504225	03-12-1985	YOSHII; Osamu	
	022	US-4505673	03-19-1985	YOSHII; Osamu	

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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Sheet 2 of 32

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Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

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	023	US-4526540	07-02-1985	DELLINGER; Eugene L.	
	024	US-4575330	03-11-1986	HULL; Charles W.	
	025	US-4575805	03-11-1986	MOERMANN; Werner H. et al.	
	026	US-4591341	05-27-1986	ANDREWS; Lawrence F.	
	027	US-4609349	09-02-1986	CAIN; Steve B.	
	028	US-4611288	09-09-1986	DURET; Francois et al.	
	029	US-4656860	04-14-1987	ORTHUBER; Wolfgang et al.	
	030	US-4663720	05-05-1987	DURET; Francois et al.	
	031	US-4664626	05-12-1987	KESLING; Peter C.	
	032	US-4676747	06-30-1987	KESLING; Christopher K.	
	033	US-4742464	05-03-1988	DURET; Francois et al.	
	034	US-4755139	07-05-1988	ABBATTE; Gerard P. et al.	
	035	US-4763791	08-16-1988	HALVERSON; George E. et al.	
	036	US-4791156	12-13-1988	HOSTETTLER; Fritz	
	037	US-4793803	12-27-1988	MARTZ; Martin G.	
	038	US-4798534	01-17-1989	BREADS; Peter R.	
	039	US-4836778	06-06-1989	BAUMRIND; Sheldon et al.	
	040	US-4837732	06-06-1989	BRANDESTINI; Marco et al.	
	041	US-4850864	07-25-1989	DIAMOND; Michael K.	
	042	US-4850865	07-25-1989	NAPOLITANO; John R.	

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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Sheet 3 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

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	043	US-4856991	08-15-1989	BREADS; Peter R. et al.	
	044	US-4877398	10-31-1989	KESLING; Peter C.	
	045	US-4880380	11-14-1989	MARTZ; Martin G.	
	046	US-4889238	12-26-1989	BATCHELOR; Jay A.	
	047	US-4890608	01-02-1990	STEER; Peter L.	
	048	US-4935635	06-19-1990	O'HARRA; Dale G.	
	049	US-4936862	06-26-1990	WALKER; Peter S. et al.	
	050	US-4937928	07-03-1990	VAN DER ZEL; Joseph M.	
	051	US-4941826	07-17-1990	LORAN; William et al.	
	052	US-4964770	10-23-1990	STEINBICHLER; Hans et al.	
	053	US-4975052	12-04-1990	SPENCER; William et al.	
	054	US-4983334	01-08-1991	ADELL; Loren S.	
	055	US-5011405	04-30-1991	LEMCHEN; Marc S.	
	056	US-5017133	05-21-1991	MIURA; Fujio	
	057	US-5024790	06-18-1991	GROSSMAN; David G. et al.	
	058	US-5027281	06-25-1991	REKOW; Elizabeth D. et al.	
	059	US-5035613	07-30-1991	BREADS; Peter R. et al.	
	060	US-5055039	10-08-1991	ABBATTE; Gerard P. et al.	
	061	US-5059118	10-22-1991	BREADS; Peter R. et al.	
	062	US-5100316	03-31-1992	WILDMAN; Alexander J.	
	063	US-5121333	06-09-1992	RILEY; Donald R. et al.	
	064	US-5125832	06-30-1992	KESLING; Peter C.	

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Sheet 4 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

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	065	US-5128870	07-07-1992	ERDMAN; Arthur G. et al.	
	066	US-5130064	07-14-1992	SMALLEY; Dennis R. et al.	
	067	US-5131843	07-21-1992	HILGERS; James J. et al.	
	068	US-5131844	07-21-1992	MARINACCIO; Paul J. et al.	
	069	US-5139419	08-18-1992	ANDREIKO; Craig A. et al.	
	070	US-5145364	09-08-1992	MARTZ; Martin G. et al.	
	071	US-5176517	01-05-1993	TRUAX; Lloyd H.	
	072	US-5184306	02-02-1993	ERDMAN; Arthur G. et al.	
	073	US-5186623	02-16-1993	BREADS; Peter R. et al.	
	074	US-5257203	10-26-1993	RILEY; Donald R. et al.	
	075	US-5273429	12-28-1993	REKOW; Dianne et al.	
	076	US-5278756	01-11-1994	LEMCHEN; Marc S. et al.	
	077	US-5328362	07-12-1994	WATSON; Sherman L. et al.	
	078	US-5338198	08-16-1994	WU; Chuang-Jy et al.	
	079	US-5340309	08-23-1994	ROBERTSON; James G.	
	080	US-5342202	08-30-1994	DESHAYES; Marie-Josephe	
	081	US-5368478	11-29-1994	ANDREIKO; Craig A. et al.	
	082	US-5382164	01-17-1995	STERN; Sylvan S.	
	083	US-5395238	03-07-1995	ANDREIKO; Craig A. et al.	
	084	US-5431562	07-11-1995	ANDREIKO; Craig A. et al.	
	085	US-5440326	08-08-1995	QUINN; Thomas J.	
	086	US-5440496	08-08-1995	ANDERSSON; Matts et al.	

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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Sheet 5 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
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	087	US-5447432	09-05-1995	ANDREIKO; Craig A. et al.	
	088	US-5452219	09-19-1995	DEHOFF; Barry D. et al.	
	089	US-5454717	10-03-1995	ANDREIKO; Craig A. et al.	
	090	US-5456600	10-10-1995	ANDREIKO; Craig A. et al.	
	091	US-5474448	12-12-1995	ANDREIKO; Craig A. et al.	
	092	US-5518397	05-21-1996	ANDREIKO; Craig A. et al.	
	093	US-5528735	06-18-1996	STRASNICK; Steven L. et al.	
	094	US-5533895	07-09-1996	ANDREIKO; Craig A. et al.	
	095	US-5542842	08-06-1996	ANDREIKO; Craig A. et al.	
	096	US-5549476	08-27-1996	STERN; Sylvan S.	
	097	US-5562448	10-08-1996	MUSHABAC; David R.	
	098	US-5587912	12-24-1996	ANDERSSON; Matts et al.	
	099	US-5605459	02-25-1997	KURODA; Takayuki et al.	
	100	US-5607305	03-04-1997	ANDERSSON; Matts et al.	
	101	US-5614075	03-25-1997	ANDRE SR., LARRY E.	
	102	US-5621648	04-15-1997	CRUMP; Craig D.	
	103	US-5645420	07-08-1997	BERGERSEN; Earl O.	
	104	US-5645421	07-08-1997	SLOOTSKY; Gary Lee	
	105	US-5655653	08-12-1997	CHESTER; Bruce E.	
	106	US-5683243	11-04-1997	ANDREIKO; Craig A. et al.	
	107	US-5692894	12-02-1997	SCHWARTZ; Dann A. et al.	

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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	108	US-5725376	03-10-1998	POIRIER; Michel	
	109	US-5725378	03-10-1998	WANG; Hong-Chi	
	110	US-5733126	03-31-1998	ANDERSSON; Matts et al.	
	111	US-5740267	04-14-1998	ECHERER; Scott J. et al.	
	112	US-5742700	04-21-1998	YOON; Douglas C. et al.	
	113	US-5799100	08-25-1998	CLARKE; Laurence P. et al.	
	114	US-5800174	09-01-1998	ANDERSSON; Matts	
	115	US-5823778	10-20-1998	SCHMITT; Stephen M. et al.	
	116	US-5848115	12-08-1998	LITTLE; Francis H. et al.	
	117	US-5857853	01-12-1999	VAN; Nifterick Willem Frederick et al.	
	118	US-5866058	02-02-1999	BATCHELDER; John Samuel et al.	
	119	US-5879158	03-09-1999	DOYLE; Walter A. et al.	
	120	US-5880961	03-09-1999	CRUMP; Craig D.	
	121	US-5880962	03-09-1999	ANDERSSON; Matts et al.	
	122	US-5934288	08-10-1999	AVILA; Ricardo Scott et al.	
	123	US-5957686	09-28-1999	ANTHONY; Wayne L.	
	124	US-5964587	10-12-1999	SATO; Mikio	
	125	US-5971754	10-26-1999	SONDHI; Anoop et al.	
	126	US-5975893	11-02-1999	CHISHTI; Muhammad et al.	
	127	US-6015289	01-18-2000	ANDREIKO; Craig A. et al.	
	128	US-6044309	03-28-2000	HONDA; Kenichi	

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	129	US-6049743	04-11-2000	BABA; Masami	
	130	US-6062861	05-16-2000	ANDERSSON; Matts	
	131	US-6068482	05-30-2000	SNOW; Michael Desmond	
	132	US-6099314	08-08-2000	KOPELMAN; Avi et al.	
	133	US-6123544	09-26-2000	CLEARY; James D.	
	134	US-6152731	11-28-2000	JORDAN; Russell A. et al.	
	135	US-6183248	02-06-2001	CHISHTI; Muhammad et al.	
	136	US-6190165	02-20-2001	ANDREIKO; Craig A. et al.	
	137	US-6217325	04-17-2001	CHISHTI; Muhammad et al.	
	138	US-6217334	04-17-2001	HULTGREN; Bruce Willard	
	139	US-6244861	06-12-2001	ANDREIKO; Craig A. et al.	
	140	US-6309215	10-30-2001	PHAN; Loc X. et al.	
	141	US-6315553	11-13-2001	SACHDEVA; Rohit et al.	
	142	US-6322359	11-27-2001	JORDAN; Russell A. et al.	
	143	US-6350120	02-26-2002	SACHDEVA; Rohit et al.	
	144	US-6382975	05-07-2002	POIRIER; Michel	
	145	US-6398548	06-04-2002	MUHAMMAD; Chishti et al.	
	146	US-6402707	06-11-2002	ERNST; Maurice M.	
	147	US-6482298	11-19-2002	BHATNAGAR; Parijat	
	148	US-6524101	02-25-2003	PHAN; Loc X. et al.	
	149	US-6554611	04-29-2003	SHISHTI; Muhammad et al.	
	150	US-6572372	06-03-2003	PHAN; Loc X. et al.	

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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Sheet 8 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	151	US-6629840	10-07-2003	CHISHTI; Muhammad et al.	
	152	US-6705863	03-16-2004	PHAN; Loc X. et al.	
	153	US-6722880	04-20-2004	CHISHTI; Muhammad et al.	
	154	US-7641828	01-05-2010	DESIMONE; Joseph M. et al.	
	155	US-8235713	08-07-2012	PHAN; Loc X. et al.	
	156	US-8496473	07-30-2013	PHAN; Loc X. et al.	
	157	US-20010041320	11-15-2001	PHAN; Loc et al.	
	158	US-20020006597	01-17-2002	ANDREIKO; Craig A. et al.	
	159	US-20030009252	01-09-2003	PAVLOVSKAIA; Elena et al.	
	160	US-20030139834	07-24-2003	NIKOLSKIY; Sergey et al.	
	161	US-20030224311	12-04-2003	CRONAUER; Edward A.	
	162	US-20040128010	07-01-2004	PAVLOVSKAIA; Elena et al.	
	163	US-20040146670	07-29-2004	CHIN; Albert et al.	
	164	US-20050055118	03-10-2005	NIKOLSKIY; Sergey et al.	
	165	US-20070148608	06-28-2007	TADROS; Safwat et al.	
	166	US-20080299507	12-04-2008	LI; Chunhua et al.	
	167	US-20090087808	04-02-2009	SOO; Chia et al.	
	168	US-20090239188	09-24-2009	TING; Kang et al.	
	169	US-20090246724	10-01-2009	CHEN; Yan et al.	
	170	US-20100055639	03-04-2010	LEWIS; Paul et al.	
	171	US-20150140300	05-21-2015	PUDLEINER; Heinz et al.	

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Sheet 9 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	172	US-20160228215	08-11-2016	LI; Chunhua et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	AU-3031677-A	05-10-1979	SUYEHIRO H.		☐
	002	AU-517102-B2	07-09-1981	HITO SUYEHIRO.		☐
	003	AU-5598894-A	06-08-1994	ORMCO CORP.		☐
	004	CA-1121955-A	04-20-1982	SUYEHIRO HITO.		☐
	005	DE-102004014023-A1	10-20-2005	KRD COATINGS GMBH [DE]		☒
	006	DE-102010009230-A1	08-25-2011	GIESECKE & DEVRIENT GMBH [DE]		☒
	007	DE-2749802-A1	05-11-1978	SUYEHIRO HITO.		☒

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Sheet 10 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
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	008	DE-69327661-T2	07-20-2000	ORMCO CORP [US]		☒
	009	EP-0091876-A1	10-19-1983	DURET FRANCOIS [FR], et al.		☒
	010	EP-0299490-A2	01-18-1989	STEINBICHLER HANS [DE]		☒
	011	EP-0376873-A2	07-04-1990	SHAFIR AARON [IL], et al.		☐
	012	EP-0490848-A2	06-17-1992	NOBELPHARMA AB [SE]		☐
	013	EP-0541500-A1	05-12-1993	NOBELPHARMA AB [SE]		☐
	014	EP-0667753-B1	01-19-2000	ORMCO CORP [US]		☐
	015	EP-0731673-B1	05-30-2001	NOBEL BIOCARE AB [SE]		☐
	016	EP-0774933-B1	12-06-2000	SANDVIK AB [SE], et al.		☐
	017	ES-463897-A1	01-01-1980	HITO SUYEHIRO D [US]		☒

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 11 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

FOREIGN PATENT DOCUMENTS

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	018	FR-2369828-A1	06-02-1978	SUYEHIRO HITO [US]		☒
	019	FR-2652256-A1	03-29-1991	JOURDA GERARD., et al.		☒
	020	GB-15500777	08-22-1979	HITO.		☐
	021	JP-08508174	09-03-1996	ANDREIKO et al.		☐
	022	JP-H0428359-A	01-30-1992	MITSUBISHI PETROCHEMICAL CO.		☒
	023	JP-S5358191-A	05-25-1978			☒
	024	WO-2013172812-A1	11-21-2013	BAYER MATERIALSCIENCE AG [DE], et al.		☐
	025	WO-9008512-A1	08-09-1990	DOLPHIN IMAGING SYSTEMS INC [US]		☐
	026	WO-9104713-A1	04-18-1991	JOURDA GERARD [FR], et al.		☒
	027	WO-9410935-A1	05-26-1994	ORMCO CORP [US]		☐

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Sheet 12 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

FOREIGN PATENT DOCUMENTS

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	028	WO-9832394-A1	07-30-1998	HULTGREN BRUCE WILLARD [US]		☐
	029	WO-9844865-A1	10-15-1998	NOBEL BIOCARE AB [SE], et al.		☐
	030	WO-9858596-A1	12-30-1998	ALIGN TECHNOLOGY INC [US], et al.		☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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Sheet 13 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	001	AADR. AMERICAN ASSOCIATION FOR DENTAL RESEARCH, Summary of Activities, March 20-23,1980, Los Angeles, CA, p. 195.	☐
	002	ALCANIZ, et aL, "An Advanced System for the Simulation and Planning of Orthodontic Treatments," Karl Heinz Hohne and Ron Kikinis (eds.), Visualization in Biomedical Computing, 4th Intl. Conf., VBC '96, Hamburg, Germany, September 22-25, 1996, Springer-Verlag, pp. 511-520.	☐
	003	ALEXANDER et al., "The DigiGraph Work Station Part 2 Clinical Management," JCO, pp. 402-407 (July 1990).	☐
	004	ALTSCHULER, "3D Mapping of Maxillo-Facial Prosthesis," AADR Abstract #607, 2 pages total, (1980).	☐
	005	ALTSCHULER et al., "Analysis of 3-D Data for Comparative 3-D Serial Growth Pattern Studies of Oral-Facial Structures, " AADR Abstracts, Program and Abstracts of Papers, 57th General Session, IADR HP Annual Session, March 29, 1979 - April 1, 1979, New Orleans Marriot, Journal of Dental Research, Vol. 58, January 1979, Special Issue A, p. 221.	☐
	006	ALTSCHULER et al., "Laser Electro-Optic System for Rapid Three-Dimensional (3D) Topographic Mapping of Surfaces," Optical Engineering, 20(6):953-961 (1981).	☐
	007	ALTSCHULER et al., "Measuring Surfaces Space-Coded by a Laser-Projected Dot Matrix," SPIE Imaging Applications for Automated Industrial Inspection and Assembly, Vol. 182, p. 187-191 (1979).	☐
	008	ANDERSSON et al., "Clinical Results with Titanium Crowns Fabricated with Machine Duplication and Spark Erosion," Acta. Odontol. Scand., 47:279-286 (1989).	☐
	009	ANDREWS, The Six Keys to Optimal Occlusion Straight Wire, Chapter 3, pp 13-24 (1989).	☐

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Sheet 14 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	010	ANDREWS, The Six Keys to Optimal Occlusion Straight Wire, Chapter 3, pp 13-24 (NO DATE GIVEN).	☐
	011	Baird Equity Research. Align Technology, Inc. (ALGN): Analyst Day Recap. May 30, 2014. 12 pages.	☐
	012	Baird Equity Research. Align Technology, Inc. (ALGN): Impressive Quarter/Guide, Momentum Stronger than We Realized. October 18, 2013. 15 pages.	☐
	013	BARTELS, et al., An Introduction to Splines for Use in Computer Graphics and Geometric Modeling, Morgan Kaufmann Publishers, pp. 422-425 (1987).	☐
	014	BAUMRIND, "A System for Craniofacial Mapping Through the Integration of Data from Stereo X-Ray Films and Stereo Photographs," an invited paper submitted to the 1975 American Society of Photogram Symposium on Close-Range Photogram Systems, University of Ill., Aug. 26-30, 1975, pp. 142-166.	☐
	015	BAUMRIND et al., "A Stereophotogrammetric System for the Detection of Prosthesis Loosening in Total Hip Arthroplasty," NATO Symposium on Applications of Human Biostereometrics," July 9-13, 1978, SPIE, Vol. 166, pp. 112-123.	☐
	016	BAUMRIND et al., "Mapping the Skull in 3-D," reprinted from J. Calif. Dent. Assoc., 48(2), 11 pages total, (1972 Fall Issue).	☐
	017	BAUMRIND, "Integrated Three-Dimensional Craniofacial Mapping: Background, Principles, and Perspectives," Semin. in Orthod., 7(4):223-232 (December 2001).	☐
	018	BEGOLE et al., "A Computer System for the Analysis of Dental Casts," The Angle Orthod., 51(3):253-259 (July 1981).	☐

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	019	BERNARD et al.," Computerized Diagnosis in Orthodontics for Epidemiological Studies: A Progress Report," Abstract, J. Dental Res. Special Issue, Vol. 67, p. 169, paper presented at International Association for Dental Research 66th General Session, March 9-13, 1988, Montreal, Canada.	☐
	020	BHATIA et al., "A Computer-Aided Design for Orthognathic Surgery," Br. J. Oral Maxillofac. Surg., 22:237- 253 (1984).	☐
	021	BIGGERSTAFF, "Computerized Diagnostic Setups and Simulations," Angle Orthod., 40(1):28-36 (January 1970).	☐
	022	BIGGERSTAFF et al., "Computerized Analysis of Occlusion in the Postcanine Dentition," Am. J. Orthod., 61(3): 245-254 (March 1972).	☐
	023	BIOSTAR OPEATION & TRAINING MANUAL. Great Lakes Orthodontics, Ltd. 199 Fire Tower Drive, Tonawanda, New York. 14150-5890, 20 pages total (1990).	☐
	024	BIOSTAR OPEATION & TRAINING MANUAL. Great Lakes Orthodontics, Ltd. 199 Fire Tower Drive, Tonawanda, New York. 14150-5890, 20 pages total (NO DATE GIVEN).	☐
	025	BLU, et al., "Linear interpolation revitalized", IEEE Trans. Image Proc., 13(5):710-719 (May 2004.	☐
	026	Boedeker.com. Polycarbonate specifications [retrieved on 10 September 2013]. Retrieved from the Internet: http://www.boedeker.com/polyc_p.htm.	☐
	027	BOURKE, "Coordinate System Transformation," (June 1996), p. 1, retrieved from the Internet 11/05/2004, URL< http://astronomy.swin.edu.au/—pbourke/prolection/coords>.	☐

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	028	BOYD et al., "Three Dimensional Diagnosis and Orthodontic Treatment of Complex Malocclusions With the Invisalipn Appliance," Semin. Orthod., 7(4):274-293 (December 2001).	☐
	029	BRANDESTINI et al., "Computer Machined Ceramic Inlays: In Vitro Marginal Adaptation," J. Dent. Res. Special Issue, Abstract 305, Vol. 64, p. 208 (1985).	☐
	030	BROOK et al., "An Image Analysis System for the Determination of Tooth Dimensions from Study Casts: Comparison with Manual Measurements of Mesio-distal Diameter," J. Dent. Res., 65(3):428-431 (March 1986).	☐
	031	BURSTONE et al., Precision Adjustment of the Transpalatal Lingual Arch: Computer Arch Form IN Predetermination, Am, Journal of Orthodontics, Vol. 79, No. 2 (Feb. 1981), pp. 115-133.	☐
	032	BURSTONE (interview), "Dr. Charles J. Burstone on The Uses of the Computer in Orthodontic Practice (Part 1)," J. Clin. Orthod., 13(7):442-453 (July 1979).	☐
	033	BURSTONE (interview), "Dr. Charles J. Burstone on The Uses of the Computer in Orthodontic Practice (Part 2)," J. Clin. Orthod., 13(8):539-551 (August 1979).	☐
	034	Cardinal Industrial Finishes, Powder Coatings information posted at< http://www.cardinalpaint.com> on Aug. 25, 2000, 2 pages.	☐
	035	CARNAGHAN, "An Alternative to Holograms for the Portrayal of Human Teeth," 4th Int'l. Conf. on Holographic Systems, Components and Applications, Sept. 15, 1993, pp. 228-231.	☐
	036	CHACONAS et al., "The DigiGraph Work Station, Part 1, Basic Concepts," JCO, pp. 360-367 (June 1990).	☐
	037	CHAFETZ et al., "Subsidence of the Femoral Prosthesis, A Stereophotogrammetric Evaluation," Clin. Orthop. Relat. Res., No. 201, pp. 60-67 (December 1985).	☐

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	038	CHIAPPONE, (1980). Constructing the Gnathologic Setup and Positioner, J. Clin. Orthod, Vol. 14, pp. 121- 133.	☐
	039	COTTINGHAM, (1969). Gnathologic Clear Plastic Positioner, Am. J. Orthod, Vol. 55, pp. 23-31.	☐
	040	CRAWFORD, "CAD/CAM in the Dental Office: Does It Work?", Canadian Dental Journal, Vol. 57, No. 2, pp. 121-123 (February 1991).	☐
	041	CRAWFORD, "Computers in Dentistry: Part 1 CAD/CAM: The Computer Moves Chairside," Part 2 F. Duret — A Man with a Vision," Part 3 The Computer Gives New Vision — Literally," Part 4 Bytes 'N Bites — The Computer Moves from the Front Desk to the Operatory," Canadian Dental Journal, Vol. 54 (9), pp. 661-666 (1988).	☐
	042	CROOKS, "CAD/CAM Comes to USC," USC Dentistry, pp. 14-17 (Spring 1990).	☐
	043	CURETON, Correcting Malaligned Mandibular Incisors with Removable Retainers, J. Clin. Orthod, Vol. 30, No. 7 (1996) pp. 390-395.	☐
	044	CURRY et al., "Integrated Three-Dimensional Craniofacial Mapping at the Craniofacial Research Instrumentation Laboratory/University of the Pacific," Semin. Orthod., 7(4):258-265 (December 2001).	☐
	045	CUTTING et a/., "Three-Dimensional Computer-Assisted Design of Craniofacial Surgical Procedures: Optimization and Interaction with Cephalometric and CT-Based Models," Plast. 77(6):877-885 (June 1986).	☐
	046	DCS Dental AG, "The CAD/CAM 'DCS Titan System' for Production of Crowns/Bridges," DSC Production AG, pp. 1-7 (January 1992.	☐

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	047	Definition for gingiva. Dictionary.com pg 1-3. Retrieved from the internet 11/5/04< http://reference.com/search/search?q=gingiva>.	☐
	048	DEFRANCO et al., "Three-Dimensional Large Displacement Analysis of Orthodontic Appliances," J. Biomechanics, 9:793-801 (1976).	☐
	049	DENTAL INSTITUTE UNIVERSITY OF ZURICH SWITZERLAND, Program for International Symposium JD on Computer Restorations: State of the Art of the CEREC-Method, May 1991, 2 pages total.	☐
	050	DENTRAC CORPORATION, Dentrac document, pp. 4-13 (1992).	☐
	051	DENTRAC CORPORATION, Dentrac document, pp. 4-13 (NO DATE GIVEN).	☐
	052	DENT-X posted on 09/24/98 at< http://www.dent-x.com/DentSim.htm>, 6 pages.	☐
	053	DOYLE, "Digital Dentistry," Computer Graphics World, pp. 50-52, 54 (October 2000).	☐
	054	DuraClearTM product information, Allesee Orthodontic Appliances-Pro Lab, 1 page (1997).	☐
	055	DuraClearTM product information, Allesee Orthodontic Appliances-Pro Lab, 1 page (NO DATE GIVEN).	☐
	056	DURET et al., "CAD/CAM Imaging in Dentistry," Curr. Opin. Dent., 1:150-154 (1991).	☐
	057	DURET et al, "CAD-CAM in Dentistry," J. Am. Dent. Assoc. 117:715-720 (November 1988).	☐
	058	DURET, "The Dental CAD/CAM, General Description of the Project," Hennson International Product Brochure, 18 pages total, January 1986.	☐

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	059	DURET,"Vers Une Prosthese Informatisee," (English translation attached), Tonus, Vol. 75, pp. 55-57 (November 15, 1985).	☐
	060	ECONOMIDES, "The Microcomputer in the Orthodontic Office," JCO, pp. 767-772 (November 1979).	☐
	061	ELSASSER, Some Observations on the History and Uses of the Kesling Positioner, Am. J. Orthod. (1950) 36:368-374.	☐
	062	English translation of Japanese Laid-Open Publication No. 63-11148 to inventor T. Ozukuri (Laid-Open on January 18, 1998) pp. 1-7.	☐
	063	FELTON et al., "A Computerized Analysis of the Shape and Stability of Mandibular Arch Form," Am. J. Orthod. Dentofacial Orthop., 92(6):478-483 (December 1987).	☐
	064	FRIEDE et al., "Accuracy of Cephalometric Prediction in Orthognathic Surgery," Abstract of Papers, J. Dent. Res., 70:754-760 (1987).	☐
	065	FUTTERLING et a/., "Automated Finite Element Modeling of a Human Mandible with Dental Implants," JS WSCG '98 -Conference Program, retrieved from the Internet:< http://wscg.zcu.cz/wscg98/papers98/Strasser 98.pdf>, 8 pages.	☐
	066	GAO et al., "3-D element Generation for Multi-Connected Complex Dental and Mandibular Structure," Proc. Intl Workshop on Medical Imaging and Augmented Reality, pp. 267-271 (June 12, 2001).	☐
	067	GIM-ALLDENT Deutschland, "Das DUX System: Die Technik," 2 pages total (2002).	☐
	068	GOTTLEIB et al., "JCO Interviews Dr. James A. McNamura, Jr., on the Frankel Appliance: Part 2: Clinical 1-1 Management, "J. Clin. Orthod., 16(6):390-407 (June 1982).	☐

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	069	GRAYSON, "New Methods for Three Dimensional Analysis of Craniofacial Deformity, Symposium: JW Computerized Facial Imaging in Oral and Maxiiofacial Surgery," AAOMS, 3 pages total, (September 13, 1990).	☐
	070	GUESS et al., "Computer Treatment Estimates In Orthodontics and Orthognathic Surgery," JCO, pp. 262- 28 (April 1989).	☐
	071	HEAVEN et a/., "Computer-Based Image Analysis of Artificial Root Surface Caries," Abstracts of Papers," J. Dent. Res., 70:528 (April 17-21, 1991).	☐
	072	HIGHBEAM RESEARCH, "Simulating Stress Put on Jaw," Tooling & Production [online], November 1996, n pp. 1-2, retrieved from the Internet on 11/05/2004, URL http://static.highbeam.com/t/toolingampproduction/november011996/simulatingstressputonfa...> .	☐
	073	HIKAGE, "Integrated Orthodontic Management System for Virtual Three-Dimensional Computer Graphic Simulation and Optical Video Image Database for Diagnosis and Treatment Planning", Journal of Japan KA Orthodontic Society, February 1987, English translation, pp. 1-38, Japanese version, 46(2), pp. 248-269 (60 pages total).	☐
	074	HOFFMANN, et al., "Role of Cephalometry for Planning of Jaw Orthopedics and Jaw Surgery Procedures," (Article Summary in English, article in German), Informatbnen, pp. 375-396 (March 1991).	☐
	075	HOJJATIE et al., "Three-Dimensional Finite Element Analysis of Glass-Ceramic Dental Crowns," J. Biomech., 23(11):1157-1166 (1990).	☐
	076	HUCKINS, "CAD-CAM Generated Mandibular Model Prototype from MRI Data," AAOMS, p. 96 (1999).	☐

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Sheet 21 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	077	Important Tip About Wearing the Red White & Blue Active Clear Retainer System," Allesee Orthodontic Appliances-Pro Lab, 1 page 1998).	☐
	078	International Preliminary Report on Patentability dated 11/18/2014 for International PCT Patent Application No. PCT/US2012/037745.	☐
	079	International Search Report and Written Opinion dated 01/30/2013 for International PCT Patent Application No. PCT/US2012/037745.	☐
	080	JCO Interviews, Craig Andreiko , DDS, MS on the Elan and Orthos Systems," JCO, pp. 459-468 (Aug. 1994).	☐
	081	JCO Interviews, Dr. Homer W. Phillips on Computers in Orthodontic Practice, Part 2," JCO. 1997; 1983:819-831.	☐
	082	JERROLD, "The Problem, Electronic Data Transmission and the Law," AJO-DO, pp. 478-479 (Apr. 1988).	☐
	083	JONES et al., "An Assessment of the Fit of a Parabolic Curve to Pre- and Post-Treatment Dental Arches," Br. J. Orthod., 16:85-93 (1989).	☐
	084	JP FABER et al., "Computerized Interactive Orthodontic Treatment Planning," Am. J. Orthod., 73(1):36-46 (January 1978).	☐
	085	KAMADA et.al., Case Reports On Tooth Positioners Using LTV Vinyl Silicone Rubber, J. Nihon University School of Dentistry (1984) 26(1): 11 -29.	☐
	086	KAMADA et.al., Construction of Tooth Positioners with LTV Vinyl Silicone Rubber and Some Case KJ Reports, J. Nihon University School of Dentistry (1982) 24(1):1-27.	☐

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	087	KANAZAWA et al., "Three-Dimensional Measurements of the Occlusal Surfaces of Upper Molars in a Dutch Population," J. Dent Res., 63(11):1298-1301 (November 1984).	☐
	088	KESLING, Coordinating the Predetermined Pattern and Tooth Positioner with Conventional Treatment, KN Am. J. Orthod. Oral Surg. (1946) 32:285-293.	☐
	089	KESLING et al., The Philosophy of the Tooth Positioning Appliance, American Journal of Orthodontics and Oral surgery. 1945; 31:297-304.	☐
	090	KLEEMAN et al., The Speed Positioner, J. Clin. Orthod. (1996) 30:673-680.	☐
	091	KOCHANEK, "Interpolating Splines with Local Tension, Continuity and Bias Control," Computer Graphics, ri 18(3):33-41 (July 1984). KM Oral Surgery (1945) 31 :297-30.	☐
	092	KUNII et al., "Articulation Simulation for an Intelligent Dental Care System," Displays 15:181-188 (1994).	☐
	093	KURODA et al., Three-Dimensional Dental Cast Analyzing System Using Laser Scanning, Am. J. Orthod. Dentofac. Orthop. (1996) 110:365-369.	☐
	094	LAURENDEAU, et al., "A Computer-Vision Technique for the Acquisition and Processing of 3-D Profiles of 7 KR Dental Imprints: An Application in Orthodontics," IEEE Transactions on Medical Imaging, 10(3):453-461 (September 1991.	☐
	095	LEINFELDER, et al., "A New Method for Generating Ceramic Restorations: a CAD-CAM System," J. Am. 1-1 Dent. Assoc., 118(6):703-707 (June 1989).	☐
	096	Lubrizol.com. I sop last 2530 data sheet [retrieved on 10 September 2013]. Retrieved from the Internet: http://www.lubrizol.com/Medicai/TDS/Isoplast-2530.pdf.	☐

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	097	MANETTI, et al., "Computer-Aided Cefalometry and New Mechanics in Orthodontics," (Article Summary in English, article in German), Fortschr Kieferorthop. 44, 370-376 (Nr. 5), 1983.	☐
	098	MCCANN, "Inside the ADA," J. Amer. Dent. Assoc., 118:286-294 (March 1989).	☐
	099	MCNAMARA et al., "Invisible Retainers," J. Cfin. Orthod., pp. 570-578 (August 1985).	☐
	100	MCNAMARA et al., Orthodontic and Orthopedic Treatment in the Mixed Dentition, Needham Press, pp. 347-353 (January 1993).	☐
	101	MOERMANN et al., "Computer Machined Adhesive Porcelain Inlays: Margin Adaptation after Fatigue Stress," IADR Abstract 339, J. Dent. Res., 66(a):763 (1987).	☐
	102	MOLES, "Correcting Mild Malalignments - As Easy As One, Two, Three," AOA/Pro Corner, Vol. 11, No. 1, 2 pages (2002).	☐
	103	MORMANN et al., "Marginale Adaptation von adhasuven Porzellaninlays in vitro," Separatdruck aus: Schweiz. Mschr. Zahnmed. 95: 1118-1129, 1985.	☐
	104	NAHOUM, "The Vacuum Formed Dental Contour Appliance," N. Y. State Dent. J., 30(9):385-390 (November 1964).	☐
	105	NASH, "CEREC CAD/CAM Inlays: Aesthetics and Durability in a Single Appointment," Dent. Today, 9(8):20, 22-23 (October 1990).	☐
	106	NISHIYAMA et al., "A New Construction of Tooth Repositioner by LTV Vinyl Silicone Rubber," J. Nihon Univ. Sch. Dent., 19(2):93-102 (1977).	☐

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	107	PAUL et al., "Digital Documentation of Individual Human Jaw and Tooth Forms for Applications in Orthodontics, Oral Surgery and Forensic Medicine" Proc. of the 24th Annual Conf. of the IEEE Industrial Electronics Society (IECON '98), Sept. 4, 1998, pp. 2415-2418.	☐
	108	PINKHAM, "Foolish Concept Propels Technology," Dentist, 3 pages total, January/February 1989.	☐
	109	PINKHAM, "Inventor's CAD/CAM May Transform Dentistry," Dentist, 3 pages total, September 1990.	☐
	110	Plastics.ides.com. Polyurethane Thermoset Elastomer Typical Properties Generic [retrieved on 27 July 2014]. Retrieved from the Internet: http://plastics.ides.com/generics/57/c/t/polyurethane-thermoset-elastomer-tsu- properties-processing.	☐
	111	PONITZ, "Invisible Retainers," Am. J. Orthod., 59(3):266-272 (March 1971).	☐
	112	PROCERA RESEARCH PROJECTS, "PROCERA Research Projects 1993 — Abstract Collection," pp. 3- 7; 28 (1993).	☐
	113	PROFFIT et al., Contemporary Orthodontics, (Second Ed.), Chapter 15, Mosby Inc., pp 470-533 (October 1993.	☐
	114	RAINTREE ESSIX & ARS MATERIALS, INC., Raintree Essix, Technical Magazine Table of contents and Essix Appliances,< http:// www.essix.com/magazine/defaulthtml> Aug. 13, 1997.	☐
	115	REDMOND et al., "Clinical Implications of Digital Orthodontics," Am. J. Orthod. Dentofacial Orthop., 117(2):240-242 (2000).	☐

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	116	REKOW, "A Review of the Developments in Dental CAD/CAM Systems," (contains references to Japanese efforts and content of the papers of particular interest to the clinician are indicated with a one line summary of their content in the bibliography), Curr. Opin. Dent., 2:25-33 (June 1992).	☐
	117	REKOW, "CAD/CAM in Dentistry: A Historical Perspective and View of the Future," J. Can. Dent. Assoc., 58(4):283, 287-288 (April 1992).	☐
	118	REKOW, "Computer-Aided Design and Manufacturing in Dentistry: A Review of the State of the Art," J. Prosthet. Dent., 58(4):512-516 (October 1987).	☐
	119	REKOW, "Dental CAD-CAM Systems: What is the State of the Art?", J. Amer. Dent. Assoc., 122:43-48 1991.	☐
	120	REKOW et a/., "CAD/CAM for Dental Restorations - Some of the Curious Challenges," IEEE Trans. Biomed. Eng., 38(4):344-345 (April 1991.	☐
	121	REKOW et al., "Comparison of Three Data Acquisition Techniques for 3-D Tooth Surface Mapping," Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 13(1):344-345 1991.	☐
	122	REKOW, "Feasibility of an Automated System for Production of Dental Restorations, Ph.D. Thesis," Univ. of Minnesota, 244 pages total, November 1988.	☐
	123	RICHMOND et al., "The Development of a 3D Cast Analysis System," Br. J. Orthod., 13(1):53-54 (January 1986).	☐
	124	RICHMOND et al., "The Development of the PAR Index (Peer Assessment Rating): Reliability and Validity," Eur. J. Orthod., 14:125-139 (1992).	☐

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	125	RICHMOND, "Recording The Dental Cast In Three Dimensions," Am. J. Orthod. Dentofacial Orthop., 92(3):199-206 (September 1987).	☐
	126	RUDGE, "Dental Arch Analysis: Arch Form, A Review of the Literature," Eur. J. Orthod., 3(4):279-284 1981.	☐
	127	SAKUDA et al., "Integrated Information-Processing System In Clinical Orthodontics: An Approach with Use of a Computer Network System," Am. J. Orthod. Dentofacial Orthop., 101(3): 210-220 (March 1992).	☐
	128	SCHELLHAS et al., "Three-Dimensional Computed Tomography in Maxillofacial Surgical Planning," Arch. Otolamp!. Head Neck Sur9., 114:438-442 (April 1988).	☐
	129	SCHROEDER et al., Eds. The Visual Toolkit, Prentice Hall PTR, New Jersey (1998) Chapters 6, 8 & 9, (pages 153-210,309-354, and 355-428, respectively.	☐
	130	SHILLIDAY, (1971). Minimizing finishing problems with the mini-positioner, Am. J. Orthod. 59:596-599.	☐
	131	SIEMENS, "CEREC - Computer-Reconstruction," High Tech in der Zahnmedizin, 14 pages total (2004).	☐
	132	SIEMENS, "CEREC - Computer-Reconstruction," High Tech in der Zahnmedizin, 14 pages total (NO DATE GIVEN).	☐
	133	SINCLAIR, "The Readers' Corner," J. Clin. Orthod., 26(6):369-372 (June 1992).	☐
	134	SIRONA DENTAL SYSTEMS GmbH, CEREC 3D, Manuel utiiisateur, Version 2.0X (in French), 2003,114 pages total.	☐

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	135	STIFEL. TAM Survey. Properly Aligning Expectations Ahead of 4Q13 Guidance. Align Technology, Inc. October 10, 2013. 12 pages.	☐
	136	STOLL et al., "Computer-aided Technologies in Dentistry," (article summary in English, article in German), Dtsch Zahna'rztl Z 45, pp. 314-322 (1990).	☐
	137	STURMAN, "Interactive Keyframe Animation of 3-D Articulated Models," Proceedings Graphics Interface '84, May-June 1984, pp. 35-40.	☐
	138	The Choice Is Clear: Red, White & Blue .. . The Simple, Affordable, No-Braces Treatment," Allesee HI Orthodontic Appliances-Pro Lab product information for doctors. http://ormco.com/aoa/appliancesservices/RWB/doctorhtml>, 5 pages (May 19, 2003).	☐
	139	The Choice is Clear: Red, White & Blue ... The Simple, Affordable, No-Braces Treatment," Allesee HJ Orthodontic Appliances-Pro Lab product information for patients,< http://ormco.com/aoa/appliancesservices/RWB/patients.html>, 2 pages (May 19, 2003).	☐
	140	The Choice Is Clear: Red, White & Blue ... The Simple, Affordable, No-Braces Treatment," Allesee Orthodontic Appliances-Pro Lab product information, 6 pages (2003).	☐
	141	The Red, White & Blue Way to Improve Your Smile!" Allesee Orthodontic Appliances-Pro Lab product information for patients, 2 pages 1992.	☐
	142	TRUAX L., "Truax Clasp-Less(TM) Appliance System," Funct. Orthod., 9(5):22-4, 26-8 (September-October 1992).	☐
	143	TRU-TAIN ORTHODONTIC & DENTAL SUPPLIES, Product Brochure, Rochester, Minnesota 55902, 16 pages total (1996).	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 28 of 32

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	144	TRU-TAIN ORTHODONTIC & DENTAL SUPPLIES, Product Brochure, Rochester, Minnesota 55902, 16 pages total (NO DATE GIVEN).	☐
	145	U.S. Department of Commerce, National Technical Information Service, "Automated Crown Replication Using Solid Photography SM," Solid Photography Inc., Melville NY, October 1977, 20 pages total.	☐
	146	U.S. Department of Commerce, National Technical Information Service, "Holodontography: An Introduction to Dental Laser Holography," School of Aerospace Medicine Brooks AFB Tex, March 1973, 37 pages total.	☐
	147	U.S. Provisional Patent Application No. 60/050342, filed on June 20,1997, 41 pages total.	☐
	148	VAN DER LINDEN, "A New Method to Determine Tooth Positions and Dental Arch Dimensions," J. Dent. Res., 51(4):1104 (July-August 1972).	☐
	149	VAN DER LINDEN et al., "Three-Dimensional Analysis of Dental Casts by Means of the Optocom," J. Dent. Res., p. 1100 (July-August 1972).	☐
	150	VAN DER ZEL, "Ceramic-Fused-to-Metal Restorations with a New CAD/CAM System," Quintessence Int., 24(11):769-778 (1993.	☐
	151	VARADY et al., "Reverse Engineering Of Geometric Models—An Introduction," Computer-Aided Design, 29(4):255-268,1997.	☐
	152	VERSTREKEN et al., "An Image-Guided Planning System for Endosseous Oral Implants," IEEE Trans. Med. Imaging, 17(5):842-852 (October 1998).	☐
	153	WARUNEK et al., "Physical and Mechanical Properties of Elastomers in Orthodonic Positioners, Am J. Orthod. Dentofac. Orthop, Vol. 95, No. 5, (May 1989) pp. 399-400.	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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	154	WARUNEK et.al., Clinical Use of Silicone Elastomer Applicances, JCO (1989) XXIII(10):694-700.	☐
	155	WELLS, Application of the Positioner Appliance in Orthodontic Treatment, Am. J. Orthodont. (1970) 58:351-366.	☐
	156	WILLIAMS, "Dentistry and CAD/CAM: Another French Revolution," J. Dent. Practice Admin., pp. 2-5 (January/March 1987).	☐
	157	WILLIAMS, "The Switzerland and Minnesota Developments in CAD/CAM," J. Dent. Practice Admin., pp. 50-55 (April/June 1987.	☐
	158	WISHAN, "New Advances in Personal Computer Applications for Cephalometric Analysis, Growth Prediction, Surgical Treatment Planning and Imaging Processing," Symposium: Computerized Facial Imaging in Oral and Maxilofacial Surgery Presented on September 13,1999.	☐
	159	WSCG'98 - Conference Program, "The Sixth International Conference in Central Europe on Computer Graphics and Visualization '98," February 9-13, 1998, pp. 1-7, retrieved from the Internet on 11/05/2004, URL<http://wscg.zcu.cz/wscg98/wscg98.h>.	☐
	160	XIA et al., "Three-Dimensional Virtual-Reality Surgical Planning and Soft-Tissue Prediction for Orthognathic Surgery," IEEE Trans. Inf. Technol. Biomed., 5(2):97-107 (June 2001).	☐
	161	YAMAMOTO et al., "Optical Measurement of Dental Cast Profile and Application to Analysis of Three-Dimensional Tooth Movement in Orthodontics," Front. Med. Biol. Eng., 1(2):119-130 (1988).	☐
	162	YAMAMOTO et al., "Three-Dimensional Measurement of Dental Cast Profiles and Its Applications to Orthodontics," Conf. Proc. IEEE Eng. Med. Biol. Soc., 12(5):2051-2053 (1990).	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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	163	YAMANY et al., "A System for Human Jaw Modeling Using Intra-Oral Images," Proc. of the 20th Annual Conf. of the IEEE Engineering in Medicine and Biology Society, November 1, 1998, Vol. 2, pp. 563-566.	☐
	164	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); I. The D.P. Concept and Implementation of Transparent Silicone Resin (Orthocon)," Nippon Dental Review, 452:61-74 (June 1980).	☐
	165	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); II. The D.P. Manufacturing Procedure and Clinical Applications," Nippon Dental Review, 454:107-130 (August 1980).	☐
	166	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); III. The General Concept of the D.P. Method and Its Therapeutic Effect, Part 1, Dental and Functional Reversed Occlusion Case Reports," Nippon Dental Review, 457:146-164 (November 1980).	☐
	167	YOSHII, "Research on a New Orthodontic Appliance: The Dynamic Positioner (D.P.); III.- The General Concept of the D.P. Method and Its Therapeutic Effect, Part 2. Skeletal Reversed Occlusion Case Reports," Nippon Dental Review, 458:112-129 (December 1980).	☐
	168	You May Be A Candidate For This Invisible No-Braces Treatment," Allesee Orthodontic Appliances-Pro Lab product information for patients, 2 pages (2002).	☐
	169	You May Be A Candidate For This Invisible No-Braces Treatment," Allesee Orthodontic Appliances-Pro Lab product information for patients, 2 pages (NO DATE GIVEN).	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	03/07/2019

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 31 of 32

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	Not assigned yet
Examiner Name	Not assigned yet
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Charles Hagadorn/	Date (YYYY-MM-DD)	2017-03-31
Name/Print	Charles Hagadorn	Registration Number	62,367

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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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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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 07/23/2019

WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER
MONTIEL, CAROLINE

ART UNIT	PAPER NUMBER
1748	

NOTIFICATION DATE	DELIVERY MODE
07/23/2019	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):

patentdocket@wsgr.com

Applicant-Initiated Interview Summary	**Application No.** 15/476,655	**Applicant(s)** LI et al.	
	Examiner Caroline Montiel	**Art Unit** 1748	**AIA (FITF) Status** No

All participants (applicant, applicants representative, PTO personnel):

(1) Caroline Montiel.

(2) Anthony Calandra.

(3) Melissa Harwood.

(4) Garrett Potter.

Date of Interview: 18 July 2019.

Type: ☑ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☑ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☑103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 20.

Identification of prior art discussed: --.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant discussed filing a 132 declaration for the 103 rejection. Applicant also discussed on changing the independent claim so that there would be 2 layers instead of 3 layers. Further search and consideration would be required once the Applicant's response is submitted..

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CAROLINE MONTIEL/ Examiner, Art Unit 1748	/Anthony Calandra/ Primary Examiner, Art Unit 1748

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.

PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/476,655	Filing Date 03/31/2017	☐ 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 $80 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $420 =	
☐ 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	09/16/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/NICOLE LOVE HENSLEY/
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6390812	05-21-2002	CHISHTI; Muhammad et al.	
	002	US-6485298	11-26-2002	CHISHTI; Muhammad et al.	
	003	US-6705861	03-16-2004	CHISHTI; Muhammad et al.	
	004	US-7121825	10-17-2006	CHISHTI; Muhammad et al.	
	005	US-20020192617	12-19-2002	PHAN; Loc X. et al.	
	006	US-20030190576	10-09-2003	PHAN; Loc X. et al.	
	007	US-20040170941	09-02-2004	PHAN; Loc X. et al.	
	008	US-20070231765	10-04-2007	PHAN; Loc X. et al.	
	009	US-20080020337	01-24-2008	PHAN; Loc X. et al.	
	010	US-20190159870-A1	05-30-2019	LI; Chunhua et al.	
	011	US-20190183611-A1	06-20-2019	LI; Chunhua et al.	
	012	US-20190231484-A1	08-01-2019	LI; Chunhua et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-0180762-A2	11-01-2001	ALIGN TECHNOLOGY INC [US], et al.		☐

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Sheet 2 of 4

Complete if Known	
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First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

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	002	WO-0180764-A1	11-01-2001	ALIGN TECHNOLOGY INC [US], et al.		☐

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
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Sheet 3 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

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(71) Applicant *(for all designated States except US)*: **ALIGN TECHNOLOGY, INC.** [US/US]; 851 Martin Avenue, Santa Clara, CA 94086 (US).

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(75) Inventors/Applicants *(for US only)*: **PHAN, Loc, X.** [US/US]; 31 Jacklin Circle, Milpitas, CA 95035 (US). **CHISHTI, Muhammad** [US/US]; 970 Corte Madera Avenue, Apt. 302, Sunnyvale, CA 94086 (US). **MILLER, Ross, J.** [US/US]; 243 Buena Vista Avenue, #1513, Sunnyvale, CA 94086 (US). **VAN DEN BERG, H., Robert** [NL/US]; 1501 Bollinger Canyon Road, Suite A, San Ramon, CA 94583 (US). **KUO, Eric** [US/US]; 101 Woodland Avenue, San Francisco, CA 94117 (US). **AHN, Jae, Hyun** [KR/US]; 340 Serrano Drive, San Francisco, CA 94132 (US). **TRICCA, Robert, E.** [US/US]; 1062 Allegheny Drive, Danville, CA 94526 (US).

(74) Agents: **HESLIN, James, M.**; Townsend and Townsend and Crew LLP, Two Embarcadero Center, Eight Floor, San Francisco, CA 94111 et al. (US).

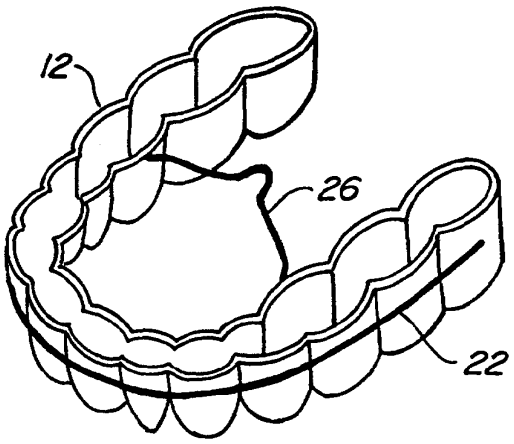
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(54) Title: EMBEDDED FEATURES AND METHODS OF A DENTAL APPLIANCE



(57) Abstract: Traditional orthodontic treatment often involves the use of basic repositioning devices, such as braces, and the use of supplementary devices, components or accessories to achieve desired end results. Such components may be mounted on fixed, non-removable devices or they may be part of a removable appliance typically worn prior to the application of the fixed devices. As with traditional treatment, it may be desired to utilize similar components when repositioning teeth with removable elastic repositioning appliances. Due to the nature of elastic appliances, such components may take a variety of forms ranging from readily available traditional accessories to specially created devices. Thus, traditional components may be mounted on or embedded in an elastic appliance, or the appliance may be formed to provide similar components. Likewise, the appliance may be modified to provide additional features for specific orthodontic treatments.

WO 01/80762 A2

EMBEDDED FEATURES AND METHODS OF A DENTAL APPLIANCE

BACKGROUND OF THE INVENTION

The present invention is related generally to the field of orthodontics. Particularly, this invention relates to the use of removable orthodontic appliances for producing tooth movements. More particularly, this invention relates to improved devices, systems and methods for producing such tooth movements with elastic repositioning appliances.

Orthodontic treatments involve repositioning misaligned teeth and bite configurations for improved cosmetic appearance and dental function. Repositioning teeth is accomplished by applying controlled forces to the teeth over an extended period of time. This is conventionally accomplished by wearing what are commonly referred to as "braces." Braces are typically comprised of brackets or bands which are bonded to the teeth and linked with the use of archwires, ligatures and O-rings. After the archwire is in place, periodic appointments with the orthodontist are required, during which the patient's braces will be adjusted. This involves installing different archwires having different force-inducing properties or by replacing or tightening existing ligatures. Between meetings, the patient may be required to wear supplementary appliances, such as elastic bands or headgear, to supply additional or extraoral forces.

Although conventional braces are effective, they are often a tedious and time consuming process requiring many visits to the orthodontists office. Moreover, from a patient's perspective, they are unsightly and uncomfortable. The archwire and ligatures which connect the brackets in a continuous network make brushing, flossing between the teeth and other dental hygiene procedures difficult, possibly contributing to the development of gingivitis, caries, and other dental disease. Consequently, alternative orthodontic treatments are needed. In particular, it would be desirable to use appliances which can be removed by the patient during daily dental hygiene routines, while participating in athletic activities, or for cosmetic purposes.

A particularly promising approach relies on the use of elastic positioning appliances for realigning teeth. Such appliances comprise a thin shell of elastic material that generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the elastic positioner over the teeth applies controlled

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forces in specific locations to gradually move the teeth into the new configuration. Repetition of this process with successive appliances comprising new configurations eventually move the teeth through a series of intermediate configurations to a final desired configuration. A full description of an exemplary elastic polymeric positioning appliance is described in U.S. Patent No. 5,975,893, and in published PCT application WO 98/58596 which designates the United States and which is assigned to the assignee of the present invention. Both documents are incorporated by reference for all purposes.

In addition to their ease of use, polymeric positioning appliances are generally transparent, providing an improved cosmetic appearance, and impart substantial force on the teeth, due to stiffness of the appliance. The stiffness of an elastic positioning appliance is a result of the modulus of the thermoformable polymer materials from which it is made. The higher the modulus of the materials, the higher the stiffness of the appliance. By designing the appliance to cover the teeth, a much larger and/or more varied contact surface area may be afforded compared to traditional spring retainers and wire-based appliances. Consequently, more dramatic tooth movements may be achieved.

In some cases, however, orthodontic treatment may involve more complex tooth movements or treatment plans requiring additional devices or accessories. For example, it may be desirable to apply forces to surfaces of the teeth that may not be easily achieved by the appliance alone, either due to the location or characteristics of the surface itself or of the surrounding teeth. Similarly, it may be desirable to apply extraoral forces to some tooth surfaces to achieve certain tooth movements or to control growth and development of the bite and jaws. Likewise, it may be desirable to achieve such control indirectly through soft tissue stretch and muscular activity. Alternatively, it may be preferable to allow the passive eruption and movement of certain teeth, free of applied forces. The devices and accessories commonly utilized for these situations are typically separate removable appliances worn prior to the application of conventional braces, or accessories used in conjunction with conventional braces. Thus, such devices and accessories may not be compatible with the use of elastic polymeric positioning appliances for orthodontic treatment.

Consequently, improved methods and apparatus for achieving these treatment objectives are desired for complete orthodontic treatment in such patients. Such devices, systems and methods would maintain the advantages of and be compatible with a removable appliance while providing supplementary features to assist in the improvement of jaw structuring, alignment and tooth repositioning, to name a few. At

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least some of these objectives will be met by the designs and methods of the present invention described hereinafter.

SUMMARY OF THE INVENTION

The present invention provides improved devices, systems and methods for repositioning teeth from a first orientation to a successive orientation in a series of movements to a final tooth and bite configuration. Such repositioning is based on a system comprising at least one and usually a plurality of three or more elastic repositioning appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth, usually in a series of successive steps. In cases involving more complex movements or treatment plans, it may be desired to utilize additional devices, components or accessories. The present invention provides for the utilization of such devices, components or accessories typically used in conventional or novel orthodontic treatments. In some instances the present invention provides improved elastic repositioning appliances that take the place of such additional accessories. Further, the present invention may provide improved elastic repositioning appliances that provide simultaneous repositioning of tooth and bite configurations that may be unachievable with conventional devices.

In a first aspect of the present invention, a removable elastic positioning appliance, typically used in a series of successive elastic appliances for orthodontic treatment, may be comprised of a polymeric shell having at least one orthodontic component or accessory. Usually and preferably, the orthodontic component will be configured to interact with a "non-tooth" oral surface and/or another orthodontic device. The non-tooth oral surface may be selected from the group consisting of the palate, cheeks, lips, tongue, and gingiva. Usually the interaction will be intended to provide force or anchoring from the non-tooth oral surface to the tooth positioning appliance. Similarly, the orthodontic devices will usually be selected from the group consisting of head gear, elastic bands, ligatures, springs, attachment devices, and elastic repositioning appliance. Such orthodontic devices are usually intended to apply an external force on to the orthodontic component and thus on to the elastic tooth positioning appliances. In this way, forces which could not conveniently be achieved with the tooth positioning appliance by itself can be effected. Such forces in some instances can provide for tooth movements which would otherwise not be possible. The orthodontic components will usually not include anchors, brackets, or other structures which are attached directly to

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one or more teeth. Thus, the components in the first aspect of the invention will usually not be intended to act as an intermediate member or an interface between the tooth positioning appliance and the tooth itself.

These components or accessories may be independent entities that are embedded in the polymeric shell during production of the appliance. Or, they may be mounted on the polymeric shell with a suitable adhesive in a post-production assembly protocol. In either case, the components may be traditional accessories that are typically used with conventional orthodontic devices, such as braces, or they may be any other readily available components used for dental treatment. Alternatively, the components may be specially created accessories designed for specific purposes when used with removable elastic positioning appliances. Such specially created accessories may be independent entities present on or in the polymeric shell as described above, or they may be formed by the polymeric shell itself. In these cases, the component may be a formed protrusion or shape in the wall of the polymeric shell, providing a variety of advantages, including but not limited to increased stability, safety from breakage, ease of manufacturing, cost savings, shortened treatment time and improved cosmetic appearance and patient compliance.

In a first embodiment, the orthodontic components or accessories may be conventional accessories typically used with fixed, non-removable orthodontic devices. For example, headgear tubes are conventional accessories typically mounted on traditional braces for inserting a headgear device and applying extraoral force to the teeth and jaws. Tubes for receiving headgear may be mounted on or embedded in the polymeric shell of an elastic positioning appliance for a similar effect. Similarly, orthodontic hooks may be mounted on traditional braces to support elastic bands which may also apply distinct forces to the teeth and jaws. As with headgear tubes, such hooks may also be mounted on or embedded in the polymeric shell of a positioning appliance for a similar effect. Likewise, a number of other conventional accessories, such as brackets, springs, bumper tubes, palatal bars, frameworks, pin-and-tube apparatuses and the like, may be used in conjunction with polymeric positioning appliances. In some cases, such as with brackets, the accessory may be used to join a removable elastic appliance with a portion of teeth supporting fixed conventional devices, such as braces.

In a second embodiment, the orthodontic components or accessories may be those which are primarily exclusive to removable appliances. These components are not generally suited for use with fixed appliances and devices due to their bulk and size.

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In addition, they are often used prior to the use of fixed devices to create a favorable environment for later tooth repositioning. For example, when a patient's teeth are still erupting, a number of devices may be used to foster improved eruption and development of the tooth arrangement and bite configuration. These may include buccal shields, buccinator bows or wire shields, bite plates, palatal expanders and bars, lingual flanges and pads, lip pads or bumpers, and the like. Since these components are currently used with removable appliances, they are ideally suited for use with removable elastic positioning appliances. Thus, the components may be mounted on or embedded in the polymeric shell of an elastic appliance. Similarly, supporting structures for such components may also be mounted or embedded in the polymeric shell for the removable application of a component. For example, a bumper tube may be embedded in the polymeric shell for later insertion and removal of a bumper. Alternatively, the components may be formed by the appliance itself, such components comprising a formed protrusion or shape in the wall of the polymeric shell. In these cases, the elastic repositioning appliance may take the place of any additional accessories.

An added advantage of the use of elastic repositioning appliances having these components or accessories is the ability to provide the conventional benefit of the accessory while simultaneously repositioning the teeth, a combination previously limited. In conventional treatment, the use of fixed devices to reposition the teeth negated the ability of simultaneously using accessories provided by some removable appliances since removable appliances may not be readily applied with fixed devices in place. For example, situations in which it is desired to control eruption of specific teeth concomitant with repositioning of the same or other teeth would cause great difficulty if not an impossible dilemma with traditional devices. The present invention may provide such simultaneous maneuvers which are unachievable with conventional treatment.

In a second aspect of the present invention, a removable dental positioning appliance, typically used in a series of successive elastic appliances for orthodontic treatment, may be comprised of at least one protrusion shaped to be used for an orthodontic function. As described above, such a protrusion may resemble, in form or function, a traditional component or accessory used in conventional orthodontic treatment with fixed, non-removable devices or with removable appliances. For example, an appliance may have a protrusion or shape in the wall of the polymeric shell in the form of a hook for mounting flexible bands, ligatures or adjunct devices. Such a hook may resemble traditional hooks found in dental care, or it may be specially designed for use

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with elastic repositioning appliances. Likewise, such a protrusion may form a spring which transmits force to one or more teeth to reposition teeth from a first arrangement to a successive arrangement. A spring of this type may be of a traditional design or it may be specially designed for use with elastic repositioning appliances. Further, it may be specially designed to engage an attachment body mounted on a tooth, a device primarily utilized in conjunction with removable elastic appliances. A full description of exemplary attachment bodies and devices is described in published PCT application WO 99/28228, which corresponds to co-pending application serial number 09/454278, assigned to the assignee of the present invention. Both documents are incorporated by reference for all purposes. Thus, in these and similar cases, such as a palatal bar, the protrusion may take the place of a traditional accessory or component, or it may be utilized in a specialized manner.

In one embodiment, the protrusion may contact one or more dental surfaces to assist in holding the elastic appliance in position. For example, one or more protrusions may be sized and located to contact interdental areas of the patient's teeth, often near the gingival margin, when the appliance is properly inserted and positioned. Such protrusions may be formed in the wall of the polymeric shell, or they may be adhered to or embedded into the polymeric shell to protrude from the wall. Such placement of the protrusions may provide additional friction and "grab" in dental regions conducive to this effect. Similarly, a protrusion may be sized and located to contact a tooth along a portion of the gingival margin, with or without contact in the interdental areas. Or, the protrusion may be a continuous protrusion contacting more than one tooth along the gingival margin and the interdental areas. In each of these cases, the contact of the protrusion may assist in holding the appliance in proper position.

In another embodiment, the one or more protrusions may form a bite plate. A bite plate is a device which prevents the teeth from closing completely. By opening the bite in this manner, unopposed teeth may be allowed to passively erupt in a controlled manner to beneficially alter vertical dental relationships. In addition, such an open state or disclusion may relieve teeth which are in crossbite allowing orthodontic forces to correct the crossbite.

To provide anterior disclusion, an elastic positioning appliance may have an increase in thickness of material in the posterior occlusal regions. This increase in thickness may be applied to the appliance or formed by the appliance to create a protrusion over the designated occluding surfaces. Similarly, posterior disclusions may

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be provided by forming a protrusion which extends at least a portion of an upper palatal region with added thickness. Alternatively, posterior disclusions may be provided by forming a protrusion in an upper lingual or lower facial anterior region. Such protrusions may prevent the front teeth from closing completely, thus discluding the posterior teeth. As previously described, such protrusions may be formed in the appliance or applied to the surface of the appliance.

Such embodiments of the present invention may be utilized in the treatment of patients with a condition commonly termed a "deep bite". In these cases, the lower teeth contact the upper teeth and/or the palate in the natural bite. This occurs when the posterior teeth are not fully erupted in the correct position allowing the anterior teeth to become overclosed or overlap more than is desirable. Such a bite is injurious to the palate, tends to crowd the lower teeth, and affects flaring of the upper teeth leading to upper spaces. This may be alleviated with the use of a bite plate which provides posterior disclusion. Such disclusion allows the posterior teeth to naturally erupt without contacting the opposing teeth which may impede their eruption into the correct position. The present invention may provide the function of a bite plate while additionally providing repositioning forces and other orthodontic treatment to the patient. These functions may be simultaneous, an attribute not previously afforded by conventional orthodontic treatment.

In a third aspect of the present invention, a removable dental positioning appliance, typically used in a series of successive elastic appliances for orthodontic treatment, may be comprised of at least one space filler shaped to align with a gap between adjacent teeth. If a tooth is extracted from a patient's dentition, a space or gap will be left behind between adjacent teeth. A similar gap may also be present due to general misalignment of the teeth. An elastic positioning appliance may be made to be positioned over a gap and its surrounding teeth. In such a case, a space filler may be shaped to align with the gap. In a preferred embodiment, the space filler may be a cavity in the polymer shell having the shape of at least a portion of a tooth, dental feature, sphere, oval or three-dimensional curved and/or flat sided object. In the case of a tooth shape, the space filler may act as a "pontic," a fake tooth placed where a tooth is missing to give the appearance of the presence of a tooth. This same effect may also be given by other shapes. Likewise, as a gap is gradually eliminated due to repositioning of the teeth, a variety of shapes may be suitable throughout the repositioning process.

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To further conceal the presence of a space or gap between teeth during orthodontic treatment, a space filler may be opacified. By making the space filler at least partially opaque, it may give a more convincing appearance of the presence of a tooth or dental feature. Such opacity may be an effect of surface treatment of the space filler. For example, the inside and/or outside surfaces of the space filler may be painted with a tooth-colored material. Alternatively, the surfaces may be microetched to give a more frosted appearance to the polymeric shell material. In either case, the space or gap may be less visible.

In addition to improving cosmetic appearance, a space filler may also provide structural support for the elastic appliance. When a space filler is a cavity, as described above, the presence of the cavity improves the structural integrity of the appliance by providing a uniform geometry. Alternatively, a space filler may be any number of structures providing similar support. For example, a space filler may be a structure that is at least partially solid. This may be achieved by the formation of a solid section of material spanning the gap, similar to a bridge or slab between adjacent teeth. Such a solid section may be formed by the fusing of the walls of the polymeric shell together. Alternatively, the shell may be filled with a solid material. In this case, the shell may be designed with undercuts or prongs to retain the solid material. In addition, a solid section may be corrugated to additionally improve the integrity of the appliance.

In a fourth aspect of the present invention, a removable dental positioning appliance, typically used in a series of successive elastic appliances for orthodontic treatment, may be comprised of a polymeric shell having cavities shaped to receive and reposition teeth, wherein one or more cavities has a window to expose at least a portion of a received tooth. Such windows may be portions of the wall of the polymer shell which are removed. When the shell is positioned over the patient's teeth, portions of the teeth beneath the windows may be exposed. Exposing such tooth surfaces may allow brackets, buttons or other orthodontic components to be utilized in conjunction with the elastic appliance or to be exposed for other purposes.

In a preferred embodiment, a polymeric shell may have a plurality of windows over portions of the occlusal surfaces of the teeth. In this case, segments of the shell may still be present along the facial and lingual surfaces of the teeth and across the interdental regions or spaces between the teeth. Exposure of the occlusal surfaces in appropriate size and location may allow interdigitation of the upper and lower teeth. This may also be achieved with the presence of one or a few larger windows over portions of

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the occlusal surfaces of the teeth. In these cases, segments of the shell may not be present across the interdental regions or spaces between the teeth. In either case, interdigitation of at least portions of the upper and lower teeth may benefit tooth and jaw orientations, leading to improved treatment, appearance, comfort and consequently patient compliance. Likewise, similarly placed windows may provide the benefits offered by a lower elastic modulus, such that the lowest stiffness may be provided by the absence of the material. Such benefits and a full description is provided in co-pending application [Attorney Docket No. 018563-001310], assigned to the assignee of the present invention.

In yet other aspects of the present invention, removable elastic tooth positioning appliances will comprise at least one, and usually a plurality of polymeric shells which are shaped to be placed over and conform to teeth such that the exterior of the shell, i.e., the surface which is remote from the teeth when the appliance is placed over the teeth, mimics the shape of the teeth. In contrast to the prior appliance descriptions, in the present aspect of the present invention, it is desired that the shell be at least partially opacified, often being completely opacified. By "opacified," it is meant that the appliance will be opaque so that the teeth beneath the appliance are not visible, at least on the surfaces which would be apparent by persons looking at the user who wears the appliance. Thus, in some cases, only a single tooth of the appliance may be opacified to conceal the absence of a missing tooth therebeneath. In other cases, at least the six front teeth of the appliance are opacified to hide the teeth therebeneath, often being eight front teeth, and sometimes being ten front teeth. By opacifing the front teeth, those teeth which are most likely to be visible will be covered.

Usually, the opacification will be achieved by coloring the appliance with a tooth-colored material and/or forming the appliance from a tooth-colored material. In other instances, however, it may be desirable to color the appliance in non-tooth colors and in other instances to use multiple tooth and/or non-tooth colors on the same appliance. It will be appreciated that in addition to coloring, pattern of shades and/or colors could be provided on a single appliance.

In a particular aspect of the coloring methods, a removable elastic appliance comprising a shell which conforms to a patient's teeth is provided. In addition, a plurality of coating materials are provided to a user, who may be the patient. The user can then select which of the colored coating materials the user desires to coat at least a portion of the appliance with. Optionally, kits may be provided including the appliance(s), plurality of coating materials having different colors, and means for

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applying the selected coating materials to the removable appliance, such as paint brushes, dipping trays, spray cans, or other applicators for applying the coating to the appliance. In some instances, the colors will be a variety of shades of tooth colors, permitting the user to most closely match the patient's natural tooth color. Preferably, the kits will contain multiple removable elastic appliances for effecting tooth positioning as described above.

The present invention further comprises methods for fabricating pre-colored removable elastic tooth positioning appliances. First, a desired color is determined. Typically, the desired color is determined by the patient or other user and transmitted to the manufacturer. The manufacturer then selects a material from which to fabricate the appliance having the desired color. The appliance is then molded from the selected material. Frequently, determining the desired color may comprise matching the patient's native tooth color to a color chart and selecting the color which most closely matches the tooth color. Alternatively, the patient or other user may select one or more colors from a group of colors which do not match natural or native tooth colors.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective illustration a variety of orthodontic components or accessories typically used with fixed orthodontic devices mounted on or embedded in the polymeric shell of a removable elastic repositioning appliance.

Fig. 2 is a perspective illustration of a typical transpalatal arch bar mounted on or embedded in the polymeric shell of an appliance.

Fig. 3 is a perspective illustration an appliance having a lip pad.

Fig. 4 is a perspective illustration of an appliance having a buccal shield.

Fig. 5 is a perspective illustration of an appliance having buccinator bow.

Fig. 6 is a perspective illustration of an appliance having lingual pad.

Fig. 7 is a perspective illustration of appliances joined by frameworks used in Herbst Appliances.

Fig. 8 is a perspective illustration of appliances joined by frameworks used in Jasper Jumpers.

Fig. 9 illustrates of an appliance having a protrusion formed in the polymeric shell in the shape of a hook.

Figs. 10A and 10B illustrate steps of producing a protrusion depicted in Fig. 9.

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Fig. 11 illustrates an appliance having a protrusion formed in the polymeric shell in the shape of a spring.

Fig. 12 is a perspective illustration of an appliance having a protrusion in the polymeric shell to form a transpalatal bar.

Fig. 13 is a perspective illustration of an appliance having a corrugated protrusion in the polymeric shell to form a transpalatal bar.

Fig. 14A is a side view of a patient's teeth showing the placement of protruding divots contacting interdental areas, and Fig. 14B is a perspective illustration of a portion of an appliance having such divots.

Fig. 15A is a perspective illustration of a portion of an appliance having a continuous protrusion along the gingival line, and Fig. 15B is a cross-sectional view of a tooth having such an appliance in place.

Fig. 16 is a side view of a posterior portion of an appliance illustrating an increase in thickness of material to form a bite plate.

Fig. 17 is a perspective illustration of an appliance having a protrusion of an upper palatal region to form a bite plate.

Fig. 18A and 18B are cross-sectional views of appliances having protrusions in an upper lingual and lower facial anterior regions, respectively, to form bite plates.

Fig. 19 illustrates a patient having a gap between adjacent teeth.

Fig. 20 is a perspective illustration of an appliance having a space filler cavity in the shape of a tooth placed over the patient's dentition illustrated in Fig. 19.

Fig. 21 is a perspective illustration of an appliance having a space filling structure formed between two cavities in the polymeric shell.

Fig. 22 is a perspective illustration of an appliance having a space filling corrugated structure formed between two cavities in the polymeric shell.

Fig. 23A illustrates an unwanted disclusion due to thickness of the appliance along the occlusional surfaces. Fig. 23B illustrates the elimination of the disclusion of Fig. 23A by eliminating material along the occlusional surfaces. Fig. 23C illustrates a preferred embodiment of an appliance with portions of the occlusional surfaces eliminated.

Fig. 24A illustrates a release tab embedded in the polymeric shell of an appliance. Fig. 24B illustrates a preferred embodiment of an appliance with release tabs encircling areas of occlusional surfaces of the appliance.

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Fig. 25 illustrates a kit according to the present invention including a plurality of appliances, a multiplicity of colored coating materials, and a kit container.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Traditional orthodontic treatment often involves the use of basic repositioning devices, such as braces, and the use of supplementary devices, components or accessories to achieve desired end results. As previously described, such supplementary components may be mounted on fixed, non-removable devices or they may be part of a removable appliance typically worn prior to the application of the fixed devices. As with traditional treatment, it may be desired to utilize similar supplementary components when repositioning teeth with removable elastic repositioning appliances. Due to the nature of elastic appliances, such components may take a variety of forms ranging from readily available traditional accessories to specially created devices, as will be described below.

Referring to Fig. 1, a variety of orthodontic components or accessories typically used with fixed orthodontic devices, such as braces, are shown in conjunction with a removable elastic positioning appliance 10. The majority of these accessories may be readily available since they are typically used with conventional treatment. They are also typically mounted on fixed devices, so they are available as separate individual components. As previously described, these components may be embedded in the polymeric shell 12 of an elastic repositioning appliance 10 during production or they may be mounted on the shell 12 in a post-production assembly. One such type of component is a tube 14 which is used in pairs to mount a headgear appliance. Headgear appliances are typically mounted on opposite posterior molars of the upper jaw for a number of purposes, including keeping the upper jaw from growing, pulling the upper teeth backward, and pulling the upper jaw and teeth upward and backward so that they align with the lower jaw and teeth. Therefore, tubes 14 for receiving headgear may be mounted on the buccal surfaces of the polymeric shell 12 covering the posterior molars. The distal ends of the headgear which enter the oral cavity may then be inserted into the tubes 14 to apply extra oral forces to the teeth and jaw. Other components may include hooks 16, primarily used for mounting elastic bands, brackets 18, used for mounting additional components and accessories or possibly for interconnection with fixed brackets or devices, and buttons 20, primarily used as an attachment point for various purposes. It may be appreciated that such components have been shown on the same appliance 10 for

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illustrative purposes, however typical use may involve one or a few of such components with varying arrangements.

Referring to Fig. 2, an additional component which may be mounted on or embedded in a polymeric shell 12 is a transpalatal arch bar 26. Such palatal bars typically span the palate and are fixed at both ends to permanent devices mounted on opposing molars. This is often used to stabilize and maintain positioning after active arch expansion. In the case of an elastic repositioning appliance 10, the conventional arch bar 26 may be positioned in a similar location, attached at both ends to the polymeric shell covering the lingual surfaces of opposing upper molars. In addition, a low hanging transpalatal bar for control of vertical dimension may be used. Also shown in Fig. 2, one or more wires 22 may be mounted on or embedded in the polymeric shell 12. Such wires 22 may span the majority of the arch, as in the case of a conventional archwire, as shown. Or, such wires 22 may span only portions of the arch, may be present on or within the facial and/or lingual surfaces of the shell, may be multiple in number at a given location, and may be curved, straight or a combination of these, to name a few. The presence of such a wire 22 may be used most commonly for structural reinforcement but may also be used to aid in the application of orthodontic repositioning forces. Again, it may be appreciated that such components have been shown on the same appliance 10 for illustrative purposes, however typical use may involve one or a few of such components with varying arrangements.

Figs. 3-8 illustrate the use of a variety of orthodontic components or accessories which are typically used with removable functional appliances. These components are not generally suited for use with fixed appliances and devices due to their bulk and size. However, they may be readily used with removable elastic repositioning appliances. In most functional appliances, flanges are used to provide the stimulus to posture the mandible to a new position. Growth modification is most effective if the patient uses his or her own musculature to posture the mandible forward, as opposed to the mandible being held forward by external pressure while the patient relaxes. Thus, the key to mandibular repositioning is the contact of the pad or flange with soft tissue. Such pads or flanges may be mounted or embedded in elastic repositioning appliances. Referring to Fig. 3, a lip pad 30 may be positioned on the polymeric shell 12 so that it is low in the vestibule, holding the lips away from the teeth and forcing the lips to stretch to form an oral seal. This forces the lip musculature to stretch during function, presumably

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improving the tonicity of the lips and perhaps promoting some soft tissue remodeling that would contribute to stability of changes in incisor position.

Referring to Figs. 4 and 5, plastic buccal shields 34 and wire buccinator bows 36 may be mounted on or embedded in the polymer shell 12 to hold the soft tissues away from the teeth. A buccal shield 34 or bow 36 may be positioned on the buccal surface of the polymeric shell 12 to lie between the teeth and the cheek. The buccal shield 34 is most useful to hold the cheek away from the dentition to facilitate posterior dental expansion by disrupting the tongue-cheek equilibrium. This in turn leads to facial movement of the teeth and arch expansion. A combination of lip pads 30 and buccal shields 34 will result in an increase in arch circumference as well. It may be appreciated that similar shields may be mounted on the lingual surface of the polymeric shell to remove the resting tongue from between the teeth. This has the effect of enhancing tooth eruption in designated areas. In addition, a lingual pad or flange 38 may be positioned on the lingual surfaces of the polymeric shell 12 covering the lower anterior teeth, as shown in Fig. 6. The lingual pad 38 determines the anteroposterior and vertical mandibular posture for most functional appliances. Such pads 38 may not only position the mandible forward but also exert a protrusive effect on the mandibular incisors when the mandible attempts to return to its original position.

Referring to Figs. 7 and 8, a number of components and accessories may be removably or fixedly attached to both an upper and lower elastic positioning appliance. Components commonly used in this arrangement are frameworks used in Herbst Appliances and Jasper Jumpers. Herbst Appliances are devices in which the maxillary and mandibular arches are splinted with frameworks that are connected with a pin-and-tube device that holds the mandible forward. When used with elastic repositioning appliances, Fig. 7, the pin-and-tube apparatus 40 may be mounted on the buccal surfaces of the upper polymeric shell 42 and lower polymeric shell 44 as shown. The Jasper Jumper functions in a similar manner as the maxillary and mandibular arches are splinted with frameworks that are connected with a spring covered by a plastic sheath. When used with elastic repositioning appliances, Fig. 8, the sheath covered spring 48 may be mounted in a similar manner as shown.

As an alternative to mounting or embedding conventional orthodontic components on an elastic repositioning device, protrusions or other shapes may be formed in the polymeric shell of the device to be used for orthodontic functions. For example, referring to Fig. 9, a hook 50 may be formed in the polymeric shell 12 of an elastic

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repositioning appliance 10 for use in mounting a flexible band 52. Such a hook 50 may resemble traditional hooks found in dental care, or it may be specially designed for use with elastic repositioning appliances. The embodiment illustrated in Fig. 9 may be produced by a series of production steps. First, a mold of the dentition is produced by any method. Second, Fig. 10A, a wedge or similar protruding mass 54 is then mounted on the mold 55 in the location desired for the resulting hook. It may be appreciated that such a protruding mass 54 may be formed in the original mold 55 by a variety of methods, particularly in the case of computer-guided production methods. Next, a polymeric sheet is thermoformed over the mold 55 to form the appliance 10. The appliance 10 may then be trimmed along the dashed line 56, Fig. 10B, and the polymeric material removed from the joining area 57 to create a hook 50 shown in Fig. 9.

In another embodiment, shown in Fig. 11, a spring 60 may be formed in the polymeric shell 12 of an elastic repositioning appliance 10 for use in transmitting repositioning force to one or more teeth. Such a spring 60 may resemble traditional springs found in dental care, or it may be specially designed for use with elastic repositioning appliances. In this example, the spring 60 is comprised of a pre-formed strip or portion of the polymeric shell 12 which engages an attachment body 62 mounted on an underlying tooth 64. The attachment body 62 is accessible through a window 66 in the appliance 10.

In further embodiments, larger protrusions may also be formed in the polymeric shell to provide additional support for the appliance and/or to provide orthodontic functions. Such a protrusion may form a palatal bar 70, as shown in Fig. 12. Here, a palatal bar 70 is formed in the polymeric shell 12 itself. In addition, a variety of palatal bars may be formed in the shell, such as a low hanging transpalatal bar for control of vertical dimension. These may provide orthodontic functions as described above in relation to conventional palatal bars, and they may also provide support for the appliance 10. This may be particularly useful in highly flexible appliances. For increased support of the construction, the protrusion may be a corrugated palatal bar 71, as shown in Fig. 13.

In still further embodiments, protrusions in an elastic repositioning appliance may assist in holding the elastic appliance in place when it is properly inserted and positioned. Such protrusions may be divots 74 sized and located to contact interdental areas 76 of the patient's teeth 78, often near the gingival margin 79 as shown in Fig. 14A. Such placement may provide additional friction and "grab" in dental regions

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conducive to this effect. Such divots 74 may be most visible by viewing the hollow cavities of the appliance 10, as shown in Fig. 14B. These protrusions may be solid divots 80 adhered to or embedded in the polymeric shell 12 to inwardly protrude from the wall. Alternatively, the protrusions may be formed divots 82 in the wall of the polymeric shell 12 so that essentially the wall protrudes inwardly in these areas. As shown, the divots may be of any shape, number and configuration, including paired divots 84 and single divots 86 as shown.

Similarly, these protrusions may be a continuous protrusion contacting more than one tooth along the gingival margin and the interdental areas. This is illustrated in Fig. 15A as a continuous protrusion 90 is shown along the edges of the hollow cavities of the appliance. This may be a solid protrusion 92 adhered to or embedded in the polymeric shell 12 to inwardly protrude from the wall, or it may be a formed protrusion 94 in the wall of the polymeric shell 12 so that essentially the wall protrudes inwardly in these areas. When the appliance is positioned over the teeth, such a protrusion 90 may fit in the undercut of the tooth 64 along the gingival margin 79, as shown in Fig. 15B. Here a solid protrusion 92 and a formed protrusion 94 are shown in cross-section. Such positioning along the undercut of the teeth may assist in holding the appliance in place. It may be appreciated that such a protrusions may be sized, formed and located in any combination within the polymer shell so as to assist in holding the appliance in a desired position.

In another embodiment, the one or more protrusions may form a bite plate. A bite plate is a device which prevents the teeth from closing completely. The resulting open state, or disclusion, may be useful for a number of orthodontic treatments, including crossbite correction and controlled passive eruption. To provide anterior disclusion, an elastic positioning appliance 10 may have an increase in thickness of material 100 in the posterior occlusion regions of the polymeric shell 12, as shown in Fig. 16. The increase in thickness of material 100 may be applied to the appliance 10 or formed by the appliance 10 to create a protrusion over the designated occluding surfaces. Similarly, as shown in Fig. 17, posterior disclusions may be provided by forming a protrusion 102 in the polymer shell 12 which extends at least a portion of an upper palatal region with added thickness. This protrusion may be formed in the appliance 10 or applied to the surface of the appliance 10.

Alternatively, posterior disclusions may be provided by forming a protrusion in an upper lingual or lower facial anterior region, as depicted in Figs. 18A and

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18B. Here, the bite is shown in cross-section, with an upper incisor 110 overlapping a lower incisor 112 and a molar 114 positioned for reference. In Fig. 18A, the polymeric shell 12 of an elastic positioning appliance 10 is shown covering the upper incisor 110. On the lingual surface of the shell 12, a protrusion 116 is shown which may contact the lower incisor 112 during biting, thus acting like a bite plate. This protrusion 116 may be formed into the polymeric shell 12 or applied along the lingual surfaces of the appliance 10. Such an arrangement may thus provide posterior disclusions. Similarly, the polymeric shell 12 may cover the lower incisor 112, as shown in Fig. 18B. In this case, a protrusion 118 on the facial surface of the shell 12 is shown which may contact the upper incisor 110 during biting. Again, this protrusion 118 may be formed into the polymeric shell 12 or applied along the facial surfaces of the appliance 10. This arrangement may also provide posterior disclusions.

Referring to Fig. 19, many patient's dentition present a gap 120 or space between adjacent teeth 67. Such a gap 120 may be the size of a tooth 67, as may be the case when a tooth is extracted, or the gap 120 may be larger or smaller than the size of a typical tooth 67, as is often the case due to general misalignment of the teeth. In either case, an elastic positioning appliance 10 may be made to be positioned over the gap 120 and the surrounding teeth 67 with a space filler aligning with the gap 120. In a preferred embodiment, shown in Fig. 20, the space filler may be a cavity 122 in the polymer shell 12 having the shape of a tooth. Thus, the space filler may act as a "pontic", a fake tooth placed where a tooth is missing to give the appearance of the presence of a tooth. Likewise, such a cavity 122 may have the shape of any portion of a tooth, dental feature, sphere, oval or three-dimensional curved and/or flat sided object for any desired effect. To further conceal the presence of a space or gap 120 between teeth 67 during orthodontic treatment, the space filler may be opacified, as depicted by shading 124 in Fig. 20.

In addition to improving cosmetic appearance, a space filler may also provide structural support for the elastic appliance. When a space filler is a cavity, as described above, the presence of the cavity improves the structural integrity of the appliance by providing a uniform geometry. Alternatively, a space filler may be any number of structures providing similar support. In a preferred embodiment, shown in Fig. 21, the space filler may be a structure 130 formed between two cavities in the polymeric shell 12 of an appliance 10. The structure 130 may be comprised of the facial wall 132 and lingual wall 133 of the polymeric shell 12 fusing together to form an at least partially

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solid slab or bridge. In addition, suitable fillers or reinforcements may be used in the fusing or similar process for added support. Likewise, a corrugated structure 135 may be formed between the cavities, as shown in Fig. 22. Such corrugation may further reinforce the structure for added support. In any case, a designated cavity 122 or structure 130, 135 in the polymeric shell 12 may be designed to align with a gap 120 between adjacent teeth 67 when the appliance 10 positioned over the patient's teeth for improved cosmetic appearance and/or structural support.

Although forming protrusions or adding additional material to elastic repositioning appliances may provide useful features in orthodontic treatment, it may also be beneficial to remove material or form windows in an appliance. Referring to Fig. 23A, if the occlusional surfaces 140 of an upper appliance 142 and a lower appliance 143 are relatively thick, simultaneous wearing of the appliances 142, 143 may provide unwanted disclusion of the teeth. For example, when closing the jaws, the double layer of occlusional surfaces 140 between the jaws may cause the posterior teeth to prematurely contact, thus preventing the anterior teeth to suitably close. This may be avoided by reducing or eliminating the occlusional surfaces of the appliances, as shown in Figs. 23B and 23C. In a preferred embodiment, shown in Fig. 23C, a polymeric shell 12 of an appliance 10 may have a plurality of windows 150 in the portions which cover the occlusal surfaces of the teeth. In this example, segments of the shell 12 are still present along the facial surfaces 152 and lingual surfaces 153 of the appliance 10 and across the interdental regions 154 or spaces between the teeth. When such an appliance is placed over the upper teeth 155 and lower teeth 156, the teeth may interdigitate, as shown in Fig. 23B. Interdigitation of at least portions of the upper and lower teeth may benefit tooth and jaw orientations, leading to improved treatment, appearance, comfort and consequently patient compliance.

Removal of material may be aided by the use of a release tab 200, as shown in Figs. 24A and 24B. A release tab 200 may be used to remove a layer of material from the polymeric shell 12 or to remove an entire portion of the shell 12, such as to either create a window, as described above, or to eliminate the shell 12 from covering specific teeth or portions of the patient's teeth. Referring to Fig. 24A, a release tab 200 may be embedded in the polymeric shell 12 along a line 202 for future separation between portion A (shaded) and portion B. Although such a line 202 is depicted as a dashed line adjacent to the tab 200 edge, such a line 202 may lie directly over the tab or in any close relation to the tab 202. In the case of a polymeric shell 12 comprised of

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multiple layers of material, the tab 200 may be embedded between the layers with a portion exposed for grasping. By grasping the tab 200 and pulling the tab 200 along its length, one or more layers of material may be released along a line 202 of separation and removed from the shell 12. In this example, the result may be portion A comprising two layers of material and portion B comprising only one. Alternatively, the result may be portion A comprising one or more layers and portion B removed entirely. Other combinations or examples are possible. Such alterations may be beneficial for patient comfort, ease of use, or obtainment of orthodontic repositioning goals, to name a few. Fig. 24B illustrates a preferred embodiment of placement of such a release tab 200 in a polymeric shell 12 of an elastic repositioning appliance 10. The tab 200 may be placed to encircle areas 206 of the occlusional surfaces of the appliance 10. Thus, the orthodontic treatment of a patient may allow material in these areas 206 of an appliance 10 for a given duration of the treatment plan. At a given point in the treatment, the orthodontic practitioner may prefer to remove a layer of material or the material entirely in these areas 206 during a patient office visit. The practitioner may perform such a removal by pulling on the appropriate release tabs 200 as described above. This may thus reduce time and cost of patient treatment.

The appliances of the present invention may desirably be opacified or colored for a number of purposes. For example, as discussed above, it may be desirable to opacify or color a portion of a polymeric shell appliance in order to hide a missing tooth, teeth, or tooth defect(s) beneath the appliance during the course of treatment. Optionally, several teeth, such as the front teeth, or the entire appliance can be colored in order to achieve a cosmetic effect. While it will usually be desirable to color the appliance in a tooth-colored hue, there may be instances where a patient wishes to color in a non-tooth color, combination of colors, or the like. Colored appliances may be fabricated from a colored starting material, typically a colored sheet of the polymeric material which is later molded into the appliance. Alternatively, the appliance may be painted, coated, or otherwise covered with a colored coating material (e.g., paint) after it has been formed. Such a coating material should, of course, be non-toxic and suitable for a long-term placement in the oral environment. These coatings may be applied at the time of fabrication, or thereafter by a user or patient, by a variety of conventional techniques, such as painting, spraying, dipping, or the like. Conveniently, clear or neutrally colored aligners may be provided in kits together with a number of coating materials having different colors. As illustrated in Fig. 25, appliances 300 may be

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packaged together in a box, tray, pouch, or other conventional container 302 together with a plurality of vials or other receptacles 304 containing colored coating materials and a brush 306 or other suitable applicator. In this way, the patient or other user can apply the colored coating material to the appliances 300 as desired at or before the time of use.

Although the forgoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications and equivalents may be used and the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.

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WHAT IS CLAIMED IS:

1. A system of removable elastic tooth positioning appliances, said system comprising:

a plurality of polymeric shell appliances, at least some of which include at least one orthodontic component, wherein each appliance is shaped to receive and reposition teeth from a first orientation to a successive orientation and the component is shaped to interact with a non-tooth oral surface or an orthodontic device.

2. An appliance as in claim 1, wherein the orthodontic component is embedded in the shell.

3. An appliance as in claim 1, wherein the orthodontic component is mounted on the shell.

4. An appliance as in claim 1, wherein the orthodontic component is formed by the shell.

5. An appliance as in claim 1, wherein the component is configured to interact with is a soft tissue surface selected from the group of the palate, cheeks, lips, tongue, and gingiva.

6. An appliance as in claim 1, wherein the orthodontic component is adapted to couple to an orthodontic device selected from the group of headgears, elastic bands, ligatures, springs, brackets, attachment devices and elastic repositioning appliances.

7. An appliance as in claim 1, wherein the orthodontic component is adapted to transmit force from the non-tooth oral surface or orthodontic device to one or more teeth to help reposition said teeth from a first arrangement to a successive arrangement.

8. An appliance as in claim 1, wherein the orthodontic component is selected from the group of tubes, lingual flanges, lingual pads, lip pads or bumpers, buccal shields, buccinator bows or wire shields, brackets, hooks, buttons, springs, palatal bars, frameworks, pin-and-tube apparatuses and sheath covered springs.

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9. An appliance as in claim 12, wherein the system comprises at least three elastic repositioning appliances.

10. A removable dental positioning appliance comprising:

a polymeric shell having cavities shaped to receive and reposition teeth from a first orientation to a successive orientation and at least one space filler shaped to align with a gap between adjacent said teeth.

11. An appliance as in claim 10, wherein the space filler is a cavity in the shape of a at least a portion of a tooth, dental feature, sphere, oval, or three-dimensional curved and/or flat-sided object.

12. An appliance as in claim 11, wherein the space filler is at least partially opaque.

13. An appliance as in claim 12, wherein the opacity is an effect of surface treatment of the space filler.

14. An appliance as in claim 10, wherein the space filler is a structure between the adjacent teeth which is at least partially solid.

15. An appliance as in claim 14, wherein the structure is corrugated.

16. A removable dental positioning appliance comprising:

a plurality of polymeric shells having cavities shaped to receive and reposition teeth from a first orientation to a successive orientation, wherein at least some of the shells have at least one window to expose at least a portion of an occlusal surface of a received tooth.

17. An appliance as in claim 15, wherein the shells have a plurality of windows which are sized to allow interdigitation of upper and lower teeth.

18. A removable elastic appliance comprising:

a shell which is shaped to be placed over and conform to teeth such that the exterior of the shell mimics the shape of teeth, wherein at least a portion of the shell is opacified.

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19. A removable appliance as in claim 18, wherein the at least a portion of the shell is opacified by paint with a tooth-colored material.

20. A removable appliance as in claim 19, wherein a single tooth of the appliance is opacified to conceal the absence of a tooth therebeneath.

21. A removable appliance as in claim 19, wherein at least the front six teeth are opacified.

22. A removable appliance as in claim 18, wherein the entire appliance is opacified.

23. A method for coloring a removable elastic appliance comprising a shell which is shaped to be placed over and conform to teeth of a user, said method comprising:

providing at least one appliance to a user; and

providing a plurality of coating materials having different colors to the user;

wherein the user can select one of the coating materials having a desired color and coat at least a portion of the appliance with that coating material.

24. A kit comprising:

a removable elastic appliance comprising a shell which is shaped to be placed over and conform to teeth such that the exterior of the shell mimics the shape of the teeth; and

a plurality of coating materials having different colors; and

means for applying a selected coating material to the removable appliance.

25. A kit as in claim 24, wherein the colors of the coating materials include two or more tooth colors whereby a color may be selected to match a patient's natural tooth color.

26. A kit as in claim 24, comprising a multiplicity of removable elastic appliances comprising shells having different geometries, selected to move a patient's teeth from a starting geometry to a finishing geometry.

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27. A method for supplying a precolored removable elastic tooth appliance to a patient, said method comprising:

determining a desired color;

selecting a material having the desired color; and

molding the appliance from the material.

28. A method as in claim 27, wherein determining the desired color comprises matching the patient's teeth to a color chart and selecting a color which most closely matches the teeth.

29. A method as in claim 27, wherein determining the desired color comprises selecting a color from the group of colors which do not match teeth.

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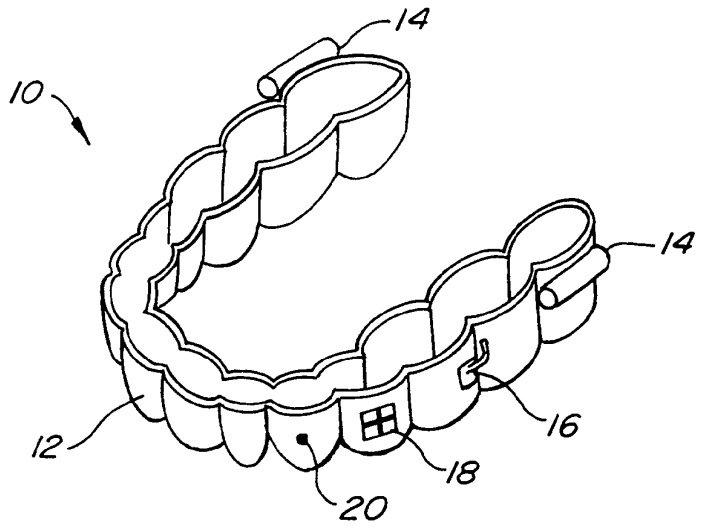


FIG. 1.

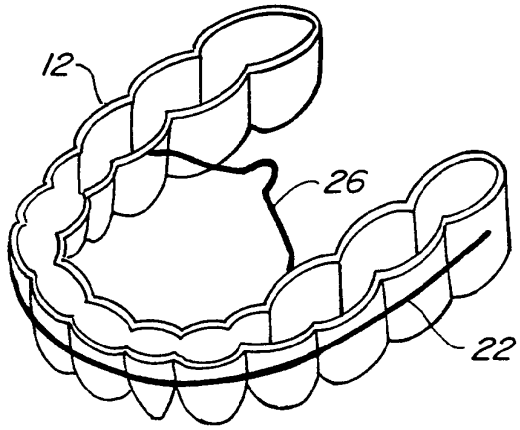


FIG. 2.

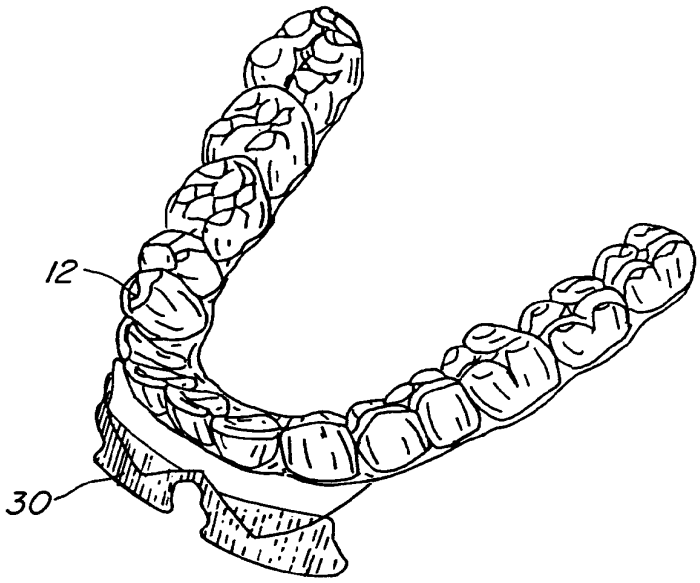


FIG. 3.

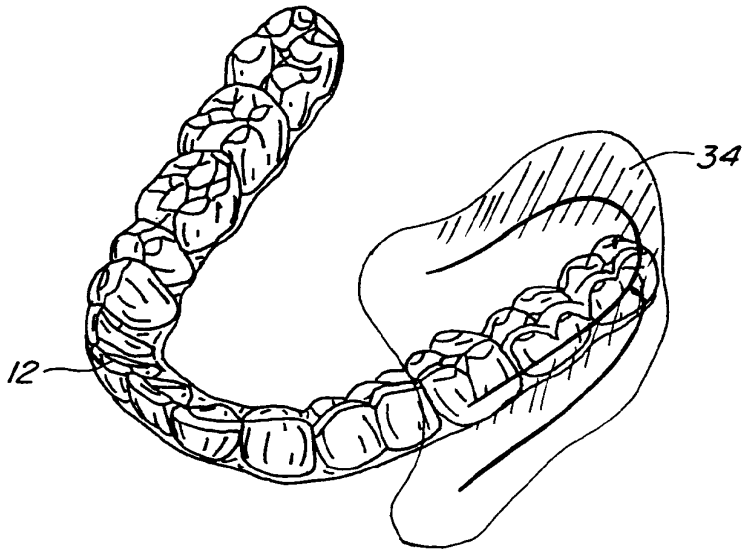


FIG. 4.

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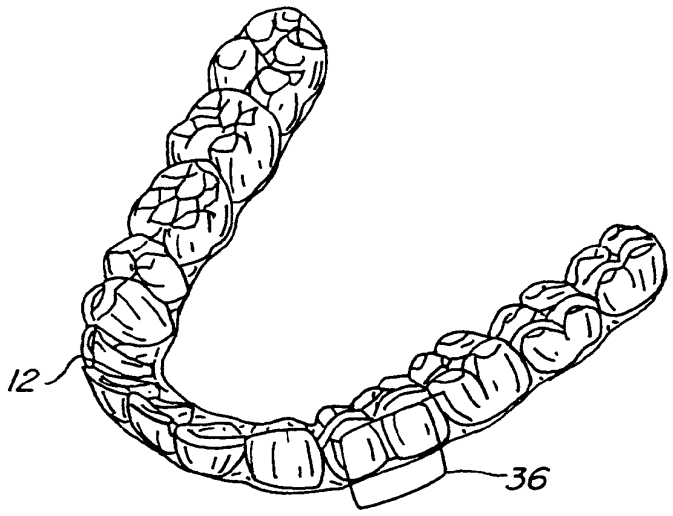


FIG. 5.

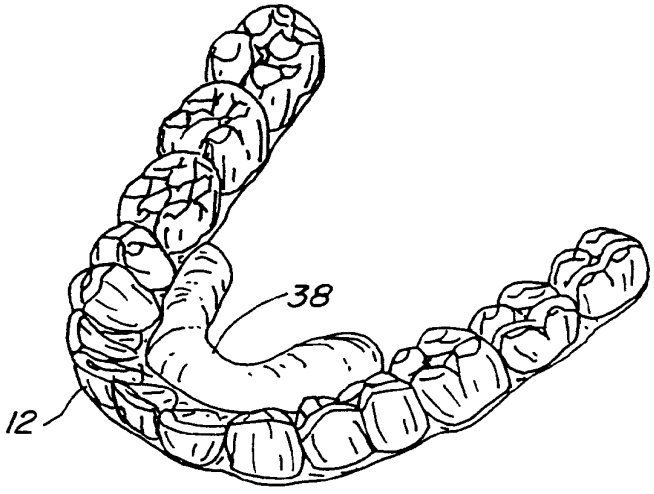


FIG. 6.

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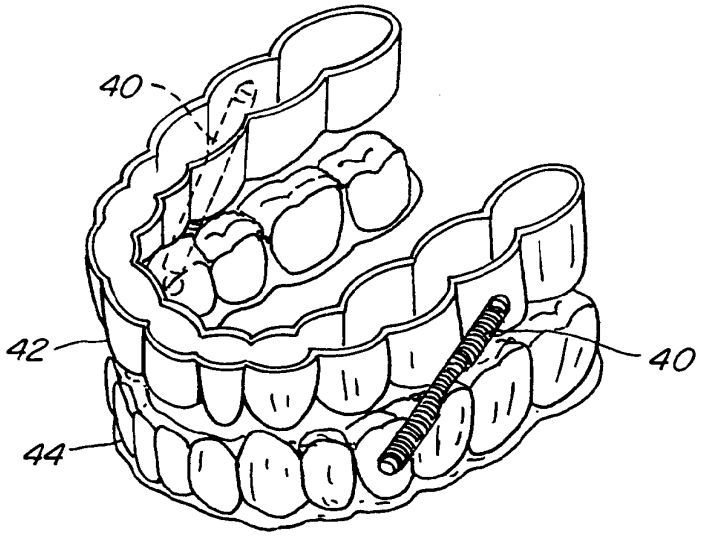


FIG. 7.

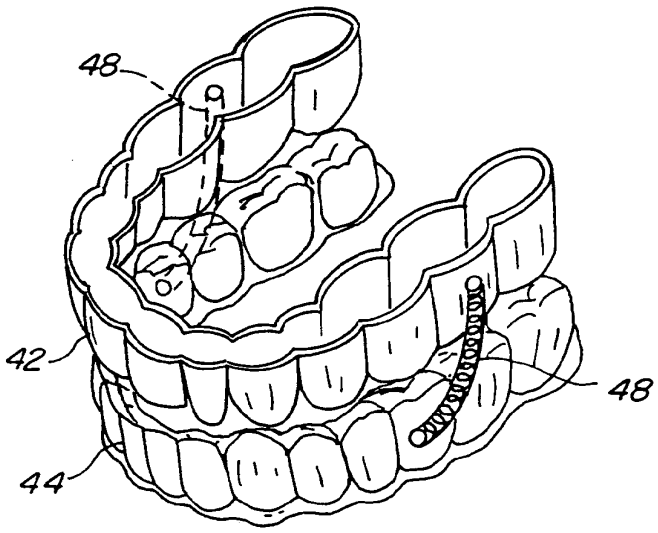


FIG. 8.

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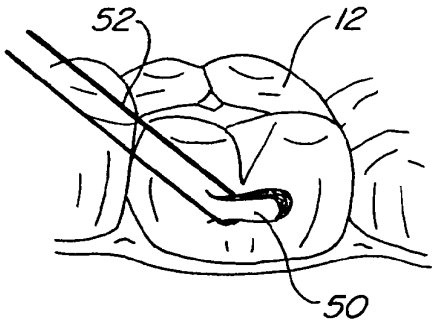


FIG. 9.

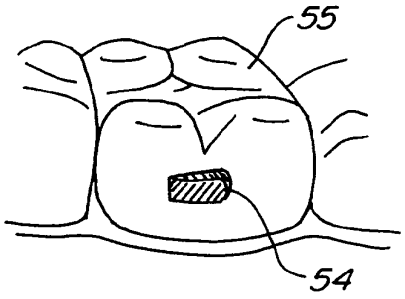


FIG. 10A.

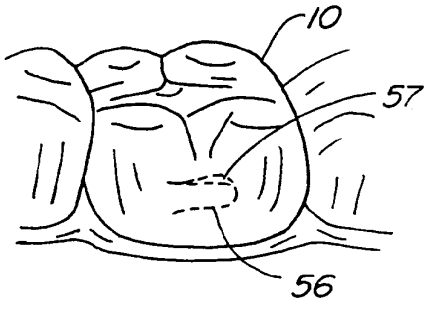


FIG. 10B.

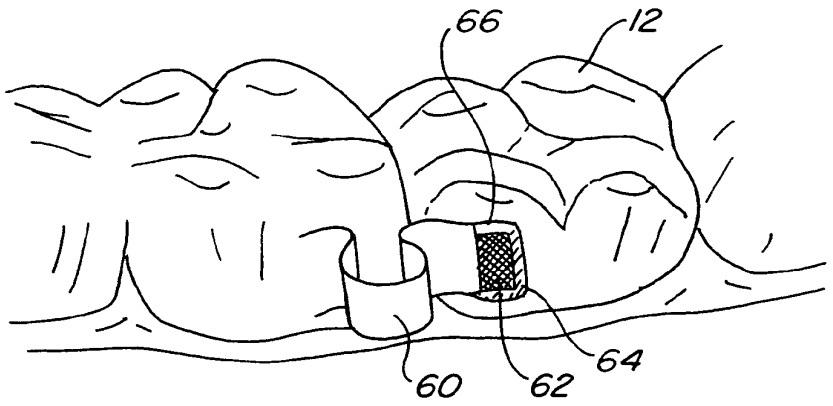


FIG. 11.

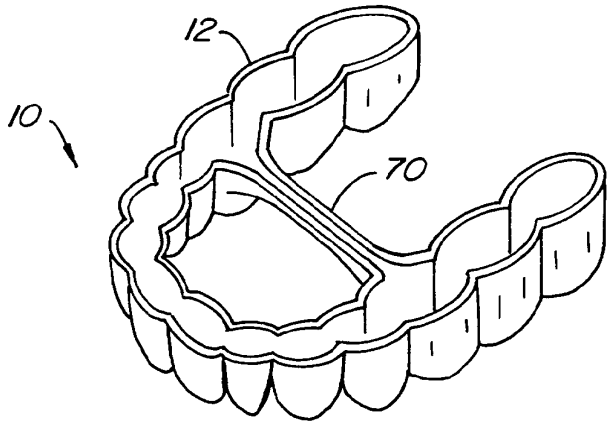


FIG. 12.

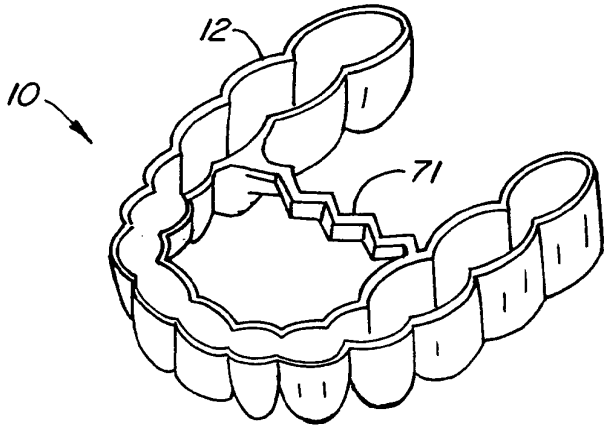


FIG. 13.

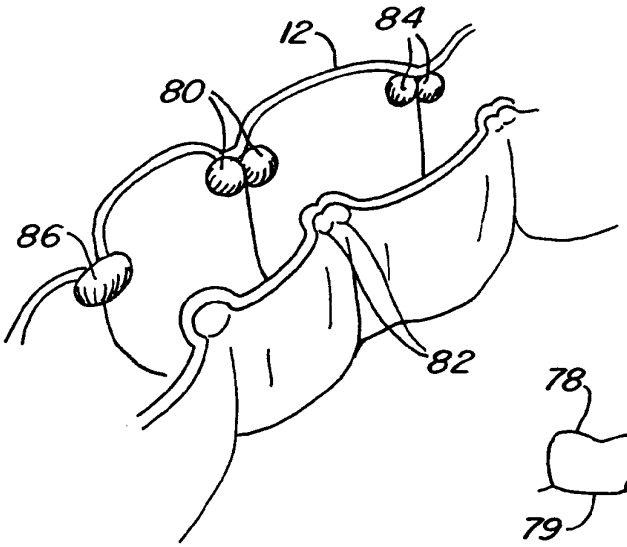


FIG. 14B.

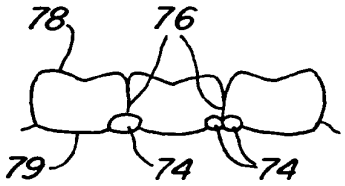


FIG. 14A.

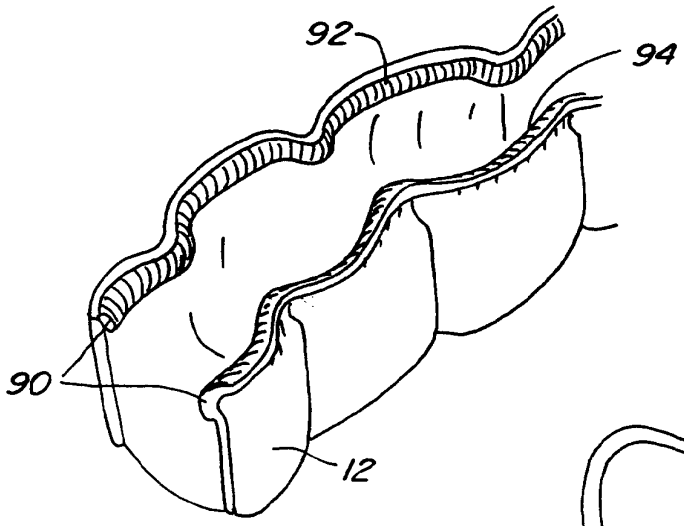


FIG. 15A.

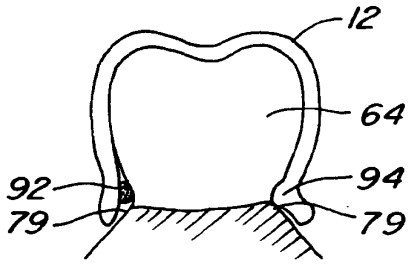


FIG. 15B.

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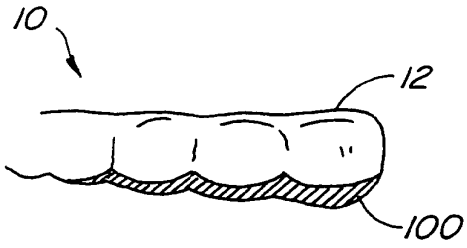


FIG. 16.

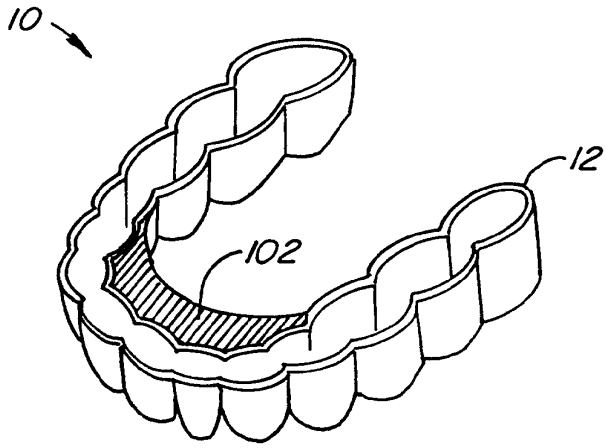


FIG. 17.

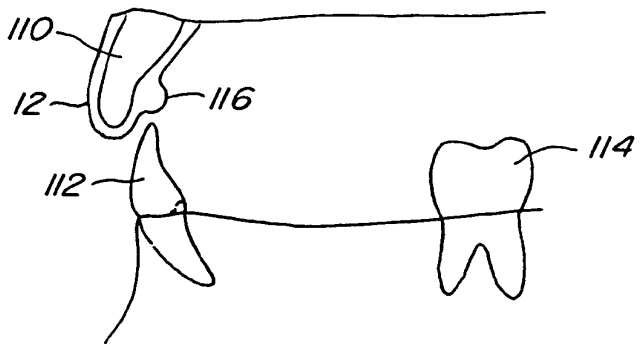


FIG. 18A.

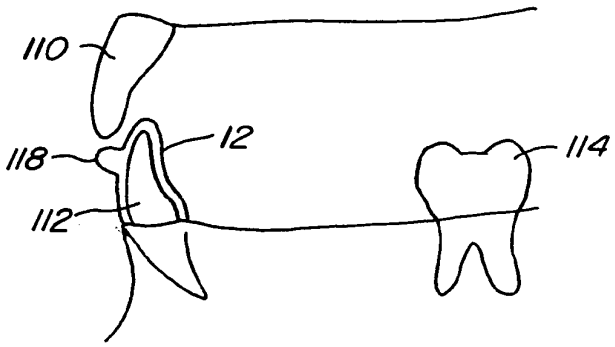


FIG. 18B.

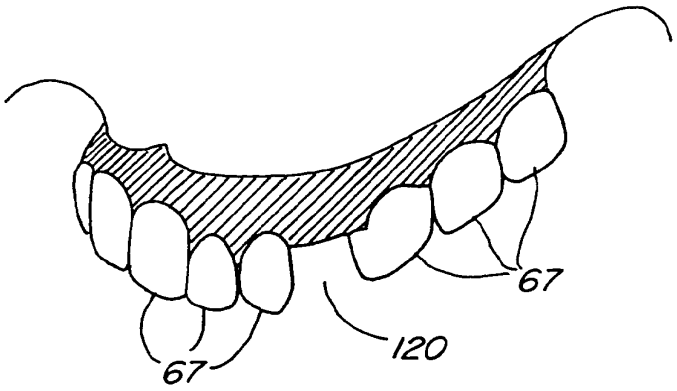


FIG. 19.

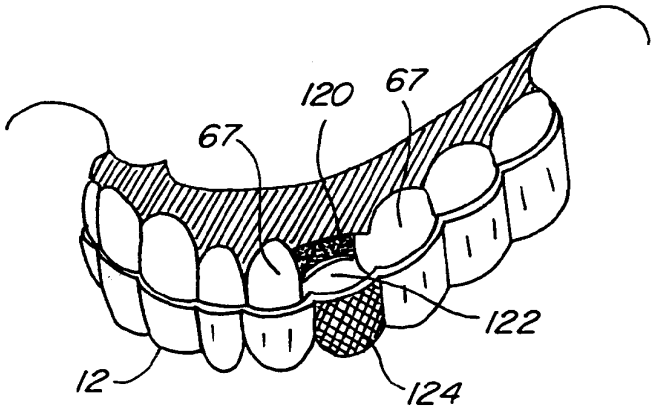


FIG. 20.

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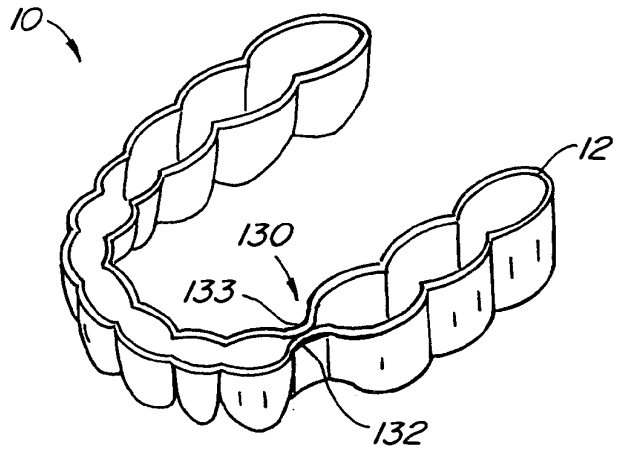


FIG. 21.

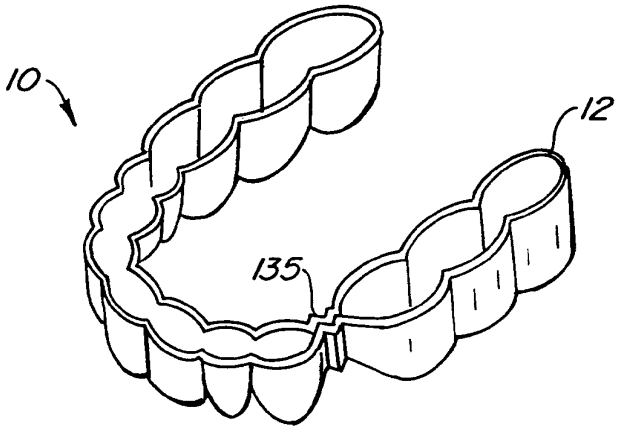


FIG. 22.

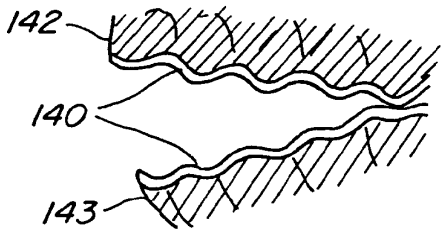


FIG. 23A.

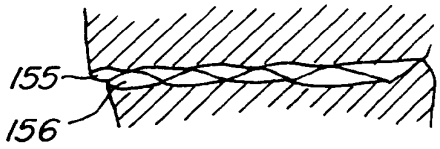


FIG. 23B.

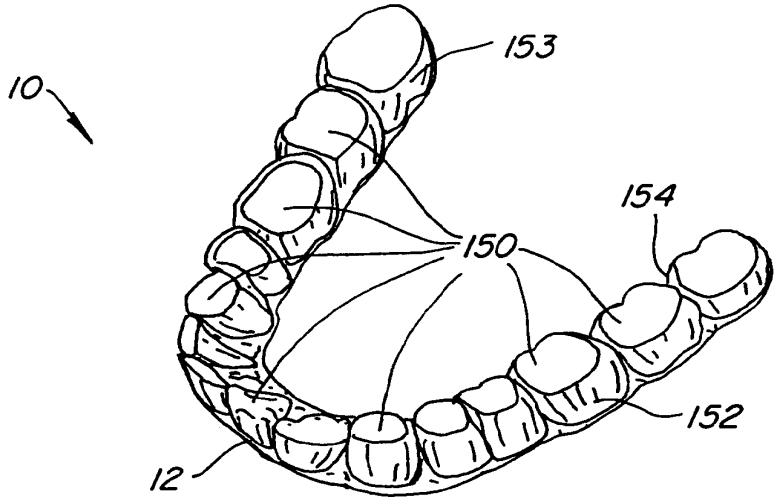


FIG. 23C.

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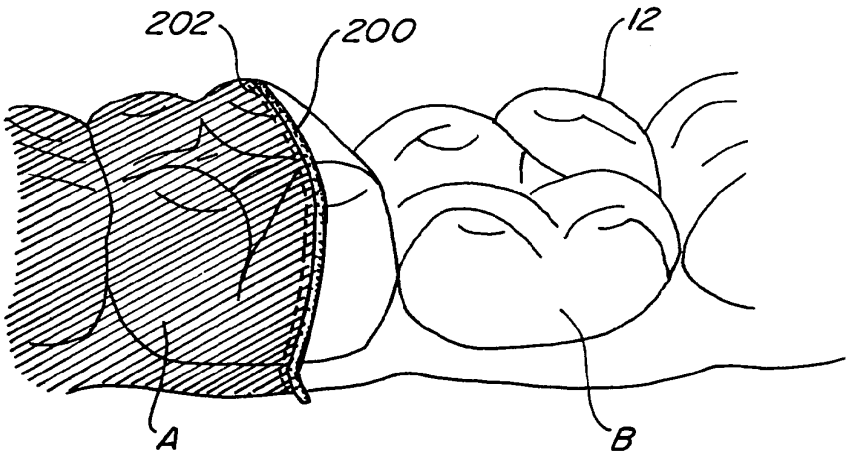


FIG. 24A.

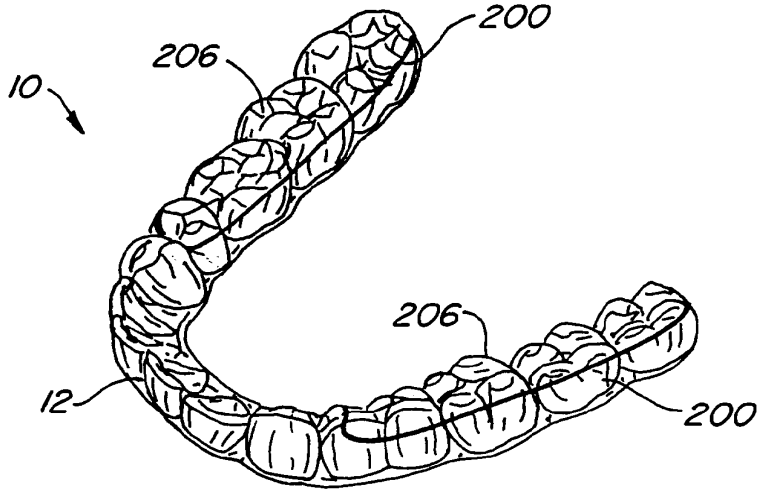


FIG. 24B.

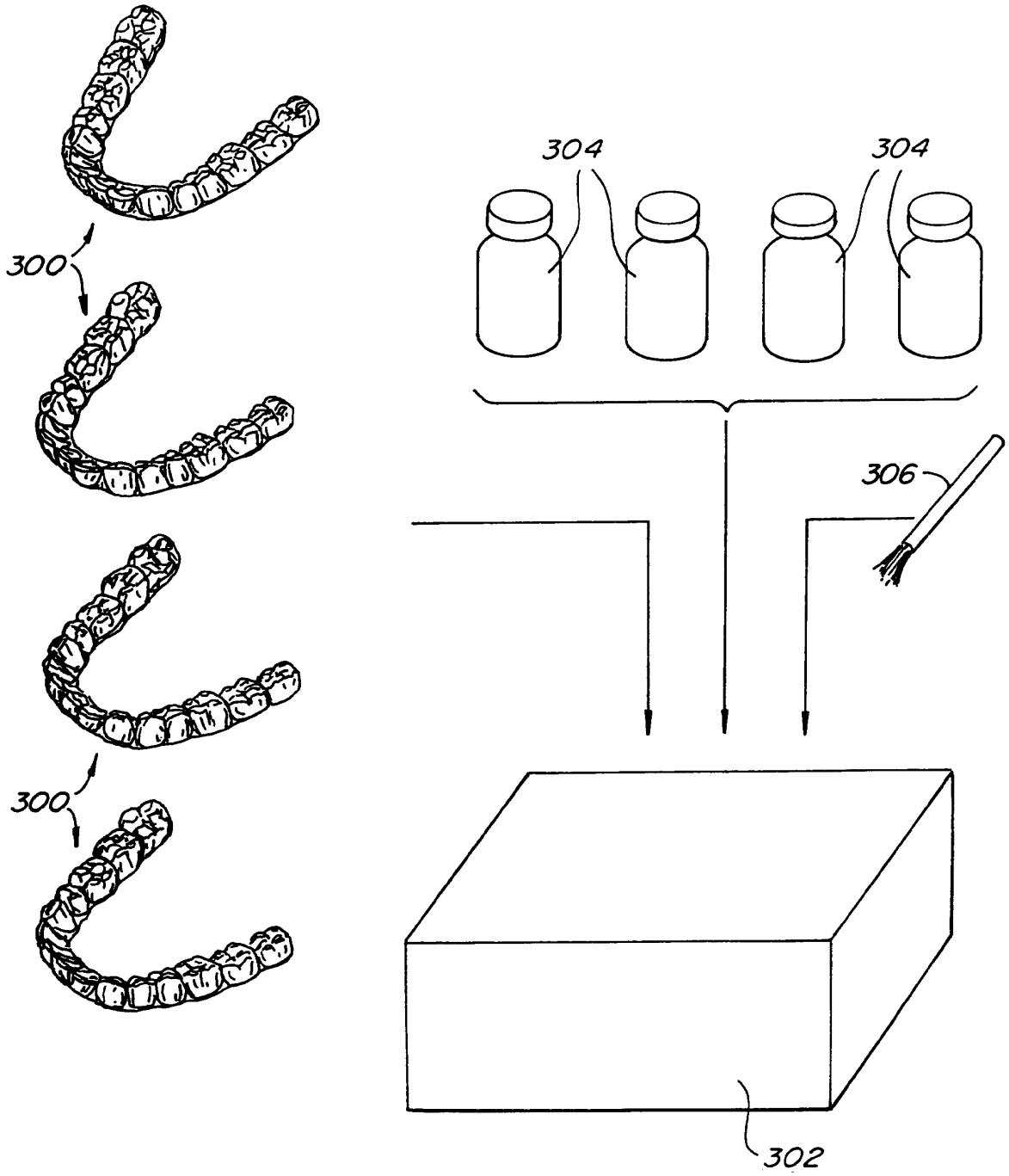


FIG. 25.

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(71) Applicant *(for all designated States except US)*: **ALIGN TECHNOLOGY, INC.** [US/US]; 851 Martin Avenue, Santa Clara, CA 95050 (US).

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(74) Agents: **HESLIN, James, M.**; Townsend and Townsend and Crew LLP, Two Embarcadero Center, Eight Floor, San Francisco, CA 94111 et al. (US).

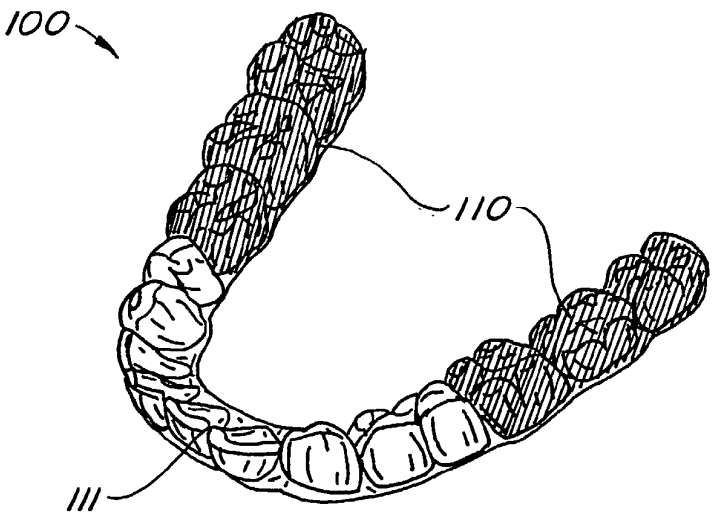
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Published:
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[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR VARYING ELASTIC MODULUS APPLIANCES



(57) Abstract: Improved devices, systems and methods for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of polymeric shell appliances (100) configured to receive the teeth (115) and incrementally reposition individual teeth in a series of successive steps. The individual appliances may be formed from layers (110, 111) having different stiffnesses (elastic moduluses), and the stiffnesses of successive appliances may be different, or both.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEMS AND METHODS FOR VARYING ELASTIC MODULUS APPLIANCES

BACKGROUND OF THE INVENTION

This invention relates in general to a method of repositioning teeth for use in orthodontic treatment. Particularly, this invention relates to the use of orthodontic appliances for producing tooth movements. More particularly, this invention relates to the use of a plurality of elastic repositioning appliances for producing such tooth movements.

Orthodontic treatments involve repositioning misaligned teeth and improving bite configurations for improved cosmetic appearance and dental function. Repositioning teeth is accomplished by applying controlled forces to the teeth over an extended period of time. This is conventionally accomplished by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, bands, archwires, ligatures, and O-rings. After they are bonded to the teeth, periodic meetings with the orthodontist are required to adjust the braces. This involves installing different archwires having different force-inducing properties or by replacing or tightening existing ligatures. Between meetings, the patient may be required to wear supplementary appliances, such as elastic bands or headgear, to supply additional or extraoral forces.

Although conventional braces are effective, they are often a tedious and time consuming process requiring many visits to the orthodontists office. Moreover, from a patient's perspective, they are unsightly and uncomfortable. Consequently, alternative orthodontic treatments have developed. A particularly promising approach relies on the use of elastic positioning appliances for realigning teeth. Such appliances comprise a thin shell of elastic material that generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the elastic positioner over the teeth applies controlled forces in specific locations to gradually move the teeth into the new configuration. Repetition of this process with successive appliances comprising new configurations eventually move the teeth through a series of intermediate configurations to a final desired configuration. A full description of an exemplary elastic polymeric positioning appliance is described in U.S. Patent No. 5,975,893, and in published PCT

application WO 98/58596 which designates the United States and which is assigned to the assignee of the present invention. Both documents are incorporated by reference for all purposes.

In addition to their ease of use, polymeric positioning appliances are generally transparent, providing an improved cosmetic appearance, and impart substantial force on the teeth, due to stiffness of the appliance. The stiffness of an elastic positioning appliance is a result of the modulus of the thermoformable polymer materials from which it is made. The higher the modulus of the materials, the higher the stiffness of the appliance. When a patient positions such an appliance over a prescribed group of teeth, one or more of the teeth will provide a base or anchor region for holding the positioning appliance in place while the stiffness of the polymeric material will impart a resilient repositioning force against one or a portion of the remaining teeth. However, the stiffer the appliance, the more difficult it is to slip the misaligned appliance over the teeth and fully engage the appropriate surfaces; the appliance often has the tendency to disengage or "pop off". Likewise, once it is firmly seated, it is more difficult to remove. Further, a stiff appliance is less forgiving in cases of lowered patient compliance. If a patient were to remove the appliance for an unprescribed period of treatment time, the patient's teeth may move slightly out of the planned tooth arrangement. When attempting to reapply the appliance, it may be too rigid to accommodate these slight differences and a new appliance may need to be created. Similarly, the tooth positions defined by the cavities in each successive appliance must not differ beyond a limiting dimension from those defined by the prior appliance or, again, it may be too rigid to accommodate the differences. Consequently, only small increments in tooth repositioning may be made with each appliance.

Thus, it would be desirable to provide tooth positioners, systems, and methods which apply adequate force to selected teeth yet overcome the inherent limitations of stiffness in the polymeric material. Likewise, it would be desirable to reduce the number of positioners required for a treatment plan by increasing the size of the repositioning increments throughout the plan. Further, it would be desirable to reduce the cost of lowered patient compliance by reducing the need for new appliances to be created for patient treatment resumption. At least some of these objectives will be met by the designs and methods of the present invention described hereinafter.

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SUMMARY OF THE INVENTION

The present invention provides improved devices, systems and methods for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of polymeric appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of successive steps. This is accomplished by applying force to specific surfaces of the teeth to cause directed movement. In order to apply such force, one or more of the teeth will provide a base or anchor region for holding the positioning appliance in place while the stiffness of the polymeric material will impart a resilient repositioning force against one or more of the remaining teeth. However, such stiffness creates limitations in ease of use, patient compliance, and overall cost in material, manufacturing labor and treatment time.

To overcome these limitations, the present invention utilizes polymeric or other material appliances with portions differing in rigidity, hardness, or stiffness. Portions of the appliance designed to apply specific forces may have different elastic moduluses (stiffnesses) and/or hardnesses than other portions. Alternatively, elastic moduluses and/or hardnesses may vary from one appliance to the next in a successive series to accomplish various treatment goals. Thus, the systems and methods of the present invention provide the design, production and use of such multiple stiffness positioning appliances in orthodontic treatment. Similarly, the devices of the present invention provide variable stiffness appliances which may be used independently for purposes other than repositioning, such as for retaining teeth in a desired position. Thus, reference hereinafter to repositioning appliances with portions having differing or varying stiffnesses or hardnesses is not intended to limit the scope of the present invention and is understood to include appliances of the described design for other purposes.

In a first aspect of the present invention, an elastic repositioning appliance may be comprised of portions with differing elastic moduluses. Elastic modulus may be used to express or describe the stiffness of a material or a material's resistance to elastic deformation. Therefore, elastic modulus may be used hereinafter to refer to stiffness. The different portions of the appliances will also usually vary in hardness. More usually, stiffer portions will be harder while the less stiff portions will be softer. Hardness is usually measured as a "durometer" reading on either the A or the D scale. In most instances, the present invention will be more concerned with the elastic modulus of the material since that will effect the force applied to the teeth for either moving the teeth or

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for gripping or anchoring the teeth. In other instances, however, the hardness of the material may be more important, e.g., to avoid trauma to soft tissue regions engaged by the appliance. The remaining description and claims generally refer to materials having greater and lesser stiffnesses. It will be appreciated that such terminology will also comprise materials having greater and lesser hardnesses.

The elastic modulus of a material is the ratio of the increment of unit stress to an increment of unit deformation within the elastic limit. When a material is deformed within the elastic limit, the bonds between adjacent atoms are stretched but not broken. The magnitude of the elastic modulus is indicative of the atomic and molecular bonding forces. When the stress is relieved, the material returns to its original shape and the deformation is nonpermanent. Different materials may have different elastic moduluses based on their molecular structures. Some materials, such as certain polymers, may be specially produced to have different elastic moduluses while retaining similar chemical compositions (and thus assuring compatibility of the different modulus materials in a single structure). Likewise, the elastic modulus of a polymer or other material may be enhanced or otherwise modified. This may be achieved by adding a powder, such as $CaCO_3$, talc, TiO_2, glass, diamond or a polymer powder, to name a few. In addition, this may be achieved by embedding structural reinforcements, such as metal pieces, strips, wires, mesh, lattices, networks, polymeric filaments, or the like. In addition, the elastic modulus may be altered by post-production methods, such as layering, coating, interpenetrating, treating with various chemical agents, and altering the temperature, to name a few. In the resulting appliance, the elastic moduluses of the varying portions will usually range from 0.5 to 5 GigaPascal (GPa), although in some instances portions of the appliance may fall outside of this range. The elastic modulus of one portion may differ from another portion by 25% to 600%, or more.

The differing elastic moduluses of different portions of the dental appliance shells of the present invention will exist while the device is present over teeth in a normal oral environment. Thus, different portions of the appliance shell will impart different forces to the immediately underlying teeth, where the level of the force depends both on the device geometry or tooth positions (relative to the underlying tooth or teeth, which may vary over time) and on the elastic modulus of that portion of the device (which will remain constant over time in the normal oral environment). The present invention should be distinguished from that described in copending application no. 09/250,962, where the stiffness of a dental appliance shell may change over time by

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expose to a non-oral environment, such as elevated temperature or changed osmolality. Of course, the dental appliance shells of the present invention which have different portions with differing stiffness may also incorporate regions (including the entire appliance) where a change in stiffness may be induced according to the teachings of application no. 09/250,962, the full disclosure of which is incorporated herein by reference.

In a first embodiment, portions of the shell of an elastic repositioning appliance may be composed of material(s) which differ in elastic moduluses and/or hardnesses along a mesial-distal axis. A mesial-distal axis may be defined as an axis following the gingival line or dental arch. Thus, the elastic repositioning appliance may be comprised of portions with a lower elastic modulus covering the molars, for example, and portions with a higher elastic modulus covering the remainder of the teeth. In this example, the portions may be relatively large so that a portion may receive one or more teeth, such as contiguous molars. This may be utilized when one or more teeth are to provide an anchor or base region for imparting repositioning force against another tooth or teeth. The portion of the appliance covering the anchor teeth may be of a relatively flexible nature with a lower elastic modulus than the portion covering the teeth to be repositioned. This is because the portions covering the anchor teeth may not need to apply repositioning forces to the teeth they cover; they may merely be designed to hold the appliance in place. Consequently, a high level of rigidity or stiffness may not be required. However, it may be appreciated that portions covering anchor teeth may in fact require a higher stiffness material than other portions, including portions which are designed to apply repositioning forces. Thus, any variation of stiffness or elastic modulus along a mesial-distal axis is included in this embodiment.

The introduction of such portions or regions with more flexibility provides utility in ease of use for the patient. The patient may find ease in positioning the appliance with the more flexible portions first which may guide the appliance in placement of the more rigid, slightly misfit portions designed for repositioning. This sequence may be reversed in removal of the appliance. Likewise, such flexibility may also allow for any slight differences in mold versus appliance versus dentition geometry which may otherwise make placement and removal of the appliance more difficult. In some cases, a generally misfit appliance may "pop off" or have a tendency to disengage even when properly positioned over the teeth. Increased flexibility may reduce these tendencies.

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In further embodiments, portions of the elastic repositioning appliance may vary in elastic moduluses along different and/or additional axes. For example, moduluses may vary along a facial-lingual axis. Facial may be defined as next to or toward the lips or cheek, including terms labial and buccal. Lingual may be defined as next to or toward the tongue. Thus, a facial-lingual axis may be described as an axis following a radial or similar line from the tongue toward the lips or cheek and vice versa. Likewise, moduluses may vary along a gingival-crown axis. This may be described as a substantially vertical axis following a line from the top of the crown at the edge of the occlusal surface of a tooth toward the gingival line or root and vice versa. In a preferred embodiment, an appliance may have a portion with a lower elastic modulus covering the occlusal surfaces of the teeth and a portion with a higher elastic modulus covering the remaining surfaces of the teeth. Thus, the moduluses may vary along a facial-lingual axis and/or a gingival-crown axis, depending on the boundaries of the delineated portions. Such a design may incorporate added flexibility to the appliance while maintaining adequate repositioning forces in the most efficient areas.

In addition to varying in stiffness along the axes described above, the appliances of the present invention may vary in stiffness or hardness over the "thickness" of the appliance. Usually, such variations and stiffness over the thickness will be accomplished by layering the device, i.e., with layers of differing stiffnesses or hardnesses being placed successively over the mold used to form the appliances, as described in more detail below. Thus, the appliances may comprise shells having first and second portions, as generally described above, where each of those portions comprise layers in a laminar structure. Usually, at least one of the first and second portions will comprise a continuous layer along the mesial-distal axis. The second and optionally additional layers may also be continuous along the mesial-distal axis, but will often be discontinuous, i.e., broken into two or more segments. Such layered devices can provide a variety of benefits. For example, layers formed from stiffer or harder materials can be used to more firmly engage teeth, while the less stiff or softer layers can be used to provide compliance and greater elasticity. In a particular preferred embodiment, the appliance comprises a discontinuous inner layer and a continuous outer layer. At least a portion of the inner layer is configured to engage individual teeth or groups of teeth and will be stiffer or harder than the outer layer. The outer layer, which is less stiff and therefore more compliant, provides the elasticity to move the teeth relative to one another,

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while the harder inner layer firmly engages the teeth to provide a better grip or anchor upon the teeth.

It may be appreciated that the elastic modulus of the appliance shells may vary over any number of delineated portions. Such portions may be of any size, shape, thickness, or dimension. Thus, such portions may receive entire teeth or they may be of the size to cover only a portion of a tooth or dental surface. When portions are relatively large, an appliance may be divided into, for example, two to five portions. Portions adjacent to one another differ in elastic moduluses, however not all portions of an appliance may differ from each other, such as in the case of an appliance with portions alternating between two moduluses. When portions are relatively small, an appliance may contain an unlimited number of portions, varying along any axis or combination of axes.

In a second aspect of the present invention, such appliances comprised of portions having differing stiffness may be used independently or in a series with similar or differing devices. When used independently, the appliance may be worn to achieve a specific goal with a single device. For example, the appliance may be used as a "retainer" to hold the teeth in a desired position. Or, the appliance may be used for a specific one-time repositioning movement, such as "finishing" or correcting a slight misalignment. When used in a series, the appliances may comprise a system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. In this case, a plurality of incremental elastic position adjustment appliances comprising polymeric or other material shells are successively worn by a patient to move teeth from one arrangement to a successive arrangement. Individual appliances may be configured so that their tooth-receiving cavity has a shape or geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. Thus, successive individual appliances may have a shape or geometry differing from that of the immediately prior appliance. According to the present invention, some or all of the individual appliances may also be comprised of a material stiffness differing from the stiffness of the immediately prior appliance. In addition, each individual appliance be comprised of portions with varying stiffnesses. In some cases, of course, individual appliances in the system may not vary in stiffness from prior or successive appliances, but only in geometry. In other cases, individual appliances may vary only in stiffness (and not in geometry) when compared to immediately prior or subsequent appliances. Thus, systems according to the present

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invention may be comprised of appliances having stiffness varying within the appliance and/or from one appliance to the next in the series.

In a specific embodiment, a system of elastic repositioning appliances may comprise individual appliances having uniform elastic moduluses over their entire tooth contact area where the moduluses will differ among successive appliances used in a course of treatment. The elastic modulus of a given appliance may be chosen to be most suitable for a specific type of tooth movement, such as translating, tipping, root uprighting, rotation, extrusion, intrusion or a combination of these. For example, translation may require 70-120 gm of force, whereas rotation may only require 35-60 gm of force. Therefore, an elastic positioning appliance designed for translating teeth may need to have a higher elastic modulus than one designed for purely rotating teeth. This is again due to the fact that stiffness of the appliance is a critical factor in imparting repositioning force. Consequently, a series of appliances may be produced for a treatment plan in which successive appliances designed for a specific tooth movement may all have substantially similar elastic moduluses. At the point in the treatment plan in which a different type of tooth movement is desired, further appliances designed for the new tooth movement may have substantially similar elastic moduluses to each other but different from the previous appliances. Such a sequence may be repeated at any time or may continue with new moduluses and tooth movements.

In an additional specific embodiment, one or more appliances may be produced with a suitably flexible elastic modulus to receive and resiliently reposition teeth from an unprescribed arrangement to a prescribed arrangement. This might be necessary in cases of lowered patient compliance. If a patient were to remove an appliance for an unintended and/or extended period of a prescribed treatment time, the patient's teeth may move slightly out of the planned tooth progression. When attempting to reapply the appliance, an appliance which is too rigid may not be able to accommodate these slight differences. Thus, a more flexible appliance (but having an identical geometry) may be produced for this purpose and may be incorporated into the treatment plan at any given point in the series of successive appliances. The ability to return to the same geometry is an advantage because it minimizes the need to replan the treatment protocol.

In a third aspect of the present invention, systems for repositioning teeth from an initial tooth arrangement to a successive tooth arrangement comprise a plurality of incremental elastic position adjustment appliances in which at least one appliance has

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the same shape yet different elastic modulus as an immediately prior appliance. In a specific embodiment, a series of incremental appliances may be produced with differing elastic moduluses to reposition teeth from an initial tooth arrangement to the next successive tooth arrangement in a progression of arrangements to the final arrangement. Each of the appliances in the series from the first to the next successive tooth arrangement may have the same shape or geometry since the tooth movement represents one step in tooth movement. However, the variance in elastic moduluses may allow for a larger step or increment in tooth movement than may be obtainable with consistent, rigid appliances. For example, an appliance may be produced with a tooth arrangement which is substantially misaligned from the initial arrangement. High modulus appliances may not be flexible enough to allow the appliance to fit over the teeth in the initial arrangement. However, a series of appliances of the same shape may be produced with increasing elastic moduluses from relatively low to adequately high. The patient may begin with the lowest elastic modulus appliance which may be the most flexible to fit over the teeth. As the teeth are repositioned, the patient may successively utilize each appliance in increasing modulus until the teeth have conformed to the successive tooth arrangement. At that time, the patient may begin a new series of appliances with varying moduluses and a shape to reposition the teeth to the arrangement of the next step in the repositioning progression. The ability to reduce the number of different appliance geometries required for a single course of treatment can provide a significant reduction in planning effort and manufacturing costs.

In a fourth aspect of the present invention, the elastic modulus of an appliance or portions of an appliance may be modified in a number of different ways. To begin with, the elastic modulus may be determined by the choice of materials. For example, metals will generally have a higher elastic modulus than polymers due to atomic structure. For example, the modulus values for metals may range between 48 and 414 GPa , whereas the modulus for polymers may range from 0.5 to 35 GPa. Thus, it will be possible to form appliances having moduluses which differ greatly by forming different portions from metal(s) and polymer(s), or by forming successive appliances from metals and polymers. Usually, however, the appliances will comprise or consist of a polymeric shell formed from a single polymer, multiple polymers, copolymers, and the like, typically by thermoforming and/or lamination. Stiffness of a polymer may be varied within a range (typically 0.5 GPa to 5 GPa) by changing the molecular structure of the polymer chains. Polymer chains with hindered side-chains are unable to pack as closely

as those with smaller side-chains. Thus, such a polymer may have more intermolecular motion and therefore a lower bulk elastic modulus. Stiffness can also be changed by controlling the degree of cross-linking as well as the cross-linking entity within a polymer or copolymer. Further, alternatively, differing elastic moduluses may be created within the same polymer shell by layering or laminating the same or different polymers. Two layers of a polymer material bonded together to form an integral appliance, i.e., an appliance having a monolithic shell structure where the layers are resistant to delamination, may have a higher elastic modulus than a single layer of such material. Thirdly, different elastic moduluses may be created with a single layer of one type of polymer material by production methods, such as coating, treating with various chemical agents, and altering the temperature, to name a few.

Further, different elastic moduluses may be produced by forming selectively reinforced and/or composite-type materials. For example, a polymer material may be reinforced with structures such as strips, wires, pieces, mesh, lattices, networks, and the like. These structures may be comprised of any suitable material, particularly metals and alloys but also including polymer filaments, wires, braids, and the like. Likewise, composite materials may be comprised of interpenetrating polymeric networks. An interpenetrating polymeric network is comprised of a base material and an additional material that interpenetrates the base material to alter its mechanical properties. For example, the base material (A) may be a solid polycarbonate. The added material (B) may be a liquid polymer, monomer or crosslinking agent which is allowed to interpenetrate and activate to form a composite network. The composite (A+B) may have a stiffness which is greater than the sum of its parts, (A) and (B). Further, another material (C) may also be allowed to interpenetrate and activate to form a new composite network. The composite (A + B + C) may also have a stiffness which is greater than the sum of its parts, (A), (B) and (C). With this method, any number of composites may be formed providing a wide range of mechanical properties, specifically stiffnesses. In addition, a number of these production methods may provide materials with gradual changes in elastic moduluses. For example, purposely irregular coating of a polymer material may provide higher stiffness in areas with thicker coating and lower stiffness in areas with thinner coating. This may be applied to a number of production methods.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective illustration of an embodiment of an appliance of the present invention and descriptive axes.

Fig. 2 illustrates an embodiment of an appliance with relatively large portions varying in elastic modulus along a mesial-distal axis.

Fig. 3 illustrates an embodiment of an appliance with smaller portions varying in elastic modulus in a non-symmetric pattern along a mesial-distal axis.

Fig. 4 illustrates an embodiment of an appliance varying in elastic modulus along a mesial-distal axis in which portions covering proximal or interproximal spaces are of differing modulus.

Fig. 5 illustrates a variety of appliance portions varying in elastic modulus along a mesial-distal axis.

Fig. 6 is a perspective illustration of an embodiment of an appliance varying in elastic modulus along a facial-lingual axis.

Fig. 7 illustrates a variety of appliance portions varying in elastic modulus along a facial-lingual axis.

Fig. 8 is a perspective illustration of an embodiment of an appliance varying in elastic modulus along a gingival-crown axis.

Fig. 9 illustrates a variety of appliance portions varying in elastic modulus along a gingival-crown axis.

Fig. 10 illustrates a variety of appliance portions varying in elastic modulus along one or more described axes.

Fig. 11 depicts a series of appliances differing in elastic modulus at specific intervals throughout a treatment plan.

Fig. 12 illustrates the use of an "off track" appliance in a prescribed treatment plan.

Fig. 13 illustrates the use of a series of appliances with gradually increasing elastic moduluses and similar or identical geometry in a series of intervals throughout a treatment plan.

Fig. 14 illustrates a method of fabricating a multi-modulus appliance.

Fig. 15 illustrates a method of layering to fabricate a multi-modulus appliance.

Fig. 16 illustrates an additional method of layering to fabricate a multi-modulus appliance.

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Fig. 17 illustrates an exemplary layered appliance according to the present invention with portions broken away.

Fig. 18 is a cross-sectional view taken along line 18-18 of Fig. 17.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides improved devices, systems and methods for incrementally repositioning teeth using a plurality of discrete polymeric appliances of variable flexibility, where each appliance successively repositions one or more of the patient's teeth by relatively small amounts. Flexibility may be defined by elastic modulus of the polymeric material and may vary within a given appliance or may vary throughout a series of appliances according to a prescribed orthodontic treatment plan.

Referring to Fig. 1, portions of an elastic repositioning appliance 100 may vary in elastic modulus along a mesial-distal axis 101, facial-lingual axis 102, gingival-crown axis 103, or any axis in-between these representative axes. As previously described, a mesial-distal axis may be described as an axis following the gingival line or dental arch, a facial-lingual axis may be described as an axis following a radial or similar line from the tongue area toward the lip or cheek area, and a gingival-crown axis may be described as an axis following a substantially vertical line from the crown of a tooth toward the gingival line or root. Such axes are defined for descriptive purposes and are not intended to limit the scope of the present invention.

As shown in Fig. 2, portions of an elastic repositioning appliance 100 may vary in elastic modulus mesial-distally. For illustrative purposes, portions with a lower elastic modulus 110 are shaded to easily distinguish differences in elastic modulus throughout a device. In this example, the appliance 100 may be described as having three portions. Two portions cover contiguous sets of molars and are comprised of an elastomeric material of a lower elastic modulus 110 and are thus shaded. The portion in-between these portions is of a higher elastic modulus 111 and is thus not shaded. All portions in this embodiment are relatively large so that the portions may receive one or more teeth, such as molars, premolars, incisors, and the like. Likewise, nonadjacent portions may have the same elastic modulus, such as the two lower elastic modulus 110 portions, or they may be different from each other while maintaining a difference from the higher elastic modulus 111 portion. In other words, an appliance 100 with three distinct portions may be comprised of two or three elastic moduluses.

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As illustrated in Fig. 3, such portions may not be symmetrical and they may not cover more than one tooth. Portions with a lower elastic modulus 110 may alternate in an uneven fashion along a mesial-distal axis as shown. In addition, adjacent portions may be of a size to cover only a portion of a tooth or dental surface. Referring to Fig. 4, portions of lower elastic modulus 110 may be present covering the facial or lingual surfaces of the teeth, while portions of higher elastic modulus 111 may be present covering the proximal or interproximal spaces. This may be advantageous to provide repositioning forces, such as translation forces, at the most efficient locations for this type of movement. At the same time, flexibility is provided in portions that may be less involved in the application of force, allowing more freedom and comfort for the patient.

Referring to Fig. 5, the elastic modulus of an appliance 100 may vary over any number of delineated portions and may be of any size, shape, thickness or dimension, to name a few. Such portions may be sized to receive an entire tooth 115 or they may be of the size to cover only a portion of a tooth. For example, a portion with a lower elastic modulus 110 may be sized to cover a proximal or interproximal space 116, including portions covering the gingival line. This may be desirable to provide comfort to the gums when wearing the appliance, and also to increase the contact of the appliance with the interproximal regions. In this case, softer, more flexible material may be able to form more closely to the interproximal regions, enabling a higher level of repositioning force to be applied.

Portions may also be sized and arranged to cover part of a facial surface 117, or two or more of such portions may cover part of a facial surface 118, allowing the elastic modulus to vary mesial-distally within a single tooth. Further, the portion may be sized to cover an isolated region of a facial surface 119. Such embodiments are a limited presentation of the possible sizes, configurations, and combinations of varying elastic modulus portions in an appliance 100 of the present invention. Such possibilities may be unlimited.

As shown in Fig. 6, portions of an elastic repositioning appliance 100 may vary in elastic modulus facial-lingually. In this embodiment, the appliance 100 is shown to have a portion with a lower elastic modulus 110 covering a portion of the occlusal surfaces of the teeth and a portion with a higher elastic modulus 111 covering the remaining surfaces of the teeth. Thus, the elastic modulus varies along a facial-lingual axis. Such a design may be beneficial to provide repositioning forces, such as translation forces, along the proximal and/or interproximal spaces which are the most efficient

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locations for this type of movement. At the same time, flexibility is provided in portions that may be less involved in the application of force, the occlusal surfaces. This may allow increased freedom and comfort for the patient while maintaining adequate repositioning forces.

Referring to Fig. 7, the elastic modulus of an appliance 100 may again vary over any number of delineated portions and may be of any size, shape, thickness or dimension, to name a few. A portion of lower elastic modulus 110 may be sized to cover only a portion of a tooth. For example, it may cover the center of the occlusal surface 125, alternating cusps or cusp tips 126, or isolated portions of any given cusp or cusp tip 127. Likewise, a portion of lower elastic modulus 110 may be of a larger size to cover, for example, the outside margin or buccal cusps of a tooth 128 or the inside margin or lingual cusps of a contiguous grouping of teeth 129. As before, such embodiments are a limited presentation of the possible sizes, configurations, and combinations of varying elastic modulus portions in an appliance 100 of the present invention. Such possibilities may be unlimited.

As shown in Fig. 8, portions of an elastic repositioning appliance 100 may vary in elastic modulus crown-gingivally. In this embodiment, the appliance 100 is shown to have a portion with a lower elastic modulus 110 covering the occlusal surfaces of the teeth and a portion with a higher elastic modulus 111 covering the remaining surfaces of the teeth. This is a modified representation of the embodiment depicted in Fig. 6 in which the portion of lower elastic modulus 110 partially covered a portion of the occlusal surfaces. In this embodiment, the occlusal surface is substantially covered with the lower elastic modulus 110 material, therefore it may be considered to be uniform, non-variable, along a facial-lingual axis. It may be more properly described as varying along a gingival-crown axis, as the lower elastic modulus 110 portion may extend over the cusps of the tooth crowns. Thus, the lower elastic modulus 110 material may be seen as being located at the tip of the crown region and vary to a higher elastic modulus 111 material toward the gingival line or margin. In addition, a higher elastic modulus 111 material along the gingival line or margin may improve retention of the device on the teeth. This may also reduce the need for attachment devices to aid in retention. A full description of exemplary attachment devices and methods for a dental appliance is described in co-pending application no. 09/454,278, incorporated by reference for all purposes and assigned to the assignee of the present inventor . However, such modulus

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differences are presented only for descriptive purposes and such portions may vary over one or many axes simultaneously or in isolated regions of an appliance 100.

It may be appreciated that the advantages offered by a lower elastic modulus along the occlusional surfaces, as depicted in Fig. 6 and Fig. 8, may be further increased by removing the material from the shell in these areas. Removal of material may form a window such that when the shell is positioned over the patient's teeth, portions of the teeth beneath the window may be exposed. In a preferred embodiment, a polymeric shell may have a plurality of windows over portions of the occlusal surfaces of the teeth. In this case, segments of the shell may still be present along the facial and lingual surfaces of the teeth and across the interdental regions or spaces between the teeth. Exposure of the occlusal surfaces in appropriate size and location may allow interdigitation of the upper and lower teeth. This may also be achieved with the presence of one or a few larger windows over portions of the occlusal surfaces of the teeth. In these cases, segments of the shell may not be present across the interdental regions or spaces between the teeth. In either case, interdigitation of at least portions of the upper and lower teeth may benefit tooth and jaw orientations, leading to improved treatment, appearance, comfort and consequently patient compliance. Thus, such windows may provide the benefits offered by a lower elastic modulus, such that the lowest stiffness may be provided by the absence of the material, while providing additional benefits described above. A full description is provided in co-pending application [Attorney Docket No. 018563-001510], assigned to the assignee of the present invention.

Referring to Fig. 9, the elastic modulus of an appliance 100 may again vary over any number of delineated portions and may be of any size, shape, thickness or dimension, to name a few. A portion of lower elastic modulus 110 may be sized to cover only a portion of a tooth along this axis. For example, it may cover the upper portion of the lingual surfaces near the cusps of the crown 135, or a midway "stripe" through the lingual surface of a tooth 136. Likewise, it may be sized so that more than one "stripe" may cover the surface of a tooth 137, as in the case of a portion at the gingival margin and a portion near the cusps of the crown. Similarly, a portion of lower modulus may be sized so that it covers a contiguous grouping of teeth, such as the buccal surfaces along the gingival margin 138. As before, such embodiments are a limited presentation of the possible sizes, configurations, and combinations of varying elastic modulus portions in an appliance 100 of the present invention. Such possibilities may be unlimited.

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As illustrated in Fig. 10, variance in elastic modulus in relation to size, shape, location, orientation, and axis, as described above, may be combined in a single appliance 100 to provide an unlimited variety of appliance 100 designs and constructions. In this example, portions of the appliance 100 vary mesial-distally, such as by comparing the lower elastic modulus 110 portion covering a group of incisors with the higher elastic modulus 111 portion covering the canine tooth. Portions may also vary facial-lingually, as depicted by the partial covering of the occlusal surfaces of the molars 150 or the isolated portion of a given cusp or cusp tip 127. Likewise, portions may vary crown-gingivally, such as the portions covering the buccal surfaces along the gingival margin 138. These portions also vary mesial-distally creating a compound variance, as portions adjacent to these areas are not identical, as in comparison of portions covering the buccal surfaces along the gingival margin 138 with the adjacent tooth 151 having partial covering of the occlusal surface of the molar 150. Portions may also vary along the three major axes simultaneously. This can be seen in the portion covering the center of an occlusal surface 125, which varies facial-lingually, the lingual face of a molar along the gingival margin 152; which varies crown-gingivally, and the adjacent uniformly covered molar 153, which varies mesial-distally in relation to the previous portions.

According to the present invention, systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement may be comprised of a plurality of incremental elastic position adjustment appliances with varying elastic moduluses. Thus, in addition to combined variances in a given appliance 100, as described above, a plurality of such appliances 100 with differing patterns of elastic modulus variance may be used in a system for repositioning teeth throughout a sequence of tooth arrangements. This may be illustrated by Figs. 2-10 with differing tooth geometries, viewed as a series of appliances 100 for a single treatment plan.

Alternatively, as shown in Fig. 11, the polymeric shells of the appliances 100 may have uniform elastic moduluses over their entire tooth contact area. In this depiction, each appliance 100 differs in shape or tooth geometry and represents a stage in the overall treatment plan. Thus, five stages are depicted, as there are five appliances 100 shown. The first three appliances 200, 201, and 202, respectively, may have a uniform elastic modulus chosen for a specific type of tooth movement. For example, appliances 200, 201 and 202 may be designed for pure translation, requiring a relatively high elastic modulus 111. Thus, the appliances are not shaded in the illustration. At stage 4, a different type of tooth movement, such as tipping, may be desired requiring a lower

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elastic modulus 110. Therefore, appliances 203 and 204 may continue the series of differing shape or tooth geometries to create such movements, but the elastic modulus may differ from the prior appliances, 200, 201, and 202. Thus, these appliances are shaded in the illustration. The remainder of the treatment plan may feature a similar series of appliances, including appliances with uniform elastic moduluses which differ from the appliances immediately prior and/or any appliances previously presented in the series. Likewise, such a series may also include appliances with combined variances, as described above.

Similarly, as shown in Fig. 12, a treatment plan may be prescribed with a series of appliances 100 differing in shape or tooth geometry, of which four stages are depicted, 210, 211, 212 and 213. Such appliances may have any given elastic modulus that is suitable for the prescribed function. Likewise, such appliances may have internal variance in elastic modulus, described previously, or may vary wholly from appliance to appliance throughout the prescribed treatment plan. However, if a patient were to discontinue usage of an appliance for an unprescribed period of treatment time, such as between stages two (appliance 211) and three (appliance 212) depicted in Fig. 12, the patient's teeth may move slightly out of the planned tooth arrangement. Such a patient may be considered "off track" in which their current tooth arrangement has diverted from the series of projected tooth arrangements, creating an unprescribed tooth arrangement. When attempting to apply the next successive appliance 212, it may be too rigid to accommodate these slight differences. Therefore, a new more flexible appliance 214 may be produced for this purpose and may be incorporated into the treatment plan. Such an appliance 214 may have the same shape or tooth geometry as the next successive appliance 212, but it may have a lower elastic modulus 110, depicted by shading. The increased flexibility may allow the appliance 214 to conform to the unprescribed arrangement and reposition the teeth toward an arrangement that the next successive appliance 212 may therefore fit. Such an appliance 214 may be used at any point in the series of successive appliances.

As shown in Fig. 13, a series of incremental appliances, 300, 301, 302, 303, 304 and 305, may be produced with differing elastic moduluses, illustrated by variation in shading, to reposition teeth from an initial tooth arrangement to the next successive tooth arrangement in a progression of arrangements to the final arrangement. Fig. 13 illustrates two steps in such a progression. A step or stage represents a change in shape or geometry of an appliance 100 to reposition the teeth into the next prescribed

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arrangement in a series. Therefore, appliances 300, 301, and 302 represent the first stage and have one shape and 303, 304, and 305 represent the second stage and have a differing shape. The appliances 300, 301, and 302 representing the first stage may vary in elastic moduluses from more flexible (appliance 300) to more rigid (appliance 302). The patient may begin the treatment sequence with the more flexible appliance 300 of the first stage. Such flexibility may allow an appliance with a substantially misaligned geometry to fit over the patient's teeth and apply repositioning forces. As the teeth gradually move toward the desired arrangement, the patient may progress to the next appliance 301 in the first stage. This appliance 301 may be more rigid than the prior appliance 300. The patient may continue through any number of appliances throughout a stage. Upon completion of the stage, the patient may repeat the process in stage two, beginning with the more flexible appliance 303 and culminating with the more rigid appliance 305. The patient may then continue through any number of stages to the endpoint of treatment.

Such a system may provide a number of benefits. First, the variance in elastic modulus throughout each step may allow for a larger step or increment in tooth movement between each step than may be obtainable with consistent, rigid appliances. Such flexibility may allow the appliance to fit over a tooth arrangement that is more misaligned while the increase in rigidity throughout each stage may provide sufficient repositioning forces which may not be obtainable with highly flexible appliances. These larger steps require fewer appliances in a series to have a change in shape or geometry. Consequently, fewer molds may be required to form such appliances, which lowers cost and treatment time for the patient. In addition, if the patient were to become "off track" by suspending treatment, it may be possible for the patient to resume the prescribed treatment plan by reentering treatment at the start of the step or stage in which the patient previously aborted. This appliance may be flexible enough to fit over the teeth in the unprescribed arrangement and gradually reposition the teeth throughout the stage as originally prescribed. This may also reduce cost and treatment time since the production and fitting of a flexible "off track" appliance, as illustrated in Fig. 12, may be avoided.

The elastic modulus of an appliance or portions of an appliance of the present invention may be determined by a number of design features, methods, materials and similar means. In a preferred embodiment, the appliance may be comprised of a polymeric shell which is heat formed over a mold of a patient's dentition. This is typically accomplished by heating a thermoformable polymer material and applying vacuum or pressure to form the polymer to the mold. Alternatively, reaction casting may

be used to produce such an appliance. Hereinafter, description will pertain to thermoforming, however such concepts and techniques may be equally applied to reaction casting or similar methods and are not to limit the scope of the invention.

To produce an appliance with uniform elastic modulus, a polymer sheet with a specific elastic modulus and thickness may be thermoformed over a mold and trimmed for patient use. Appliances with differing uniform elastic moduluses may be produced by altering one or more of three variables: 1) polymer type, 2) elastic modulus, 3) thickness. To produce an appliance with portions of differing elastic moduluses, a number of techniques may be utilized. Referring to Fig. 14, portions of polymer sheeting 400 may be positioned over a mold 401 in designated areas and thermoformed together into a final polymeric appliance. Each portion of sheeting 400 may be chosen based on the three above mentioned variables to provide a desired elastic modulus. Each portion of sheeting 400 may then be positioned in the desired location for elastic modulus changes throughout the finished appliance. In Fig. 14, three portions are presented, a first sheet 402 placed over the right side molars, a second sheet 403 placed over the left side molars and a third sheet 404 placed over the remainder of the teeth. Sheets 402 and 403 are depicted as having differing elastic moduluses to each other and to sheet 404, as shown by shading gradations, however such sheets 402, 403, may be identical. After thermoforming, a finished appliance may appear as that illustrated in Fig. 2.

In addition, portions with differing elastic moduluses may be created with the same polymer or different polymers material by layering. Two layers of a polymer material bonded together may have a higher or elastic modulus than a single layer of such material. As illustrated in Fig. 15, a first sheet 405 may be placed over the incisors, canines and premolars of the mold 401 and a second sheet 406 may be placed over the entire dentition. Each sheet may be the same or may differ in terms of any or all of the above mentioned variables. After thermoforming, a finished appliance may also appear as that illustrated in Fig. 2. In this case, the shell covering the molars is comprised of one layer and the remainder of the appliance is comprised of two layers formed into an integral appliance structure. Therefore, the portions covering the molars may have a lower elastic modulus, depending on the combination of materials, than the remaining portion. However, it is possible that a multi-layered structure may have a lower elastic modulus than a single layered structure depending on the above mentioned variables. Thus, it may be appreciated that the described layering technique may provide a variety

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of moduluses and those stated examples are not intended to limit the scope of the invention.

Similarly, portions with different elastic moduluses may be created by a multi-step process of layering. Referring to Fig. 16, a first sheet may be thermoformed over the entire dentition of a mold 401 to form a base appliance 410. Portions desired to be of a differing elastic modulus 411, demarcated by a dashed line, may be cut and removed from the formed base appliance 410. A second sheet 412 may then be thermoformed over the entire dentition. This may result in a single layer of material in the portion of differing elastic modulus 411 and a double layer of material in the remaining areas.

It may be appreciated that appliances with differing and gradually changing elastic moduluses may be created by any number of production methods. For example, a base appliance 410 may be coated in a specific area with one or more polymer solutions to "build up" a portion of the appliance for localized rigidity. Such a build-up may also be gradual for a more gradual increase in rigidity. Likewise, a base appliance 410 may be treated in specific areas with various chemical agents to either increase or reduce localized rigidity. This may also include treatments involving temperature changes and other phase altering methods. Similarly, such methods may be combined, including any or all of the above described methods. Likewise, such methods may be utilized for appliances of uniform elastic modulus.

The fabrication process illustrated in Fig. 16 may be used to prepare a preferred laminated appliance structure 500, as illustrated in Figs. 17 and 18. An inner layer 502 is formed from a relatively stiff polymeric material and molded over a positive tooth model which represents the desired appliance geometry. After the layer 502 is formed, it can be segmented into two or more sections which conform to individual teeth or groups of teeth when the appliance is placed over the patient's jaw. As shown in Fig. 17, gaps 504 may be formed between individual sections 506, each of which conform to and receive an individual tooth or group of teeth. An outer layer 508 is continuous in the mesial-distal axis and covers all the segments 506 of the inner layer 502. By providing an inner layer 502 having a higher stiffness, firm gripping or anchoring of the underlying teeth can be achieved. Moreover, by providing an outer layer 508 which is less stiff or more compliant, ease of removing and replacing the appliance can be significantly improved. Moreover, the stiffness or anchoring force can be enhanced without having to concurrently modify the overall or effective elasticity of the appliance

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which can be selected based on the clinical requirements of moving teeth. That is, the elasticity of the outer layer can be selected to provide an appropriate tooth movement force while that of the inner layer can be chosen to enhance seating characteristics over the teeth. In a specific embodiment, the compliance of the outer layer 508 could be varied along the mesial-distal axis in order to provide for differing forces on the teeth, as discussed generally above.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications and equivalents may be used and the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.

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WHAT IS CLAIMED IS:

1. A dental appliance comprising:

a shell having cavities shaped to receive teeth, wherein at least a first portion of the shell is composed of a material having a first stiffness and a second portion of the shell is composed of a material having a second stiffness which differs from the first stiffness.

2. An appliance as in claim 1, wherein the first portion differs in stiffness from the second portion along a mesial-distal axis.

3. An appliance as in claim 2, wherein the first portion receives one or more said teeth and the second portion receives one or more said teeth.

4. An appliance as in claim 1, wherein the first portion differs in stiffness from the second portion along a facial-lingual axis.

5. An appliance as in claim 4, wherein the first portion partially covers an occlusional surface of a tooth and the second portion substantially covers the remainder of the tooth.

6. An appliance as in claim 1, wherein the first portion differs in stiffness from the second portion along a gingival-crown axis.

7. An appliance as in claim 6, wherein the first portion substantially covers an occlusional surface of a tooth and the second portion substantially covers the remainder of the tooth.

8. An appliance as in claim 1, further comprising a third portion having a third stiffness which differs from the first and second stiffnesses.

9. An appliance as in claim 8, wherein the third portion is located adjacent to the first portion or the second portion in a mesial-distal, facial-lingual or gingival-crown direction.

10. An appliance as in claim 1, wherein the first and second portions comprise layers in a laminar structure.

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11. An appliance as in claim 10, wherein at least one of the first and second portions is continuous along a mesial-distal axis.

12. An appliance as in claim 10, wherein at least one of the first and second portions is discontinuous along a mesial-distal axis.

13. An appliance as in claim 10, wherein the first portion comprises a discontinuous inner layer and the second portion comprises a continuous outer layer and wherein at least a portion of the inner layer is configured to engage individual teeth and the outer layer has a lower elastic modulus than the inner layer.

14. An appliance as in claim 1, wherein the first portion and the second portion have elastic moduluses in the range from 0.5 to 5 GPa.

15. An appliance as in claim 1, wherein the first portion has a first elastic modulus that differs from the second elastic modulus of the second portion by 25% to 600%.

16. An appliance as in claim 1, wherein at least a region of the shell is comprised of a material reinforced with a structure selected from the group consisting of pieces, strips, wires, mesh, lattices, and networks.

17. An appliance as in claim 16, wherein the reinforced material comprises a polymer.

18. An appliance as in claim 16, wherein the structure comprises a metal or alloy.

19. An appliance as in claim 16, wherein the structure comprises a polymer.

20. An appliance as in claim 1, wherein at least a region of the shell comprises a metal or alloy.

21. An appliance as in claim 1, wherein at least a region of the shell comprises of an interpenetrating network.

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22. In a system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of incremental position adjustment appliances comprising shells having cavities shaped to receive and reposition teeth and which are successively worn by a patient to move teeth from one arrangement to a successive arrangement, an improvement comprising:

at least one appliance including a shell wherein at least a first portion of the shell is composed of a material having a first stiffness and a second portion of the shell has a second stiffness.

23. In a system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of incremental position adjustment appliances comprising shells having cavities shaped to receive and reposition teeth and which are successively worn by a patient to move teeth from one arrangement to a successive arrangement, an improvement comprising:

at least a first appliance including a shell having a portion with a first stiffness and at least a second appliance having a shell with a portion geometrically corresponding to that of the first appliance, wherein the portion of the second appliance has a second stiffness which differs from the first stiffness.

24. A system as in claim 23, wherein the shells of the first and second appliances have uniform but different stiffnesses over their entire tooth contact area.

25. A system as in claim 24, further comprising at least a third appliance having a stiffness which is uniform and different from those of the first or second appliance.

26. A system as in claim 25, wherein appliances with substantially similar stiffnesses are used for substantially similar tooth movements, wherein the tooth movements are selected from the group of tipping, translating, root uprighting, rotation, extrusion, intrusion and a combination of these.

27. In a system for repositioning teeth from an initial tooth arrangement to a successive tooth arrangement, said system comprising a plurality of incremental position adjustment appliances comprising shells having cavities shaped to

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receive and reposition teeth and which are successively worn by a patient to move teeth from one arrangement to a successive arrangement, an improvement comprising:

a first appliance including a shell having a shape which is the same as the shape of a second appliance and having at least a portion with a stiffness which is different from the stiffness of a corresponding portion in another appliance.

28. A system as in claim 27, further comprising a third appliance having a shape which is the same as the shape of the first and second appliances and having a stiffness in a portion which is different from the stiffnesses of the corresponding portions of the first and second appliances, wherein the stiffnesses of the first, second, and third appliances increase to provide incremental tooth movements as the appliances are successively worn.

29. A method for producing a dental appliance with varying stiffnesses, said method comprising:

providing a mold of dental features;

forming a first layer of a material having a first stiffness over a first portion of said mold; and

forming a second layer of a material having a second stiffness over a second portion of said mold; and

laminating the first and second layers into an integral appliance.

30. A method as in claim 29, wherein the first portion of the mold and the second portion of the mold have no portions in common.

31. A method as in claim 30, wherein the forming steps occur simultaneously.

32. A method as in claim 29, wherein the first portion of the mold and the second portion of the mold at least partly overlap.

33. A method as in claim 32, wherein the forming steps occur in succession.

34. A method as in claim 33, wherein further comprising removing material from the first layer prior to forming the second layer.

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35. A method as in claim 34, wherein removing material comprises separating adjacent sections of the first layer so that said separated sections conform to individual teeth or groups of teeth when the appliance is placed over teeth.

36. A method as in claim 35, wherein the first layer is more stiff than the second layer.

37. A method as in claim 29, wherein said forming steps are comprised of thermoforming, reaction casting, coating, treating, or altering.

38. A method for repositioning teeth, said method comprising:

placing a first incremental position adjustment appliance over teeth in a patient's mouth, and

successively placing at least a second incremental position adjustment appliance over the teeth in the patient's mouth,

wherein the appliances comprise polymeric shells having shaped cavities and wherein the shells of the first and second appliances have the same shapes but have portions which differ in stiffness between the first and second appliances.

39. A method as in claim 38, wherein the stiffness of the shells of the first and second appliances are uniform over the entire shell.

40. A method as in claim 38, wherein the stiffnesses of the shells of the first and second appliances are non-uniform over the entire shell.

41. A method for repositioning teeth, said method comprising:

placing a first incremental position adjustment appliance over teeth in a patient's mouth, and

successively placing at least a second incremental position adjustment appliance over the teeth in the patient's mouth,

wherein the appliances comprise polymeric shells having shaped cavities and wherein at least one of the first and second appliance has a shell wherein at least a first portion of the shell has a first stiffness and a second portion of the shell has a second stiffness which differs from the first stiffness.

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42. A method as in claim 41, wherein both the shells of both the first and second appliances having shells which at least a first portion of the shell has a first stiffness and a second portion of the shell has a second stiffness which differs from the first stiffness.

43. A method as in claim 38, wherein the first and second portions of the shells of the first and second appliances are located in corresponding positions of each appliance and wherein the stiffness of the first portions of the first and second appliances differ from each other.

44. A method as in claim 43, wherein the stiffness of the second portions of the first and second appliances differ from each other.

45. A method as in claim 38, wherein the shells of the first and second appliances having the same geometry.

46. A method as in claim 38, wherein the shells of the first and second appliances have different geometries.

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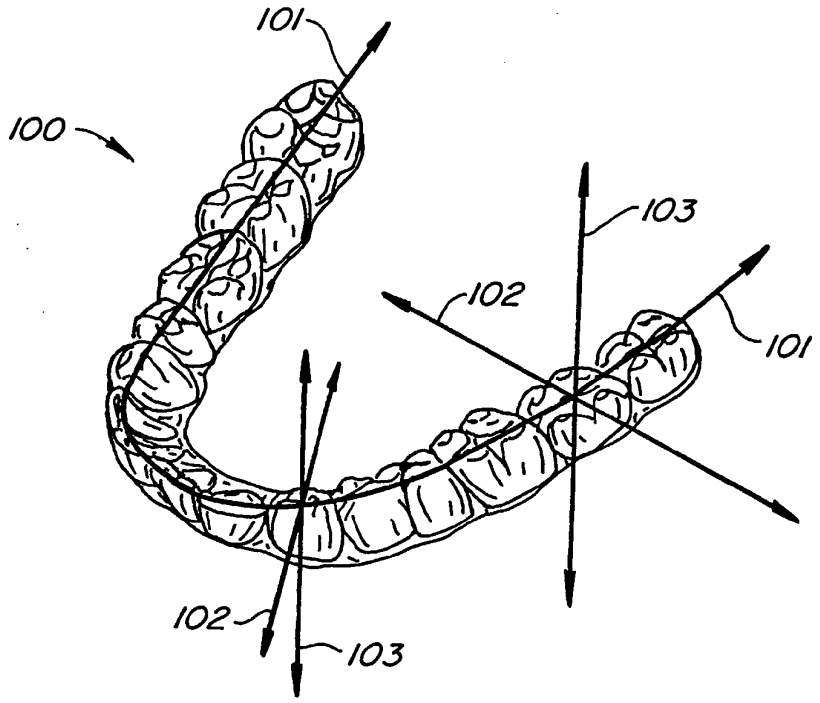


FIG. 1.

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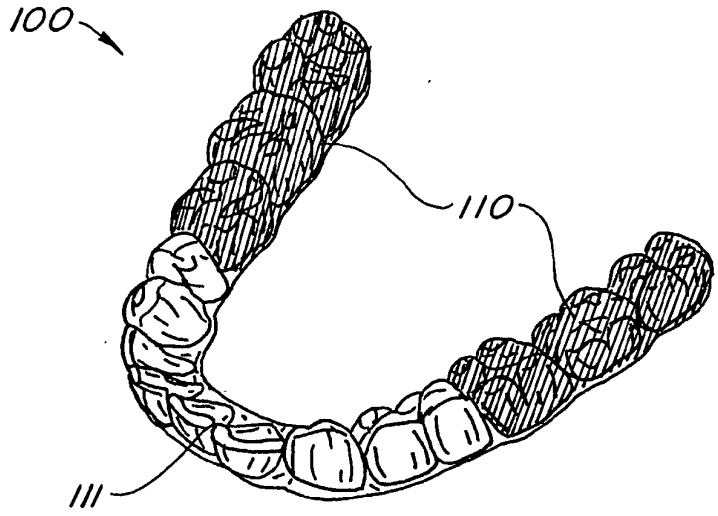


FIG. 2.

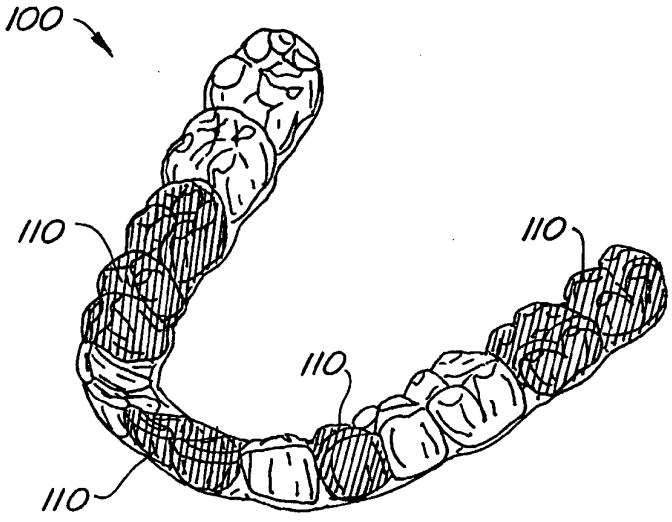


FIG. 3.

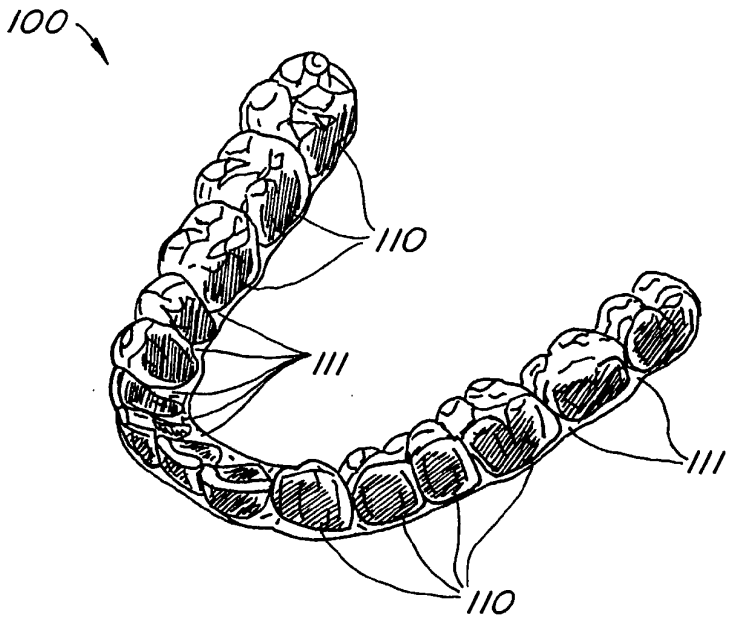


FIG. 4.

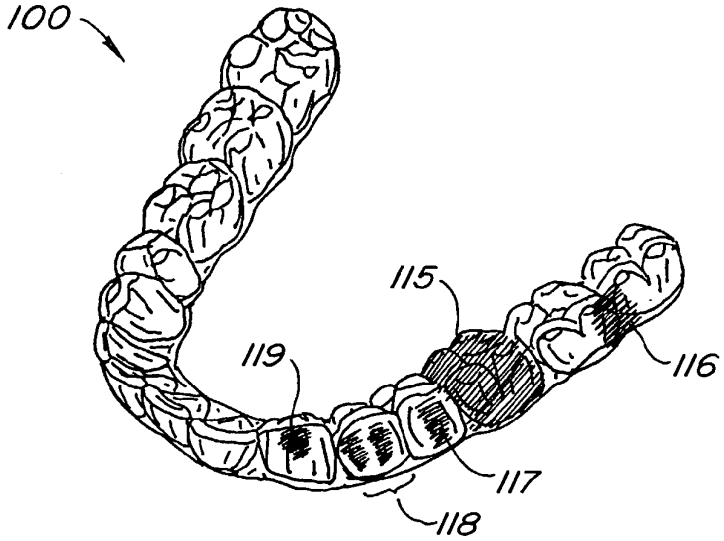


FIG. 5.

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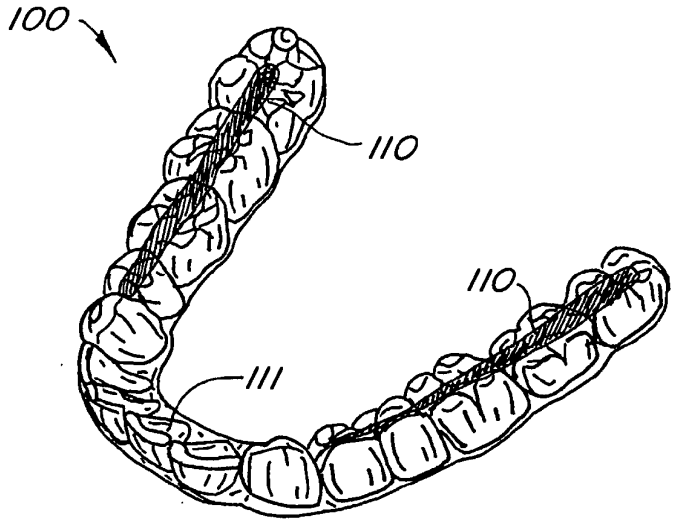


FIG. 6.

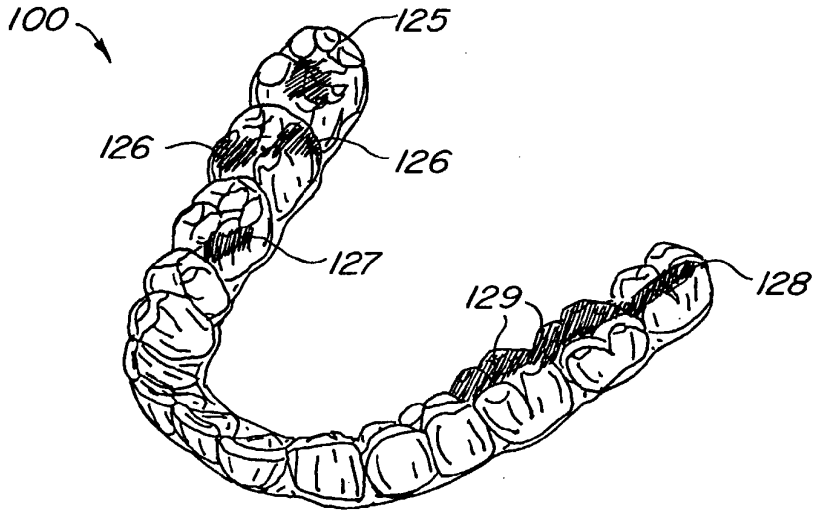


FIG. 7.

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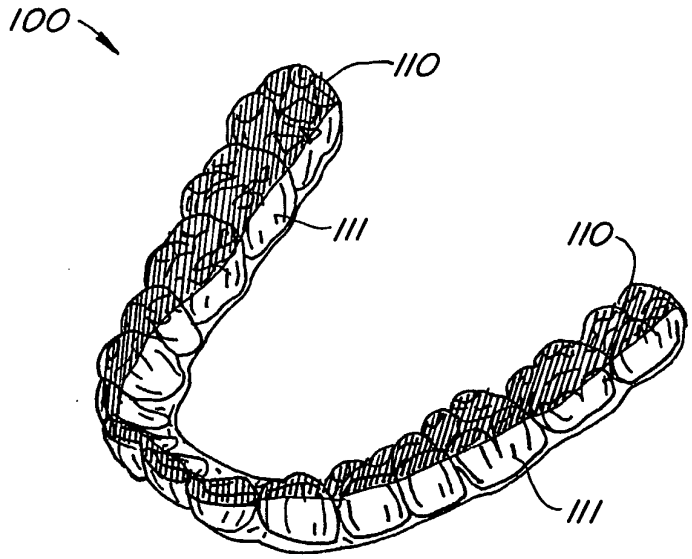


FIG. 8.

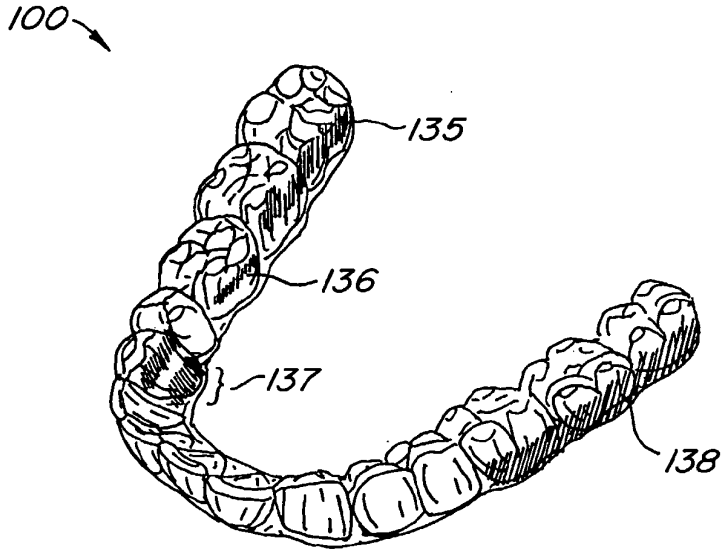


FIG. 9.

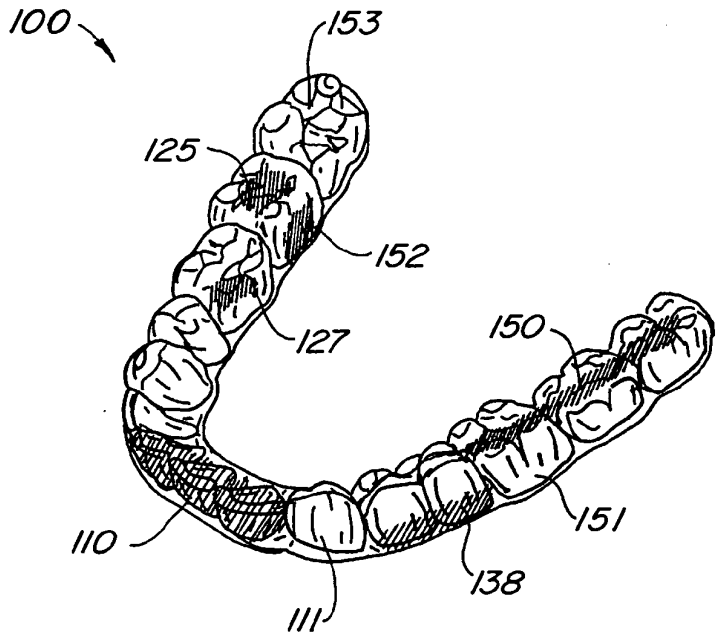


FIG. 10.

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FIG. 11.

SUBSTITUTE SHEET (RULE 26)

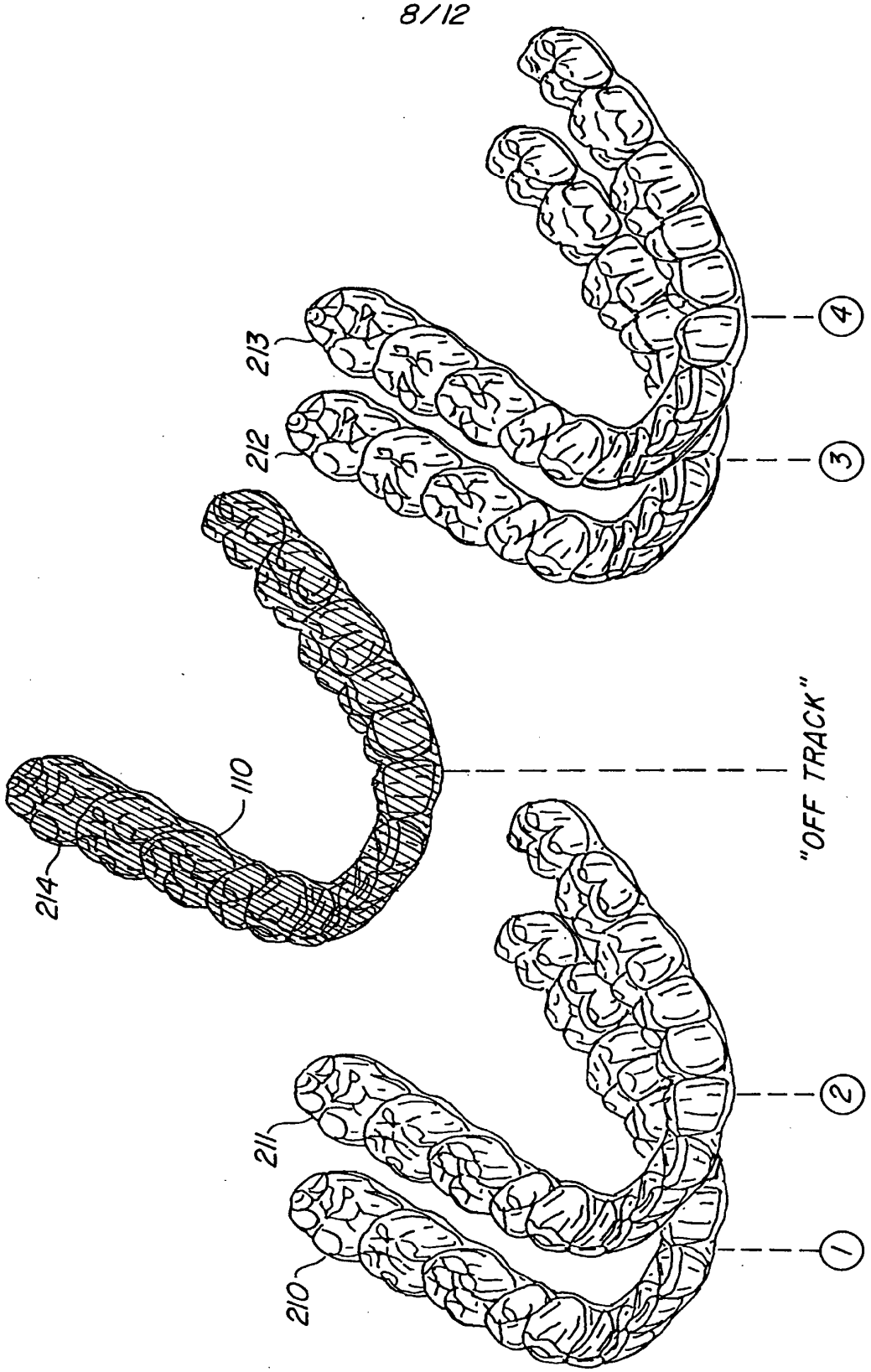


FIG. 12.

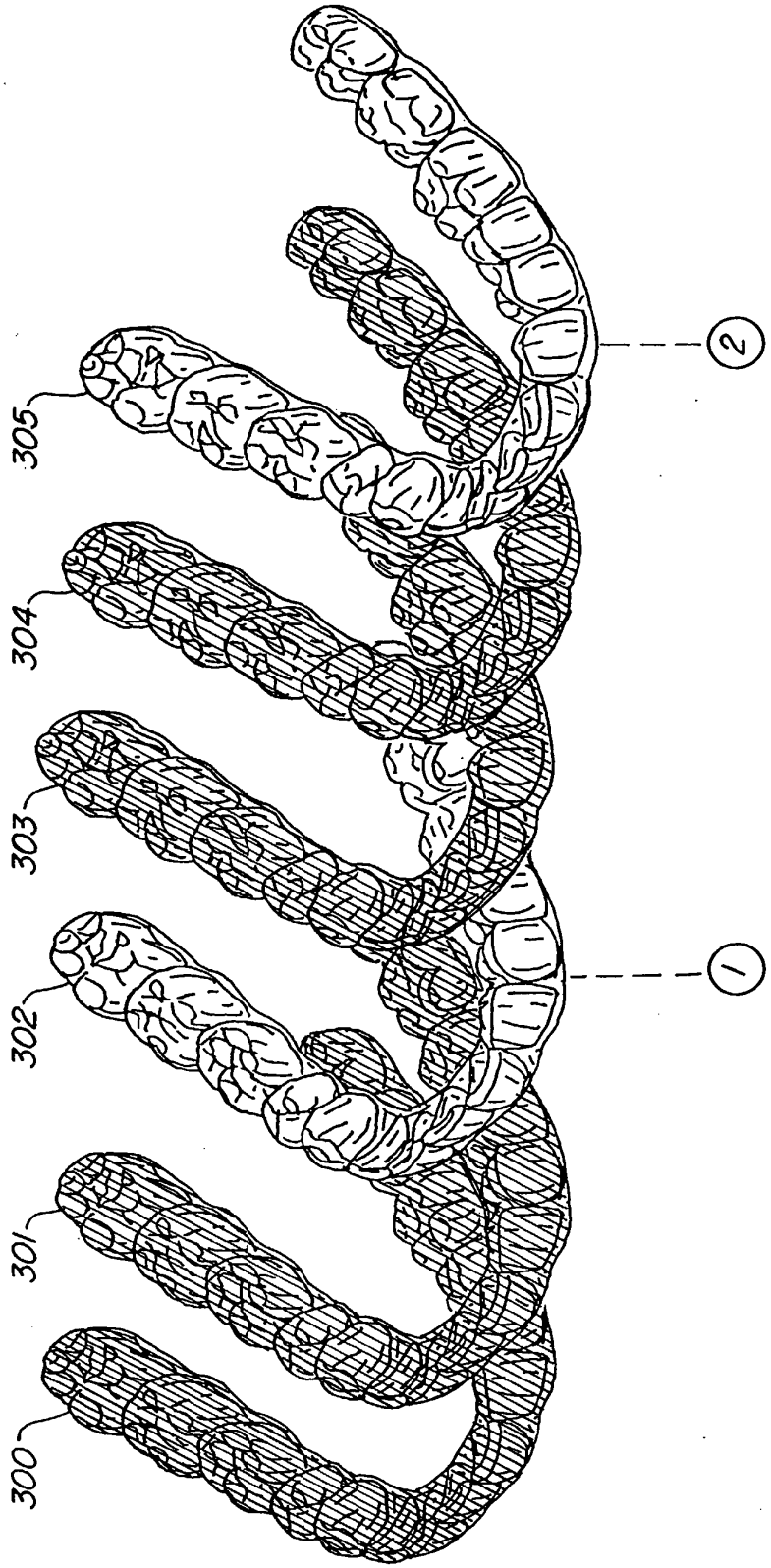


FIG. 13.

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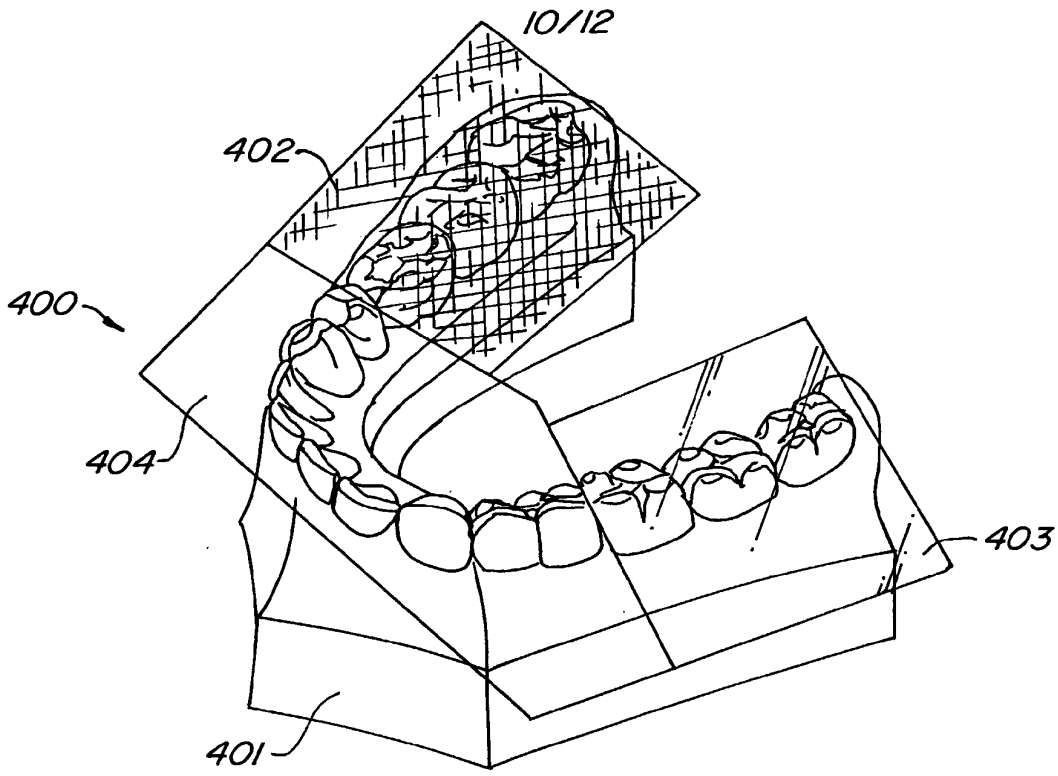


FIG. 14.

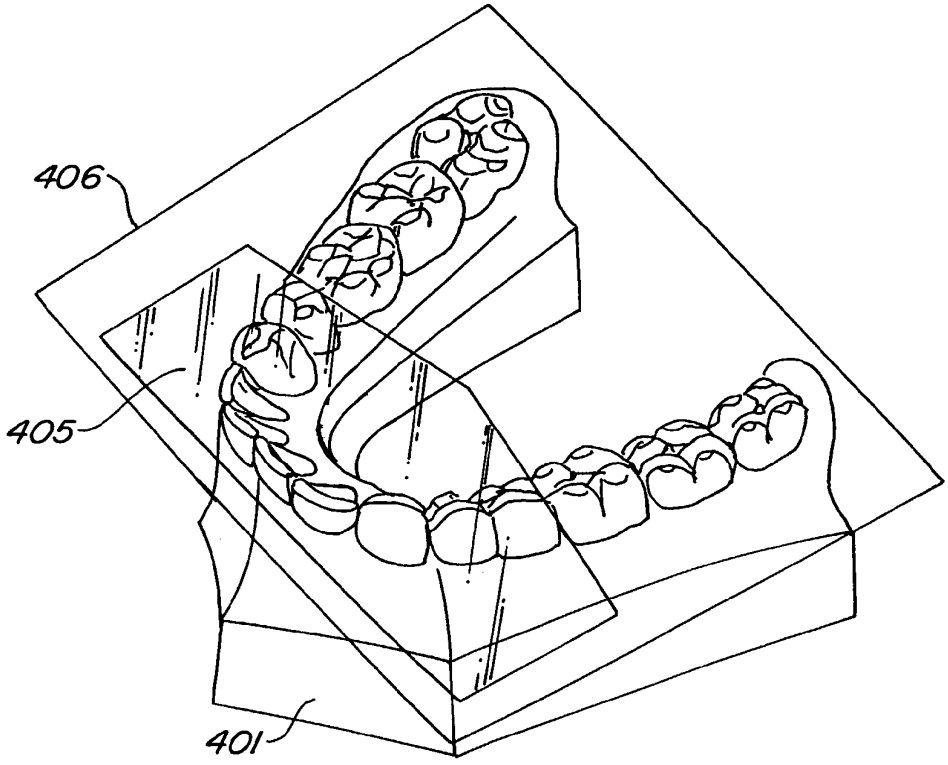


FIG. 15.

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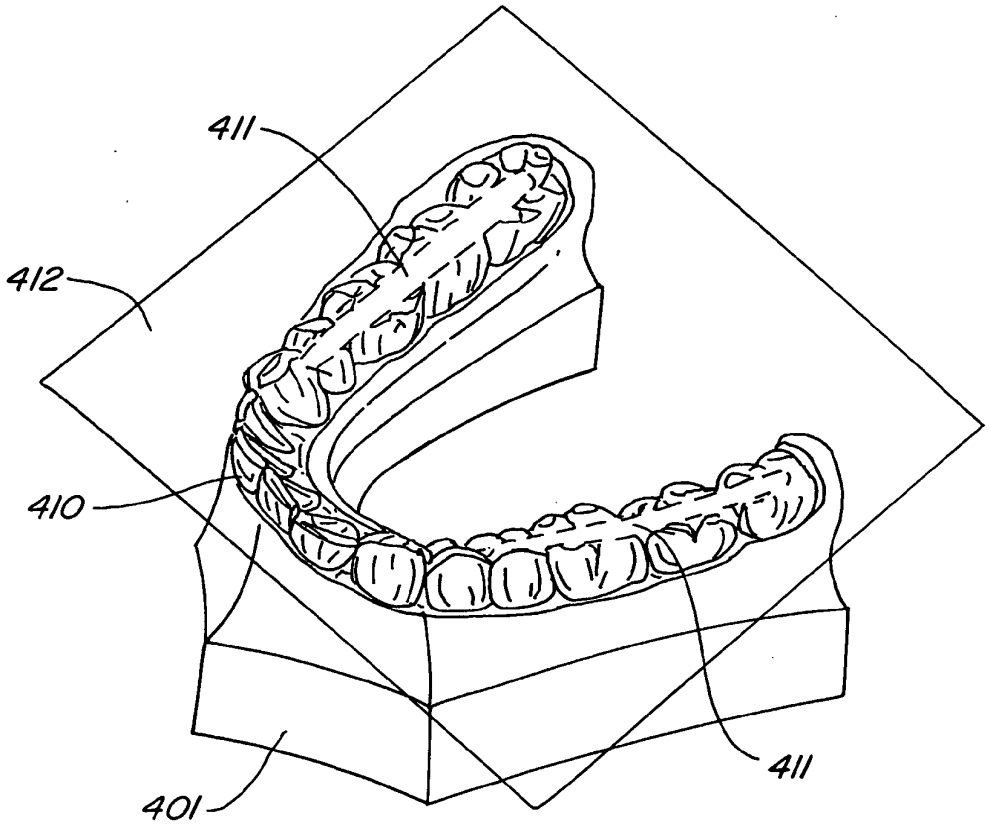


FIG. 16.

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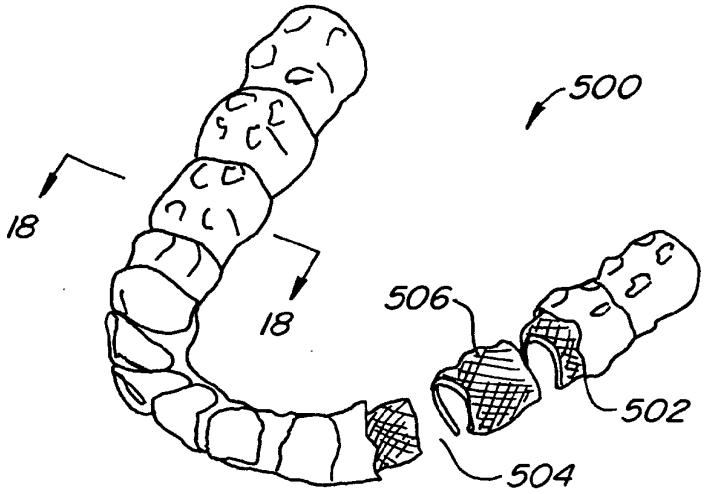


FIG. 17.

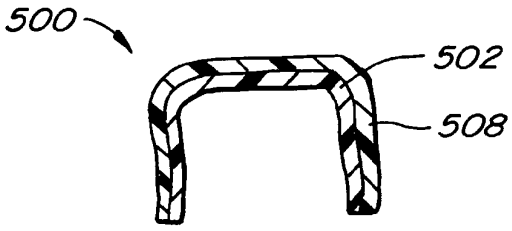


FIG. 18.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/13217

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61C 3/00
US CL : 433/6

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)
U.S. : 433/6, 24, 18

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,983,334 A (ADELL) 08 January 1991, see entire document.	1-4,6,8-12,21,22,29,30,32,37
A	US 5,536,168 A (BOURKE) 16 July 1996, see entire document.	1-46
A	US 4,370,129 A (HUGE) 25 January 1983, see entire document.	1-46

☐ 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

"E" earlier application or patent published on or after the international filing date

"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	Date of mailing of the international search report
06 July 2001 (06.07.2001)	15 AUG 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Cary E. O'Connor Telephone No. 703-308-0858

Form PCT/ISA/210 (second sheet) (July 1998)

Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Garrett T Potter/John Macalagay
Attorney Docket Number:	22773-826.401

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt	
EFS ID:	37175948
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Garrett T Potter/John Macalagay
Filer Authorized By:	Garrett T Potter
Attorney Docket Number:	22773-826.401
Receipt Date:	16-SEP-2019
Filing Date:	31-MAR-2017
Time Stamp:	15:47:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$240
RAM confirmation Number	E20199FF48183448
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		22773-826-401_IDS.pdf	320545 5e202f8d6edea33a58c96134f195728ea229a303	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	4	
	Information Disclosure Statement (IDS) Form (SB08)		5	8	
Warnings:					
Information:					
2	Foreign Reference	WO0180762A2_EFS.PDF	1662366 e8e44ccd6e364e9c1d0799fa2bf23c6de7fac74c	no	40
Warnings:					
Information:					
3	Foreign Reference	WO0180764A1_EFS.PDF	1936632 48d6d409235a91f6a53a728b42846bef192c6034	no	42
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30353 8bad988363d657a0e6ba9275a8e8fff6b7e4163d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3949896		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	1748
Serial Number:	15/476,655	Examiner:	MONTIEL, CAROLINE
Filing or 371 (c) Date:	2017-03-31	**CONFIRMATION NO:**	**5936**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: September 16, 2019

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☐ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☐ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☒ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☒ a fee of $240.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $240.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* 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 or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☐ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $240.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22773-826.401).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: September 16, 2019

By: /Garrett Potter/
Garrett Potter
Reg. No. 76,602

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 107046

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on September 16, 2019

WILSON SONSINI GOODRICH & ROSATI

By: /Hillary Pratt/

Attorney Docket No.: 22773-826.401
Align Ref. No.: 1228.US.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5936
Chunhua Li et al.	
Application No.: 15/476,655	Examiner: Caroline Montiel
Filed: March 31, 2017	Art Unit: 1748
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	AMENDMENT
Customer No.: 107046	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Office Action mailed March 14, 2019, please enter the following amendments and remarks.

Amendments to the Specification begin on page 2.

Amendments to the Claims are reflected in the listing of claims beginning on page 3.

Remarks begin on page 6.

ClearCorrect Exhibit 1011, Page 596 of 890

Amendments to the Specification:

Please replace paragraph **[0001]** with the following amended paragraph:

CROSS-REFERENCE

[0001] This application is a divisional of U.S. Patent Application No. 13/470,681, filed May 14, 2012, now U.S. Patent No. 9,655,691, issued May 23, 2017, the entire contents of which are incorporated herein by reference.

PATENT

Attorney Docket No. 22773-826.401

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:	Confirmation No.: 5936
Inventor: Chunhua Li et al.	Examiner: Caroline Montiel
Application No.: 15/476,655	Group Art Unit: 1748
Filing or 371 (c) date: March 31, 2017	Customer No. 107046
Title: **MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS**	**DECLARATION OF CHUNHUA LI UNDER 37 C.F.R. §1.132**

Mail Stop Amendments

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

DECLARATION OF CHUNHUA LI, PH.D.

Commissioner:

I, Chunhua Li, declare as follows:

I. QUALIFICATIONS

1. My name is Chunhua Li. I am the Senior Director of Materials and Biomechanical Engineering at Align Technology, Inc. I have over 25 years of experience in materials and biomechanical engineering, including over a decade designing, developing, and testing materials for dental and orthodontic use. I have worked at Align Technology, Inc., for the past 15 years, before which, I spent seven years working for Abbott Laboratories, and three years working for Cygnus, Inc. While at Align, I have been listed as a co-inventor on at least 24 issued US patents related to

dental and orthodontic applications. I hold a PhD degree from the Donghua University in Polymer Engineering. A copy of my *curriculum vitae* is attached as Appendix A.

II. SCOPE OF REVIEW

2. I am familiar with the US 15/476,655 patent application (the "'665 application"), on which I am listed as a co-inventor, including the currently pending claims. I have also reviewed the Office Action having a mail date of March 14, 2019, and understand the rejections made in it. I have been informed that the Office Action rejects the claims as allegedly being obvious over Chen et al., US 2009/0246724 (referred to herein as "Chen") in view of DeSimone et al., US 7,641,828 (referred to herein as "DeSimone"), and with regard to the features of claim 26, further in view of Hostettler, US 4,791,156 (referred to herein as "Hostettler"). The Office Action at page 5 states that, "It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the materials of DESIMONE to form the hard polymer layer in CHEN since DESIMONE teaches that such materials for the intended use of such hard layers with predictable results and/or reasonable expectation of success."

3. I am also listed as a co-inventor of Chen, which is the primary reference cited by the Examiner in the pending Office Action. I also collaborated closely with Joseph M. DeSimone and Robert E. Tricca (the inventors listed on DeSimone) while they were developing and patenting the technology described in DeSimone. It is my opinion that it would not have been obvious to one of ordinary skill in the art to use the materials taught by DeSimone to form the layered material described in Chen, at least because there would have been no reasonable expectation of success in making the combination. Moreover, the appliances recited in the claims of the '665 application exhibit unexpectedly positive results over previously known appliances. These unexpected results are evidenced by clinical studies that were performed comparing the efficacy of orthodontic appliances as described and claimed in the '665 application with that of previously known appliances. The details of those studies are provided below.

III. NOT PREDICTABLE

4. Several years ago, Align Technology set out to develop a product that could replace its single-layer, thermoplastic polyurethane appliance product (referred to herein as "EX30"). At the time, EX30 appliances were the standard of care for orthodontic treatment; for example, paragraph [0003] of Chen describes EX30 appliances when it states that "[s]ome dental appliances are made using . . . thermoplastic polyurethane." Over the course of more than seven years, Align worked diligently to develop a suitable appliance that would meet various criteria for effective orthodontic treatment. During this development process, my team evaluated, in an iterative fashion, more than 250 distinct materials and/or material combinations for possible use in an improved appliance. After years of development, Align produced the SmartTrack™ material (also referred to herein as "ST30"), which is a product according to the current claims comprising a multilayered material with a hard polymer layer between two soft polymer layers. We found that the materials with both hard and soft polymer layers according to the current claims in orthodontic appliances had surprisingly superior properties of elongation, time stress-relaxation, durability, and thermoform ability. Each of these properties is important for the production of appliances to apply orthodontic, teeth-moving forces in an oral environment. I would expect that the presence of only two such layers (i.e., a hard polymer layer and a soft polymer layer according to the current claims) would also provide beneficial and surprisingly superior properties of elongation, time stress-relaxation, durability, and thermoform ability.

5. Data obtained by Align during its development of the SmartTrack material provides significant evidence that the effectiveness of the SmartTrack material was unpredictable and unexpected. As mentioned above, the SmartTrack material was developed during more than seven years of diligent evaluation of over 250 materials, including numerous iterations in which materials were tested and compared, with the results used to design new materials. During evaluation of the over 250 materials, only the materials according to the current claims met Align's development criteria. Among those 250 materials tested were more than 180 materials either generically or specifically described in Chen and/or DeSimone, including various copolymers (Chen at [0036]) and unblended polysulfones (DeSimone at 6:47-59), as well as styrenic polymer materials such as acrylonitrile-butadiene-styrene (ABS) (*id.* at 6:24-37). Specifically, none of the 23 copolymers that

were tested during the iterative development process met Align's criteria. Similarly, none of the styrenic polymers nor unblended polysulfones tested met Align's criteria. Thus none of these materials would have yielded an orthodontic device having sufficient elongation, time stress-relaxation, durability, and thermoform ability.

6. In the course of developing the ST30 material, we evaluated numerous multilayer material combinations and determined that merely combining the materials into multiple layers was insufficient to improve performance relative to the EX30 material. In fact, many multilayer materials tested proved inferior to the EX30 material. Some of the multilayer materials that proved inferior to the EX30 material included combinations of materials disclosed in Chen and/or DeSimone. In particular, the sole exemplified multilayer material described in Chen would not be expected to show improved performance relative to EX30. For example, Chen paragraph [0032] describes a material containing polycarbonate and polyvinyl chloride (PVC); however, PVC was later evaluated by my team and found to be unsuitable for use in orthodontic aligners due to its inadequate durability. Based on these tests, we determined that materials containing PVC, either alone or in a multilayer configuration, would be inferior to EX30. For these reasons, a person of ordinary skill would not necessarily expect the addition of multiple material layers, either in general or as particularly described in Chen, to achieve performance superior to EX30.

7. In my opinion, the fact that the many materials tested did not perform to the level of the desired criteria, either as single or multiple layers, and the fact that a multilayer material combining hard polymer layer and soft polymer layers according to the current claims provided unexpectedly better results than the standard of care at the time of filing, highlights the lack of predictability in the art.

IV. NO REASONABLE EXPECTATION OF SUCCESS

8. I disagree with the Examiner's assertion that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Chen and DeSimone to arrive at the invention described in the claims of the current application.

9. As discussed above, I am a co-inventor of Chen, which is the primary reference cited by the Examiner in the pending Office Action. I was thus intimately familiar with the teachings of Chen during the development of the currently claimed orthodontic appliances. I also collaborated closely with Joseph M. DeSimone and Robert E. Tricca (the inventors listed on DeSimone) while they were developing and patenting the technology described in DeSimone. I was thus very aware of the teachings of DeSimone during the development of the orthodontic appliances according to the current claims. Even with my extensive knowledge of the teachings of Chen and DeSimone, it took me and my team over seven years to identify the combination of polymers for the claimed multilayer orthodontic appliance. Thus, I disagree that it would have been obvious to one of ordinary skill in the art to use the materials taught by DeSimone to form the layered material described in Chen.

10. Indeed, the fact that the over 250 materials tested by my team did not provide results meeting the desired criteria, while the SmartTrack material as described in the current claims was found to meet Align's criteria for a multilayer appliance, itself suggests that there was no predictability and there would have been no reasonable expectation of success in combining the teachings of Chen and DeSimone. If anything, a person of ordinary skill in the art would have expected failure in light of the above-described development history.

V. CLINICAL STUDY RESULTS

11. Align conducted a clinical study demonstrating the superior performance of multilayered orthodontic appliances as described in the current claims. The clinical study compared the performance of clear plastic appliances made with Align Technology's SmartTrack material (ST30), which is an appliance according to the current claims comprising a layered material with a hard polymer layer between two soft polymer layers, to appliances made of thermoplastic polyurethane (EX30), which was the standard clear plastic material in appliances on the market at the time of the clinical study, and was made of a single-layered material. Patients in the study were assigned to one of two groups—an Experimental Group or a Control Group. The Experimental Group received Invisalign Assist appliances made with the SmartTrack material (ST30), while the Control Group received appliances made with thermoplastic polyurethane (EX30). The methods of treatment for each group were otherwise the same. The Experimental Group consisted of all new Invisalign Assist orthodontic cases for a one-month period, totaling 1,015 patients, and the Control Group consisted of

all patients from the immediately preceding six-month period. The study followed a double-blind protocol in which neither treating doctors nor patients were informed of their group assignment.

12. Because appliances made of the EX30 material were the standard of care during our development of the SmartTrack material and were superior to many multilayer materials tested, we considered the EX30 material to be the most reasonable comparative material when performing clinical trials of the SmartTrack material.

13. Patients in the study were tracked over a five-month period, during which time, the patients were provided with clear plastic orthodontic appliances appropriate to their group of the study, and configured to produce a prescribed target movement of one or more teeth. Impressions of patient teeth were taken at the beginning and end of the treatment period, and measured amounts of tooth movement were compared to target amounts of tooth movement. Patients were placed into one of three groups based on the measured movement of teeth: On-Track, Off-Track, or Cannot Match. Patients were assigned to On-Track if the measured tooth movement matched the target tooth movement to within a predetermined degree of variance, based on the conclusion of the treating doctor or on direct analysis of data from doctor-submitted impressions. Patients with tooth movement falling outside this range were classified as Off-Track. Patients far outside the range were classified as Cannot Match.

14. Patients treated with ST30 appliances showed significantly superior outcomes compared to patients treated with EX30 appliances in various indicia. Specifically, the Experimental Group (ST30) had 26% more On-Track patients than the Control Group (EX30), representing a strongly significant improvement ($p < 0.001$). Similar improvements were measured in the other groups, with fewer patients in the Experimental Group than the Control Group in both the Off-Track (-17%, $p < 0.001$) and Cannot Match (-34%, $p < 0.001$) categories.

15. In the above-described clinical study, the ST30 appliances contained a hard polymer layer, which provided the forces needed to generate movement of the teeth, while the soft polymer layers increased the durability of the aligners allowing them to better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment as well as improving the elastic properties allowing for less degradation in the shape of the teeth receiving

cavities. A combination of a single hard polymer layer and a single soft polymer layer according to the current claims would also exhibit these beneficial functions in an appliance. Thus, I would also expect an appliance with layers of a single hard polymer material and a single soft polymer material according to the current claims to exhibit beneficial performance relative to EX30 appliances.

16. A retrospective analysis was performed providing further evidence of the superior performance of materials combining a hard polymer layer with a soft polymer layer, such as SmartTrack, as recited in the current claims. From a patient population of over two million individuals over a six-year period, 110,000 cases with both initial and secondary dental scans were randomly selected from the Invisalign patient database. The Experimental Group had 58,000 cases using appliances comprising ST30 material, while the Control Group had 52,000 cases using appliances comprising EX30 material. Tooth Movement Predictability was measured by comparing achieved versus planned tooth movement, with higher predictability corresponding to smaller deviations from planned movement. Improvement in Tooth Movement Predictability between groups was defined as: 100% x (Experimental Group Predictability - Control Group Predictability) /(Control Group Predictability). Predictability improvement was measured for a total of fourteen criteria based on type of movement (e.g., rotation, extrusion, and root tip movement) and type of tooth. Each measured movement type showed strongly significant improvement for the Experimental Group over the Control Group ($p<0.001$). Appendix B summarizes these results.

17. As a weighted average, the Experimental Group (ST30) showed greater than 75% improvement in overall tooth movement predictability over the Control Group (EX30). As EX30 appliances were the standard appliances used for orthodontic treatment up until the release of ST30, a person of ordinary skill in the art would expect that significantly superior performance relative to EX30 would translate to similarly superior performance relative to other orthodontic appliances, including some multilayered appliances. Accordingly, the use of a multilayered material comprising materials as described in the current application (e.g., with hard polymer and soft polymer layer according to the current claims) represents a large and significant improvement over the prior art. In my opinion, a person of ordinary skill in the art would not have expected this result based on the teachings of the prior art.

18. In the above-described retrospective analysis, the ST30 appliances contained a hard polymer layer, which provided the forces needed to generate movement of the teeth, while the soft polymer layers increased the durability of the aligners allowing them to better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment as well as improving the elastic properties allowing for less degradation in the shape of the teeth receiving cavities. A combination of a single hard polymer layer and a single soft polymer layer according to the current claims would also exhibit these beneficial functions in an appliance. Thus, based on the work performed by our team, one would also expect an appliance with layers of a single hard polymer material and a single soft polymer material according to the current claims to exhibit beneficial performance relative to EX30 appliances.

VI. UNEXPECTED EFFICACY OF SMARTTRACK MATERIALS

19. The above-described clinical studies demonstrate the significantly improved performance of materials containing a combination of hard polymer and soft polymer layers according to the current claims, such as SmartTrack, relative to the previous standard of care in orthodontic treatment with clear plastic appliances (EX30)—a surprising result that would not have been expected by a person of ordinary skill in the art. Prior to the development of appliances using SmartTrack materials, virtually all clear plastic orthodontic appliances sold in the United States were made with the materials used in the appliances of the Control Groups (EX30). As a result of SmartTrack's dramatically improved performance over EX30 appliances, SmartTrack appliances became the new standard for aligners produced by Align Technology. In fact, the results of the clinical comparisons between EX30 and ST30 materials were so striking that Align made an unprecedented, nearly complete switch in the U.S. from thermoplastic polyurethane (EX30) appliances to SmartTrack (ST30) appliances within a matter of only months. SmartTrack appliances now account for over 90% of the total U.S. market for clear plastic orthodontic appliances from all sellers. *See,* e.g., Baird 2014 Analyst Report at 6 ("93% share of the $550 million clear aligner orthodontic market segment"), *see also* Baird Q3 2013 Report at 9.

20. The effectiveness of appliances made with multilayered materials combining hard polymer and soft polymer layers (e.g., SmartTrack) was surprising, and a person of ordinary skill in the art would not have predicted the improved performance demonstrated in the above clinical study. In

particular, a person of ordinary skill in the field would not have expected the significantly improved clinical performance of these multilayer materials, such as SmartTrack, compared to the prior art.

21. I declare that all statements made herein are true to the best of my knowledge, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 or Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed on this 16th day of September, 2019



Chunhua Li, Ph.D.

ClearCorrect Exhibit 1011, Page 606 of 890

Appendix A – Curriculum Vitae of Chunhua Li, Ph.D.

PROFESSIONAL EXPERIENCE:
Align Technology, Inc., San Jose, CA
2015 - Present: Sr. Director, Materials Engineering and Biomechanics

Director, Materials Engineering and Biomechanics (2011-2015)
Sr. Manager, Materials Engineering (2007-2011)
Manager, Materials Engineering (2003-2007)

- Leading a team of biomechanical, materials engineering, product requirements, product analytics and software engineering for product research and development of the Invisalign system and related products
- Responsible for R&D product research and development functional area, leading, planning and execution of Invisalign product development projects and managing resources to meet company roadmap commitments
- Directing product planning, resources and strategy, working with cross functional team including marketing, clinical, operation, legal and regulatory. Managing product development cycle from conceptual, product launch to global regulatory submissions
- Working with internal and external technology leaders, developing next generation technology/materials for orthodontic medical device, working on cutting edge technologies such as 3D printing materials/technologies, addressing all technical challenges to bring new technology/material from concept to successful product launches

Abbott Laboratories, Hospital Products Division, Morgan Hill, CA
1996 - 2003: Sr. Staff Engineer

- Technical expert for the R&D department in material selection, evaluation, characterization and failure analysis for electro-mechanical and disposable medical devices
- Developed an antimicrobial-eluting catheter coating, from technology assessment and evaluation, through product development, in-vitro and in-vivo animal testing, writing a 510(k), and transferring the technology into manufacturing
- Conducted technical assessments and recommendations for new medical device in the field of cardiology, critical care and oncology, products evaluated include catheters, stent coatings, vascular hemostatic devices and drug delivery systems
- Assessed customer complaints on a disposal medical device, re-formulating a polymer compound and modifying the extrusion to provide a customer preferred product; Investigated a field failure of fiber optic pulmonary artery catheters, identifying the root cause, and providing a method for process improvement/control. Received "Abbott Chairman's Award" in 1997
- Set up polymer characterization lab, and provided material characterization and problem solving to internal customers. Supported manufacturing sites on material- related issues and cost reduction

Cygnus Inc., Redwood City, CA
1993 - 1996: Group Leader/Research Scientist

- Managed an analytical group of 8 chemists in the analysis of controlled release drug products and raw materials for product release and stability assessment. Responsible for analytical data, method validation, instrument qualification, analytical procedure and interacted with different functions across the organization to provide analytical support
- Conducted polymer characterization using GPC (triple detector), DMA, DSC, TGA and other mechanical measurements
- Provided technical support for material evaluation on various polymeric materials used in transdermal drug delivery systems
- Conducted research on chemical composition and curing mechanisms of pressure sensitive adhesives in transdermal drug delivery systems
- Studied the interactions among different ingredients in the transdermal drug delivery system, leading to the development of a more stable system and a patent

Penederm Inc., Foster City, CA
1991 - 1993: Research Scientist

- Synthesized polymers and compounds for topical drug delivery systems; scaled up candidate polymers from lab to production
- Characterized polymer structures and properties by GPC, FTIR, GC, HPLC and DSC
- Screened polymers according to their properties for topical, mucosal and cosmetic applications; conducted investigations into new areas of research such as hydrogels and muco-adhesives
- Responsible for training personnel on instrumental operations and laboratory safety techniques, radiation protection principles and decontamination control

Stanford University, Department of Chemical Engineering, Palo Alto, CA
June 1991 – Oct. 1991: Research Assistant

- Conducted research on polymer rheological properties

EDUCATION:

Ph. D. in Polymer Engineering, Dong Hua University, Shanghai, China
Thesis: Microphase Separation and Surface Modification of Segmented Polyurethanes
B.S. in Chemistry, Dong Hua University, Shanghai, China

PUBLICATIONS AND PATENTS:

24 US issued patents on dental and orthodontic application fields:

US Pat. Nos. 7,553,157; 7,766,658; 7,824,180; 7,854,609; 7,878,801; 7,883,334; 7,947,508; 8,075,309; 8,439,674; 8,708,697; 8,758,009; 8,765,031; 8,899,976; 9,241,774; 9,597,164; 9,655,691; 9,655,693; 9,730,769; 9,744,001; 9,844,424; 10,052,176; 10,154,889; 10,201,409; and 10,299,894.

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Appendix B – Retrospective study data showing the degree of improvement in tooth movement predictability for various categories of tooth movement (e.g., rotation, extrusion, and root tip movement) in the Experimental Group (ST30) relative to the Control Group (EX30). Each measured movement type showed strongly significant improvement in predictability for the Experimental Group over the Control Group ($p<0.001$).

Tooth Movement Type	Sample Size	Improvement[1]	P-Value[2]
Upper Canine Rotation[3]	81,194	118%	<0.001
Upper Premolar Rotation	10,401	60%	<0.001
Lower Canine Rotation	56,100	88%	<0.001
Lower Premolar Rotation	14,472	79%	<0.001
Upper Canine Extrusion[4]	8,515	33%	<0.001
Upper Incisor Extrusion	16,438	43%	<0.001
Lower Canine Extrusion	3,459	69%	<0.001
Lower Incisor Extrusion	8,958	123%	<0.001
Upper Canine Root Movement[5]	26,688	80%	<0.001
Upper Premolar Root Movement	19,856	56%	<0.001
Lower Canine Root Movement	27,986	94%	<0.001
Lower Premolar Root Movement	12,439	88%	<0.001
Upper Central Root Movement	24,492	100%	<0.001
Upper Lateral Root Movement	25,994	88%	<0.001

[1] "Improvement" refers to the extent of increase in tooth movement predictability for the Experimental Group (ST30) relative to the Control Group (EX30).

[2] "P-Value" is also known as "calculated probability" and is a measure of statistical significance of an observed result, with P-Values of less than 0.001 being statistically highly significant, i.e., less than 0.1% probability of the observed result being a chance occurrence.

[3] "Rotation" is defined as the turning of a tooth around its longitudinal axis.

[4] "Extrusion" is defined as elongation of a tooth or movement of a tooth in an occlusal or incisal direction.

[5] "Root Movement" is defined as a condition in which the root of a tooth moves in the direction of force but the crown position remains the same or is only minimally displaced.

Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Garrett T Potter/Hillary Pratt
Attorney Docket Number:	22773-826.401

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	1253	1	1400	1400
Miscellaneous:				
		Total in USD ($)		**1400**

Electronic Acknowledgement Receipt	
EFS ID:	37179933
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Garrett T Potter/Hillary Pratt
Filer Authorized By:	Garrett T Potter
Attorney Docket Number:	22773-826.401
Receipt Date:	16-SEP-2019
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Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1400
RAM confirmation Number	E20199FI54260644
Deposit Account	232415
Authorized User	Hillary Pratt
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		22773_826_401_Response.pdf	285244 93681b7c6f248bb679eba7baa2f8f2702ae9dec1	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Claims	3	5
	Applicant Arguments/Remarks Made in an Amendment	6	16

Warnings:					
Information:					
2	Affidavit-traversing rejectns or objectns rule 132	2019_09_16_Li_Declaration.pdf	924856 cca1aa3da41b68faa8b7727aacf8c438f1fce455	no	12
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30616 c5e56a55bc2af3b591138cf5ff4a45cef99173b3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1240716		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

REMARKS

Upon entry of this Amendment, claims 20-39 will be pending and at issue in the present application. Claims 1-19 have previously been canceled without prejudice or disclaimer. Applicants reserve the right to pursue any canceled subject matter in a related, future application. Claims 20-26 and 29 have been amended. New claims 31-39 have been added. Support for the amendments can be found in the specification as originally filed. Accordingly, no new matter has been added. Reconsideration is respectfully requested.

Claim Amendments

Claim 20 has been amended to recite that the sheet comprises "a hard polymer layer of polymeric material comprising a flexural modulus greater than about 150,000 psi; and a soft polymer layer of polymeric material comprising an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D." Support for this amendment can be found throughout the instant application as filed, at least at paragraphs [0027]-[0028].

New claims 31-39 have been added. Support for these new claims can be found throughout the specification as originally as filed, at least at the locations indicated in the table below:

Claim Number:	Exemplary support at least at:
31	Paragraphs [0006]-[0007], [0026], [0030], instant application as filed
32	Paragraphs [0025] and [0030], instant application as filed
33	Paragraph [0036], instant application as filed
34	Paragraph [0029], instant application as filed
35	Paragraph [0026], instant application as filed
36	Claim 10, parent application (US 13/470,681) as filed
37	Paragraph [0023], instant application as filed
38	Paragraph [0026], instant application as filed
39	Paragraph [0028], instant application as filed

Accordingly, no new matter has been added by way of this claim amendment or newly added claims.

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Examiner Interview

Applicants thank Examiner Montiel for participating in a telephonic interview on July 18, 2019, with Applicants' representatives, Melissa Harwood and Garrett Potter. Additional participants included Primary Examiner Anthony Calandra. The Examiner's rejections of the claims made in a Non-Final Office Action mailed on March 14, 2019, were discussed.

Claim Rejections – 35 USC § 103

i. Claims 20-25 and 27-30

Claims 20-25 and 27-30 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen et al. (U.S. Pub. No. 2009/0246724, hereinafter "Chen") and DeSimone et al. (U.S. Patent No. 7,641,828, hereinafter "DeSimone"). Specifically, the Examiner asserts that "[i]t would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify CHEN by providing a positive model of the patient's teeth in a target position and fabricating an appliance as a negative of the positive model, as suggested by DESIMONE". (Office Action at pp. 2-3).

Independent claim 20 has been amended to incorporate subject matter of claim 26, and now recites that the sheet comprises "a hard polymer layer of polymeric material comprising a flexural modulus greater than about 150,000 psi; and a soft polymer layer of polymeric material comprising an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D."

With regard to the amendment, the Examiner rejected claim 26 in view of Chen and DeSimone, and further in view of U.S. Patent No. 4,791,156, (hereinafter "Hostettler"). Specifically, the Examiner states that Hostettler "teaches a soft polyurethane elastomer having a hardness not greater than about 65 A . . . which overlaps with the claimed range of hardness of about 60 A to about 85 D." (Office Action at pp. 7-8).

Applicants respectfully disagree with the Examiner's rejections under 35 U.S.C. § 103(a) at least because (1) one of ordinary skill in the art would not have had a reasonable expectation of success for combining the teachings of Chen, DeSimone, and Hostettler to produce orthodontic appliances formed using the presently claimed methods of making a dental appliance; (2) the orthodontic appliances according to the instant claims were found to exhibit

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unexpectedly beneficial results when compared with the most relevant art; and (3) the appliances according to the instant claims gave rise to considerable commercial success.

Furthermore, a method of making or using a product is patentable if the product is itself patentable (*see, e.g.*: MPEP § 821; *see also*: USPTO Official Gazette Notice, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)", published at 1184 OG 86 on March 26, 1996). As addressed in detail below, Applicants submit that the appliance is patentable, and thus the instant claims directed toward making said appliance is patentable.

These positions are supported by the present specification and further supported by the September 16, 2019 Declaration under 37 C.F.R. § 1.132 of Dr. Chunhua Li (hereafter, the "Li Declaration"), an expert in materials and biomechanical engineering and a co-inventor of the present application. The Li Declaration describes the development history and clinical evaluation comparing appliances comprising materials according to the present claims (an example of which is referred to herein as ST30—a material that has a soft polymer layer and a hard polymer layer) to appliances of the prior art, including a thermoplastic polyurethane referred to as EX30, which was the standard of care prior to the release of ST30.

1. No Reasonable Expectation of Success

One of ordinary skill in the art would not have had a reasonable expectation of success in combining the teachings of Chen, DeSimone, and Hostettler to yield the orthodontic appliances made using the claimed method, at least because of the high level of unpredictability in the art and the lack of guidance provided in Chen and DeSimone suggesting which material combinations should be used to produce a sufficient multilayer orthodontic appliance.

Over the course of more than seven years, Applicants worked diligently to develop a suitable, improved appliance that would meet various criteria for effective orthodontic treatment. (Li Declaration at ¶4). This development process was neither easy nor straightforward. During the development process, Applicants evaluated, in an iterative fashion, more than 250 distinct materials and/or material combinations for possible use in an improved appliance device. After years of development, Applicants produced the SmartTrack™ material (also referred to herein as "ST30") and related materials, which are products formed according to the instant claims

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comprising a multilayered material comprising a hard polymer layer and a soft polymer layer. The intent of this testing was to identify a suitable replacement for Align Technology's single-layer, thermoplastic polyurethane appliance product (referred to herein as "EX30"), which was the standard of the care for plastic tooth moving appliances at the time of filing, and the materials were evaluated on this basis. (*Id.* at ¶¶4-6). From among those over 250 materials tested, only the materials according to the present claims met Align's criteria for a multilayer orthodontic appliance. (*Id.* at ¶¶4-5). The tested materials included many multilayer (*e.g.*, two-layer and three-layer) materials, yet of those tested only the materials according to the present claims proved capable of performing at a level sufficient to meet Align's criteria for an orthodontic appliance, and thus as a suitable replacement for EX30. (*Id.* at ¶¶5-7).

Data obtained by Applicants during the development of the SmartTrack material provides significant evidence of the unpredictability in the art and the unexpected effectiveness of the orthodontic appliances according to the present claims. (*Id.* at ¶7). As mentioned above, the multilayer, multi-material orthodontic appliances were developed during more than seven years of diligent evaluation of over 250 materials, including numerous iterations in which materials were tested and compared, with the results used to design new materials. (*Id.* at ¶4). It was clear from many of the materials tested, including those from the Chen and DeSimone, that such materials were not effective alone or in combination to provide the improvements sought. (*Id.* at ¶5). During those evaluations, Applicants determined that only the combinations of materials according to the instant claims met Align's development criteria. (*Id.* at ¶¶5-6). It was not a simple or predictable process to identify those materials that would work together to create the multilayer apparatus which provided the unexpectedly good results. Among those 250 materials tested were more than 180 materials either generically or specifically described in Chen and/or DeSimone, including various copolymers (*see*, *e.g.,* Chen at [0036]) and unblended polysulfones (DeSimone at 6:47-59), as well as styrenic polymer materials such as acrylonitrile-butadiene-styrene (ABS) (*id.* at 6:24-37). (Li Declaration at ¶5). Specifically, none of the 23 co-polymers that were tested during the iterative development process met Align's criteria. (*Id.*). Similarly, none of the styrenic polymers nor unblended polysulfones tested met Align's criteria. (*Id.*). Thus none of these materials would have yielded an orthodontic device having the combination of sufficient elongation, time stress-relaxation, durability, and thermoform ability. (*Id.*).

Inventor Li had extensive knowledge of the teachings of Chen and DeSimone at the time of filing, and yet it still took her team many years to identify suitable materials. (*Id.* at ¶5). Inventor Li is also listed as a co-inventor of Chen, and thus she was thus intimately familiar with the teachings of Chen during the development of the orthodontic appliances according to the present claims. Inventor Li also collaborated closely with Joseph M. DeSimone and Robert E. Tricca (the inventors listed on DeSimone) while they were developing and patenting the technology described in DeSimone. (Li Declaration at ¶9). She was thus very aware of the teachings of DeSimone during the development of the orthodontic appliances according to the present claims. Even with her extensive knowledge of the teachings of Chen and DeSimone, it took her team over seven years to identify a suitable combination of polymer layers for use in the multilayer orthodontic appliances according to the present claims. (*Id.*). Thus, one of ordinary skill in the art having far less knowledge of the teachings of Chen and DeSimone would not have had a reasonable expectation of success in producing the orthodontic appliances according to the present claims based on the teachings of Chen, DeSimone, and Hostettler. (*Id.* at ¶10).

During the course of their evaluations, Applicants determined that merely combining various materials being tested into multiple layers was insufficient to improve performance relative to the EX30 material. (*Id.* at ¶¶6-7). In fact, many multilayer materials tested proved inferior to the EX30 material. These multilayer materials included combinations of materials disclosed in Chen and/or DeSimone. (*Id.*). In particular, the sole exemplified multilayer material described in Chen would not be expected to show improved performance relative to EX30. For example, Chen paragraph [0032] describes a material containing polycarbonate and polyvinyl chloride (PVC); however, PVC was later evaluated by Applicants and found to be unsuitable for use in orthodontic aligners due to its inadequate durability. (*Id.*). Based on these tests, Applicants determined that materials containing PVC, either alone or in a multilayer configuration, would be inferior to EX30. (*Id.*). For these reasons, a person of ordinary skill would not necessarily expect combinations of any polymer layers, either in general or as particularly described in Chen, to achieve performance superior to EX30.

Based on the unpredictability exhibited in the Applicants' material evaluations, a person of ordinary skill in the art would not have had a reasonable expectation of success in producing

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an effective orthodontic appliance by combining materials from Chen and DeSimone to arrive at the appliances according to the present claims. (*Id.* at ¶¶8-10).

2. Unexpected Results

Applicants have also established that the appliances according to the present claims are unexpectedly superior to the most relevant art. The Li Declaration describes two clinical studies comparing appliances made from the prior art material described in paragraph [0003] of Chen—a thermoplastic polyurethane called EX30—to appliances made of a multilayer material, referred to as ST30, that has a hard polymer layer comprising a flexural modulus greater than about 150,000 psi and soft polymer layers having an elongation at break greater than about 200% and a hardness from about 60 A to about 85 D. (Li Declaration at ¶¶11-18).

As described in the Li Declaration, each study found that ST30 appliances provided strongly superior performance relative to the closest prior art appliances. In the first study described, a group of 1,015 patients treated with ST30 appliances for five months were 26% more likely than equivalent patients treated with EX30 appliances to have their teeth respond to treatment as intended. (*Id.* at ¶¶11-15). This result establishes the superiority of ST30 to EX30 to a high degree of statistical significance ($p < 0.001$). (*Id.* at ¶14). A second study of 110,000 cases confirmed these findings, demonstrating strongly significant ($p < 0.001$) improvements in predictability in tooth movement for 14 different movement types. (*Id.* at ¶16, Appendix B). Overall, patients treated with ST30 appliances showed a greater than 75% improvement in tooth movement predictability over patients treated with EX30 appliances. (*Id.* at ¶17). This surprising improvement would not have been predicted by a person of ordinary skill in the art. (*Id.*).

In the above-described clinical studies, the appliances contained a hard polymer layer, which provided the forces needed to generate movement of the teeth, while the soft polymer layers increased the durability of the aligners allowing them to better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment, as well as improving the elastic properties allowing for less degradation in the shape of the teeth receiving cavities. The surprising results observed for the ST30 appliances can be attributed to the combination of the hard and soft polymer materials combined together in an appliance according to the present claims. (*Id.* at ¶¶15, 18). Although the clinical results were found for a three layer appliance, a single hard polymer layer and a single soft polymer layer

according to the current claims would also be expected to exhibit these beneficial functions in a two-layered appliance because the superior performance properties flow from the claimed combination of polymer layers utilized together. (*Id.*). Thus, one would expect superior results from the appliances formed using the methods of current claim 20.

Comparison of EX30 and the Claimed Materials is Proper for Establishing Unexpected Results

EX30 was the standard of care in orthodontic appliances prior to the development of ST30, and a person of ordinary skill would have considered it the closest relevant art. Thus, the skilled artisan would consider the superiority of the orthodontic appliances according to the present claims relative to EX30 to be predictive of similar superiority of ST30 relative to other prior art appliances. (Li Declaration at ¶17). During the course of Applicants' evaluations, they determined that merely combining any materials into multiple layers was insufficient to improve performance relative to the EX30 material. (*Id.* at ¶6). In fact, many multilayer materials tested proved inferior to the EX30 material. (*Id.*). Based on these evaluations, none of these inferior multilayer materials would be expected to achieve performance comparable to EX30, much less to exceed the performance of EX30. Because the EX30 material was the standard of care during Applicants' development of the SmartTrack material and related materials, and was superior to many multilayer materials tested, the EX30 material should be considered a proper comparison for assessing unexpected results. (*See* MPEP § 716.02(e)(I) ("Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner.")). Additionally, it is not a trivial matter to conduct a clinical trial. It requires regulatory approval and a considerable amount of time and thus cannot be done for any or all materials. Accordingly, because the test comparison provided compares the standard of care (the material commercially being utilized), it should be accepted as the appropriate comparison for demonstrating unexpected results.

Additionally, the Li Declaration establishes that the surprising results observed for the ST30 appliances are attributed to the combination of the hard and soft polymer layers combined in layers together in an appliance according to the present claims. (*Id.* at ¶¶15, 18). The Li Declaration further establishes that a single hard polymer layer and a single soft polymer layer according to the current claims would also be expected to exhibit these beneficial functions in a two-layered appliance. (*Id.*). Thus, the experimental comparisons between EX30 and ST30 as

described in the Li Declaration should be accepted as the appropriate comparison for demonstrating unexpected results for the appliances according to the present claims.

Therefore, Applicants have demonstrated that there would have been no reasonable expectation of success in combining the cited art to achieve the presently claimed invention and that the appliances according to the present claims produce unexpectedly positive results relative to the closest relevant art.

3. Commercial Success

In addition to the comparative, developmental, and clinical data presented above, the commercial success of appliances comprising the ST30 material as set forth in the present claims provides further evidence of their non-obviousness. Prior to the Applicants' development of the ST30 material, the primary appliance material in the orthodontic market was EX30. (Li Declaration at ¶19). Upon establishing the superiority of ST30 appliances relative to EX30 appliances, Align Technology switched virtually all new appliance manufacturing to ST30 over the course of only a few months. (*Id.*). Thereafter, ST30 appliances captured over 90% of the total US market for clear plastic orthodontic appliances. (*Id.; see also:* Baird 2014 Analyst Report at 6, and Baird Q3 2013 Report at 9 (submitted in an IDS filed March 31, 2017)). This striking commercial success was due to the superior performance of ST30 appliances to EX30 and other appliances on the market. (Li Declaration at ¶¶19-20).

Indeed, as the Federal Circuit has stated that, "[w]hen a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention." *GrafTech Int'l Holdings, Inc. v. Laird Techs. Inc.*, No. 2015-1796, 652 Fed. Appx. 973, 978-79 (Fed. Cir. June 17, 2016) (quoting *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997)). As appliances made of the ST30 material are appliances according to the present claims, and as these appliances have demonstrated commercial success as shown by significant sales in the relevant market of clear plastic orthodontic appliances, it is presumed that the invention as claimed has led to this commercial success.

Independent analysis provides further evidence that the commercial success of ST30 appliances is due to the appliances' superior performance. An analysis by Stifel, Nicolaus &

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Company, Inc. shortly after the introduction of ST30 concluded that the introduction of SmartTrack (ST30 material) appliances resulted in an increase from 59% to 63% in the total addressable market for orthodontic malocclusions. (Stifel 4Q13 Report at 6 (submitted in an IDS filed March 31, 2017)). Survey results confirmed the conclusion among doctors that SmartTrack appliances allow a larger range of cases to be treated:

> Approximately 80% of our respondents now believe SmartTrack will help them treat more complex cases. Over 60% of our doctors said that SmartTrack has already allowed them to perform more complex cases, an increase from 48% and 29% when we surveyed the same respondents in July and April, respectively.

(Id. at 4). Thus, in addition to commanding a dominant market share, ST30 appliances have increased the size of the market treatable by clear plastic orthodontic appliances.

Accordingly, in addition to the unexpected results and lack of reasonable expectation of success described above, the commercial success of ST30 appliances according to the present claims provides evidence of the claims' non-obviousness.

The Li Declaration establishes that the commercial successes observed for the SmartTrack appliances can be attributed to the combination of the hard and soft polymer material layers combined together in an appliance according to the present claims. (*Id.* at ¶¶19-20). Thus, the commercial successes observed for ST30 as described in the Li Declaration should be accepted as providing evidence for the patentability of the present claims.

Independent claim 20 is not obvious over the combination of Chen, DeSimone, and Hostettler for at least the reasons described above. Claims 21-25 and 27-30 depend from claim 20, and are therefore allowable for similar reasons, as well as on their own merits. Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 20-25 and 27-30 under 35 U.S.C. § 103(a) is respectfully requested.

ii. Claim 26

Claim 26 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen and DeSimone as applied to claim 20, and further in view of Hostettler (U.S. Patent No. 4,791,156, hereinafter "Hostettler"). Specifically, the Examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify CHEN and DESIMONE by having a soft layer with a hardness not greater than 65A . . . in order

to provide a soft layer which provides tissue relief, is inexpensive, trouble-free, and easy to keep clean." (Office Action at pp. 7-8).

As discussed further above, amended claim 20 is allowable over the combined references of Chen, DeSimone, and Hostettler. Dependent claim 26 is at least allowable for depending from allowable independent claim 20, and on its own merits. Accordingly, for the reasons set forth above, withdrawal of the rejection of claim 26 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 23-2415.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-883-2500.

Respectfully submitted,

Dated: September 16, 2019

/Garrett T. Potter/

Garrett T. Potter, Ph.D.
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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-19. (Canceled)

20. (Currently Amended) A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising:

a hard polymer layer of a hard polymeric material comprising a flexural modulus greater than about 150,000 psi; and

a soft polymer layer of a soft polymeric material comprising an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D; ~~disposed between a first soft polymer layer and a second soft polymer layer;~~

providing a positive model of the patient's teeth in a target position; and

fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. (Currently Amended) The method of claim 20, wherein the hard ~~polymer layer~~ polymeric material comprises ~~a layer of~~ a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. (Currently Amended) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers [[are]] each independently ~~selected from a group consisting of~~ comprise a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene

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terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, [[and]] or a polytrimethylene terephthalate.

23. (Currently Amended) The method of claim 20, wherein ~~each of the first~~ the soft ~~polymer layer and the second soft polymer layer independently~~ polymeric material comprises ~~a layer of~~ a styrenic block copolymer ~~(SBC)~~, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer ~~(TPE)~~, a thermoplastic vulcanizate ~~(TPV)~~ elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. (Currently Amended) The method of claim 20, wherein ~~at least one of the first~~ the soft polymer layer ~~and the second soft polymer layer~~ comprises at least two layers, and wherein the at least two layers [[are]] each independently ~~selected from the group consisting of~~ comprise a styrenic block copolymer ~~(SBC)~~, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer ~~(TPE)~~, a thermoplastic vulcanizate ~~(TPV)~~ elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. (Currently Amended) The method of claim 20, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, ~~a flexural modulus greater than about 150,000 psi,~~ a stress relaxation greater than about 10% at 24 hours testing in a wet environment, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. (Currently Amended) The method of claim 20, wherein the ~~first~~ soft polymer layer ~~and the second soft polymer layer each independently comprise~~ comprises at least one of ~~a hardness of about 60A to about 85D,~~ an ultimate tensile strength of greater than about 5000 psi, ~~an elongation at break of greater than about 200 %,~~ a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

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27. (Original) The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

28. (Original) The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. (Currently Amended) The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising [[a]] the hard polymer layer of the hard polymeric material ~~disposed between a first~~ and the soft polymer layer of the soft polymeric material ~~and a second soft polymer layer~~.

30. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers.

31. (New) The method of claim 20, wherein the appliance comprises three or more polymer layers, the three or more polymer layers comprising the hard polymer layer and the soft polymer layer.

32. (New) The method of claim 31, wherein the three or more polymer layers alternate between soft and hard polymer layers.

33. (New) The method of claim 31, wherein the hard polymer layer is positioned adjacent to one or more soft polymer layers, the one or more soft polymer layers comprising the soft polymer layer.

34. (New) The method of claim 31, wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer, the second soft polymer layer comprising an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D.

35. (New) The method of claim 20, wherein the appliance comprises a co-extruded material.

36. (New) The method of claim 20, wherein the appliance comprises a thickness of between 500 μm and 1200 μm.

37. (New) A method of making a plurality of dental appliances for positioning a patient's teeth, the method comprising:

providing a sheet comprising:

a hard polymer layer of a hard polymeric material comprising a flexural modulus greater than about 150,000 psi; and

a soft polymer layer of a soft polymeric material comprising an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a plurality of positive models of the patient's teeth, each in a target position; and

fabricating the plurality dental appliances, each as a negative of at least one of the plurality of positive models comprising thermoforming the sheet over the at least one positive model.

38. (New) The method of claim 37, wherein the hard polymeric material comprises a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

39. (New) The method of claim 37, wherein the soft polymeric material comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 12/12/2019

WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER
MONTIEL, CAROLINE

ART UNIT	PAPER NUMBER
1748	

NOTIFICATION DATE	DELIVERY MODE
12/12/2019	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):

patentdocket@wsgr.com

Office Action Summary	Application No. 15/476,655	Applicant(s) LI et al.	
	Examiner CAROLINE MONTIEL	Art Unit 1748	AIA (FITF) Status No

-- 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 9/16/2019.

☐ 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) 20-39 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 20-39 is/are rejected.

8) ☐ Claim(s) _____ 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 3/31/2017 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 3/12/2109; 9/16/2019.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

1. The communication dated 9/16/2019 has been entered and fully considered.

2. Claims 20-24, 26, and 29 have been amended. Claims 31-39 are new.

3. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment and Arguments

4. The reference is a statutory bar under pre-AIA 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131(a).

5. The declaration under 37 CFR 1.132 filed 9/16/2019 is insufficient to overcome the rejection of claim 20 and 37 based upon DESIMONE as set forth in the current Office action below because: facts presented are not germane to the rejection below and DESIMONE is in the same field of endeavor, dental appliances, and teaches the desirable properties.

6. Furthermore, DESIMONE is 102(b) for claims 20 and 37, but regarding the dependent claims, the Examiner would add the following:

a. The Applicant has not shown EX30, the standard, is commensurate in scope with DESIMONE and CHEN because DESIMONE and CHEN teach at least two layer devices compared to the EX30, which is a single polyurethane [paragraph 4 of declaration]. In paragraphs 4 and 5 of the declaration, it is stated that none of the materials generically or specifically described in DESIMONE or CHEN would have yielded an orthodontic device having sufficient elongation, time stress-relaxation, durability, and thermoform ability; however, there is not data shown in regards to these properties.

b. Furthermore, Applicant argues there is a sole exemplified multilayer material described in CHEN; however, CHEN further teaches that the various inner and outer

layers can be made from a homopolymer, cross-linked homopolymer, copolymer, polycarbonate, cross-linked copolymer, a copolymer blend of thermoplastics, and/or similar material [0036]. Also, the Applicant argues that the PVC and polycarbonate layers of CHEN are unsuitable, but has not provided any evidence supporting that it is unsuitable. How are these layers inadequate?

c. ST30 shows improved results, but it is not clear what the polymer layers are composed of or what physical properties they have. The Applicant has provided no evidence to support ST30 being commensurate in scope to the claimed invention. Furthermore, while Applicant tried many combinations, one of ordinary skill in the art would have had the benefit of the disclosure of CHEN and DESIMONE, which teaches multilayered devices and various properties. Applicant has provided no specific scientific evidence or evidence of laboratory hardship to support that one of ordinary skill in the art would have expected failure and has further provided no evidence that the skilled artisan would have expected failure given the benefit of the teachings of CHEN and DESIMONE. Also, it is not clear that the layers of CHEN and DESIMONE would not have given the same results of ST30 as no data was given regarding the composition of ST30. One of ordinary skill would have been motivated and have tried a soft layer and a hard layer device based on DESIMONE and CHEN teachings, and the Applicant has provided no evidence to refute that the motivation provided by CHEN and DESIMONE would have been inadequate to support combining elements as presented in the rejection. There is nothing in DESIMONE and CHEN that would lead one of ordinary skill in the art to expect that undue experimentation would be necessary to combine the teachings set

forth in the rejection as both DESIMONE and CHEN teach exemplified layers and suitable materials for each layer.

d. The Applicant argues that ST30 as a single hard layer and single soft layer would also exhibit beneficial functions, as stated in paragraphs 15 and 18, but offers no evidence. ST30 is a construction of a hard layer disposed between two soft layers. At best, the Applicant has shown that this provides improvements over a single polyurethane layer. Furthermore, the declaration states that one would also expected an appliance with layers of a single hard polymer material and a single soft polymer material to exhibit beneficial performance relative to EX30 appliances; therefore, DESIMONE would be expected to have beneficial performance and also the same properties as ST30 [paragraph 18 of the declaration].

Claim Rejections - 35 USC § 102

1. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

2. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claim(s) 20-21, 23, 25-30 and 37-39 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by DeSimone et al. (U.S. 7,641,828), hereinafter DESIMONE, considered with Pudleiner et al. (U.S. PGPUB 2015/0140300), hereinafter PUDLEINER**.

4. Regarding **claim 20**, DESIMONE teaches: *A method of making a dental appliance for positioning a patient's teeth* (DESIMONE teaches methods of making dental appliances for moving patient's teeth [Abstract]), *the method comprising: providing a sheet comprising* (DESIMONE teaches providing a sheet [Col. 1, lines 64-67 – Col. 2, lines 1-3; claim 1])*: a hard polymer layer of a hard polymeric material comprising a flexural modulus greater than about 150,000 psi* (DESIMONE teaches a hard polymer layer (first transparent material: Col. 9, lines 30-37) comprising a flexural modulus greater than 200,000 psi [Col. 2, lines 16-29], which is within the claimed range)*; and a soft polymer layer of a soft polymeric material* (DESIMONE teaches a soft polymer layer (the coating of a second transparent material) [Col. 2, lines 42-48].) *comprising an elongation at break of greater than about 200%* (DESIMONE teaches the soft polymer layer has an elongation at break of greater than 80%, which encompasses the claim [Col. 2, lines 50-55]), *and a hardness from about 60 A to about 85 D* (DESIMONE teaches using a layer of the second transparent material, which Examiner is interpreting as the soft polymer layer includes ISOPLAST 2530 [Col. 10, lines 14-20], which has a hardness of 82D, which is within the claimed range, shown by PUDLEINER [0142])*; providing a positive model of the patient's teeth in a target position* (DESIMONE teaches positive tooth models of a patient's teeth using intermediate and final data sets, examiner is interpreting the intermediate and final data sets as target positions [Col. 3, lines 53-67-Col. 4, lines 1-7])*; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model* (DESIMONE further teaches fabricating positioning appliances with a molding machine that

produces shells of dental appliances from a thermoformable material [Col. 4, lines 3-12, examiner is interpreting the shells as negatives of the positive models]).

5. Regarding **claim 21**, DESIMONE teaches: *wherein the hard polymer layer comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof* (DESIMONE teaches the hard polymer layer (first transparent layer) used may be polyesters [Col. 9, lines 10-17]).

6. Regarding **claim 23**, DESIMONE teaches: *wherein the soft polymeric material comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof* (DESIMONE teaches the soft polymeric material (second transparent material) can be silicone, which Examiner is interpreting as silicone rubber [Col. 9, lines 66-67 – Col. 10, lines 1-5]).

7. Regarding **claim 25**, DESIMONE further teaches: *wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet environment, and a light transmission between 400 nm and 800 nm of greater than about 75%* (DESIMONE teaches a transparent polymeric material preferably having a tensile strength at

yield of greater than 6,000 psi, which overlaps with the claimed tensile strength at yield of between about 4000 psi and 6500 psi [Col. 7, lines 42-44, examiner is interpreting transparent polymeric material as a hard polymer layer as DESIMONE states thermoplastic polyurethanes can be used]).

8. Regarding **claim 26**, DESIMONE teaches: *wherein the soft polymer layer comprises at least one of an ultimate tensile strength of greater than about 5000 psi, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%* (DESIMONE teaches the coating (soft polymer layer) has a flexural modulus of greater than 200,000 psi, which is within the claimed range [Col. 2, lines 50-56]).

9. Regarding **claim 27**, DESIMONE further teaches: *further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth* (DESIMONE teaches fabricating a plurality of appliances based on different arrangements of the patient's teeth [Col. 3, 53-67-Col. 4, lines 1-7]).

10. Regarding **claim 28**, DESIMONE further teaches: *wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models* (DESIMONE teaches digitally staging a plurality of digital models of the patient's teeth [Col. 3, lines 53-67] and fabricating a plurality of appliances [Col. 4, lines 7-8]).

11. Regarding **claim 29**, DESIMONE teaches: *wherein two or more of the plurality of appliances comprise a sheet comprising the hard polymer layer of the hard polymeric material and the soft polymer layer of the soft polymeric material* (DESIMONE teaches a plurality of appliances [Col. 4, lines 7-12]. DESIMONE further teaches the appliance has a hard polymer

layer made of polymeric material [first transparent material: Col. 9, lines 30-37] and a soft polymer layer (coating of a second transparent material) [Col. 2, lines 42-48]).

12. Regarding **claim 30**, DESIMONE further teaches: *wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers* (DESIMONE teaches other materials that can be formed and annealed include laminates and/or blends of transparent polymeric material [Col. 7, lines 24-35]).

13. Regarding **claim 37**, DESIMONE teaches: *A method of making a plurality of dental appliances for positioning a patient's teeth* (DESIMONE teaches methods of making dental appliances for moving patient's teeth [Abstract]), *the method comprising: providing a sheet* (DESIMONE teaches providing a sheet [Col. 1, lines 64-67 – Col. 2, lines 1-3; claim 1]) *comprising: a hard polymer layer of a hard polymeric material comprising a flexural modulus greater than about 150,000 psi* (DESIMONE teaches a hard polymer layer (first transparent material: Col. 9, lines 30-37) comprising a flexural modulus greater than 200,000 psi [Col. 2, lines 16-29], which is within the claimed range)*; and a soft polymer layer of a soft polymeric material* (DESIMONE teaches a soft polymer layer (the coating of a second transparent material) [Col. 2, lines 42-48]) *comprising an elongation at break of greater than about 200%* (DESIMONE teaches the soft polymer layer has an elongation at break of greater than 80%, which encompasses the claim [Col. 2, lines 50-55]), *and a hardness from about 60 A to about 85 D* (DESIMONE teaches using a layer of the second transparent material, which Examiner is interpreting as the soft polymer layer includes ISOPLAST 2530 [Col. 10, lines 14-20], which has a hardness of 82D, which is within the claimed range, as evidenced by PUDLEINER [0142])*; providing a plurality of positive models of the patient's teeth, each in a target position* (DESIMONE teaches positive tooth models of a patient's teeth using intermediate and final data

sets, examiner is interpreting the intermediate and final data sets as target positions [Col. 3, lines 53-67-Col. 4, lines 1-7]); *and fabricating the plurality of dental appliances, each as a negative of at least one of the plurality of positive models comprising thermoforming the sheet over the at least one positive model* (DESIMONE teaches fabricating positioning appliances with a molding machine that produces shells of dental appliances from a thermoformable material [Col. 4, lines 3-12, examiner is interpreting the shells as negatives of the positive models]. DESIMONE further teaches a plurality of appliances [Col. 4, lines 7-12].).

14. Regarding **claim 38**, DESIMONE teaches: *wherein the hard polymeric material comprises a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof* (DESIMONE teaches the hard polymer layer (first transparent layer) used may be polyesters [Col. 9, lines 10-17]).

15. Regarding **claim 39**, DESIMONE teaches: *styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof* (DESIMONE teaches the soft polymeric material (second transparent material) can be silicone, which Examiner is interpreting as silicone rubber [Col. 9, lines 66-67 – Col. 10, lines 1-5]).

Claim Rejections - 35 USC § 103

16. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

17. The following is a quotation of pre-AIA 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, 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 negatived by the manner in which the invention was made.

18. Claims 22, 24 and 31-36 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (U.S. 7,641,828), hereinafter DESIMONE, considered with Pudleiner et al. (U.S. PGPUB 2015/0140300), hereinafter PUDLEINER, in view of Chen et al. (U.S. PGPUB 2009/0246724), hereinafter CHEN (DESIMONE and CHEN are provided in the IDS of 3/31/2017).

19. Regarding **claim 22**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the hard polymer layer comprises at least two layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate* (CHEN teaches the hard polymer layer comprises of at least two layers (Figs. 4A-

4D; 5; [0031-0033; 0035-0036], examiner is interpreting inner layers (132,150) as hard polymer layer). CHEN further teaches a hard polymer layer being a polycarbonate ([0036], examiner is interpreting inner layers (150) as hard polymer layer)). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with two hard layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

20. Regarding **claim 24**, DESIMONE teaches: *wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer* (DESIMONE teaches the soft polymer layer (second transparent material) is made of silicone, which Examiner is interpreting as silicone rubber [Col. 9, lines 66-67 – Col. 10, lines 1-5]. It would have been obvious to one of ordinary skill in the art at the time of the effective filing date of applicant's invention to duplicate the soft layer into two layers, since it has been held that a mere duplication of working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

21. In the alternative, CHEN teaches having at least two soft layers [Figs. 4A-4D; 0030-0031]. CHEN further teaches the soft polymer can be a copolymer blend of thermoplastics [0036], examiner is interpreting outer layers (152, 134) as soft polymer layer. CHEN further teaches thermoplastic elastomer can be used for the appliance [0025; Figs. 4A-4C, 5]. It would

have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with two layers in the soft polymer layer, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

22. Regarding **claim 31**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the appliance comprises three or more polymer layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the appliance comprises three or more polymer layers, the three or more layers comprising the hard polymer layer and the soft polymer layer* (CHEN teaches an appliance with three or more polymer layers [Fig. 4A-4C]. CHEN further teaches the layers comprise a hard polymer layer and a soft polymer layer [0026]). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with several polymer layers in the appliance, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

23. Regarding **claims 32-33**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the layers alternate. In the same field of endeavor, dental appliances, CHEN teaches the layers alternate between the soft layers (outer layers) and the hard layer (inner layers) [Figs. 4A-4C] and the hard layer is adjacent to the polymer layers [Figs 4A-4C; 0032; 0036]. It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with several polymer layers in the appliance and alternate the layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and

application requirements [0031] and for the harder segment to control the restoration of an original shape [0026].

24. Regarding **claim 34**, DESIMONE teaches all the limitations of the claimed invention as stated above, including a hard layer and a soft layer comprising an elongation at break of greater than about 200% [Col. 2, lines 50-55] and a hardness from about 60 A to about 85 D (soft polymer layer includes ISOPLAST 2530 [Col. 10, lines 14-20], which has a hardness of 82D, which is within the claimed range, as shown by PUDLEINER [0142]). Furthermore, It would have been obvious to one of ordinary skill in the art at the time of the effective filing date of applicant's invention to duplicate the soft layer into two layers with the same properties, since it has been held that a mere duplication of working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

25. DESIMONE fails to teach wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer. In the same field of endeavor, dental appliances, CHEN teaches *wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer* [Figs. 4A-4C]. It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with a hard layer disposed between two soft layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

26. Regarding **claim 35**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the appliance comprises a co-extruded material. In the same field of endeavor, dental appliances, CHEN teaches the layers may be formed by a process, such as thermoforming or similar process, such as co-extrusion, lamination or any other process

where layers are formed [0031]. It would have been obvious to one of ordinary skill in the art at the time of the effective filing date of the applicant's invention to have the layers co-extruded since it is known in the art that layers can be made by co-extrusion.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc., 127* S.Ct. 1727, 82 USPQ2d 1385 (2007).

27. Regarding **claim 36**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the hard polymer layer comprises at least two layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the appliance comprises a thickness between 500 μm and 1200 μm* (CHEN teaches an appliance with three or more layers and that the inner layers (132) as well as the outer layers (134) may each have different thicknesses, such as 5 or 10 mils [0030-0031]. Fig. 4C shows an appliance with two inner layers and two outer layers. If each layer is 10 mils, then all the layers together form the appliance and the appliance would have a thickness of 1016 μm (10 mils = 254 μm), which meets the claimed range). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE by having the appliance thickness about 1016 μm, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031] and have variable thickness depending on the modulus requirements [0036].

Conclusion

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CAROLINE MONTIEL whose telephone number is (571)272-2529. The examiner can normally be reached on MONDAY - FRIDAY 8:30 A.M. - 5:00 P.M.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ABBAS RASHID can be reached on (571) 270-7457. 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). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.M./
Examiner, Art Unit 1748

/PETER L VAJDA/
Primary Examiner, Art Unit 1737
12/9/2019

Notice of References Cited	Application/Control No. 15/476,655	Applicant(s)/Patent Under Reexamination LI et al.	
	Examiner CAROLINE MONTIEL	Art Unit 1748	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-20150140300-A1	05-2015	Pudleiner; Heinz	B32B27/08	428/215
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61C 7/08	03/07/2019	CM
B32B 7/02	03/07/2019	CM
B29C 51/14	03/07/2019	CM
B32B 27/40	03/07/2019	CM
B32B 25/08	03/07/2019	CM
B32B 25/20	03/07/2019	CM
B32B 27/08	03/07/2019	CM
B32B 27/281	03/07/2019	CM
B32B 27/286	03/07/2019	CM
B32B 27/308	03/07/2019	CM
B32B 27/32	03/07/2019	CM
B32B 27/34	03/07/2019	CM
B32B 27/36	03/07/2019	CM
B32B 27/365	03/07/2019	CM
B29K 2995/0077	03/07/2019	CM
B32B 2250/24	03/07/2019	CM
B29L 2031/753	03/07/2019	CM
B29K 2067/00	03/07/2019	CM
B29K 2075/00	03/07/2019	CM
B29K 2995/0026	03/07/2019	CM
B29K 2995/007	03/07/2019	CM
B29K 2995/0082	03/07/2019	CM
B32B 2307/54	03/07/2019	CM
B32B 2250/03	03/07/2019	CM
B32B 2274/00	03/07/2019	CM
B32B 2307/412	03/07/2019	CM

/C.M./ Examiner, Art Unit 1748	

ClearCorrect Exhibit 1011, Page 647 of 890

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

B32B 2307/536	03/07/2019	CM
B32B 2535/00	03/07/2019	CM
B32B 2307/546	03/07/2019	CM
A61C 7/08 and keywords	11/20/2019	CM
B32B 7/02 and keywords	11/20/2019	CM
B29C 51/14 and keywords	11/20/2019	CM
B32B 27/40 and keywords	11/20/2019	CM
B32B 25/08 and keywords	11/20/2019	CM
B32B 25/20 and keywords	11/20/2019	CM
B32B 27/08 and keywords	11/20/2019	CM
B32B 27/281 and keywords	11/20/2019	CM
B32B 27/286 and keywords	11/20/2019	CM
B32B 27/308 and keywords	11/20/2019	CM
B32B 27/32 and keywords	11/20/2019	CM
B32B 27/34 and keywords	11/20/2019	CM
B32B 27/36 and keywords	11/20/2019	CM
B32B 27/365 and keywords	11/20/2019	CM
B29K 2995/0077 and keywords	11/20/2019	CM
B32B 2250/24 and keywords	11/20/2019	CM
B29L 2031/753 and keywords	11/20/2019	CM
B29K 2067/00 and keywords	11/20/2019	CM
B29K 2075/00 and keywords	11/20/2019	CM
B29K 2995/0026 and keywords	11/20/2019	CM
B29K 2995/007 and keywords	11/20/2019	CM
B29K 2995/0082 and keywords	11/20/2019	CM
B32B 2307/54 and keywords	11/20/2019	CM
B32B 2250/03 and keywords	11/20/2019	CM
B32B 2274/00 and keywords	11/20/2019	CM
B32B 2307/412 and keywords	11/20/2019	CM

/C.M./ Examiner, Art Unit 1748	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
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B32B 2307/536 and keywords	11/20/2019	CM
B32B 2535/00 and keywords	11/20/2019	CM
B32B 2307/546 and keywords	11/20/2019	CM

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**
See EAST search history	03/07/2019	CM
See EAST inventor search	03/07/2019	CM
See updated Inventor/Applicant EAST search	11/20/2019	CM
See updated EAST search history	11/20/2019	CM

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6390812	05-21-2002	CHISHTI; Muhammad et al.	
	002	US-6485298	11-26-2002	CHISHTI; Muhammad et al.	
	003	US-6705861	03-16-2004	CHISHTI; Muhammad et al.	
	004	US-7121825	10-17-2006	CHISHTI; Muhammad et al.	
	005	US-20020192617	12-19-2002	PHAN; Loc X. et al.	
	006	US-20030190576	10-09-2003	PHAN; Loc X. et al.	
	007	US-20040170941	09-02-2004	PHAN; Loc X. et al.	
	008	US-20070231765	10-04-2007	PHAN; Loc X. et al.	
	009	US-20080020337	01-24-2008	PHAN; Loc X. et al.	
	010	US-20190159870-A1	05-30-2019	LI; Chunhua et al.	
	011	US-20190183611-A1	06-20-2019	LI; Chunhua et al.	
	012	US-20190231484-A1	08-01-2019	LI; Chunhua et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-0180762-A2	11-01-2001	ALIGN TECHNOLOGY INC [US], et al.		☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	09/23/2019

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Sheet 2 of 4

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Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	002	WO-0180764-A1	11-01-2001	ALIGN TECHNOLOGY INC [US], et al.		☐

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
			☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

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Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Garrett Potter/	Date (YYYY-MM-DD)	2019-09-16
Name/Print	Garrett Potter	Registration Number	76,602

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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.
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	437	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/02/14 10:59
S2	939	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/02/14 10:59
S3	2184	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:26
S4	108400	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S5	2363	S4 and dental	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S6	4722	S4 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:37
S7	2	13/470,681.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/14 11:42
S8	4	("2009/0246724").URPN.	USPAT	OR	ON	2019/02/19 10:41
S9	108672	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:42

		B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.				
S11	121	(dental teeth) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:43
S12	50	(dental teeth) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:45
S13	53	dental and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:47
S14	98	(oral dental) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:00
S15	40	(dental oral) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:01
S16	2480	(oral dental) and (braces retainers) and polymeric adj material	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:03
S17	18	(oral dental) and (braces retainers) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:04
S18	3542	(A61C7/00).IPCR.	US-PGPUB; USPAT	OR	OFF	2019/02/19 13:53
S19	124	S18 and layers and polymeric near5 material and (hardness hard durometer stiff stiffness) and sheet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 13:55
S20	821	S18 and (polyester co-polyester polycarbonate "thermoplastic polyurethane" polypropylene polyethylene polypropylene "polyethylene copolymer" acrylic "cyclic block copolymer" polyetheretherketone polyamide "polyethylene terephthalate" "polybutylene terephthalate" polyetherimide polyethersulfone "polytrimethylene terephthalate")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:17
S21	201	S18 and ((styrenic adj1 block adj1	US-PGPUB;	OR	ON	2019/02/19

		copolymer "SBC") "silicone rubber" "elastomeric alloy" (thermoplastic adj1 elastomer "TPE") (thermoplastic adj1 vulcanizate adj1 elastomer "TPV" adj1 elastomer) "polyurethane elastomer" "block copolymer elastomer" "polyolefin blend elastomer" "thermoplastic co-polyester elastomer" "thermoplastic polyamide elastomer")	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			14:19
S22	125	S21 and S20	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:20
S23	81	soft adj1 polymer adj1 layer and hard adj1 polymer adj1 layer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/21 15:43
S24	172	("20010041320" | "20020006597" | "20030009252" | "20030139834" | "20030224311" | "20040128010" | "20040146670" | "20050055118" | "20070148608" | "20080299507" | "20090087808" | "20090239188" | "20090246724" | "20100055639" | "20150140300" | "20160228215" | "2467432" | "3407500" | "3600808" | "3660900" | "3683502" | "3738005" | "3860803" | "3916526" | "3922786" | "3950851" | "3983628" | "4014096" | "4195046" | "4253828" | "4324546" | "4324547" | "4348178" | "4478580" | "4500294" | "4504225" | "4505673" | "4526540" | "4575330" | "4575805" | "4591341" | "4609349" | "4611288" | "4656860" | "4663720" | "4664626" | "4676747" | "4742464" | "4755139" | "4763791" | "4791156" | "4793803" | "4798534" | "4836778" | "4837732" | "4850864" | "4850865" | "4856991" | "4877398" | "4880380" | "4889238" | "4890608" | "4935635" | "4936862" | "4937928" | "4941826" | "4964770" | "4975052" | "4983334" | "5011405" | "5017133" | "5024790" | "5027281" | "5035613" | "5055039" | "5059118" | "5100316" | "5121333" | "5125832" | "5128870" | "5130064" | "5131843" | "5131844" | "5139419" | "5145364" | "5176517" | "5184306" | "5186623" | "5257203" | "5273429" | "5278756" | "5328362" | "5338198" | "5340309" | "5342202" | "5368478" | "5382164" | "5395238" | "5431562" | "5440326" | "5440496" | "5447432" | "5452219" | "5454717" | "5456600" | "5474448" | "5518397" | "5528735" | "5533895" | "5542842" | "5549476" | "5562448"	US-PGPUB; USPAT	OR	ON	2019/03/07 09:13

		"5587912" | "5605459" | "5607305" | "5614075" | "5621648" | "5645420" | "5645421" | "5655653" | "5683243" | "5692894" | "5725376" | "5725378" | "5733126" | "5740267" | "5742700" | "5799100" | "5800174" | "5823778" | "5848115" | "5857853" | "5866058" | "5879158" | "5880961" | "5880962" | "5934288" | "5957686" | "5964587" | "5971754" | "5975893" | "6015289" | "6044309" | "6049743" | "6062861" | "6068482" | "6099314" | "6123544" | "6152731" | "6183248" | "6190165" | "6217325" | "6217334" | "6244861" | "6309215" | "6315553" | "6322359" | "6350120" | "6382975" | "6398548" | "6402707" | "6482298" | "6524101" | "6554611" | "6572372" | "6629840" | "6705863" | "6722880" | "7641828" | "8235713" | "8496473" | "RE35169").PN.				
S25	4	"4791156".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/23 15:58
S26	112431	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:05
S27	5186	S26 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:06
S28	29	elongation near20 (2{d2} adj2 ("%" percent)) and S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:07
S29	3073	elongation near20 (2{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:12
S30	1879	elongation near20 (4{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:14
S31	2816	elongation near20 (3{d2} adj2 ("%"	US-PGPUB;	OR	ON	2019/09/23

ClearCorrect Exhibit 1011, Page 657 of 890

		percent))	USPAT; USOCR; EPO; JPO; DERWENT			16:17
S32	6273	S29 S30 S31	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S33	40	S27 and S32	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S34	29226	modulus near20 psi	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S35	1	S33 and S34	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:22
S36	7	("10052176" | "20080230938" | "20090130438" | "20170007362" | "6667101" | "9655691" | "9655693").PN.	US-PGPUB; USPAT	OR	ON	2019/09/23 16:24
S37	2	"2004146670".pn.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 17:12
S38	12	("20020192617" | "20030190576" | "20040170941" | "20070231765" | "20080020337" | "20190159870" | "20190183611" | "20190231484" | "6390812" | "6485298" | "6705861" | "7121825").PN.	US-PGPUB; USPAT	OR	ON	2019/09/23 17:18
S39	58583	resin near20 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S40	47502	resin near10 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S41	237081	resin near10 polyurethane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S42	9409	S40 and S41	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S43	3	ISOPLAST near5 "2530" near10	US-PGPUB;	OR	ON	2019/09/25

		(hardness durometer)	USPAT; USOCR; EPO; JPO; DERWENT			10:04
S44	472	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/09/25 10:17
S45	121112	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 14:57
S46	5358	S45 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 14:57
S47	36	elongation near20 (3{d2} adj2 ("%" percent)) and S46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:14
S48	5358	S45 and (dental teeth tooth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:22
S49	36	elongation near20 (3{d2} adj2 ("%" percent)) and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:24
S50	30	elongation near20 (2{d2} adj2 ("%" percent)) and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:37
S51	2379	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:40
S52	1088	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/11/12 15:45
S53	485	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/11/12 15:48

EAST Search History (Interference)

< This search history is empty>

11/20/2019 4:40:02 PM

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6667101	12-23-2003	SILAGY; David [Fr] et al.	
	002	US-9655691	05-23-2017	LI; Chunhua [Us] et al.	
	003	US-9655693	05-23-2017	LI; Chunhua et al.	
	004	US-10052176	08-21-2018	LI; Chunhua [Us] et al.	
	005	US-20080230938	09-25-2008	GREFENSTEIN; Achim [De] et al.	
	006	US-20090130438	05-21-2009	NASSI; Aldo [It] et al.	
	007	US-20170007362	01-12-2017	CHEN; Yan [Us] et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	JP-2011079284-A	04-21-2011	NIPPON KARARINGU KK.		☒
	002	JP-H08508174-A	09-03-1996	ORMCO CORP.		☒
	003	RU-2008137623-A	03-27-2010	SYROM 90		☒
	004	RU-2201944-C2	04-10-2003	ATOFINA [FR]		☒

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	09/23/2019

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Sheet 2 of 5

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Application Number	15476655
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First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	005	WO-2004041898-A1	05-21-2004	NOVEON IP HOLDINGS CORP [US]		☐
	006	WO-2006096558-A2	09-14-2006	ORTHOCLEAR HOLDINGS INC., et al.		☐
	007	WO-2010074789-A1	07-01-2010	DOW GLOBAL TECHNOLOGIES INC [US], et al.		☐
	008	WO-9711106-A1	03-27-1997	EASTMAN CHEM CO [US]		☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	09/23/2019

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 5

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Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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.	T[2]
	001	Co-pending US patent application No. US16/043,065, filed on 07-23-2018.	☐
	002	Co-pending US patent application No. US16/264,420, filed on 01-31-2019.	☐
	003	International search report with written opinion dated 06/28/2013 for PCT/EP2013/059701.	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	09/23/2019

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

Complete if Known	
Application Number	15476655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Timothy R. Welch/	Date (YYYY-MM-DD)	2019-03-11
Name/Print	Timothy R. Welch	Registration Number	74838

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

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.

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/476,655	Filing Date 03/31/2017	☐ 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 $80 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $420 =	
☐ 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	05/12/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 21	Minus	** 20	= 1		x $100 =	100
	Independent (37 CFR 1.16(h))	* 2	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	100

		(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".	/NICOLE LOVE HENSLEY/
*** 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.**

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

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	15476655	Filing Date	2017-03-31	Docket Number (if applicable)	22773-826.401	Art Unit	1748
First Named Inventor	Chunhua LI			Examiner Name	CAROLINE MONTIEL		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 232415

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Signature of Registered U.S. Patent Practitioner			
Signature	/Garrett Potter/	Date (YYYY-MM-DD)	2020-05-12
Name	Garrett Potter	Registration Number	76602

This collection of information is required by 37 CFR 1.114. 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 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.

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

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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 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.

Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Garrett T Potter/Hillary Pratt
Attorney Docket Number:	22773-826.401

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	600	600
Miscellaneous:				
RCE- 1ST REQUEST	1801	1	1300	1300
		Total in USD ($)		**1900**

Electronic Acknowledgement Receipt	
EFS ID:	39423131
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Garrett T Potter/Hillary Pratt
Filer Authorized By:	Garrett T Potter
Attorney Docket Number:	22773-826.401
Receipt Date:	12-MAY-2020
Filing Date:	31-MAR-2017
Time Stamp:	19:37:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1900
RAM confirmation Number	E20205BJ38093569
Deposit Account	232415
Authorized User	Hillary Pratt
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		22773_826_401_Response.pdf	259232 6facd0f40a6e1c906936847ec2a4400c3e089436	yes	19

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Specification	2	3
Claims	4	8
Applicant Arguments/Remarks Made in an Amendment	9	19

Warnings:

Information:

2	Request for Continued Examination (RCE)	22773_826_401_RCE_.pdf	1353328 1cfc8d0d0fc915193c35f99e0f5b91e1c3e734f4	no	3

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	32312 59dcfebafec9aaae48c7da952e7f72e33730fbb0	no	2

Warnings:

Information:

Total Files Size (in bytes):	1644872

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on May 12, 2020

WILSON SONSINI GOODRICH & ROSATI

By: /Hillary Pratt/

Attorney Docket No.: 22773-826.401
Client Ref. No.: 1228.US.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5936
Chunhua LI et al.	
Application No.: 15/476,655	Examiner: Caroline Montiel
Filed: March 31, 2017	Art Unit: 1748
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	AMENDMENT
Customer No.: 107046	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Final Office Action mailed December 12, 2019, please enter the following amendments and remarks. A Request for Continued Examination and Petition for Extension of time of two months accompanies this response.

Amendments to the Specification begin on page 2.

Amendments to the Claims are reflected in the listing of claims beginning on page 4.

Remarks begin on page 9.

Amendments to the Specification:

Please replace paragraph **[0025]** of the Specification with the following amended paragraph:

[0025] Figure 2 shows a multilayer structure according to the present invention. As shown, a multilayer sheet 20 can include a three layer structure: a hard polymer layer 24 and two soft polymer layers 22, 26. The hard polymer layer can be disposed between a first soft polymer layer and a second soft polymer layer. In some embodiments, the hard polymer layer can be thicker than either of the soft polymer layers. The soft polymer layers can have the same or different thicknesses. For example, the hard polymer layer can ~~range from a thickness of~~ have a thickness in a range from about 400 µm to about 1100 µm, about 450 µm to about 1000 µm, about 500 µm to about 900 µm, or about 550 µm to about 750 µm. The soft polymer layers can have a thickness in a range from ~~a thickness of~~ about 25 µm to about 100 µm, about 30 µm to about 90 µm, or about 35 µm to about 80 µm. Multilayer sheets used for making appliances having a hard polymer layer disposed between two soft polymer layers can range from a thickness of about 500 µm to about 1200 µm, about 550 µm to about 1100 µm, or about 600 µm to about 1000 µm. In some embodiments, the thicknesses of the various layers can be tailored for a particular stage of treatment for the patient.

Please replace paragraph **[0036]** of the Specification with the following amended paragraph:

[0036] Figures 5-8 provide example test results that compare various physical properties of the multilayer sheet appliances of the present invention with other already existing aligner materials (Material 1). Samples of varied thicknesses were tested. For example, multilayer sheets were tested having a hard polymer layer with thicknesses ranging from about 580 µm to about 715 µm thick. In some examples, the hard layer was a co-polyester hard polymer layer. The soft layers tested ranged between about 50 µm to about 100 µm. In some examples, the hard polymer layer was disposed between thermoplastic polyurethane elastomer soft polymer layers. As shown in Figures 5 and 6, one example of the multilayer sheet material (Material 2) showed improved

stress relaxation properties as compared to another already existing material (Material 1) at room temperature and at a 37 °C/90-100% relative humidity condition. In addition, Figure 7 shows improved long-term unloading characteristics of the multilayer sheet Material 2 versus the already existing Material 1 in a 37 °C/90-100% relative humidity condition. The multilayer sheet showed less deflection under force loads. Figure 8 also shows improved long-term movement data for the multilayer sheet Material 2 versus Material 1 in a 37 °C/90-100% relative humidity condition.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-19. (Canceled)

20. (Currently Amended) A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising:

a hard polymer layer comprising a co-polyester and having ~~of a hard polymeric material comprising~~ a flexural modulus greater than about 150,000 psi; and

a soft polymer layer of a soft polymeric material ~~comprising~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a positive model of the patient's teeth in a target position; and

fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. (Currently Amended) The method of claim 20, wherein the hard ~~polymeric material~~ polymer layer further comprises a polyester, ~~a co-polyester,~~ a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers each independently comprise a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a

polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

23. (Previously Presented) The method of claim 20, wherein the soft polymeric material comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. (Previously Presented) The method of claim 20, wherein the soft polymer layer comprises at least two layers, and wherein the at least two layers each independently comprise a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet environment, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. (Previously Presented) The method of claim 20, wherein the soft polymer layer comprises at least one of an ultimate tensile strength of greater than about 5000 psi, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

27. (Original) The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

28. (Original) The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. (Currently Amended) The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising the hard polymer layer ~~of the hard polymeric material~~ and the soft polymer layer ~~of the soft polymeric material~~.

30. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers.

31. (Previously Presented) The method of claim 20, wherein the appliance comprises three or more polymer layers, the three or more polymer layers comprising the hard polymer layer and the soft polymer layer.

32. (Previously Presented) The method of claim 31, wherein the three or more polymer layers alternate between soft and hard polymer layers.

33. (Previously Presented) The method of claim 31, wherein the hard polymer layer is positioned adjacent to one or more soft polymer layers, the one or more soft polymer layers comprising the soft polymer layer.

34. (Previously Presented) The method of claim 31, wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer, the second soft polymer layer comprising an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D.

35. (Previously Presented) The method of claim 20, wherein the appliance comprises a co-extruded material.

36. (Previously Presented) The method of claim 20, wherein the appliance comprises a thickness of between 500 μm and 1200 μm.

37. (Currently Amended) A method of making a plurality of dental appliances for positioning a patient's teeth, the method comprising:

providing a sheet comprising:

a hard polymer layer ~~of a hard polymeric material~~ comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer of a soft polymeric material ~~comprising~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a plurality of positive models of the patient's teeth, each in a target position; and

fabricating the plurality dental appliances, each as a negative of at least one of the plurality of positive models comprising thermoforming the sheet over the at least one positive model.

38. (Currently Amended) The method of claim 37, wherein the hard ~~polymeric material~~ polymer layer further comprises a polyester, ~~a co-polyester,~~ a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

39. (Previously Presented) The method of claim 37, wherein the soft polymeric material comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

40. (New) The method of claim 20, wherein the hard polymer layer comprises at least

two layers and the at least two layers each independently comprise a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

REMARKS

Upon entry of this Amendment, claims 20-40 will be pending and at issue in the present application. Claims 1-19 have previously been canceled without prejudice or disclaimer. Applicants reserve the right to pursue any canceled subject matter in a related, future application. Claims 20, 21, 29, 37, and 38 have been amended. New claim 40 has been added. Support for the amendments and new claim can be found in the specification as originally filed. Accordingly, no new matter has been added. Reconsideration is respectfully requested.

Support for Amendments

Independent claims 20 and 37 have been amended and now recite "a hard polymer layer comprising a co-polyester[.]" Support for these amendments can be found throughout the application as originally filed, at least at paragraphs [0026] and [0030].

New claim 40 has been added. Support for this new claim can be found throughout the application as originally filed, at least at paragraphs [0026] and [0030].

Support for amendments to Paragraph [0025] can be found in parent application US 13/470,681 (now U.S. Patent No. 9,655,691) in the application as originally filed at least at paragraph [0024].

Support for amendments to Paragraph [0036] can be found in parent application US 13/470,681 (now U.S. Patent No. 9,655,691) in the application as originally filed at least at paragraph [0035].

Accordingly, no new matter has been added by way of these amendments to the claims, newly added claims, or amendments to the specification.

Claim Rejections – 35 USC § 102

Claims 20, 21, 23, 25-30, and 37-39 stand rejected under pre-AIA 35 U.S.C. § 102(b) as allegedly being anticipated by DeSimone et al. (U.S. Patent No. 7,641,828, hereinafter "DeSimone"), considered with Pudleiner et al. (U.S. Pub. No. 2015/0140300, hereinafter "Pudleiner").

Independent claims 20 and 37 have each been amended to recite "a hard polymer layer comprising a co-polyester". DeSimone does not teach or suggest providing a sheet comprising: a

hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and a soft polymer layer of a soft polymeric material having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D, as recited by independent claims 20 and 37. Therefore Desimone does teach or suggest each feature of amended independent claims 20 and 37. Accordingly, claims 20 and 37 are novel over DeSimone.

Applicants also note that Pudleiner was filed May 10, 2013 and published May 21, 2015, while the instant application has a priority date of at least May 14, 2012. Therefore Pudleiner is not prior art under pre-AIA 35 U.S.C. § 102(b).

Claims 21, 23, 25-30, 38, and 39 depend from one of allowable claims 20 and 37, respectively, and are therefore allowable at least for their dependence on one of claims 20 and 37, and on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 20, 21, 23, 25-30, and 37-39 under pre-AIA 35 U.S.C. § 102(b) is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 22, 24, and 31-36 stand rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being unpatentable over DeSimone, considered with Pudleiner, in view of Chen et al. (U.S. Pub. No. 2009/0246724, hereinafter "Chen"). Specifically, the Examiner considers DeSimone "fails to teach wherein the hard polymer layer comprises at least two layers" and relies on Chen to allegedly disclose this feature (Office Action, pp. 10-11). The Examiner further relies on Chen to disclose "a hard polymer layer being a polycarbonate" and alleges a person of ordinary skill would "modify DESIMONE with two hard layers, as suggested by CHEN" to arrive at the claimed subject matter. (*Id.*, p. 11).

As discussed above, independent claim 20 has been amended to recite "a hard polymer layer comprising a co-polyester". The combined teachings of DeSimone and Chen do not teach or suggest a method of making a dental appliance including providing a sheet comprising: a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and a soft polymer layer of a soft polymeric material having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D, as recited by

independent claim 20. Accordingly, the combined references of DeSimone and Chen do not disclose each and every element of amended independent claim 20 and a *prima facie* case of obviousness is not established. Claims 22, 24, and 31-36 depend from allowable claim 20, and are therefore allowable at least for their dependence on claim 20, and on their own merits.

Furthermore, as discussed above, Pudleiner was filed May 10, 2013 and published May 21, 2015, while the instant application has a priority date of at least May 14, 2012. Therefore Pudleiner is not prior art.

Additionally, a method of making or using a product is patentable if the product is itself patentable *(see, e.g.:* MPEP § 821; *see also:* USPTO Official Gazette Notice, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)", published at 1184 OG 86 on March 26, 1996). As addressed in detail below, Applicants submit that the appliance is patentable, and thus the instant claims directed toward making said appliance is patentable.

Applicants also disagree with the Examiner's rejections under 35 U.S.C. § 103(a) at least because (1) one of ordinary skill in the art would not have had a reasonable expectation of success for combining the teachings of DeSimone, Pudleiner, and Chen to produce orthodontic appliances formed using the presently claimed methods of making a dental appliance; (2) the orthodontic appliances according to the instant claims were found to exhibit unexpectedly beneficial results when compared with the most relevant art; and (3) the appliances according to the instant claims gave rise to considerable commercial success.

These positions are supported by the present specification and further supported by the September 16, 2019 Declaration under 37 C.F.R. § 1.132 of Dr. Chunhua Li (hereafter, the "Li Declaration"), an expert in materials and biomechanical engineering and a co-inventor of the present application. The Li Declaration describes the development history and clinical evaluation comparing appliances comprising materials according to the present claims (an example of which is referred to herein as ST30-a material that has a soft polymer layer and a hard polymer layer) to appliances of the prior art, including a thermoplastic polyurethane referred to as EX30, which was the standard of care prior to the release of ST30.

1. No Reasonable Expectation of Success

One of ordinary skill in the art would not have had a reasonable expectation of success in combining the teachings of DeSimone and Chen to yield the orthodontic appliances made using the claimed method, at least because of the high level of unpredictability in the art and the lack of guidance provided in Chen and DeSimone suggesting which material combinations should be used to produce a sufficient multilayer orthodontic appliance.

Over the course of more than seven years, Applicants worked diligently to develop a suitable, improved appliance that would meet various criteria for effective orthodontic treatment. (Li Declaration at ¶4). This development process was neither easy nor straightforward. During the development process, Applicants evaluated, in an iterative fashion, more than 250 distinct materials and/or material combinations for possible use in an improved appliance device. After years of development, Applicants produced the SmartTrack™ material (also referred to herein as "ST30") and related materials, which are products formed according to the instant claims comprising a multilayered material comprising a hard polymer layer and a soft polymer layer. The intent of this testing was to identify a suitable replacement for Align Technology's single layer, thermoplastic polyurethane appliance product (referred to herein as "EX30"), which was the standard of the care for plastic tooth moving appliances at the time of filing, and the materials were evaluated on this basis. (*Id.* at ¶¶4-6). From among those over 250 materials tested, only the materials according to the present claims met Align' s criteria for a multilayer orthodontic appliance. (*Id.* at ¶¶4-5). The tested materials included many multilayer *(e.g.,* two-layer and three-layer) materials, yet of those tested only the materials according to the present claims proved capable of performing at a level sufficient to meet Align' s criteria for an orthodontic appliance, and thus as a suitable replacement for EX30. (*Id.* at ¶7).

Data obtained by Applicants during the development of the SmartTrack material provides significant evidence of the unpredictability in the art and the unexpected effectiveness of the orthodontic appliances according to the present claims. (*Id* at ¶7). As

mentioned above, the multilayer, multi-material orthodontic appliances were developed during more than seven years of diligent evaluation of over 250 materials, including numerous iterations in which materials were tested and compared, with the results used to design new materials. (*Id.* at ¶4). It was clear from many of the materials tested, including those from the Chen and DeSimone, that such materials were not effective alone or in combination to provide the improvements sought. (*Id.* at ¶5). During those evaluations, Applicants determined that only the combinations of materials according to the instant claims met Align's development criteria. (*Id.* at ¶6). It was not a simple or predictable process to identify those materials that would work together to create the multilayer apparatus which provided the unexpectedly good results. Among those 250 materials tested were more than 180 materials either generically or specifically described in Chen and/or DeSimone, including various copolymers (*see, e.g.,* Chen at [0036]) and unblended polysulfones (DeSimone at 6:47-59), as well as styrenic polymer materials such as acrylonitrile-butadiene styrene (ABS) (*id.* at 6:24-37). (Li Declaration at ¶5). Specifically, none of the 23 co-polymers that were tested during the iterative development process met Align's criteria. (*Id.*). Similarly, none of the styrenic polymers nor unblended polysulfones tested met Align's criteria. (*Id.*). Thus none of these materials would have yielded an orthodontic device having the combination of sufficient elongation, time stress-relaxation, durability, and thermoform ability. (*Id.*).

Inventor Li had extensive knowledge of the teachings of Chen and DeSimone at the time of filing, and yet it still took her team many years to identify suitable materials. (*Id.* at ¶5). Inventor Li is also listed as a co-inventor of Chen, and thus she was thus intimately familiar with the teachings of Chen during the development of the orthodontic appliances according to the present claims. Inventor Li also collaborated closely with Joseph M. DeSimone and Robert E. Tricca (the inventors listed on DeSimone) while they were developing and patenting the technology described in DeSimone. (Li Declaration at ¶9). She was thus very aware of the teachings of DeSimone during the development of the orthodontic appliances according to the present claims. Even with her extensive knowledge of the teachings of Chen and DeSimone, it took her team over seven years to identify a

suitable combination of polymer layers for use in the multilayer orthodontic appliances according to the present claims. (*Id.*). Thus, one of ordinary skill in the art having far less knowledge of the teachings of Chen and DeSimone would not have had a reasonable expectation of success in producing the orthodontic appliances according to the present claims based on the teachings of DeSimone, Pudleiner, and Chen. *(Id.* at ¶10).

During the course of their evaluations, Applicants determined that merely combining various materials being tested into multiple layers was insufficient to improve performance relative to the EX30 material. (*Id.* at ¶¶6-7). In fact, many multilayer materials tested proved inferior to the EX30 material. These multilayer materials included combinations of materials disclosed in Chen and/or DeSimone. (*Id.*). In particular, the sole exemplified multilayer material described in Chen would not be expected to show improved performance relative to EX30. For example, Chen paragraph [0032] describes a material containing polycarbonate and polyvinyl chloride (PVC); however, PVC was later evaluated by Applicants and found to be unsuitable for use in orthodontic aligners due to its inadequate durability. (*Id.*). Based on these tests, Applicants determined that materials containing PVC, either alone or in a multilayer configuration, would be inferior to EX30. (*Id.*). For these reasons, a person of ordinary skill would not necessarily expect combinations of any polymer layers, either in general or as particularly described in Chen, to achieve performance superior to EX30.

Based on the unpredictability exhibited in the Applicants' material evaluations, a person of ordinary skill in the art would not have had a reasonable expectation of success in producing an effective orthodontic appliance by combining materials from Chen and DeSimone to arrive at the appliances according to the present claims. *(Id.* at ¶10).

2. Unexpected Results

Applicants have also established that the appliances according to the present claims are unexpectedly superior to the most relevant art. The Li Declaration describes two clinical studies comparing appliances made from the prior art material described in paragraph [0003] of Chen—a thermoplastic polyurethane called EX30—to appliances made of a multilayer material made in accordance with the instant claims, referred to as ST30, that has

a hard polymer layer comprising a flexural modulus greater than about 150,000 psi and soft polymer layers having an elongation at break greater than about 200% and a hardness from about 60 A to about 85 D. (Li Declaration at ¶¶11-18).

As described in the Li Declaration, each study found that ST30 appliances provided strongly superior performance relative to the closest prior art appliances. In the first study described, a group of 1,015 patients treated with ST30 appliances for five months were 26% more likely than equivalent patients treated with EX30 appliances to have their teeth respond to treatment as intended. (*Id.* at ¶11-15). This result establishes the superiority of ST30 to EX30 to a high degree of statistical significance ($p < 0.001$). (*Id.* at ¶14). A second study of 110,000 cases confirmed these findings, demonstrating strongly significant ($p < 0.001$) improvements in predictability in tooth movement for 14 different movement types. (*Id.* at ¶16, Appendix B). Overall, patients treated with ST30 appliances showed a greater than 75% improvement in tooth movement predictability over patients treated with EX30 appliances. (*Id.* at ¶17). This surprising improvement would not have been predicted by a person of ordinary skill in the art. (*Id.*).

In the above-described clinical studies, the appliances contained a hard polymer layer, which provided the forces needed to generate movement of the teeth, while the soft polymer layers increased the durability of the aligners allowing them to better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment, as well as improving the elastic properties allowing for less degradation in the shape of the teeth receiving cavities. The surprising results observed for the ST30 appliances can be attributed to the combination of the hard and soft polymer materials combined together in an appliance according to the present claims. (*Id.* at ¶¶15, 18). Although the clinical results were found for a three layer appliance, a single hard polymer layer and a single soft polymer layer according to the current claims would also be expected to exhibit these beneficial functions in a two-layered appliance because the superior performance properties flow from the claimed combination of polymer layers utilized together. (*Id.*). Thus, one would expect superior results from the appliances formed using the methods of current claim 20.

Comparison of EX30 and the Claimed Materials is Proper for Establishing Unexpected Results

EX30 was the standard of care in orthodontic appliances prior to the development of ST30, and a person of ordinary skill would have considered it the closest relevant art. Thus, the skilled artisan would consider the superiority of the orthodontic appliances according to the present claims relative to EX30 to be predictive of similar superiority of ST30 relative to other prior art appliances. (Li Declaration at ¶17). During the course of Applicants' evaluations, they determined that merely combining any materials into multiple layers was insufficient to improve performance relative to the EX30 material. *(Id.* at ¶6). In fact, many multilayer materials tested proved inferior to the EX30 material. (*Id.*). Based on these evaluations, none of these inferior multilayer materials would be expected to achieve performance comparable to EX30, much less to exceed the performance of EX30. Because the EX30 material was the standard of care during Applicants' development of the SmartTrack material and related materials, and was superior to many multilayer materials tested, the EX30 material should be considered a proper comparison for assessing unexpected results. (*See* MPEP § 716.02(e)(I) ("Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner.")). Additionally, it is not a trivial matter to conduct a clinical trial. It requires regulatory approval and a considerable amount of time and thus cannot be done for any or all materials. Thus, because the test comparison provided compares the standard of care (the material commercially being utilized), it should be accepted as the appropriate comparison for demonstrating unexpected results.

Additionally, the Li Declaration establishes that the surprising results observed for the ST30 appliances are attributed to the combination of the hard and soft polymer layers combined in layers together in an appliance according to the present claims. (*Id.* at ¶¶15, 18). The Li Declaration further establishes that a single hard polymer layer and a single soft polymer layer according to the current claims would also be expected to exhibit these beneficial functions in a two-layered appliance. (*Id.*). Thus, the experimental comparisons between EX30 and ST30 as described in the Li Declaration should be accepted as the

appropriate comparison for demonstrating unexpected results for the appliances according to the present claims.

Therefore, Applicants have demonstrated that there would have been no reasonable expectation of success in combining the cited art to achieve the presently claimed invention and that the appliances according to the present claims produce unexpectedly positive results relative to the closest relevant art.

3. Commercial Success

In addition to the comparative, developmental, and clinical data presented above, the commercial success of appliances comprising the ST30 material as set forth in the present claims provides further evidence of their non-obviousness. Prior to the Applicants' development of the ST30 material, the primary appliance material in the orthodontic market was EX30. (Li Declaration at ¶19). Upon establishing the superiority of ST30 appliances relative to EX30 appliances, Align Technology switched virtually all new appliance manufacturing to ST30 over the course of only a few months. (*Id.*). Thereafter, ST30 appliances captured over 90% of the total US market for clear plastic orthodontic appliances. (*Id.; see also:* Baird 2014 Analyst Report at 6, and Baird Q3 2013 Report at 9 (submitted in an IDS filed March 31, 2017)). This striking commercial success was due to the superior performance of ST30 appliances to EX30 and other appliances on the market. (Li Declaration at ¶¶19-20).

Indeed, as the Federal Circuit has stated that, "[w]hen a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention." *GrajTech Int'l Holdings, Inc. v. Laird Techs. Inc.,* No. 2015-1796, 652 Fed. Appx. 973, 978-79 (Fed. Cir. June 17, 2016) (quoting *J T Eaton & Co. v. Atl. Paste & Glue Co.,* 106 F.3d 1563, 1571 (Fed. Cir. 1997)). As appliances made of the ST30 material are appliances according to the present claims, and as these appliances have demonstrated commercial success as shown by significant sales in

the relevant market of clear plastic orthodontic appliances, it is presumed that the invention as claimed has led to this commercial success.

Independent analysis provides further evidence that the commercial success of ST30 appliances is due to the appliances' superior performance. An analysis by Stifel, Nicolaus & Company, Inc. shortly after the introduction of ST30 concluded that the introduction of SmartTrack (ST30 material) appliances resulted in an increase from 59% to 63% in the total addressable market for orthodontic malocclusions. (Stifel 4Q13 Report at 6 (submitted in an IDS filed March 31, 2017)). Survey results confirmed the conclusion among doctors that SmartTrack appliances allow a larger range of cases to be treated:

> Approximately 80% of our respondents now believe SmartTrack will help them treat more complex cases. Over 60% of our doctors said that SmartTrack has already allowed them to perform more complex cases, an increase from 48% and 29% when we surveyed the same respondents in July and April, respectively.

(*Id.* at 4). Thus, in addition to commanding a dominant market share, ST30 appliances have increased the size of the market treatable by clear plastic orthodontic appliances.

Accordingly, in addition to the unexpected results and lack of reasonable expectation of success described above, the commercial success of ST30 appliances according to the present claims provides evidence of the claims' non-obviousness.

The Li Declaration establishes that the commercial successes observed for the SmartTrack appliances can be attributed to the combination of the hard and soft polymer material layers combined together in an appliance according to the present claims. (*Id.* at ¶¶19-20). Thus, the commercial successes observed for ST30 as described in the Li Declaration should be accepted as providing evidence for the patentability of the present claims.

Independent claim 20 is not obvious over the combination of DeSimone and Chen for at least the reasons described above. Claims 22, 24, and 31-36 depend from claim 20, and are therefore allowable for similar reasons, as well as on their own merits. Accordingly, for

the reasons set forth above, withdrawal of the rejection of claims 22, 24, and 31-36 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 23-2415.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-883-2500.

Respectfully submitted,

Dated: May 12, 2020

/Garrett T. Potter/

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6454565	09-24-2002	PHAN; Loc X. et al.	
	002	US-6746757	06-08-2004	TAKAGI; Kiyoji. et al.	
	003	US-7201575	04-10-2007	ADELL; Loren S. et al.	
	004	US-7354270	04-08-2008	ABOLFATHI; Amir. et al.	
	005	US-20080248438	10-09-2008	DESIMONE; Joseph M. et al.	
	006	US-20090298006	12-03-2009	SCHWARTZ; Dann.	
	007	US-20110020761	01-27-2011	KALILI; Thomas.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		None				

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	001	BAYER CORPORATION, "TEXIN® 990R," Pages 1-4, November 2002, Pittsburgh, PA .	☐
	002	CAMPO, E. A. "Mechanical Properties of Polymeric Materials," from "Selection of Polymeric Materials: Plastics Design Library," 2008, 4 pages .	☐
	003	Co-pending US patent application No. 16/835,101, filed on 03-30-2020.	☐
	004	EMBLEM, A. "Plastics properties for packaging materials," from "Packaging Technology: Fundamentals, Materials and Processes," 2012, 3 pages .	☐
	005	"Polycarbonate," Encyclopaedia Britannica, 24 August 2017, 1 page, URL: https://www.britannica.com/science/polycarbonate.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

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Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Garrett Potter/	Date (YYYY-MM-DD)	2020-05-12
Name/Print	Garrett Potter	Registration Number	76,602

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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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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.

Electronic Acknowledgement Receipt	
EFS ID:	39423340
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Garrett T Potter/John Macalagay
Filer Authorized By:	Garrett T Potter
Attorney Docket Number:	22773-826.401
Receipt Date:	12-MAY-2020
Filing Date:	31-MAR-2017
Time Stamp:	19:54:05
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		22773-826-401_IDS.pdf	336395 ef96edde5e6f05466ace637395fd41763a339891	yes	8

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	4	
	Information Disclosure Statement (IDS) Form (SB08)		5	8	
Warnings:					
Information:					
2	Non Patent Literature	BAYERCORPORATION_TEXIN990R_4PAGES.PDF	445442 06e2dc725c6be99fa1ba8f1e1631320cd61b731f	no	4
Warnings:					
Information:					
3	Non Patent Literature	CAMPO_MECHANICALPROPERTIESOFPOLYMERIC_4PAGES.PDF	280931 de128fbdb00de473ccbf61e5e467f5cd823fde6c	no	4
Warnings:					
Information:					
4	Non Patent Literature	US16835101_30Mar2020.pdf	3341276 ed3cbfeb805ca7f627945d9f186a1496ceb902a3	no	42
Warnings:					
Information:					
5	Non Patent Literature	EMBLEM_PLASTICSPROPERTIESFORPACKING_3PAGES.PDF	569444 8e56072d51107b17704618a4d5ba4170afea9c74	no	3
Warnings:					
Information:					
6	Non Patent Literature	ENCYCLOPAEDIABRITANNICA_POLYCARBONATE_1PAGE.PDF	87300 346d45faf80b865639014f4e98a0710bb5da8913	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	5060788		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	1748
Serial Number:	15/476,655	Examiner:	MONTIEL, CAROLINE
Filing or 371 (c) Date:	2017-03-31	**CONFIRMATION NO:**	**5936**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: May 12, 2020

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☒ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☐ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☒ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☐ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☐ a fee of $240.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $240.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* 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 or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☒ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☐ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22773-826.401).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: May 12, 2020

By: /Garrett Potter/
Garrett Potter
Reg. No. 76,602

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United States Patent and Trademark Office

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Sale Item Reference Number	Effective Date
15476655	05/12/2020

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I20205D712119375	1202	CLAIMS IN EXCESS OF 20	$100.00	Deposit Account

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 06/24/2020

WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER
MONTIEL, CAROLINE

ART UNIT	PAPER NUMBER
1748	

NOTIFICATION DATE	DELIVERY MODE
06/24/2020	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):

patentdocket@wsgr.com

Office Action Summary	Application No. 15/476,655	Applicant(s) LI et al.	
	Examiner CAROLINE MONTIEL	Art Unit 1748	AIA (FITF) Status No

-- 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 5/12/2020.

☐ 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) 20-40 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 20-40 is/are rejected.

8) ☐ Claim(s) _____ 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 3/31/2017 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 5/12/2020.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/12/2020 has been entered.

2. Claims 20-21, 29, and 37-38 have been amended. Claim 40 is new.

3. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment and Arguments

4. Applicant's arguments filed 5/12/2020 have been fully considered but they are not persuasive. The Applicant argues that DESIMONE, CHEN or PUDLEINER does not teach the newly added feature of the hard layer having co-polyester. The Examiner respectfully disagrees. DESIMONE teaches co-polyesters and blends may be used [Col. 5, lines 65-67]. The Applicant also argues that PUDLEINER is not prior art since it has a prior art date after the claimed application. The Examiner would like to note that PUDLEINER is used to teach the property of ISOPLAST 2530 (which is used in DESIMONE; Col. 10, lines 14-20) having a hardness of 82D."[R]eferences cited to showa universal fact need not be available as prior art before applicant's filing date." See MPEP 2124.

5. The reference is a statutory bar under pre-AIA 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131(a).

6. The declaration under 37 CFR 1.132 filed 9/16/2019 is insufficient to overcome the rejection of claim 20 and 37 based upon DESIMONE as set forth in the current Office action

below because: facts presented are not germane to the rejection below and DESIMONE is in the same field of endeavor, dental appliances, and teaches the desirable properties.

7. Furthermore, DESIMONE is applied under 35 USC 102(b) for claims 20 and 37, but regarding the dependent claims, the Examiner would add the following:

a. The Applicant has not shown EX30, the standard, is commensurate in scope with DESIMONE and CHEN because DESIMONE and CHEN teach at least two layer devices compared to the EX30, which is a single polyurethane [paragraph 4 of declaration]. In paragraphs 4 and 5 of the declaration, it is stated that none of the materials generically or specifically described in DESIMONE or CHEN would have yielded an orthodontic device having sufficient elongation, time stress-relaxation, durability, and thermoform ability; however, there is not data shown in regards to these properties.

b. Furthermore, Applicant argues there is a sole exemplified multilayer material described in CHEN; however, CHEN further teaches that the various inner and outer layers can be made from a homopolymer, cross-linked homopolymer, copolymer, polycarbonate, cross-linked copolymer, a copolymer blend of thermoplastics, and/or similar material [0036]. Also, the Applicant argues that the PVC and polycarbonate layers of CHEN are unsuitable, but has not provided any evidence supporting that it is unsuitable. The Applicant has not demonstrated or provided any evidence to support the allegation that these specific polymers taught by CHEN are unsuitable.

c. ST 30 shows improved results, but it is not clear what the polymer layers are composed of or what physical properties they have. The Applicant has provided no evidence to support ST 30 being commensurate in scope to the claimed invention. Furthermore, while Applicant tried many combinations, one of ordinary skill in the art

would have had the benefit of the disclosure of CHEN and DESIMONE, which teaches multilayered devices and various properties. Applicant has provided no specific scientific evidence or evidence of laboratory hardship to support that one of ordinary skill in the art would have expected failure and has further provided no evidence that the skilled artisan would have expected failure given the benefit of the teachings of CHEN and DESIMONE. Also, it is not clear that the layers of CHEN and DESIMONE would not have given the same results of ST 30 as no data was given regarding the composition of ST 30. It is also unclear whether the claims as currently recited are commensurate with ST 30 as the composition of ST 30 is not known. Furthermore, the claims recite that the hard layer is comprised of a co-polyester and that even if ST 30 can be shown to be unexpectedly superior to inventions of CHEN and DESIMONE, one embodiment (ST 30) would not be sufficient to establish unexpected results over the broad genus of all co-polyesters. One of ordinary skill would have been motivated and have tried a soft layer and a hard layer device based on DESIMONE and CHEN teachings, and the Applicant has provided no evidence to refute that the motivation provided by CHEN and DESIMONE would have been inadequate to support combining elements as presented in the rejection. There is nothing in DESIMONE and CHEN that would lead one of ordinary skill in the art to expect that undue experimentation would be necessary to combine the teachings set forth in the rejection as both DESIMONE and CHEN teach exemplified layers and suitable materials for each layer.

d. The Applicant argues that ST 30 as a single hard layer and single soft layer would also exhibit beneficial functions, as stated in paragraphs 15 and 18, but offers no evidence. ST 30 is a construction of a hard layer disposed between two soft layers. At

best, the Applicant has shown that this provides improvements over a single polyurethane layer. Furthermore, the declaration states that one would also expected an appliance with layers of a single hard polymer material and a single soft polymer material to exhibit beneficial performance relative to EX30 appliances; therefore, DESIMONE would be expected to have beneficial performance and also the same properties as ST30 [paragraph 18 of the declaration].

e. The Applicant argues that SmartTrack (ST30) appliances account for over 90% of the total U.S. market for clear plastic orthodontic appliances from all sellers. However, the Baird report states that "ALGN currently maintains a dominating 93% share of the $550 million clear aligner orthodontic market segment", which includes ST30 appliances, and other appliances are also included, such as G3 and G4, according to BAIRD [pg. 9 and pg. 3 of Baird Q3 2013 report].

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claim(s) 20-21, 23, 25-30 and 37-39 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by DeSimone et al. (U.S. 7,641,828), hereinafter DESIMONE, as evidenced by Pudleiner et al. (U.S. PGPUB 2015/0140300), hereinafter PUDLEINER**.

8. Regarding **claim 20**, DESIMONE teaches: *A method of making a dental appliance for positioning a patient's teeth* (DESIMONE teaches methods of making dental appliances for moving patient's teeth [Abstract]), *the method comprising: providing a sheet comprising* (DESIMONE teaches providing a sheet [Col. 1, lines 64-67 – Col. 2, lines 1-3; claim 1]): *a hard polymer layer comprising a co-polyester* (DESIMONE teaches a single polyester material may not be used and co-polyesters and blends may be used [Col. 5, lines 65-67]) *and having a flexural modulus greater than about 150,000 psi* (DESIMONE teaches a hard polymer layer (first transparent material: Col. 9, lines 30-37) comprising a flexural modulus greater than 200,000 psi [Col. 2, lines 16-29], which is within the claimed range)*; and a soft polymer layer of a soft polymeric material* (DESIMONE teaches a soft polymer layer (the coating of a second transparent material) [Col. 2, lines 42-48].) *having an elongation at break of greater than about 200%* (DESIMONE teaches the soft polymer layer has an elongation at break of greater than 80%, which encompasses the claim [Col. 2, lines 50-55]), *and a hardness from about 60 A to about 85 D* (DESIMONE teaches using a layer of the second transparent material, which Examiner is interpreting as the soft polymer layer includes ISOPLAST 2530 [Col. 10, lines 14-20], which has a hardness of 82D, which is within the claimed range, shown by PUDLEINER [0142])*; providing a positive model of the patient's teeth in a target position* (DESIMONE teaches positive tooth models of a patient's teeth using intermediate and final data sets, examiner is interpreting the intermediate and final data sets as target positions [Col. 3, lines 53-67-Col. 4, lines 1-7])*; and fabricating an appliance as a negative of the positive model comprising*

thermoforming the sheet over the positive model (DESIMONE further teaches fabricating positioning appliances with a molding machine that produces shells of dental appliances from a thermoformable material [Col. 4, lines 3-12, examiner is interpreting the shells as negatives of the positive models]).

9. Regarding **claim 21**, DESIMONE teaches: *wherein the hard polymer layer further comprises a layer of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof* (DESIMONE teaches the hard polymer layer (first transparent layer) used may be polyesters [Col. 9, lines 10-17]).

10. Regarding **claim 23**, DESIMONE teaches: *wherein the soft polymeric material comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof* (DESIMONE teaches the soft polymeric material (second transparent material) can be silicone, which Examiner is interpreting as silicone rubber [Col. 9, lines 66-67 – Col. 10, lines 1-5]).

11. Regarding **claim 25**, DESIMONE further teaches: *wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 pounds psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet*

environment, and a light transmission between 400 nm and 800 nm of greater than about 75% (DESIMONE teaches a transparent polymeric material preferably having a tensile strength at yield of greater than 6,000 psi, which overlaps with the claimed tensile strength at yield of between about 4000 psi and 6500 psi [Col. 7, lines 42-44, examiner is interpreting transparent polymeric material as a hard polymer layer as DESIMONE states thermoplastic polyurethanes can be used]).

12. Regarding **claim 26**, DESIMONE teaches: *wherein the soft polymer layer comprises at least one of an ultimate tensile strength of greater than about 5000 psi, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%* (DESIMONE teaches the coating (soft polymer layer) has a flexural modulus of greater than 200,000 psi, which is within the claimed range [Col. 2, lines 50-56]).

13. Regarding **claim 27**, DESIMONE further teaches: *further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth* (DESIMONE teaches fabricating a plurality of appliances based on different arrangements of the patient's teeth [Col. 3, 53-67-Col. 4, lines 1-7]).

14. Regarding **claim 28**, DESIMONE further teaches: *wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models* (DESIMONE teaches digitally staging a plurality of digital models of the patient's teeth [Col. 3, lines 53-67] and fabricating a plurality of appliances [Col. 4, lines 7-8]).

15. Regarding **claim 29**, DESIMONE teaches: *wherein two or more of the plurality of appliances comprise a sheet comprising the hard polymer layer and the soft polymer layer*

(DESIMONE teaches a plurality of appliances [Col. 4, lines 7-12]. DESIMONE further teaches the appliance has a hard polymer layer made of polymeric material [first transparent material: Col. 9, lines 30-37] and a soft polymer layer (coating of a second transparent material) [Col. 2, lines 42-48]).

16. Regarding **claim 30**, DESIMONE further teaches: *wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers* (DESIMONE teaches other materials that can be formed and annealed include laminates and/or blends of transparent polymeric material [Col. 7, lines 24-35]).

17. Regarding **claim 37**, DESIMONE teaches: *A method of making a plurality of dental appliances for positioning a patient's teeth* (DESIMONE teaches methods of making dental appliances for moving patient's teeth [Abstract]), *the method comprising: providing a sheet* (DESIMONE teaches providing a sheet [Col. 1, lines 64-67 – Col. 2, lines 1-3; claim 1]) *comprising: a hard polymer layer comprising a co-polyester* (DESIMONE teaches a single polyester material may not be used and co-polyesters and blends may be used [Col. 5, lines 65-67]) *and having a flexural modulus greater than about 150,000 psi* (DESIMONE teaches a hard polymer layer (first transparent material: Col. 9, lines 30-37) comprising a flexural modulus greater than 200,000 psi [Col. 2, lines 16-29], which is within the claimed range)*; and a soft polymer layer of a soft polymeric material* (DESIMONE teaches a soft polymer layer (the coating of a second transparent material) [Col. 2, lines 42-48]) *having an elongation at break of greater than about 200%* (DESIMONE teaches the soft polymer layer has an elongation at break of greater than 80%, which encompasses the claim [Col. 2, lines 50-55]), *and a hardness from about 60 A to about 85 D* (DESIMONE teaches using a layer of the second transparent material, which Examiner is interpreting as the soft polymer layer includes ISOPLAST 2530 [Col. 10,

lines 14-20], which has a hardness of 82D, which is within the claimed range, as evidenced by PUDLEINER [0142])*; providing a plurality of positive models of the patient's teeth, each in a target position* (DESIMONE teaches positive tooth models of a patient's teeth using intermediate and final data sets, examiner is interpreting the intermediate and final data sets as target positions [Col. 3, lines 53-67-Col. 4, lines 1-7])*; and fabricating the plurality of dental appliances, each as a negative of at least one of the plurality of positive models comprising thermoforming the sheet over the at least one positive model* (DESIMONE teaches fabricating positioning appliances with a molding machine that produces shells of dental appliances from a thermoformable material [Col. 4, lines 3-12, examiner is interpreting the shells as negatives of the positive models]. DESIMONE further teaches a plurality of appliances [Col. 4, lines 7-12].).

18. Regarding **claim 38**, DESIMONE teaches: *wherein the hard polymer layer further comprises a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof* (DESIMONE teaches the hard polymer layer (first transparent layer) used may be polyesters [Col. 9, lines 10-17]. DESIMONE further teaches that co-polyesters and blends may be used [Col. 5, lines 65-67]).

19. Regarding **claim 39**, DESIMONE teaches: *styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof* (DESIMONE teaches the soft polymeric material (second transparent material) can be

silicone, which Examiner is interpreting as silicone rubber [Col. 9, lines 66-67 – Col. 10, lines 1-5]).

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of pre-AIA 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, 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 negatived by the manner in which the invention was made.

18. Claims 22, 24 and 31-36 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (U.S. 7,641,828), hereinafter DESIMONE, considered with Pudleiner et al. (U.S. PGPUB 2015/0140300), hereinafter PUDLEINER, in view of Chen et al. (U.S. PGPUB 2009/0246724), hereinafter CHEN (DESIMONE and CHEN are provided in the IDS of 3/31/2017).

19. Regarding **claim 22**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the hard polymer layer comprises at least two layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the hard polymer layer comprises at least two layers and the at least two layers are independently selected from a group consisting of a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic*

block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate (CHEN teaches the hard polymer layer comprises of at least two layers (Figs. 4A-4D; 5; [0031-0033; 0035-0036], examiner is interpreting inner layers (132,150) as hard polymer layer). CHEN further teaches a hard polymer layer being a polycarbonate ([0036], examiner is interpreting inner layers (150) as hard polymer layer)). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with two hard layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

20. Regarding **claim 24**, DESIMONE teaches: *wherein at least one of the first soft polymer layer and the second soft polymer layer comprises at least two layers, and wherein the at least two layers are independently selected from the group consisting of a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer* (DESIMONE teaches the soft polymer layer (second transparent material) is made of silicone, which Examiner is interpreting as silicone rubber [Col. 9, lines 66-67 – Col. 10, lines 1-5]. It would have been obvious to one of ordinary skill in the art at the time of the effective filing date of applicant's invention to duplicate the soft layer into two layers, since it has been held that a mere duplication of working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

21. In the alternative, CHEN teaches having at least two soft layers [Figs. 4A-4D; 0030-0031]. CHEN further teaches the soft polymer can be a copolymer blend of thermoplastics [0036], examiner is interpreting outer layers (152, 134) as soft polymer layer. CHEN further teaches thermoplastic elastomer can be used for the appliance [0025; Figs. 4A-4C, 5]. It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with two layers in the soft polymer layer, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

22. Regarding **claim 31**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the appliance comprises three or more polymer layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the appliance comprises three or more polymer layers, the three or more layers comprising the hard polymer layer and the soft polymer layer* (CHEN teaches an appliance with three or more polymer layers [Fig. 4A-4C]. CHEN further teaches the layers comprise a hard polymer layer and a soft polymer layer [0026]). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with several polymer layers in the appliance, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

23. Regarding **claims 32-33**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the layers alternate. In the same field of endeavor, dental appliances, CHEN teaches the layers alternate between the soft layers (outer layers) and the hard layer (inner layers) [Figs. 4A-4C] and the hard layer is adjacent to the polymer layers [Figs 4A-4C; 0032; 0036]. It would have been obvious to one of ordinary skill in the art at the

time of the filing date of applicant's invention to modify DESIMONE with several polymer layers in the appliance and alternate the layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031] and for the harder segment to control the restoration of an original shape [0026].

24. Regarding **claim 34**, DESIMONE teaches all the limitations of the claimed invention as stated above, including a hard layer and a soft layer comprising an elongation at break of greater than about 200% [Col. 2, lines 50-55] and a hardness from about 60 A to about 85 D (soft polymer layer includes ISOPLAST 2530 [Col. 10, lines 14-20], which has a hardness of 82D, which is within the claimed range, as shown by PUDLEINER [0142]). Furthermore, It would have been obvious to one of ordinary skill in the art at the time of the effective filing date of applicant's invention to duplicate the soft layer into two layers with the same properties, since it has been held that a mere duplication of working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

25. DESIMONE fails to teach wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer. In the same field of endeavor, dental appliances, CHEN teaches *wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer* [Figs. 4A-4C]. It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with a hard layer disposed between two soft layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

26. Regarding **claim 35**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the appliance comprises a co-extruded material. In the same field of endeavor, dental appliances, CHEN teaches the layers may be formed by a process, such as thermoforming or similar process, such as co-extrusion, lamination or any other process where layers are formed [0031]. It would have been obvious to one of ordinary skill in the art at the time of the effective filing date of the applicant's invention to have the layers co-extruded since it is known in the art that layers can be made by co-extrusion.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc., 127* S.Ct. 1727, 82 USPQ2d 1385 (2007).

27. Regarding **claim 36**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the hard polymer layer comprises at least two layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the appliance comprises a thickness between 500 μm and 1200 μm* (CHEN teaches an appliance with three or more layers and that the inner layers (132) as well as the outer layers (134) may each have different thicknesses, such as 5 or 10 mils [0030-0031]. Fig. 4C shows an appliance with two inner layers and two outer layers. If each layer is 10 mils, then all the layers together form the appliance and the appliance would have a thickness of 1016 μm (10 mils = 254 μm), which meets the claimed range). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE by having the appliance thickness about 1016 μm, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031] and have variable thickness depending on the modulus requirements [0036].

28. Regarding **claim 40**, DESIMONE teaches all the limitations of the claimed invention as stated above, but fails to teach wherein the hard polymer layer comprises at least two layers. In the same field of endeavor, dental appliances, CHEN teaches: *wherein the hard polymer layer comprises at least two layers and the at least two layers each independently comprise a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyehterimide, a polyethersulfone, or a polytrimethylene terephthalate* (CHEN teaches the hard polymer layer comprises of at least two layers (Figs. 4A-4D; 5; [0031-0033; 0035-0036], examiner is interpreting inner layers (132,150) as hard polymer layer). CHEN further teaches a hard polymer layer being a polycarbonate ([0036], examiner is interpreting inner layers (150) as hard polymer layer)). It would have been obvious to one of ordinary skill in the art at the time of the filing date of applicant's invention to modify DESIMONE with two hard layers, as suggested by CHEN, in order to have variable glass transition temperatures and various orientations and configurations to suit the modulus and application requirements [0031].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CAROLINE MONTIEL whose telephone number is (571)272-2529. The examiner can normally be reached on MONDAY - FRIDAY 8:30 A.M. - 5:00 P.M.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is

encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ABBAS RASHID can be reached on (571) 270-7457. 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). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.M./
Examiner, Art Unit 1748

/PETER L VAJDA/
Primary Examiner, Art Unit 1737
06/19/2020

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61C 7/08	03/07/2019	CM
B32B 7/02	03/07/2019	CM
B29C 51/14	03/07/2019	CM
B32B 27/40	03/07/2019	CM
B32B 25/08	03/07/2019	CM
B32B 25/20	03/07/2019	CM
B32B 27/08	03/07/2019	CM
B32B 27/281	03/07/2019	CM
B32B 27/286	03/07/2019	CM
B32B 27/308	03/07/2019	CM
B32B 27/32	03/07/2019	CM
B32B 27/34	03/07/2019	CM
B32B 27/36	03/07/2019	CM
B32B 27/365	03/07/2019	CM
B29K 2995/0077	03/07/2019	CM
B32B 2250/24	03/07/2019	CM
B29L 2031/753	03/07/2019	CM
B29K 2067/00	03/07/2019	CM
B29K 2075/00	03/07/2019	CM
B29K 2995/0026	03/07/2019	CM
B29K 2995/007	03/07/2019	CM
B29K 2995/0082	03/07/2019	CM
B32B 2307/54	03/07/2019	CM
B32B 2250/03	03/07/2019	CM
B32B 2274/00	03/07/2019	CM
B32B 2307/412	03/07/2019	CM

/C.M./ Examiner, Art Unit 1748	

ClearCorrect Exhibit 1011, Page 724 of 890

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	Art Unit
	CAROLINE MONTIEL	1748

B32B 2307/536	03/07/2019	CM
B32B 2535/00	03/07/2019	CM
B32B 2307/546	03/07/2019	CM
A61C 7/08 and keywords	11/20/2019	CM
B32B 7/02 and keywords	11/20/2019	CM
B29C 51/14 and keywords	11/20/2019	CM
B32B 27/40 and keywords	11/20/2019	CM
B32B 25/08 and keywords	11/20/2019	CM
B32B 25/20 and keywords	11/20/2019	CM
B32B 27/08 and keywords	11/20/2019	CM
B32B 27/281 and keywords	11/20/2019	CM
B32B 27/286 and keywords	11/20/2019	CM
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B32B 27/34 and keywords	11/20/2019	CM
B32B 27/36 and keywords	11/20/2019	CM
B32B 27/365 and keywords	11/20/2019	CM
B29K 2995/0077 and keywords	11/20/2019	CM
B32B 2250/24 and keywords	11/20/2019	CM
B29L 2031/753 and keywords	11/20/2019	CM
B29K 2067/00 and keywords	11/20/2019	CM
B29K 2075/00 and keywords	11/20/2019	CM
B29K 2995/0026 and keywords	11/20/2019	CM
B29K 2995/007 and keywords	11/20/2019	CM
B29K 2995/0082 and keywords	11/20/2019	CM
B32B 2307/54 and keywords	11/20/2019	CM
B32B 2250/03 and keywords	11/20/2019	CM
B32B 2274/00 and keywords	11/20/2019	CM
B32B 2307/412 and keywords	11/20/2019	CM

/C.M./ Examiner, Art Unit 1748	

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B32B 2307/536 and keywords	11/20/2019	CM
B32B 2535/00 and keywords	11/20/2019	CM
B32B 2307/546 and keywords	11/20/2019	CM
A61C 7/08 and keywords	06/10/2020	CM
B32B (7/02; 27/40; 25/08; 25/20; 27/08; 27/281; 27/286; 27/308; 27/32; 27/34; 27/36; 27/365; 2250/24; 2307/54; 2250/03; 2274/00; 2307/412; 2307/536; 2535/00; 2307/546) and keywords	06/10/2020	CM
B29C 51/14 and keywords	06/10/2020	CM
B29K (2995/0077; 2067/00; 2075/00; 2995/0026; 2995/007; 2995/0082) and keywords	06/10/2020	CM
B29L 2031/753 and keywords	06/10/2020	CM

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**
See EAST search history	03/07/2019	CM
See EAST inventor search	03/07/2019	CM
See updated Inventor/Applicant EAST search	11/20/2019	CM
See updated EAST search history	11/20/2019	CM
See updated Inventor/Applicant search	06/10/2020	CM
See updated EAST search history	06/10/2020	CM

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
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Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6454565	09-24-2002	PHAN; Loc X. et al.	
	002	US-6746757	06-08-2004	TAKAGI; Kiyoji. et al.	
	003	US-7201575	04-10-2007	ADELL; Loren S. et al.	
	004	US-7354270	04-08-2008	ABOLFATHI; Amir. et al.	
	005	US-20080248438	10-09-2008	DESIMONE; Joseph M. et al.	
	006	US-20090298006	12-03-2009	SCHWARTZ; Dann.	
	007	US-20110020761	01-27-2011	KALILI; Thomas.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		None				

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	06/10/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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.	T[2]
	001	BAYER CORPORATION, "TEXIN® 990R," Pages 1-4, November 2002, Pittsburgh, PA .	☐
	002	CAMPO, E. A. "Mechanical Properties of Polymeric Materials," from "Selection of Polymeric Materials: Plastics Design Library," 2008, 4 pages .	☐
	003	Co-pending US patent application No. 16/835,101, filed on 03-30-2020.	☐
	004	EMBLEM, A. "Plastics properties for packaging materials," from "Packaging Technology: Fundamentals, Materials and Processes," 2012, 3 pages .	☐
	005	"Polycarbonate," Encyclopaedia Britannica, 24 August 2017, 1 page, URL: https://www.britannica.com/science/polycarbonate.	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	06/10/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Garrett Potter/	Date (YYYY-MM-DD)	2020-05-12
Name/Print	Garrett Potter	Registration Number	76,602

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

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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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	437	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/02/14 10:59
S2	939	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/02/14 10:59
S3	2,184	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:26
S4	108,400	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S5	2,363	S4 and dental	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S6	4,722	S4 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:37
S7	2	13/470,681.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/14 11:42
S8	4	("2009/0246724").URPN.	USPAT	OR	ON	2019/02/19 10:41

S9	108,672	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:42
S11	121	(dental teeth) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:43
S12	50	(dental teeth) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:45
S13	53	dental and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:47
S14	98	(oral dental) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:00
S15	40	(dental oral) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:01
S16	2,480	(oral dental) and (braces retainers) and polymeric adj material	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:03
S17	18	(oral dental) and (braces retainers) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:04

S18	3,542	(A61C7/00).IPCR.	US-PGPUB; USPAT	OR	OFF	2019/02/19 13:53
S19	124	S18 and layers and polymeric near5 material and (hardness hard durometer stiff stiffness) and sheet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 13:55
S20	821	S18 and (polyester co-polyester polycarbonate "thermoplastic polyurethane" polypropylene polyethylene polypropylene "polyethylene copolymer" acrylic "cyclic block copolymer" polyetheretherketone polyamide "polyethylene terephthalate" "polybutylene terephthalate" polyetherimide polyethersulfone "polytrimethylene terephthalate")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:17
S21	201	S18 and ((styrenic adj1 block adj1 copolymer "SBC") "silicone rubber" "elastomeric alloy" (thermoplastic adj1 elastomer "TPE") (thermoplastic adj1 vulcanizate adj1 elastomer "TPV" adj1 elastomer) "polyurethane elastomer" "block copolymer elastomer" "polyolefin blend elastomer" "thermoplastic co-polyester elastomer" "thermoplastic polyamide elastomer")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:19
S22	125	S21 and S20	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:20
S23	81	soft adj1 polymer adj1 layer and hard adj1 polymer adj1 layer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/21 15:43
S24	172	("20010041320" | "20020006597" | "20030009252" | "20030139834" | "20030224311" | "20040128010" | "20040146670" | "20050055118" | "20070148608" | "20080299507" | "20090087808" | "20090239188" | "20090246724" | "20100055639" |	US-PGPUB; USPAT	OR	ON	2019/03/07 09:13

		"20150140300" | "20160228215" | "2467432" | "3407500" | "3600808" | "3660900" | "3683502" | "3738005" | "3860803" | "3916526" | "3922786" | "3950851" | "3983628" | "4014096" | "4195046" | "4253828" | "4324546" | "4324547" | "4348178" | "4478580" | "4500294" | "4504225" | "4505673" | "4526540" | "4575330" | "4575805" | "4591341" | "4609349" | "4611288" | "4656860" | "4663720" | "4664626" | "4676747" | "4742464" | "4755139" | "4763791" | "4791156" | "4793803" | "4798534" | "4836778" | "4837732" | "4850864" | "4850865" | "4856991" | "4877398" | "4880380" | "4889238" | "4890608" | "4935635" | "4936862" | "4937928" | "4941826" | "4964770" | "4975052" | "4983334" | "5011405" | "5017133" | "5024790" | "5027281" | "5035613" | "5055039" | "5059118" | "5100316" | "5121333" | "5125832" | "5128870" | "5130064" | "5131843" | "5131844" | "5139419" | "5145364" | "5176517" | "5184306" | "5186623" | "5257203" | "5273429" | "5278756" | "5328362" | "5338198" | "5340309" | "5342202" | "5368478" | "5382164" | "5395238" | "5431562" | "5440326" | "5440496" | "5447432" | "5452219" | "5454717" | "5456600" | "5474448" | "5518397" | "5528735" | "5533895" | "5542842" | "5549476" | "5562448" | "5587912" | "5605459" | "5607305" | "5614075" | "5621648" | "5645420" | "5645421" | "5655653" | "5683243" | "5692894" | "5725376" | "5725378" | "5733126" | "5740267" | "5742700" | "5799100" | "5800174" | "5823778" | "5848115" | "5857853" | "5866058" | "5879158" | "5880961" | "5880962" | "5934288" | "5957686" | "5964587" | "5971754" | "5975893" | "6015289" | "6044309" | "6049743" | "6062861" | "6068482" | "6099314" | "6123544" | "6152731" | "6183248" | "6190165" | "6217325" | "6217334" | "6244861" | "6309215" | "6315553" | "6322359" | "6350120" | "6382975" | "6398548" | "6402707" | "6482298" | "6524101" | "6554611" | "6572372" | "6629840" | "6705863" | "6722880" | "7641828" |			

		"8235713" | "8496473" | "RE35169").PN.				
S25	4	"4791156".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/23 15:58
S26	112,431	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:05
S27	5,186	S26 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:06
S28	29	elongation near20 (2{d2} adj2 ("%" percent)) and S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:07
S29	3,073	elongation near20 (2{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:12
S30	1,879	elongation near20 (4{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:14
S31	2,816	elongation near20 (3{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:17

S32	6,273	S29 S30 S31	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S33	40	S27 and S32	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S34	29,226	modulus near20 psi	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S35	1	S33 and S34	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:22
S36	7	("10052176" | "20080230938" | "20090130438" | "20170007362" | "6667101" | "9655691" | "9655693").PN.	US-PGPUB; USPAT	OR	ON	2019/09/23 16:24
S37	2	"2004146670".pn.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 17:12
S38	12	("20020192617" | "20030190576" | "20040170941" | "20070231765" | "20080020337" | "20190159870" | "20190183611" | "20190231484" | "6390812" | "6485298" | "6705861" | "7121825").PN.	US-PGPUB; USPAT	OR	ON	2019/09/23 17:18
S39	58,583	resin near20 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S40	47,502	resin near10 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S41	237,081	resin near10 polyurethane	US-PGPUB; USPAT; USOCR; EPO;	OR	ON	2019/09/25 09:58

			JPO; DERWENT			
S42	9,409	S40 and S41	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S43	3	ISOPLAST near5 "2530" near10 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 10:04
S44	472	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/09/25 10:17
S45	121,112	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 14:57
S46	5,358	S45 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 14:57
S47	36	elongation near20 (3{d2} adj2 ("%" percent)) and S46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:14
S48	5,358	S45 and (dental teeth tooth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:22
S49	36	elongation near20 (3{d2} adj2 ("%" percent)) and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:24

S50	30	elongation near20 (2{d2} adj2 ("%" percent)) and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:37
S51	2,379	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:40
S52	1,088	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/11/12 15:45
S53	485	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/11/12 15:48
S54	1,225	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2020/06/09 11:07
S55	2,536	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/09 11:07
S56	129,293	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/09 11:15
S57	5,836	S56 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/09 11:15
S58	547	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2020/06/09 11:58
S59	7	("20080248438" | "20090298006" | "20110020761" | "6454565" | "6746757" | "7201575" | "7354270").PN.	US-PGPUB; USPAT	OR	ON	2020/06/10 09:03

EAST Search History (Interference)

<This search history is empty>

6/10/2020 12:41:04 PM
C:\Users\cmontiel\Documents\EAST\Workspaces\15476655.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO Automated Interview Request (AIR)

Oct 29 2020

This paper requesting to schedule and/or conduct an interview is appropriate because:

This submission is requested to be accepted as an authorization for this interview to communicate via the internet. Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned concerning scheduling of the interview via video conference, instant messaging, or electronic mail, and to conduct the interview in accordance with office practice including video conferencing.

Name(s):
Patrick Medley

S-signature:
/Patrick Medley/

Registration Number:
74735

U.S. Application Number:
15476655

Confirmation Number:
5936

E-mail Address:
pmedley@wsgr.com

Phone Number:
+1 2065498301

Proposed Time of Interview:
11-6-2020 3:00 PM ET

Alternative Proposed Time(s) of Interview:
11-4-2020 1:30 PM ET

Alternative Proposed Time(s) of Interview:
11-5-2020 4:00 PM ET

Prefered Interview Type:
Video Conference

I am the applicant or applicant's representative for this application.

Topic for Discussion:

uspto UNITED STATES PATENT AND TRADEMARK OFFICE

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.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 11/12/2020

Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
MONTIEL, CAROLINE	

ART UNIT	PAPER NUMBER
1748	

NOTIFICATION DATE	DELIVERY MODE
11/12/2020	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):

patentdocket@wsgr.com

Applicant-Initiated Interview Summary	**Application No.** 15/476,655	**Applicant(s)** LI et al.		
	Examiner CAROLINE MONTIEL	**Art Unit** 1748	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
CAROLINE MONTIEL	Examiner	WebEx/Video Conference
JACOB MINSKEY	Primary Examiner	
PATRICK MEDLEY	Attorney	
LORA GREEN	Attorney	

Date of Interview: 06 November 2020

Issues Discussed:

Proposed Amendment(s)

Arguments and proposed amendments are found persuasive and overcome the current rejection. Further search and consideration is needed.

☑ Attachment

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Agenda for Examiner Interview
Application No. 15/467,655
Office Action Mail Date: June 24, 2020
Attorney Docket No.: 22773-826.401
Friday, Nov. 6, 2020, 3:00 PM EST

Proposed discussion points:

- Claim elements of pending independent claims missing from DeSimone
- Related Pudleiner hardness disclosure issues
- Claim amendment proposals
- Adequacy of present declaration

Claim amendment example for discussion:

20. A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising three or more polymeric layers, the three or more polymeric layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and ~~of a soft polymeric material~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a positive model of the patient's teeth in a target position; and

fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on November 13, 2020

WILSON SONSINI GOODRICH & ROSATI

By: Robyn Fairbrother

Attorney Docket No.: 22773-826.401
Client Ref. No.: 1228.US.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5936
Chunhua LI et al.	
Application No.: 15/476,655	Examiner: Caroline Montiel
Filed: March 31, 2017	Art Unit: 1748
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	AMENDMENT
Customer No.: 107046	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Non-Final Office Action mailed June 24, 2020, please enter the following amendments and remarks.

A Petition for a two-month Extension of Time is requested and the fee set forth under 37 C.F.R. §1.17(a)(3) is electronically submitted herewith.

Amendments to the Claims are reflected in the listing of claims beginning on page 2.

Remarks begin on page 7.

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Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Patrick Michael Medley/Robyn Fairbrother
Attorney Docket Number:	22773-826.401

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	1	100	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 2 months with $0 paid	1252	1	640	640
Miscellaneous:				
		Total in USD ($)		**740**

Electronic Acknowledgement Receipt	
EFS ID:	41117788
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Patrick Michael Medley/Robyn Fairbrother
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.401
Receipt Date:	13-NOV-2020
Filing Date:	31-MAR-2017
Time Stamp:	14:58:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$740
RAM confirmation Number	E2020ACE59269717
Deposit Account	232415
Authorized User	Robyn Fairbrother
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.21 (Miscellaneous fees and charges) 37 CFR 1.19 (Document supply fees)	

37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		22773_826_401_Amend_NFOA.pdf	200516 610852ec3246cb2198a44e6690c2404dd98f7b99	yes	11

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Applicant Arguments/Remarks Made in an Amendment	7	11
Claims	2	6
Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	32414 e81d3d2afca4d1f7716d2073725bce61584f8f70	no	2

Warnings:

Information:

3	EFS Acknowledgment Receipt	efilingAck.pdf	51548 2326a238371b660c97c1f7d2cf345a03229fcc29	no	2

Warnings:

Information:

Total Files Size (in bytes):	284478

REMARKS

Upon entry of this amendment, claims 20-40 will be pending in the present application. Claims 20, 23, 31, 24, 27, and 39 have been amended. Claim 41 has been newly added. Support for the amendments can be found in the specification as originally filed. Accordingly, no new matter has been added. Reconsideration is respectfully requested.

Examiner Interview

Applicants thank Examiner Montiel for participating in a WebEx interview on November 6, 2020, with Applicants' representatives Lora Green and Patrick Medley. Additional participants included Primary Examiner Jacob Minsky. The Examiner's rejections of the claims made in a Non-Final Office Action mailed on June 24, 2020, were discussed.

Claim Rejections – 35 USC § 102

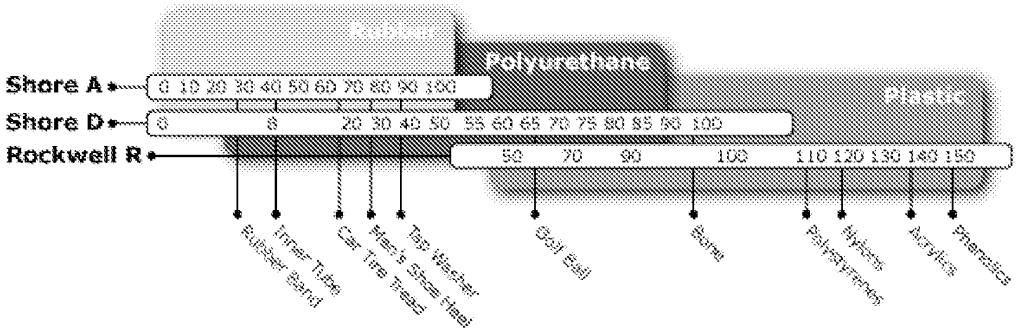
Claims 20-21, 23, 25-30, and 37-39 were rejected under pre-AIA 35 U.S.C. § 102(b) as allegedly anticipated by DeSimone et al. (U.S. Patent No. 7,641,828, hereinafter "DeSimone"), as evidenced by Pudleiner et al. (U.S. Pub. No. 2015/0140300, hereinafter "Pudleiner"). Applicants respectfully traverse the rejection.

The Office Action identifies DeSimone's disclosure of ISOPLAST 2530 as allegedly teaching "a soft polymeric layer of a soft polymeric material having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D," as recited in previously presented independent claims 20 and 37. Office Action at 6, 9-10. However, ISOPLAST 2530 fails to satisfy these material requirements. ISOPLAST 2530 is a thermoplastic polyurethane produced by Lubrizol Advanced Materials, Inc. The ISOPLAST 2530 datasheet was cited in an IDS in this application on March 17, 2017, and is available for download at https://www.lubrizol.com/-/media/Lubrizol/Life-Sciences/Documents/TDS/Isoplast-2530-ETPU-English.pdf. The datasheet identifies ISOPLAST 2530 as having a Rockwell Hardness of 121 R and an elongation at break of 160%. These properties put ISOPLAST 2530 outside the scope of the present claims.

With regard to hardness, materials with a Rockwell Hardness of 121 R are generally substantially harder than materials with a Shore Hardness of about 82 D, which is the hardness

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the Office Action relies on for ISOPLAST 2530 as allegedly taught by Pudleiner. Office Action at 6, 9-10. Although the Shore and Rockwell scales use different measurements, leading to some variation in converting between scales, a hardness of 121 R is generally much harder than the claimed hardness range of about 60 A to about 85 D. For example, a conversion chart provided by one plastics company (available at http://www.midwestinnovators.com/material-properties/durometer.html) shows that 121 R falls far outside the claimed hardness range of about 60 A to about 85 D for the soft layer:



This undermines the assertion that the ISOPLAST 2530 material disclosed by DeSimone had a hardness within the claimed range. To the extent Pudleiner discloses a different formulation of this material, Applicants note that Pudleiner is not prior art, so its disclosure cannot be applied as teaching such a material. In addition, the ordinary artisan, looking for the properties of a disclosed material such as ISOPLAST 2530, would have looked to the manufacturer's datasheet.

Regardless, even if ISOPLAST 2530 were to have a hardness within the claimed range, the ISOPLAST 2530 datasheet also indicates that its elongation at break is not "greater than about 200%" as recited in independent claim 21. In particular, the ISOPLAST 2530 datasheet discloses an elongation at break of 160%, which is not "greater than about 200%."

Although the Office Action relies on a statement by DeSimone of a material with "an elongation at break of greater than 80%, which encompasses the claim," this fails for at least two reasons. First, the disclosure of a broad range can only anticipate a narrow range if the broad range discloses the narrow range with "sufficient specificity." MPEP § 2131.03. The recited soft material has more than twice the elongation at its lower limit as does DeSimone's range (80 is less than half of 200). The Office Action has not claimed that such a large discrepancy can disclose the range with "sufficient specificity," as required to sustain an anticipation ground.

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Second, the Office Action relies on ISOPLAST 2530 specifically as disclosing the soft polymeric material. Yet ISOPLAST 2530's elongation at break of 160% is not greater than about 200% as recited in the claims. Accordingly, DeSimone fails to disclose "a soft polymeric layer" with "an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D," as recited in independent claims 20 and 37.

DeSimone also fails to anticipate the independent claims 20 and 37 because it fails to disclose the step of "fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model" as recited in claim 20, or the similar last limitation in claim 37. The Office Action cites to "the coating of a second transparent material" as described in DeSimone as disclosing the soft layer of the sheet recited in independent claims 20 and 37. Office Action at 6, 9. However, DeSimone describes "forming a sheet of transparent curable polymeric material into a shell having cavities shaped to receive and reposition teeth from a first orientation to a successive orientation and **then** coating the polymeric shell with a second transparent material." DeSimone, 2:42-48 (emphasis added); *accord id.*, 8:37-43; *see also id.*, Fig 4 (showing coating step performed after sheet-forming step). If the coating is applied only after thermoforming, it cannot be a layer of the sheet that is thermoformed. Thus, DeSimone does not disclose thermoforming with a sheet comprising a hard layer and a soft layer, as recited in claims 20 and 37, because it instead discloses thermoforming with a single-layer sheet, then adding a coating afterwards.

As discussed above, DeSimone fails to disclose either "a soft polymer layer . . . having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D" or a step of thermoforming the recited sheet over a positive model, as recited in independent claims 20 and 37. Accordingly, DeSimone does not anticipate independent claims 20 and 37. Claims 21, 23, 25-30, 38, and 39 depend from one of allowable claims 20 and 37, respectively, and are therefore allowable at least for their dependence on one of claims 20 and 37, and on their own merits.

Nevertheless, in order to expedite prosecution, independent claim 20 and 37 have been amended to further recite that the sheet comprises three or more polymeric layers and that the soft polymeric layer comprises a thermoplastic polyurethane elastomer. DeSimone also fails to disclose these additional elements.

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Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 20-21, 23, 25-30, and 37-39 under 35 U.S.C. § 102(b) is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 22, 24, 31-36, and 40 were rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly unpatentable over DeSimone, considered with Pudleiner, in view of Chen et al. (U.S. Pub. No. 2009/0246724, hereinafter "Chen"). Applicants respectfully traverse the rejection.

Claims 22, 24, 31-36, and 40 are allowable over DeSimone as evidenced by Pudleiner for at least the same reasons as discussed above, with respect to the rejection of independent claims 20 and 37. Chen is cited for purportedly teaching more than one hard or soft polymer layers, Office Action at 11-12, 35-36, three or more polymer layers, *id.* at 13, the arrangement thereof, *id.* at 13-14, or co-extrusion of layers, *id.* at 15. However, even if these characterizations of Chen were correct, which Applicants do not concede, they would not remedy the deficiencies of DeSimone and Pudleiner, as described above. For example, neither DeSimone nor Chen discloses "a soft polymer layer . . . having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D," as recited in previously-presented independent claims 20 and 37, nor do they disclose that the soft polymeric layer comprises a thermoplastic polyurethane elastomer, as recited in amended independent claims 20 and 37. Accordingly, claims 22, 24, 31-36, and 40 are allowable over DeSimone and Chen due to their dependency from independent claims 20 and 37, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 22, 24, 31-36, and 40 under 35 U.S.C. § 103(a) is respectfully requested.

New Claims

Claim 41 is newly added. Support for this new claim can be found throughout the application as originally filed, for example at paragraphs [0024], [0025], and [0027]-[0030]. The new claim is allowable for its dependency from independent claim 20, as well as on its own merits.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 23-2415.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-883-2500.

Respectfully submitted,

Dated: November 13, 2020

/Patrick Medley/

Patrick Medley
Registration No. 74,735

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-19. (Canceled)

20. (Currently Amended) A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and ~~of a soft polymeric material~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a positive model of the patient's teeth in a target position; and

fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. (Previously Presented) The method of claim 20, wherein the hard polymer layer further comprises a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers each independently comprise a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a

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polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

23. (Currently Amended) The method of claim 20, wherein the soft ~~polymeric material~~ polymer layer further comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, ~~a polyurethane elastomer,~~ a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. (Previously Presented) The method of claim 20, wherein the soft polymer layer comprises at least two layers, and wherein the at least two layers each independently comprise a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet environment, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. (Previously Presented) The method of claim 20, wherein the soft polymer layer comprises at least one of an ultimate tensile strength of greater than about 5000 psi, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

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27. (Original) The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

28. (Original) The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. (Previously Presented) The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising the hard polymer layer and the soft polymer layer.

30. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers.

31. (Currently Amended) The method of claim 20, wherein the ~~appliance comprises~~ three or more polymer layers each comprise: ~~the three or more polymer layers comprising the hard polymer layer and the soft polymer layer~~

co-polyester material having a flexural modulus greater than about 150,000 psi; or

thermoplastic polyurethane elastomer material having an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D.

32. (Previously Presented) The method of claim 31, wherein the three or more polymer layers alternate between soft and hard polymer layers.

33. (Previously Presented) The method of claim 31, wherein the hard polymer layer is positioned adjacent to one or more soft polymer layers, the one or more soft polymer layers comprising the soft polymer layer.

34. (Currently Amended) The method of claim 20[[31]], wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer, the second soft

polymer layer comprising an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D.

35. (Previously Presented) The method of claim 20, wherein the appliance comprises a co-extruded material.

36. (Previously Presented) The method of claim 20, wherein the appliance comprises a thickness of between 500 μm and 1200 μm.

37. (Currently Amended) A method of making a plurality of dental appliances for positioning a patient's teeth, the method comprising:

providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and ~~of a soft polymeric material~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a plurality of positive models of the patient's teeth, each in a target position; and

fabricating the plurality of dental appliances, each as a negative of at least one of the plurality of positive models comprising thermoforming the sheet over the at least one positive model.

38. (Previously Presented) The method of claim 37, wherein the hard polymer layer further comprises a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

39. (Currently Amended) The method of claim 37, wherein the soft ~~polymeric material~~ polymer layer further comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, ~~a polyurethane elastomer,~~ a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

40. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers each independently comprise a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

41. (New) The method of claim 32, wherein the sheet has three polymer layers.

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/476,655	Filing Date 03/31/2017	☐ 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 $80 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $420 =	
☐ 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	11/13/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $480 =	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".	/PAMELA V THERATT/
*** 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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I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on November 13, 2020

WILSON SONSINI GOODRICH & ROSATI

By: Robyn Fairbrother

Attorney Docket No.: 22773-826.401
Client Ref. No.: 1228.US.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5936
Chunhua LI et al.	
Application No.: 15/476,655	Examiner: Caroline Montiel
Filed: March 31, 2017	Art Unit: 1748
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	AMENDMENT
Customer No.: 107046	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Non-Final Office Action mailed June 24, 2020, please enter the following amendments and remarks.

A Petition for a two-month Extension of Time is requested and the fee set forth under 37 C.F.R. §1.17(a)(3) is electronically submitted herewith.

Amendments to the Claims are reflected in the listing of claims beginning on page 2.

Remarks begin on page 7.

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Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Patrick Michael Medley/Robyn Fairbrother
Attorney Docket Number:	22773-826.401

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	1	100	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 2 months with $0 paid	1252	1	640	640
Miscellaneous:				
		Total in USD ($)		**740**

Electronic Acknowledgement Receipt	
EFS ID:	41117788
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Patrick Michael Medley/Robyn Fairbrother
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.401
Receipt Date:	13-NOV-2020
Filing Date:	31-MAR-2017
Time Stamp:	14:58:32
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		22773_826_401_Amend_NFOA.pdf	200516 610852ec3246cb2198a44e6690c2404dd98f7b99	yes	11

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	7	11
	Claims	2	6
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32414 e81d3d2afca4d1f7716d2073725bce61584f8f70	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	232930		

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<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.

REMARKS

Upon entry of this amendment, claims 20-40 will be pending in the present application. Claims 20, 23, 31, 24, 27, and 39 have been amended. Claim 41 has been newly added. Support for the amendments can be found in the specification as originally filed. Accordingly, no new matter has been added. Reconsideration is respectfully requested.

Examiner Interview

Applicants thank Examiner Montiel for participating in a WebEx interview on November 6, 2020, with Applicants' representatives Lora Green and Patrick Medley. Additional participants included Primary Examiner Jacob Minsky. The Examiner's rejections of the claims made in a Non-Final Office Action mailed on June 24, 2020, were discussed.

Claim Rejections – 35 USC § 102

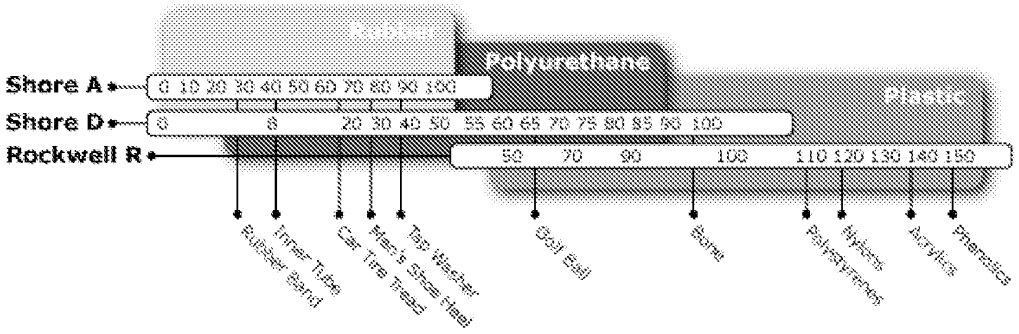
Claims 20-21, 23, 25-30, and 37-39 were rejected under pre-AIA 35 U.S.C. § 102(b) as allegedly anticipated by DeSimone et al. (U.S. Patent No. 7,641,828, hereinafter "DeSimone"), as evidenced by Pudleiner et al. (U.S. Pub. No. 2015/0140300, hereinafter "Pudleiner"). Applicants respectfully traverse the rejection.

The Office Action identifies DeSimone's disclosure of ISOPLAST 2530 as allegedly teaching "a soft polymeric layer of a soft polymeric material having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D," as recited in previously presented independent claims 20 and 37. Office Action at 6, 9-10. However, ISOPLAST 2530 fails to satisfy these material requirements. ISOPLAST 2530 is a thermoplastic polyurethane produced by Lubrizol Advanced Materials, Inc. The ISOPLAST 2530 datasheet was cited in an IDS in this application on March 17, 2017, and is available for download at https://www.lubrizol.com/-/media/Lubrizol/Life-Sciences/Documents/TDS/Isoplast-2530-ETPU-English.pdf. The datasheet identifies ISOPLAST 2530 as having a Rockwell Hardness of 121 R and an elongation at break of 160%. These properties put ISOPLAST 2530 outside the scope of the present claims.

With regard to hardness, materials with a Rockwell Hardness of 121 R are generally substantially harder than materials with a Shore Hardness of about 82 D, which is the hardness

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the Office Action relies on for ISOPLAST 2530 as allegedly taught by Pudleiner. Office Action at 6, 9-10. Although the Shore and Rockwell scales use different measurements, leading to some variation in converting between scales, a hardness of 121 R is generally much harder than the claimed hardness range of about 60 A to about 85 D. For example, a conversion chart provided by one plastics company (available at http://www.midwestinnovators.com/material-properties/durometer.html) shows that 121 R falls far outside the claimed hardness range of about 60 A to about 85 D for the soft layer:



This undermines the assertion that the ISOPLAST 2530 material disclosed by DeSimone had a hardness within the claimed range. To the extent Pudleiner discloses a different formulation of this material, Applicants note that Pudleiner is not prior art, so its disclosure cannot be applied as teaching such a material. In addition, the ordinary artisan, looking for the properties of a disclosed material such as ISOPLAST 2530, would have looked to the manufacturer's datasheet.

Regardless, even if ISOPLAST 2530 were to have a hardness within the claimed range, the ISOPLAST 2530 datasheet also indicates that its elongation at break is not "greater than about 200%" as recited in independent claim 21. In particular, the ISOPLAST 2530 datasheet discloses an elongation at break of 160%, which is not "greater than about 200%."

Although the Office Action relies on a statement by DeSimone of a material with "an elongation at break of greater than 80%, which encompasses the claim," this fails for at least two reasons. First, the disclosure of a broad range can only anticipate a narrow range if the broad range discloses the narrow range with "sufficient specificity." MPEP § 2131.03. The recited soft material has more than twice the elongation at its lower limit as does DeSimone's range (80 is less than half of 200). The Office Action has not claimed that such a large discrepancy can disclose the range with "sufficient specificity," as required to sustain an anticipation ground.

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Second, the Office Action relies on ISOPLAST 2530 specifically as disclosing the soft polymeric material. Yet ISOPLAST 2530's elongation at break of 160% is not greater than about 200% as recited in the claims. Accordingly, DeSimone fails to disclose "a soft polymeric layer" with "an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D," as recited in independent claims 20 and 37.

DeSimone also fails to anticipate the independent claims 20 and 37 because it fails to disclose the step of "fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model" as recited in claim 20, or the similar last limitation in claim 37. The Office Action cites to "the coating of a second transparent material" as described in DeSimone as disclosing the soft layer of the sheet recited in independent claims 20 and 37. Office Action at 6, 9. However, DeSimone describes "forming a sheet of transparent curable polymeric material into a shell having cavities shaped to receive and reposition teeth from a first orientation to a successive orientation and **then** coating the polymeric shell with a second transparent material." DeSimone, 2:42-48 (emphasis added); *accord id.*, 8:37-43; *see also id.*, Fig 4 (showing coating step performed after sheet-forming step). If the coating is applied only after thermoforming, it cannot be a layer of the sheet that is thermoformed. Thus, DeSimone does not disclose thermoforming with a sheet comprising a hard layer and a soft layer, as recited in claims 20 and 37, because it instead discloses thermoforming with a single-layer sheet, then adding a coating afterwards.

As discussed above, DeSimone fails to disclose either "a soft polymer layer . . . having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D" or a step of thermoforming the recited sheet over a positive model, as recited in independent claims 20 and 37. Accordingly, DeSimone does not anticipate independent claims 20 and 37. Claims 21, 23, 25-30, 38, and 39 depend from one of allowable claims 20 and 37, respectively, and are therefore allowable at least for their dependence on one of claims 20 and 37, and on their own merits.

Nevertheless, in order to expedite prosecution, independent claim 20 and 37 have been amended to further recite that the sheet comprises three or more polymeric layers and that the soft polymeric layer comprises a thermoplastic polyurethane elastomer. DeSimone also fails to disclose these additional elements.

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Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 20-21, 23, 25-30, and 37-39 under 35 U.S.C. § 102(b) is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 22, 24, 31-36, and 40 were rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly unpatentable over DeSimone, considered with Pudleiner, in view of Chen et al. (U.S. Pub. No. 2009/0246724, hereinafter "Chen"). Applicants respectfully traverse the rejection.

Claims 22, 24, 31-36, and 40 are allowable over DeSimone as evidenced by Pudleiner for at least the same reasons as discussed above, with respect to the rejection of independent claims 20 and 37. Chen is cited for purportedly teaching more than one hard or soft polymer layers, Office Action at 11-12, 35-36, three or more polymer layers, *id.* at 13, the arrangement thereof, *id.* at 13-14, or co-extrusion of layers, *id.* at 15. However, even if these characterizations of Chen were correct, which Applicants do not concede, they would not remedy the deficiencies of DeSimone and Pudleiner, as described above. For example, neither DeSimone nor Chen discloses "a soft polymer layer . . . having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D," as recited in previously-presented independent claims 20 and 37, nor do they disclose that the soft polymeric layer comprises a thermoplastic polyurethane elastomer, as recited in amended independent claims 20 and 37. Accordingly, claims 22, 24, 31-36, and 40 are allowable over DeSimone and Chen due to their dependency from independent claims 20 and 37, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 22, 24, 31-36, and 40 under 35 U.S.C. § 103(a) is respectfully requested.

New Claims

Claim 41 is newly added. Support for this new claim can be found throughout the application as originally filed, for example at paragraphs [0024], [0025], and [0027]-[0030]. The new claim is allowable for its dependency from independent claim 20, as well as on its own merits.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 23-2415.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-883-2500.

Respectfully submitted,

Dated: November 13, 2020

/Patrick Medley/

Patrick Medley
Registration No. 74,735

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-19. (Canceled)

20. (Currently Amended) A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and ~~of a soft polymeric material~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a positive model of the patient's teeth in a target position; and

fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

21. (Previously Presented) The method of claim 20, wherein the hard polymer layer further comprises a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

22. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers each independently comprise a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a

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polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

23. (Currently Amended) The method of claim 20, wherein the soft ~~polymeric material~~ polymer layer further comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, ~~a polyurethane elastomer,~~ a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

24. (Previously Presented) The method of claim 20, wherein the soft polymer layer comprises at least two layers, and wherein the at least two layers each independently comprise a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

25. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least one of a tensile strength at yield of between about 4000 psi and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a stress relaxation greater than about 10% at 24 hours testing in a wet environment, and a light transmission between 400 nm and 800 nm of greater than about 75%.

26. (Previously Presented) The method of claim 20, wherein the soft polymer layer comprises at least one of an ultimate tensile strength of greater than about 5000 psi, a compression set at about 70 °C of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

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27. (Original) The method of claim 20, further comprising fabricating a plurality of appliances corresponding to different arrangements of the patient's teeth.

28. (Original) The method of claim 27, wherein fabricating the plurality of appliances comprises digitally staging a plurality of digital models of the patient's teeth and generating a plurality of physical models from the digital models.

29. (Previously Presented) The method of claim 27, wherein two or more of the plurality of appliances comprise a sheet comprising the hard polymer layer and the soft polymer layer.

30. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises a plurality of co-extruded or laminated polymer layers.

31. (Currently Amended) The method of claim 20, wherein the ~~appliance comprises~~ three or more polymer layers each comprise: ~~the three or more polymer layers comprising the hard polymer layer and the soft polymer layer~~

co-polyester material having a flexural modulus greater than about 150,000 psi; or

thermoplastic polyurethane elastomer material having an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D.

32. (Previously Presented) The method of claim 31, wherein the three or more polymer layers alternate between soft and hard polymer layers.

33. (Previously Presented) The method of claim 31, wherein the hard polymer layer is positioned adjacent to one or more soft polymer layers, the one or more soft polymer layers comprising the soft polymer layer.

34. (Currently Amended) The method of claim 20[[31]], wherein the hard polymer layer is disposed between the soft polymer layer and a second soft polymer layer, the second soft

polymer layer comprising an elongation at break of greater than about 200% and a hardness from about 60 A to about 85 D.

35. (Previously Presented) The method of claim 20, wherein the appliance comprises a co-extruded material.

36. (Previously Presented) The method of claim 20, wherein the appliance comprises a thickness of between 500 μm and 1200 μm.

37. (Currently Amended) A method of making a plurality of dental appliances for positioning a patient's teeth, the method comprising:

providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and ~~of a soft polymeric material~~ having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a plurality of positive models of the patient's teeth, each in a target position; and

fabricating the plurality of dental appliances, each as a negative of at least one of the plurality of positive models comprising thermoforming the sheet over the at least one positive model.

38. (Previously Presented) The method of claim 37, wherein the hard polymer layer further comprises a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

39. (Currently Amended) The method of claim 37, wherein the soft ~~polymeric material~~ polymer layer further comprises a styrenic block copolymer, a silicone rubber, an elastomeric alloy, a thermoplastic elastomer, a thermoplastic vulcanizate elastomer, ~~a polyurethane elastomer,~~ a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

40. (Previously Presented) The method of claim 20, wherein the hard polymer layer comprises at least two layers and the at least two layers each independently comprise a polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

41. (New) The method of claim 32, wherein the sheet has three polymer layers.

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Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Patrick Michael Medley/Robyn Fairbrother
Attorney Docket Number:	22773-826.401

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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Claims:				
CLAIMS IN EXCESS OF 20	1202	1	100	100
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Petition:				
Patent-Appeals-and-Interference:				
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Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 2 months with $0 paid	1252	1	640	640
Miscellaneous:				
		Total in USD ($)		**740**

Electronic Acknowledgement Receipt	
EFS ID:	41119944
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Patrick Michael Medley/Robyn Fairbrother
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.401
Receipt Date:	13-NOV-2020
Filing Date:	31-MAR-2017
Time Stamp:	15:08:17
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	Fee Worksheet (SB06)	fee-info.pdf	32414 44f22bbe279f9ab0f117da7f97d0b548e95e574a	no	2

Warnings:

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Total Files Size (in bytes):	32414

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New International Application Filed with the USPTO as a Receiving Office
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Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-3763109	10-02-1973	WITSIEPE; W. et al.	
	002	US-3766146	10-16-1973	WITSIEPE; W. et al.	
	003	US-4346195	08-24-1982	HORNBAKER; Edwin D. et al.	
	004	US-4410595	10-18-1983	MATSUMOTO; Koichi et al.	
	005	US-4824723	04-25-1989	CAMPBELL; Richard W. et al.	
	006	US-20020146549	10-10-2002	KRANENBURG-VAN DIJK; Saskia I. et al.	
	007	US-20050100853	05-12-2005	TADROS; Safwat et al.	
	008	US-20090306327	12-10-2009	STEWART; Ray F. et al.	
	009	US-20110069134	03-24-2011	SAKAGAMI; Toshinori et al.	
	010	US-20120315484	12-13-2012	RIEDL; Josef et al.	
	011	US-20150374464	12-31-2015	STEWART; Ray F.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	JP-H06256630-A	09-13-1994	DENKI KAGAKU KOGYO KK., et al.	Abstract:	☒

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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.	T[2]
	001	Material Data Sheet of Ecdel 9966. 3 pages total (Year: 2020).	☐
	002	"Overview of Materials for PETG Copolyester" 2 pages (http://www.nnatweb.conn/search/DataSheet.aspx?MatGUID=4de1c85bb946406a86c52b688e3810d0&ckck=1) (webpage retrieved on 10/27/2020) (Year: 2020).	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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 (1-800-786-9199) and select option 2.

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Patrick Medley/	Date (YYYY-MM-DD)	2020-11-13
Name/Print	Patrick Medley, Ph.D.	Registration Number	74,735

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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.**

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	1748
Serial Number:	15/476,655	Examiner:	MONTIEL, CAROLINE
Filing or 371 (c) Date:	2017-03-31	**CONFIRMATION NO:**	**5936**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: November 13, 2020

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☐ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☐ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☒ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☒ a fee of $260.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $260.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* 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 or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $260.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22773-826.401).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: November 13, 2020

By: /Patrick Medley/
Patrick Medley, Ph.D.
Reg. No. 74,735

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 107046

Bibliographic data

Title:	POLYETHYLENE TEREPHTHALATE RESIN COMPOSITION, SHEET AND MOLDING
Pub/Pat no:	JPH06256630A
Pub/Issue Date:	1994-09-13
Inventor(s):	SUGIMOTO YUTAKA| HIDA MASAYUKI| YOKOBORI KATSUICHI|SUGIMOTO YUTAKA |HIDA MASAYUKI |YOKOBORI KATSUICHI
Applicant(s):	DENKI KAGAKU KOGYO KK| DENKA KAKO KK
Classification:	B32B27/36AI; C08J5/00AI; C08L67/00AI; C08L67/02AI
Application number:	JP19930043961 1993-03-04
Priority number:	JP19930043961 1993-03-04;

Abstract of JPH06256630A

PURPOSE:To obtain the subject composition excellent in transparency, slipperiness and stackablity, a sheet formed from the composition, and its molding. CONSTITUTION:This resin composition comprises 99.5-90wt.% polyethylene terephthalate resin (A) having a Shore D hardness of at least 70 and 0.5-10wt.% thermoplastic polyester elastomer (B) having a Shore D hardness of 25 to 80, and a difference in Shore D hardness between the components A and B is at least 2.

(19)日本国特許庁（ＪＰ）　(12) **公開特許公報**（Ａ）　(11)特許出願公開番号

特開平6－256630

(43)公開日　平成６年(1994)９月13日

(51)Int.Cl.[5]	識別記号	庁内整理番号	ＦＩ	技術表示箇所
Ｃ０８Ｌ　67/02	ＬＰＤ	8933－4Ｊ		
Ｂ３２Ｂ　27/36		7016－4Ｆ		
Ｃ０８Ｊ　5/00	ＣＦＤ	7016－4Ｆ		

審査請求　未請求　請求項の数５　ＯＬ　（全　８　頁）

(21)出願番号　特願平5－43961

(22)出願日　平成５年(1993)３月４日

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最終頁に続く

(54)【発明の名称】　ポリエチレンテレフタレート系樹脂組成物、シート及び成形品

(57)【要約】
【目的】　透明性、スリップ性及びスタッキング性に優れたポリエチレンテレフタレー系樹脂組成物、該組成物からなるシート及びその成形品を得る。
【構成】　Ａ成分としてショアＤスケール硬度が70以上のポリエチレンテレフタレー系樹脂99.5～90重量％と、Ｂ成分としてショアＤスケール硬度が25～80の熱可塑性ポリエステルエラストマー0.5 ～10重量％を含有し、Ａ成分とＢ成分のショアＤスケール硬度差が２以上であることを特徴とするポリエチレンテレフタレー系樹脂組成物、該組成物からなるシート及び成形品。

【特許請求の範囲】
【請求項１】　Ａ成分として、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂99.5～90重量％と、Ｂ成分としてショアＤスケール硬度が25～80の熱可塑性ポリエステルエラストマー0.5 ～10重量％を含有し、Ａ成分とＢ成分のショアＤスケール硬度差が２以上であることを特徴とするポリエチレンテレフタレート系樹脂組成物。
【請求項２】　請求項１記載の樹脂組成物からなるシート。
【請求項３】　請求項１記載の樹脂組成物からなる層をスキン層とし、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂からなる層をコア層として、スキン層：コア層の肉厚比率が１：２～５０からなることを特徴とする多層シート。
【請求項４】　請求項１記載の樹脂組成物からなる層をスキン層とし、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂からなる層をコア層として、スキン層Ａ：コア層：スキン層Ｂの３層からなり、スキン層Ａ又はスキン層Ｂ：コア層の肉厚比率が１：２～５０からなることを特徴とする多層シート。
【請求項５】　請求項２、請求項３又は請求項４記載のシートを熱成形してなる成形品。
【発明の詳細な説明】
【０００１】
【産業上の利用分野】本発明は、主に食品、玩具或いは電気部品の包装容器、ブリスターパックなどに用いられる透明性、スリップ性及びスタッキング性に優れたポリエステル系樹脂組成物、該組成物からなるシート及びその成形品に関する。
【０００２】
【従来の技術】従来、ポリエチレンテレフタレート系樹脂シートを用い成形した容器は、特に透明性、機械的強度及び食品衛生性に優れるため、食品、玩具或いは電気部品の包装容器、ブリスターパックなどに数多く使用されている。ポリエチレンテレフタレート系樹脂シートは、表面が平滑で透明性に優れているが、スリップ性が悪く、シートを押出成形する際には、シートの巻きズレやしわが発生し易く、特に薄物シートにおいて、良好なロールシートが得られ難い欠点がある。更に、このシートを熱成形して得られる成形品は、積み重ねた際に成形品が一枚づつ剥がれ難いというスタッキング性不良の欠点がある。
【０００３】これらの問題を解決する手段としては、シリカ等の無機系の滑剤、有機系の滑剤及び可塑剤を樹脂に練り込む方法、さらにシリコンエマルジョン等の潤滑剤をシート或いは成形品の表面に塗布する方法が知られている。
【０００４】しかしながら、前者の滑剤の練込みによる方法では、熱成形において加熱時にポリエチレンテレフタレート系樹脂の結晶化を促進する事により、得られた成形品の透明性が著しく低下する問題があった。また、上記の問題に加え、特に有機系の滑剤を使用する場合、練込みや押出等の加工工程において、ポリエチレンテレフタレート系樹脂の加工温度が高いため、低沸点の滑剤・可塑剤が蒸発揮散する等して、シートのスリップ性及び成形品のスタッキング性向上ができなかった。また、後者のシリコンエマルジョン等の潤滑剤塗布の方法は、成形加工後の処理のため、成形加工時の熱結晶化による透明性の低下は少ないが、塗布むら等による滑性効果のばらつき、シート外観不良、表面の印刷性不良及びヒートシール性不良等に欠点が有る。
【０００５】
【発明が解決しようとする課題】本発明は、かかる欠点を解決するものであり、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂とショアＤスケール硬度が25～80の熱可塑性ポリエステルエラストマーを含有し、前記２成分のショアＤスケール硬度差が２以上である樹脂組成物からなる、透明性、スリップ性及びスタッキング性に優れたポリエチレンテレフタレート系樹脂組成物、該樹脂組成物を用いたシート及びその成形品を提供することを目的とするものである。本発明者等は、該樹脂組成物を用いて作成したシートが、透明性、機械的強度に優れ、しかもシート表面のスリップ性が良好で、シート原反の巻きずれもなく、また、成形性も良く、シートの垂れ下がりも小さく成形条件幅が広くとれ、更に、積み重ねられた成形品は、スタッキング性が良好であることを見いだし、本発明を完成するに至った。
【０００６】
【課題を解決するための手段】すなわち、本発明は
（１）　Ａ成分として、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂99.5～90重量％と、Ｂ成分としてショアＤスケール硬度が25～80の熱可塑性ポリエステルエラストマー0.5 ～10重量％を含有し、Ａ成分とＢ成分のショアＤスケール硬度差が２以上であることを特徴とするポリエチレンテレフタレート系樹脂組成物。
（２）　（１）記載の樹脂組成物からなるシート。
（３）　（１）記載の樹脂組成物からなる層をスキン層とし、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂からなる層をコア層として、スキン層：コア層の肉厚比率が１：２～５０からなることを特徴とする多層シート。
（４）　（１）記載の樹脂組成物からなる層をスキン層とし、ショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂からなる層をコア層として、スキン層Ａ：コア層：スキン層Ｂの３層からなり、スキン層Ａ又はスキン層Ｂ：コア層の肉厚比率が１：２～５０からなることを特徴とする多層シート。

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（５）　（２）、（３）又は（４）記載のシートを熱成形してなる成形品。である。

【０００７】以下、本発明を更に詳細に説明する。本発明のＡ成分として用いられるショアＤスケール硬度が70以上のポリエチレンテレフタレート系樹脂（以下、ＰＥＴ系樹脂と略す）は、通常、エチレングリコールとテレフタル酸の重縮合によって得られるものが使用できる。この他、グリコール成分としては、エチレングリコールに替えてジエチレングリコール、１，４－テトラメチレングリコール、１，４－シクロヘキサンジメタノール、ヘプタメチレングリコールを、ジカルボン酸成分としては、テレフタル酸に変えて、イソフタル酸、１，５－ナフタレンジカルボン酸、アジピン酸等を、全量または一部、置き換えたＰＥＴ系樹脂を使用出来る。３成分系のＰＥＴ系樹脂としては、エチレングリコール、１，４－シクロヘキサンジメタノール及びテレフタル酸の重縮合物が特に好ましい。食品、玩具或いは電気部品の包装容器、ブリスターパック等に使用可能であるためには、ＰＥＴ系樹脂のショアＤスケール硬度は70以上が好ましく、特に好ましくは74～９０の範囲である。

【０００８】次に、本発明のＢ成分として用いられる熱可塑性ポリエステルエラストマー（以下、ポリエステルエラストマーと略す）は、ポリエステルのハードセグメントとポリエステルまたはポリエーテルのソフトセグメントからなり、ショアＤスケール硬度が25～80の範囲、特に好ましくは30～75の範囲のポリエステルエラストマーであればその構成モノマーや重合比率、重合形態、架橋剤、添加剤等について限定するものではない。ポリエステルエラストマーのショアＤスケール硬度が25未満のもの及び80を越えるものを用いると、透明性、スリップ性および成形品のスタッキング性に優れたポリエチレンテレフタレート系樹脂組成物は得られない。

【０００９】ポリエステルエラストマーとしては、例えば、ハードセグメントにポリブチレンテレフタレート単位、ソフトセグメントにポリ（テトラメチレンオキシド）グリコール単位等の脂肪族ポリエーテルをもつポリエステル・ポリエーテル型のポリエステルエラストマーや、ハードセグメントにポリブチレンテレフタレート単位、ソフトセグメントにポリ（ε－カプロラクトン）、ポリブチレンアジペート単位等の脂肪族ポリエステルをもつポリエステル・ポリエステル型のポリエステルエラストマー等があげられる。また、上記以外にもそのソフトセグメント、ハードセグメントがポリブタジエングリコール単位、ポリラクトン単位、ポリプロピレングリコール単位、１，４－ブチンジオール、長鎖脂肪酸などが変性または共重合されていてもよい。

【００１０】ポリエステルエラストマーは、全樹脂組成物に0.5 重量％～10重量％含有することが好ましく、特に１重量％～７重量％含有することが好ましい。全樹脂組成物におけるポリエステルエラストマーの含有量が0.5 重量％未満では、シートのスリップ性不足及びシートの巻きずれを生じ、更にシートを熱成形して得られた成形品のスタッキング性が良好でない。また、10重量％を越えると、シートの透明性の低下を招く、ポリエチレンテレフタレート樹脂の熱結晶化の促進剤として働く及び熱成形の再加熱時に結晶化によるシートの失透が起こる等のため、成形品の透明性が著しく低下する。

【００１１】透明性、スリップ性及びスタッキング性に優れたポリエステル系樹脂組成物、該組成物からなるシート及びその成形品を得るためには、Ａ成分（ポリエチレンテレフタレート系樹脂）とＢ成分（熱可塑性ポリエステルエラストマー）のショアＤスケール硬度差が２以上で、Ａ成分の数値がＢ成分の数値より大なるものが使用される。

【００１２】本発明の樹脂組成物は、必要に応じて着色剤、酸化防止剤、帯電防止剤、防曇剤、熱安定剤、充填剤等を添加する事が出来る。

【００１３】本発明のポリエチレンテレフタレート系樹脂組成物は、単層または多層シートに加工されて用いられる時に性能を発揮するものである。。シートの全体肉厚は、特に制限はないが、通常0.１ ～３㎜の範囲である。シートのスリップ性及び成形品のスタッキング性は、シート及び成形品それぞれの表面部分の性能が関与している。よって、ポリエステルエラストマーの添加効果をあげるためには、多層シートとし、スキン層（表面層を言う）がポリエステルエラストマーを含有する樹脂組成物で構成されることが好ましい。

【００１４】多層シートとしては、具体的には、ＰＥＴ系樹脂からなるコア層（中芯層を言う）の片面、若しくは両面に前記スキン層を積層したものである。また、スキン層とコア層の構成比率は(1) 使用する押出機の規模・構成及び(2) シートを多層構造にするためのフィードブロック・ダイスの構造や性能等に依存するため、特に限定するものではないが、通常、２層シートの場合、スキン層：コア層の肉厚比率が１：２～５０の範囲が好ましく、３層シートの場合、スキン層Ａ：コア層：スキン層Ｂから構成され、スキン層Ａ又はスキン層Ｂ：コア層の肉厚比率が１：２～５０の範囲が好ましく、特に好ましくは１：３～２０である。スキン層Ａとスキン層Ｂの肉厚が等しい場合が、シートを製造しやすいが、上記範囲内ならば異なっていてもよい。

スキン層：コア層の比率は、１：２よりスキン層を厚くすると、コスト的にみて多層化のメリットが生じない。また、１：５０よりスキン層が薄いと、特にシートの全体厚みが薄い場合に、スキン層厚みの管理限界の問題があり望ましくない。

【００１５】また、実際のシート製造においては、該シートのトリミングロスやミスロール等のスクラップリターンの目的で、コア層にスクラップを一定の比率、定常的に混入させてもよい。コア層へのスクラップのリター

ン量は、著しく透明性を阻害しなければ特に限定するものではないが、通常１重量％～５０重量％のスクラップをコア層にリターンしてもよい。又、スクラップのリターン等を行うことにより、コア層にポリエステルエラストマーが含まれてもよい。

【００１６】本発明において、ＰＥＴ系樹脂とポリエステルエラストマーの混合方法は、(1) シート成形時に各樹脂ペレットを混合し押出機に直接投入する方法、(2) ＰＥＴ系樹脂とポリエステルエラストマーをペレット状態で混合した後、押出機にて溶融混練りしてペレット化し、シート押出成形時に使用する方法、および(3) ＰＥＴ系樹脂にポリエステルエラストマーを高濃度で混合したマスターペレットを作成しておき、シート作成時にＰＥＴ系樹脂で希釈して使用する方法のいずれであっても差し支えない。

【００１７】

【実施例】以下本発明を実施例により説明する。

実施例１

結晶化装置付き脱湿乾燥機にて、予め水分量を50ppm 以下としたポリエチレンテレフタレート系樹脂（以下、ＰＥＴ系樹脂と略す）のPET 9921（ショアＤスケール硬度77、エチレングリコール、１，４－シクロヘキサンジメタノール及びテレフタル酸の重縮合物、イーストマンコダック社製）に、熱風循環式乾燥機にて水分量が0.1%以下になるように乾燥した熱可塑性ポリエステルエラストマー（以下、ポリエステルエラストマーと略す）ハイトレル4056（ショアＤスケール硬度40、ポリエステル・ポリエーテル型、東レ・デュポン社製）をポリエステルエラストマー含有量が１重量％になるように混合し、該樹脂組成物を65㎜押出機にて押出温度240 ℃～280 ℃の範囲で溶融し、Ｔダイで0.5㎜ 厚のシートを作成し、更に、該シートを真空成形機で成形し、物性を測定した。ポリエステルエラストマーの品名、硬度及び配合量を表１に、シート及び成形品の性能評価結果を表２に示す。

実施例２

実施例１において、ＰＥＴ系樹脂のPET 9921に替えて、PET 9902（ショアＤスケール硬度78、エチレングリコールおよびテレフタル酸の重縮合物、イーストマンコダック社製）を用い、ポリエステルエラストマーのハイトレル4056に替えてハイトレル5557（ショアＤスケール硬度55、東レ・デュポン社製）を用いた以外は、同様の操作を行った。ポリエステルエラストマーの品名、硬度及び配合量を表１に、シート及び成形品の性能評価結果を表２に示す。

実施例３

実施例１において、ポリエステルエラストマーのハイトレル4056に替えてハイトレル7247を用いた以外は同様の操作を行った。ポリエステルエラストマーの品名、硬度及び配合量を表１に、シート及び成形品の性能評価結果を表２に示す。

実施例４

実施例３において、ポリエステルエラストマーのハイトレル7247を増量した以外は同様の操作を行った。ポリエステルエラストマーの品名、硬度及び配合量を表１に、シート及び成形品の性能評価結果を表２に示す。

実施例５

実施例１において、ポリエステルエラストマーのハイトレル4056に替えてペルプレンP153D （ポリエステル・ポリエーテル型、東洋紡社製）を用いた以外は同様の操作を行った。ポリエステルエラストマーの品名、硬度及び配合量を表１に、シート及び成形品の性能評価結果を表２に示す。

実施例６

結晶化装置付き脱湿乾燥機にて予め水分量を50ppm 以下としたＰＥＴ系樹脂のPET9921 に、熱風循環式乾燥機にて水分量が0.1 %以下に乾燥したポリエステルエラストマーのハイトレル7247（東レ・デュポン社製）をポリエステルエラストマー含有量が１重量％になるように混合し、得られた樹脂組成物をスキン層Ａ用及びスキン層Ｂ用とし、結晶化装置付き脱湿乾燥機にて予め水分量を50 ppm 以下としたＰＥＴ系樹脂のPET9921 をコア層用とした。65㎜押出機（コア層用）と40㎜押出機（スキン層用）及び２種３層のフィードブロックを使用し、スキン層Ａ：コア層：スキン層Ｂの肉厚比率が１：１０：１で、シート全体厚みが0.35㎜の２種３層シートを作成した。次いで、実施例１と同様に成形品を作成した後、物性を測定した。シートの肉厚比率、シート性能及び成型品性能を表３に示す。

実施例７

実施例６において、スキン層Ａ及びスキン層Ｂ用樹脂組成物として、ハイトレル7247の含有量が３重量％の樹脂組成物を用いた以外は同様に行った。シートの肉厚比率、シート性能及び成型品性能を表３に示す。

実施例８

実施例６において、スキン層Ａ及びスキン層Ｂ用樹脂組成物として、ハイトレル7247の含有量が５重量％の樹脂組成物を用いた以外は同様に行った。シートの肉厚比率、シート性能及び成型品性能を表３に示す。

実施例９

実施例８において、スキン層Ａ：コア層：スキン層Ｂの肉厚比率を替えた以外は同様に行った。シートの肉厚比率、シート性能及び成型品性能を表３に示す。

【００１８】比較例１

実施例１において、ポリエステルエラストマーのハイトレル4056を添加せず、ＰＥＴ系樹脂のPET 9921を単独で用いた以外は同様の操作を行った。シート及び成形品の性能評価結果を表２に示す。

比較例２

実施例１において、ポリエステルエラストマーのハイトレル4056に替えてシリカ微粉末を用い、組成物中のシリ

カ微粉末の含有量が0.2 重量％である樹脂組成物を用いた以外は同様に行った。シート及び成形品の性能評価結果を表２に示す。

比較例３

実施例１において、ポリエステルエラストマーのハイトレル4056の含有量が0.2 重量％である樹脂組成物を用いた以外は、同様の操作を行った。ポリエステルエラストマーの品名、硬度及び配合量を表１に、シート及び成形品の性能評価結果を表２に示す。

比較例４

実施例６において、スキン層Ａ及びスキン層Ｂ用として、組成物中のハイトレル7247の含有量が0.2 重量％の樹脂組成物を用いた以外は同様に行った。シートの肉厚比率、シート性能及び成型品性能を表３に示す。

【００１９】

【表１】

表　１

	熱可塑性ポリエステルエラストマー		
	品　　名	シ ョ ア D 硬 度	配合量（％）
実施例１	ハイトレル４０５６	４０	1.0
実施例２	ハイトレル５５５７	５５	1.0
実施例３	ハイトレル７２４７	７２	1.0
実施例４	ハイトレル７２４７	７２	3.0
実施例５	ペルプレンＰ１５３Ｄ	５７	5.0
比較例１	－	－	－
比較例２	－	－	－
比較例３	ハイトレル４０５６	４０	0.2

【００２０】

【表２】

表　2

	シート性能		成形品性能	
	ヘーズ（%）	動摩擦係数	スタッキング性	白化
実施例1	2.0	0.37	○	○
実施例2	1.7	0.36	○	○
実施例3	0.9	0.37	○	○
実施例4	3.9	0.26	○	○
実施例5	2.8	0.29	○	○
比較例1	0.5	0.50	×	○
比較例2	3.1	0.45	×	×
比較例3	0.6	0.45	×	○

【0021】　　【表3】

表　３

	シートの肉厚比率	シート性能		成型品性能	
	スキン：コア層：スキン 層Ａ　　層Ｂ	ヘーズ（％）	動摩擦係数	スタッキング性	白化
実施例６	１　：　１０　：　１	１．２	０．２８	○	○
実施例７	１　：　１０　：　１	１．５	０．２５	○	○
実施例８	１　：　１０　：　１	２．０	０．２２	○	○
実施例９	１　：　２０　：　１	０．５	０．２３	○	○
比較例４	１　：　１０　：　１	０．２	０．４９	×	○

【００２２】シート及び成形品の性能は、以下の方法で測定した。

（１）ショアＤスケール硬度

ポリエチレンテレフタレート系樹脂及び塑性ポリエステルエラストマーシートを用い、ASTM D2240に準拠し、ショアＤスケールにて測定した。

（２）ヘーズ（透明性）

シートから測定用のサンプルを切り出し、JIS K-7105に準拠して測定した。

（３）動摩擦係数

スリップ性評価として、シートサンプルを切り出し、ＪＩＳ Ｋ -7125 に準拠して測定した。

（４）スタッキング性

シートを用いて、真空成形機で深さ２０㎜、縦６０㎜、横１２０㎜の成形品を作成した。この成形品５個を積み重ね、１ｋｇの荷重を１分間かけた後、成形品の引き剥がしやすさを評価した。

○：成形品一個ずつが自重で剥がれる。

×：成形品一個ずつが自重で剥がれ難い。

（５）白化

シートを用いて、真空成形機にて深さ２０㎜、縦６０㎜、横１２０㎜の成形品を一定条件にて作成し、成形品の白化の程度を、目視にて評価した。

○：白化無し

×：白化有り

【００２３】

【発明の効果】以上の様に、本発明によれば、ショアＤスケール硬度差が２以上なる、特定硬度のポリエチレンテレフタレート系樹脂と特定硬度の熱可塑性ポリエステルエラストマーを含有するポリエチレンテレフタレート系樹脂組成物を得ることができる。また、この樹脂組成物を用いて作成したシートは、透明性と機械的強度に優れ、しかもシート表面のスリップ性が良好となり、シート原反の巻きずれもなく、また、シートの垂れ下がりも小さい。成形性も良好で、積み重ねられた成形品はスタッキング性が優れている。

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フロントページの続き

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Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Patrick Michael Medley/John Macalagay
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.401
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Filing Date:	31-MAR-2017
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		22773_826-401_IDS_11-13-2020.pdf	326985 10b8d6a38db86e6047b0853d8d60c5ced0555ce2	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Information Disclosure Statement (IDS) Form (SB08)		5	8	
	Transmittal Letter		1	4	
Warnings:					
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2	Foreign Reference	JPH06256630A_EFS.pdf	294550 a7a6829d01320dbc559019f82cea9fc0d250975a	no	9
Warnings:					
Information:					
3	Non Patent Literature	Overview-PETGCopolyester_2pages.pdf	506373 edaec10473a1225eaffceb52b71fe28df0d628d1	no	2
Warnings:					
Information:					
4	Non Patent Literature	MATERIALDATASHEETOFECDEL9966_3PAGES.PDF	654595 bdd9417ee055cad2448a9060564e2ba85e29947e	no	3
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30380 f52341096dd4e51b0f9a51b11ef011f121976c23	no	2
Warnings:					
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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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		None			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-2010043419-A1	04-22-2010	HINZ LABOR FACHLABORATORIUM FU [DE], et al.	Abstract:	☒

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS			
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	001	LARSON, Kent "Can You Estimate Modulus From Durometer Hardness for Silicones?" Dow White Paper, 2019 The Dow Chemical Company, Form No. 11-3716-01A S2D, pp. 1-5.	☐

Examiner Signature		Date Considered	

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Sheet 3 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

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☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Patrick Medley/	Date (YYYY-MM-DD)	2020-12-09
Name/Print	Patrick Medley, Ph.D.	Registration Number	74,735

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(19) Weltorganisation für geistiges Eigentum
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[Fortsetzung auf der nächsten Seite]

(54) **Title**: METHOD FOR PRODUCING A MULTI-LAYER DENTAL SPLINT IN A DEEP-DRAWING DEVICE AND DENTAL SPLINT

(54) **Bezeichnung** : VERFAHREN ZUR HERSTELLUNG EINER MEHRSCHICHTIGEN DENTALSCHIENE IN EINEM TIEFZIEHGERÄT UND DENTALSCHIENE

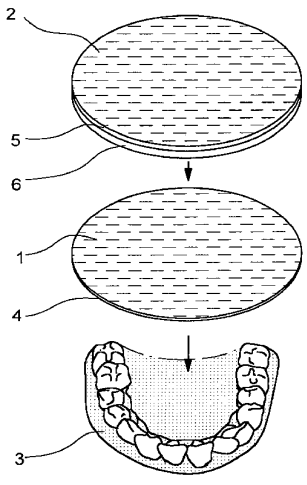


Fig. 1

(57) **Abstract**: The invention illustrates and describes a method for producing a multi-layer dental splint in a deep-drawing device. According to the invention, a first deep-drawing film (1) and at least one second deep-drawing film (2, 7), and optionally at least one third deep-drawing film (9) are connected to each other on a jaw model (3) in the deep-drawing device, wherein the first deep-drawing film (1) and the second deep-drawing film (2, 7), or the third deep-drawing film (9) have a hard layer (4, 5, 10) made from a first plastic material, and at least one deep-drawing film (2, 7) has a soft layer (6, 8) made from a second plastic material, and wherein the deep-drawing films (1, 2, 7, 9) are connected to each other to obtain a layered composite having a hard exterior layer (4, 5, 10) on each of the two exterior sides, and having a soft interior layer (6, 8) that is embedded between the hard layers (4, 5, 10).

(57) **Zusammenfassung**: Dargestellt und beschrieben ist ein Verfahren zur Herstellung einer mehrschichtigen Dentalschiene in einem Tiefziehgerät. Erfindungsgemäß ist vorgesehen, daß in dem Tiefziehgerät eine erste Tiefziehfolie (1) und wenigstens eine zweite Tiefziehfolie (2, 7) und gegebenenfalls wenigstens eine dritte Tiefziehfolie (9) durch Tiefziehen auf ein Kiefermodell (3) miteinander verbunden werden, wobei die erste Tiefziehfolie (1) und die zweite Tiefziehfolie (2, 7) oder die dritte Tiefziehfolie (9) eine harte Schicht (4, 5, 10) aus einem ersten Kunststoffmaterial und wenigstens eine Tiefziehfolie (2, 7) eine weiche Schicht (6, 8) aus einem zweiten Kunststoffmaterial aufweist

[Fortsetzung auf der nächsten Seite]

WO 2010/043419 A1

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— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

— *vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eingehen (Regel 48 Absatz 2 Buchstabe h)*

und wobei die Tiefziehfolien (1, 2, 7, 9) derart miteinander verbunden werden, daß ein Schichtverbund mit einer harten äußeren Schicht (4, 5, 10) auf jeder der beiden Außenseiten und mit einer weichen zwischen den harten Schichten (4, 5, 10) eingebetteten inneren Schicht (6, 8) erhalten wird.

Verfahren zur Herstellung einer mehrschichtigen Dentalschiene in einem Tiefziehgerät und Dentalschiene

Die Erfindung betrifft ein Verfahren zur Herstellung einer mehrschichtigen Dentalschiene in einem Tiefziehwerkzeug. Darüber hinaus betrifft die vorliegende Erfindung eine Dentalschiene.

Dentalschienen werden in der Kieferorthopädie als Aufbiß-Schienen, Dehnplatten, Positioner oder Retentionsschienen zur Retention nach einem Abschluß der aktiven Behandlungsphase, zur Korrektur geringfügiger Zahnfehlstellungen oder als sonstige herausnehmbare kieferorthopädische Behandlungsapparate eingesetzt. Dentalschienen werden für intraorale Protrusionsgeräte zur Behandlung von obstruktiven Schlafatmungsregulationsstörungen eingesetzt, die über eine Lageveränderung des Unterkiefers ein Zurückfallen der pharyngealen Weichteile und damit eine Verlegung der Atemwege verhindern. Um die im Schlaf auftretenden Kräfte aufzufangen und den Unterkiefervorschub über die Dauer des gesamten Schlafes zu gewährleisten, benötigen die Protrusionsgeräte eine maximale Retention an den Zähnen. Die Retention der Geräte wird über hart-weiche Tiefziehschienen zahntechnisch gelöst. Zusätzlich in die Schiene eingearbeitete Klammern können die Retention erhöhen. In der Therapie von kraniomandibulären Dysfunktionen (CMD) werden Okklusionsschienen aus Kunststoff eingesetzt. Der Angriffspunkt von Okklusionsschienen ist die Aufhebung der bestehenden Kontaktbeziehung der Zähne zueinander. Andere intraorale Kunststoffschienen haben eine Trägerfunktion und dienen als Träger von Medikamenten und Fluorid. Sie erleichtern beispielsweise die Applikation von carbamid- oder wasserstoffperoxidhaltigen Gelen bei der externen Bleichtherapie und verhindern gleichzeitig ein schnelles Abspülen oder Abwischen der Substanzen durch den Speichel bzw. die intraoralen Weichteile. Eine Schutzfunktion erlangen Dentalschienen bei der Anwendung als Kompressions- oder Verbandplatten nach chirurgischen Eingriffen oder als Mundschutz bei einigen Zahntrauma gefährdeten Sportarten.

Zur Herstellung der vorgenannten Dentalschienen kann eine im Dentalbereich bekannte Tiefziehtechnik angewandt werden, bei der thermoplastische Folien in Tiefziehgeräten erwärmt und über ein Kiefermodell aus Gips verformt werden.

CONFIRMATION COPY

Tiefziehfolien werden in den verschiedensten Formen und Größen sowie in unterschiedlichen Farben angeboten. Die Folienform richtet sich nach dem für die Verarbeitung empfohlenen Tiefziehgerät, die Dicke der Folie nach der angestrebten Konstruktionsform und der Anwendung der Schiene und ist häufig auch von den Vorlieben des Behandlers abhängig. Aus den Folien kann die gewünschte Verarbeitungsform herausgestanzt werden, welche im Labor durch Erwärmung und mittels Druck in die gewünschte Form bzw. auf das jeweilige Modell aufgebracht wird. Verschiedene Tiefziehgeräte finden dabei Anwendung, deren Unterschiede unter anderem in der Erwärmungs- und der Tiefziehtechnik liegen. Unterschieden wird dabei zwischen Vakuum- und Druckformtechnik.

Aus dem Stand der Technik sind Dentalschienen aus Polycarbonat bekannt, die sich durch ihr kristallklares Aussehen auszeichnen, das bei entsprechender Pflege auch keine Verfärbungen aufweist. Von Nachteil bei den bekannten Schienen aus Polycarbonat ist jedoch, daß sie sehr hart sind, zumal sie oberflächlich mit Acryl verstärkt und/oder mit Acrylhilfsteilen an der Oberfläche befestigt sind. Die bekannten Dentalschienen werden beim Einsetzen in den Mund und beim Herausnehmen aus dem Mund sowie beim Tragen mechanisch beansprucht, was zum Bruch der Dentalschiene führen kann.

Darüber hinaus sind aus dem Stand der Technik Dentalschienen bekannt, die einen zweischichtigen Aufbau aufweisen, der aus einer harten Trägerschicht aus Polycarbonat und einer weichen mit der Trägerschicht verbundenen Polyurethanschicht gebildet wird. Durch die weiche Oberfläche wird das Einsetzen der Schiene erleichtert und der Halt an Zähnen verbessert. Von Nachteil hier ist allerdings, daß nach wenigen Monaten eine Verfärbung der weichen Polyurethanschicht auftritt. Halt- bzw. Hilfselemente, beispielsweise für Vorschubstäbe von intraoralen Protrusionsgeräten, wie sie zur Schnarchtherapie eingesetzt werden, können mit selbsthärtenden oder lichthärtenden Kunststoffen mit der Oberfläche der Trägerschicht aus Polycarbonat befestigt sein, nachdem die Polycarbonatschicht mehrmals mit einem Haftvermittler bestrichen worden ist. Häufig wird hier durch Auftragen von Acrylat eine Verstärkung der Dentalschiene erzielt. Die aufgetragenen Acrylatflächen müssen mit rotierenden Instrumenten ausgearbeitet und anschließend poliert werden, was arbeitsaufwendig ist.

Aufgabe der vorliegenden Erfindung ist es, ein Verfahren zur Herstellung einer mehrschichtigen Dentalschiene zur Verfügung zu stellen, das die einfache und kostengünstige Herstellung von Dentalschienen ermöglicht, wobei die so erhältlichen Dentalschienen verbesserte mechanische Eigenschaften aufweisen und sich in einfacher Weise von einem Patienten ein- und ausgliedern lassen sollen. Zudem ist es Aufgabe der vorliegenden Erfindung, eine Dentalschiene zur Verfügung zu stellen, die verbesserte mechanische Eigenschaften aufweist, kostengünstig herstellbar ist und sich einfach vom Patienten ein- und ausgliedern läßt.

Die vorgenannte Aufgabe ist bei einem Verfahren der eingangs genannten Art dadurch gelöst, daß in dem Tiefziehgerät eine erste Tiefziehfolie und wenigstens eine zweite Tiefziehfolie und gegebenenfalls wenigstens eine dritte Tiefziehfolie durch Tiefziehen auf ein Kiefermodell miteinander verbunden werden, wobei die erste Tiefziehfolie und die zweite Tiefziehfolie oder die dritte Tiefziehfolie eine harte Schicht aus einem ersten Kunststoffmaterial und wenigstens eine Tiefziehfolie eine weiche Schicht aus einem zweiten Kunststoffmaterial aufweist und wobei die Tiefziehfolien derart miteinander verbunden werden, daß ein Schichtverbund mit einer harten äußeren Schicht auf jeder der beiden Außenseiten der Dentalschiene und mit einer weichen zwischen den harten Schichten eingebetteten inneren Schicht erhalten wird. Die so erhältliche Dentalschiene weist einen wenigstens dreischichtigen Aufbau auf mit zwei harten äußeren Schichten und mit einer weichen zwischen den harten Schichten eingebetteten inneren Schicht. Es versteht sich, daß die erfindungsgemäße Dentalschiene mehr als drei Schichten mit unterschiedlicher Härte aufweisen kann, wobei jedoch die beiden außenliegenden Schichten eine höhere Härte und Steifigkeit aufweisen sollen als die wenigstens eine weiche Schicht im Inneren der Dentalschiene. Die Eigenschaften "hart" und "weich" im Sinne der Erfindung beziehen sich auf unterschiedliche Shore-Härten der Schichten. Die erfindungsgemäße Dentalschiene weist eine erhöhte Bruchfestigkeit und ein besseres Ein- und Ausgliederungsverhalten durch eine erhöhte Elastizität der Dentalschiene auf, was durch die innenliegende weiche Schicht mit höherer Elastizität bewirkt wird. Darüber hinaus weist die erfindungsgemäße Dentalschiene auf beiden Außenseiten vorzugsweise eine glatte Oberfläche auf, was zu einem verminderten Plaquebefall führt.

Bei einer bevorzugten Ausführungsform der Erfindung wird zur Herstellung der Dentalschiene eine Tiefziehfolie mit einer harten Schicht aus einem Polyester-

Kunststoff, vorzugsweise aus Polycarbonat (PC) oder Polyethylenterephthalat (PET), ausgewählt. Die im Schichtverbund außenliegenden harten Schichten aus dem Polyester-Kunststoff sind stabil gegen eine Verfärbung und ermöglichen ein kristallklares Aussehen der erfindungsgemäßen Dentalschiene. Darüber hinaus ist die harte Schicht ausreichend bruchstabil, so daß ein Ausbrechen von Halte- oder Hilfselementen, wie Verankerungsteilen für Vorschub- bzw. Führungsstäbe von intraoralen Protrusionsgeräten, nicht befürchtet werden muß. Vorzugsweise weist die erfindungsgemäße Dentalschiene harte Schichten aus demselben Kunststoffmaterial auf.

Bei einer weiter bevorzugten Ausführungsform wird eine Tiefziehfolie mit einer weichen Schicht aus einem thermoplastischen Polyurethan (TPU) oder Ethylen-vinylacetat (EVA) ausgewählt. Die vorgenannten Kunststoffmaterialien führen zu einer ausreichend hohen Elastizität der erfindungsgemäßen Dentalschiene, so daß ein Bruch der Dentalschiene beim Ein- und Ausgliedern und beim Tragen nicht befürchtet werden muß.

Zur Herstellung der erfindungsgemäßen Dentalschiene kann eine Tiefziehfolie eingesetzt werden, die einen wenigstens zweischichtigen Aufbau mit wenigstens einer harten Schicht und mit wenigstens einer weichen Schicht aufweist. Die vorgenannte Tiefziehfolie kann dann mit einer weiteren Tiefziehfolie, die einen vorzugsweise einschichtigen Aufbau mit einer harten Schicht aufweist, durch Tiefziehen verbunden werden, so daß sich ein Schichtverbund mit zwei außenliegenden harten Schichten und einer zwischen der harten Schichten eingebetteten weichen Schicht ergibt. Beispielsweise kann eine erste Tiefziehfolie aus Polycarbonat bestehen und einen einschichtigen Aufbau aufweisen. Diese Tiefziehfolie wird zunächst auf ein Kiefermodell tiefgezogen, so daß eine einschichtige Schiene erhalten wird. Diese Schiene verbleibt dann zunächst auf dem Kiefermodell und wird mit einer zweiten Tiefziehfolie durch Tiefziehen verbunden, wobei die zweite Tiefziehfolie einen zweischichtigen Aufbau mit einer harten Schicht aus Polycarbonat und mit einer zweiten weichen Schicht aus Polyurethan aufweisen kann. Um den vorgesehenen Schichtaufbau zu erhalten, wird die zweite Tiefziehfolie mit der weichen Schicht aus Polyurethan auf die aus der ersten Tiefziehfolie aus Polycarbonat erhaltenen Schiene aufgelegt und über die erste Schiene verformt und auf das Kiefermodell tiefgezogen, so daß sich ein dreischichtiger Aufbau ergibt. Gegebenenfalls kann hier ein Haftvermittler auf die

erste Schiene aus Polycarbonat aufgebracht werden, um eine vollflächige Verbindung der Schichten zu gewährleisten. Grundsätzlich können natürlich auch mehrere Folien in einem Arbeitsgang gleichzeitig auf das Kiefermodell tiefgezogen werden.

Die harte Schicht der Tiefziehfolie kann eine Schichtdicke von kleiner oder gleich 3,0 mm, vorzugsweise von 1,0 bis 1,5 mm, weiter vorzugsweise von kleiner oder gleich 0,5 mm, insbesondere von 0,2 bis 0,5 mm aufweisen. Die weiche Schicht kann eine Schichtdicke von 0,5 bis 2,0 mm, insbesondere von 1,0 bis 1,3 mm, aufweisen. Es versteht sich, daß alle Zwischenwerte der vorgenanten Intervalle offenbart sind, auch wenn dies nicht im einzelnen beschrieben ist. Im übrigen versteht es sich, daß beim Tiefziehen die Schichtdicke der Tiefziehfolie verringert wird. Die erfindungsgemäß vorgesehenen Schichtdicken der eingesetzten Tiefziehfolien stellen sehr gute mechanisch Eigenschaften der erfindungsgemäßen Dentalschiene sicher.

Besonders gute mechanische Eigenschaften werden darüber hinaus dann erreicht, wenn eine ersten Tiefziehfolie aus Polycarbonat mit einer Schichtdicke von ca. 0,5 mm mit einer zweischichtigen Tiefziehfolie durch Tiefziehen verbunden wird, wobei die zweischichtige Tiefziehfolie eine harte Schicht aus Polycarbonat mit einer Schichtdicke von 0,8 bis 1,2 mm und eine weiche Schicht aus Polyurethan mit einer Schichtdicke von 1,0 bis 1,3 mm aufweist. Dementsprechend weist die so erhaltene dreischichtige Dentalschiene eine harte Schicht auf einer Außenseite mit einer Schichtdicke von weniger als 0,5 mm und eine zweite harte Schicht auf der anderen Außenseite mit einer Schichtdicke von weniger als 1,2 mm bis weniger als 0,8 mm auf. Die Schichtdicke der weichen Schicht der erfindungsgemäßen Dentalschiene beträgt weniger als 1,3 mm bis weniger als 1,0 mm.

Bei der Herstellung der erfindungsgemäßen Dentalschiene kann verfahrensgemäß vorgesehen sein, daß zuerst die erste Tiefziehfolie auf das Kiefermodell tiefgezogen wird, wobei die so erhaltene einschichtige Schiene anschließend auf dem Kiefermodell verbleibt. Nachfolgend wird dann die zweite Tiefziehfolie auf dem Kiefermodell positioniert und über die erste Schiene auf das Kiefermodell tiefgezogen, was zum Verbund der zweiten Tiefziehfolie mit der zuvor gebildeten ersten Schiene führt, so daß eine zumindest zweischichtige Schiene erhalten

wird. Sofern eine dritte Tiefziehfolie zur Herstellung der erfindungsgemäßen Dentalschiene vorgesehen ist, verbleibt die aus der ersten Tiefziehfolie und der zweiten Tiefziehfolie gebildete zweischichtige Schiene auf dem Kiefermodell und es wird anschließend die dritte Tiefziehfolie auf dem Kiefermodell positioniert und über die zweischichtige Schiene auf dem Kiefermodell tiefgezogen, was zu einer Dentalschiene mit drei Schichten führt.

Weist die erste Tiefziehfolie eine harte Schicht aus Polycarbonat auf oder besteht vollständig aus Polycarbonat, kann die durch Tiefziehen der ersten Tiefziehfolie erhaltene Schiene zumindest bereichsweise, vorzugsweise vollständig, mit einem Acrylatanlöser, insbesondere einer Zubereitung aus einem Methacrylsäuremethlester (MMA) und Dichlormethan, beschichtet werden. Dadurch wird der Verbund der Tiefziehfolien beim Tiefziehen verbessert.

Sind bei der erfindungsgemäßen Dentalschiene Halte- oder Hilfselemente erforderlich, wie beispielsweise für Führungs-, Vorschub- und/oder Verankerungsstäbe zwischen zwei Schienen eines intraoralen Protrusionsgerätes, kann nach dem Tiefziehen der ersten Tiefziehfolie wenigstens ein Halte- oder Hilfselement an der Oberfläche der so erhaltenen ersten Schiene befestigt werden, wobei, vorzugsweise, die Oberfläche der ersten Schiene zumindest bereichsweise mit einem Acrylatanlöser, insbesondere mit einer Zubereitung aus einem Methacrylsäuremethylester (MMA) und Dichlormethan, beschichtet und das Halte- oder Hilfselement mit einem Autopolymerisat befestigt wird. Die aus der ersten Tiefziehfolie erhaltene erste Schiene verbleibt auf dem Kiefermodell. Anschließend kann dann eine weitere Tiefziehfolie auf dem Kiefermodell positioniert und über die erste Schiene auf das Kiefermodell tiefgezogen werden, so daß das Halte- oder Hilfselement zwischen der ersten Schiene und der zweiten Tiefziehfolie sicher eingebettet wird und das Halte- oder Hilfselement nicht über die Oberfläche der erfindungsgemäßen Dentalschiene übersteht und die Dentalschiene eine glatte Oberfläche aufweist. Dies führt auch zu einem verminderten Plaquebefall beim Tagen der Schiene.

Nachfolgend wird die Erfindung anhand von Ausführungsbeispielen exemplarisch beschrieben, wobei die Erfindung nicht auf die beschriebenen Merkmale der Ausführungsbeispiele beschränkt ist. In der Zeichnung zeigen:

Fig. 1 schematisch den Verfahrensablauf bei der Herstellung einer erfindungsgemäßen Dentalschiene bei einer ersten Ausführungsform des erfindungsgemäßen Verfahrens,

Fig. 2 schematisch den Verfahrensablauf bei der Herstellung einer erfindungsgemäßen Dentalschiene bei einer zweiten Ausführungsform des erfindungsgemäßen Verfahrens und

Fig. 3 schematisch den Verfahrensablauf bei der Herstellung einer erfindungsgemäßen Dentalschiene bei einer dritten Ausführungsform des erfindungsgemäßen Verfahrens.

In Fig. 1 ist schematisch ein Verfahren zur Herstellung einer mehrschichtigen Dentalschiene in einem nicht-dargestellten Tiefziehgerät gezeigt. Die so hergestellte Dentalschiene kann beispielsweise für ein Schnarch-Therapiegerät verwendet werden, wie es in der DE 203 19 088 U1 oder der DE 201 02 432 U1 beschrieben ist. Bei dem Tiefziehgerät kann es sich beispielsweise um ein Universal-Druckformgerät für alle Anwendungen der dentalen Tiefziehtechnik und der Kieferorthopädie handeln, wie es unter dem Handelsnamen BIOSTAR® von der Scheu-Dental GmbH vertrieben wird. Auch kann ein kompaktes Druckformgerät mit dem Handelsnamen MINISTAR S® der Scheu-Dental GmbH zur Herstellung der Dentalschiene eingesetzt werden. In dem Tiefziehgerät werden eine erste Tiefziehfolie 1 und wenigstens eine zweite Tiefziehfolie 2 durch Tiefziehen auf ein Kiefermodell 3 aus Gips miteinander verbunden, wobei die erste Tiefziehfolie 1 aus Polycarbonat besteht. Beispielsweise kann eine Polycarbonat-Tiefziehfolie mit dem Handelsnamen IMPRELON® »S« der Scheu-Dental GmbH eingesetzt werden. Die Tiefziehfolie 1 weist vorzugsweise eine Schichtdicke von 0,5 mm auf, kann jedoch auch eine kleinere Schichtdicke aufweisen.

Im ersten Schritt wird eine hauchdünne Isolierfolie, die sich nicht mit der ersten Tiefziehfolie 1 verbindet und nur für die Isolierung zum Kiefermodell 3 erforderlich ist, tiefgezogen. Anschließend wird die erste Tiefziehfolie 1 tiefgezogen. Nach dem Tiefziehen der ersten Tiefziehfolie 1 wird der Folienüberschuß von der so erhaltenen ersten Schiene, die einschichtig ist, kurz unter dem Äquator der Zähne mit einer Fräse auf die Endlänge vestibulär und gingival/palatinal abge-

trennt, ohne das die durch Tiefziehen der ersten Tiefziehfolie 1 erhaltene erste Schiene von dem Kiefermodell 3 abgenommen wird.

Danach wird die gesamte Oberfläche der auf dem Kiefermodell angeordneten ersten Schiene mit einem Haftvermittler bestrichen, wobei als Haftvermittler ein Acrylatanlöser, nämlich eine Zubereitung aus Methacrylsäuremethylester (MMA) und Dichlormethan, erhältlich unter dem Handelsnamen PERLIBOND® der Scheu-Dental GmbH, eingesetzt werden kann. Anschließend können Halteelemente für Vorschubstäbe, wie sie beispielsweise bei intraoralen Schnarch-Therapiegeräten vorgesehen sind, oder andere Hilfsteile auf der Oberfläche der auf das Kiefermodell 3 aufgezogenen Tiefziehfolie 1 mit Acryl befestigt werden.

Die zweite Tiefziehfolie 2 weist einen zweischichtigen Aufbau mit einer harten Schicht 5 aus Polycarbonat und einer weichen Schicht 6 aus einem thermoplastischen Polyurethan auf. Bei der Tiefziehfolie 2 handelt es sich um eine Verbundplatte mit einer harten Schicht und einer weichen Schicht mit dem Handelsnamen DURASOFT® der Scheu-Dental GmbH. Die harte Schicht läßt sich mit einem Autopolymerisat verbinden, wobei ein Autopolymerisat der Scheu-Dental GmbH mit dem Handelsnamen DURASPLINT® eingesetzt werden kann. Die harte Schicht 5 kann eine Schichtdicke von 0,8 mm und die weiche Schicht 6 eine Schichtdicke von 1,0 mm aufweisen. Ebenso gut ist es möglich, daß die harte Schicht 5 eine Schichtdicke von 1,2 mm und die weiche Schicht 6 eine Schichtdicke von 1,3 mm aufweist. Die zweite Tiefziehfolie 2 wird dann mit der weichen Polyurethanschicht 6 auf die zuerst tiefgezogene erste Tiefziehfolie 1, die auf dem Kiefermodell 3 aufgezogen ist, aufgelegt und anschließend auf das Kiefermodell 3 über die Tiefziehfolie 1 tiefgezogen. Dabei verbindet sich die zweite Tiefziehfolie 2 mit der ersten Tiefziehfolie 1. Dadurch wird eine Dentalschiene mit einem dreischichtigen Aufbau aus zwei äußeren harten Schichten 4, 5 und einer dazwischen angeordneten weichen Schicht 6 erhalten, die eine erhöhte Bruchfestigkeit und ein verbessertes Eingliederungs- und Ausgliederungsverhalten durch eine erhöhte Elastizität aufweist.

Nach dem Umformen der zweiten Tiefziehfolie 2 wird der Folienüberschuß von der erhaltenen dreischichtigen Dentalschiene abgetrennt, ohne daß der Schichtverbund von dem Kiefermodell 3 abgenommen wird. Die Dentalschiene wird erst anschließend vom Kiefermodell 3 abgenommen. Schließlich erfolgt eine

Glättung der Ränder der Dentalschiene. Eine weitere Bearbeitung oder Politur der Dentalschiene ist nicht vorgesehen.

In Fig. 2 ist eine alternative Ausführungsform eines Verfahrens zur Herstellung einer mehrschichtigen Dentalschiene dargestellt. Bei der in Fig. 2 dargestellten Ausführungsform wird die Tiefziehfolie 1 aus Fig. 1 mit einer zweiten Tiefziehfolie 7 verbunden, die lediglich eine weiche Schicht 8 aus Polyurethan aufweist. Wie bei dem in Fig. 1 beschriebenen Verfahren wird zunächst die Tiefziehfolie 1 auf das Kiefermodell 3 tiefgezogen. Anschließend verbleibt diese so erhaltene erste Schiene aus der Tiefziehfolie 1 auf dem Kiefermodell 3 und es wird die zweite Tiefziehfolie 7 über die erste Schiene auf das Kiefermodell 3 tiefgezogen, so daß eine zweischichtige Schiene erhalten wird. Zwischen der Tiefziehfolie 1 und der Tiefziehfolie 7 kann wiederum wenigstens ein Halte- oder Hilfselement eingebettet werden. Um den gewünschten Schichtverbund zu erhalten, wird anschließend eine dritte Tiefziehfolie 9, die einschichtig ist und eine harte Schicht 10 aus Polycarbonat aufweist, über die zweischichtige Schiene auf das Kiefermodell 3 tiefgezogen, so daß eine erfindungsgemäße dreischichtige Dentalschiene erhalten wird. Entsprechend dem in Fig. 1 dargestellten Verfahren wird der Folienüberschuß jeder durch Umformen der Tiefziehfolien 1, 7, 9 erhaltenen Schiene vor dem Tiefziehen der nächstfolgenden Tiefziehfolie 7, 9 abgetrennt, ohne daß die Schiene vom Kiefermodell 3 gelöst wird. Im übrigen kann vor dem Tiefziehen einer nächstfolgenden Tiefziehfolie 7, 9 eine Beschichtung der zuvor erhaltenen Schiene mit einem Haftvermittler vorgesehen sein.

In Fig. 3 ist schließlich dargestellt, daß eine erfindungsgemäße dreischichtige Dentalschiene auch in einem einstufigen Tiefziehprozeß durch Tiefziehen einer Tiefziehfolie 11 erhalten werden kann, die einen dreischichtigen Aufbau mit zwei äußern harten Schichten 12, 13 aus Polycarbonat und einer zwischen den harten Schichten 12, 13 eingebetteten weichen Schicht 14 aus Polyurethan aufweist.

Die Schichtdicke der harten Schicht 10, 12 der Tiefziehfolien 9, 11 entspricht der Schichtdicke der harten Schicht 5 der Tiefziehfolie 2. Dies ergibt sich aus einem Vergleich der Figuren 1 bis 3. Die Schichtdicken der harten Schicht 13 der in Figur 3 gezeigten Tiefziehfolie 11 entspricht der Schichtdicke der harten Schicht 4 der Tiefziehfolie 1 aus Fig. 1.

Die Schichtdicke der weichen Schicht 8 der zweiten Tiefziehfolie 7 aus Fig. 2 und die Schichtdicke der weichen Schicht 14 der Tiefziehfolie 11 aus Fig. 3 entsprechen der Schichtdicke der weichen Schicht 6 der Tiefziehfolie 2 aus Fig. 1.

Nicht dargestellt ist im übrigen, daß aufgrund der Werkstoffeigenschaften von Polycarbonat ein Vortrocknen unerläßlich ist, um durch Feuchtigkeit entstehende Bläschenbildung beim Beheizen im Tiefziehgerät zu vermeiden. Im übrigen kann vor dem Tiefziehen der ersten Tiefziehfolie 1 eine Isolierfolie für Gips/Kunststoff als Platzhalterfolie auf das Kiefermodell 3 aufgezogen werden. Hier kann beispielsweise eine Isolierfolie mit dem Handelsnamen ISOFOLAN® der Scheu-Dental GmbH eingesetzt werden. Die Isolierfolie kann nach der Herstellung der Dentalschiene von der Dentalschiene in einfacher Weise abgezogen werden.

Patentansprüche:

1. Verfahren zur Herstellung einer mehrschichtigen Dentalschiene in einem Tiefziehgerät, wobei in dem Tiefziehgerät eine erste Tiefziehfolie (1) und wenigstens eine zweite Tiefziehfolie (2, 7) und gegebenenfalls wenigstens eine dritte Tiefziehfolie (9) durch Tiefziehen auf ein Kiefermodell (3) miteinander verbunden werden, wobei die erste Tiefziehfolie (1) und die zweite Tiefziehfolie (2, 7) oder die dritte Tiefziehfolie (9) eine harte Schicht (4, 5, 10) aus einem ersten Kunststoffmaterial und wenigstens eine Tiefziehfolie (2, 7) eine weiche Schicht (6, 8) aus einem zweiten Kunststoffmaterial aufweist und wobei die Tiefziehfolien (1, 2, 7, 9) derart miteinander verbunden werden, daß ein Schichtverbund mit einer harten äußeren Schicht (4, 5, 10) auf jeder der beiden Außenseiten und mit einer weichen zwischen den harten Schichten (4, 5, 10) eingebetteten inneren Schicht (6, 8) erhalten wird.

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß eine Tiefziehfolie (1, 2, 9) mit einer harten Schicht (4, 5, 10) aus einem Polyester-Kunststoff, vorzugsweise aus Polycarbonat (PC) oder Polyethylenterephthalat (PET), ausgewählt wird.

3. Verfahren nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß eine Tiefziehfolie (2, 7) mit einer weichen Schicht (6, 8) aus einem thermoplastischen Polyurethan (TPU) oder Ethylenvinylacetat (EVA) ausgewählt wird.

4. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß eine Tiefziehfolie (2) mit einem wenigstens zweischichtigen Aufbau mit wenigstens einer harten Schicht (5) und mit wenigstens einer weichen Schicht (6) ausgewählt wird.

5. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß eine erste Tiefziehfolie (1) und eine zweite Tiefziehfolie (2) miteinander verbunden werden, wobei die erste Tiefziehfolie (1) aus Polycarbonat besteht und wobei die zweite Tiefziehfolie (2) eine zweischichtigen Aufbau mit einer harten Schicht (5) aus Polycarbonat und mit einer zweiten weichen Schicht (6) aus Polyurethan aufweist.

6. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß eine Tiefziehfolie (1, 2, 9) mit einer harten Schicht (4, 5, 10) mit einer Schichtdicke von kleiner oder gleich 3,0 mm, vorzugsweise von 1,0 bis 1,5 mm, weiter vorzugsweise von kleiner oder gleich 0,5 mm, insbesondere von 0,2 bis 0,5 mm, ausgewählt wird.

7. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß eine Tiefziehfolie (2, 7) mit einer weichen Schicht (6, 8) mit einer Schichtdicke von 0,5 bis 2,0 mm, insbesondere von 1,0 bis 1,3 mm, ausgewählt wird.

8. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß zuerst die erste Tiefziehfolie (1) auf das Kiefermodell (3) tiefgezogen wird und daß die tiefgezogene erste Tiefziehfolie (1) auf dem Kiefermodell (3) verbleibt und anschließend die zweite Tiefziehfolie (2, 7) auf das Kiefermodell (3) tiefgezogen wird.

9. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die erste Tiefziehfolie (1) nach dem Tiefziehen zumindest bereichsweise, vorzugsweise vollständig, mit einem Acrylatanlöser, insbesondere einer Zubereitung aus einem Methacrylsäuremethylester (MMA) und Dichlormethan, beschichtet wird.

10. Verfahren nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß nach dem Tiefziehen der ersten Tiefziehfolie (1) wenigstens ein Halte- oder Hilfselement an der Oberfläche der ersten Tiefziehfolie (1) befestigt wird, wobei, vorzugsweise, die Oberfläche der ersten Tiefziehfolie (1) zumindest bereichsweise mit einem Acrylatanlöser, insbesondere mit einer Zubereitung aus einem Methacrylsäuremethylester (MMA) und Dichlormethan, beschichtet und das Halte- oder Hilfselement mit einem Autopolymerisat befestigt wird.

11. Dentalschiene mit einem wenigstens dreischichtigen Aufbau, insbesondere hergestellt nach einem der vorhergehenden Ansprüche, mit zwei äußeren harten Schichten (4, 5, 10, 12, 13) und mit einer inneren zwischen den harten Schichten (4, 5, 10, 12, 13) eingebetteten weichen Schicht (6, 8, 14).

12. Dentalschiene nach Anspruch 11, dadurch gekennzeichnet, daß zwei harte Schichten (4, 5, 10, 12, 13) aus einem Polyester-Kunststoff, vorzugsweise aus Polycarbonat (PC) oder Polyethylenterephthalat (PET), und eine innere weiche Schicht (6, 8, 14) aus einem thermoplastischen Polyurethan (TPU) oder Ethylenvinylacetat (EVA) vorgesehen sind.

13. Dentalschiene nach Anspruch 11 oder 12, dadurch gekennzeichnet, daß eine harte Schicht (4, 13) auf einer im Tragezustand der Dentalschiene Zahnflächen des Patienten zugewandten Außenseite der Dentalschiene eine Schichtdicke von weniger als 0,5 mm, insbesondere von weniger als 0,2 mm, und eine harte Schicht (5, 10, 12) auf einer von den Zahnflächen abgewandten Außenseite der Dentalschiene eine Schichtdicke von weniger als 1,2 mm, insbesondere von weniger als 0,8 mm, aufweist.

14. Dentalschiene nach einem der Ansprüche 11 bis 13, dadurch gekennzeichnet, daß die weiche Schicht (6, 8, 14) eine Schichtdicke von weniger als 1,3 mm, insbesondere von weniger als 1,0 mm, aufweist.

15. Dentalschiene nach einem der Ansprüche 11 bis 14, dadurch gekennzeichnet, daß zwischen der weichen Schicht (6, 8) und einer harten Schicht (4, 5, 10) wenigstens ein Halte- oder Hilfselement eingebettet ist.

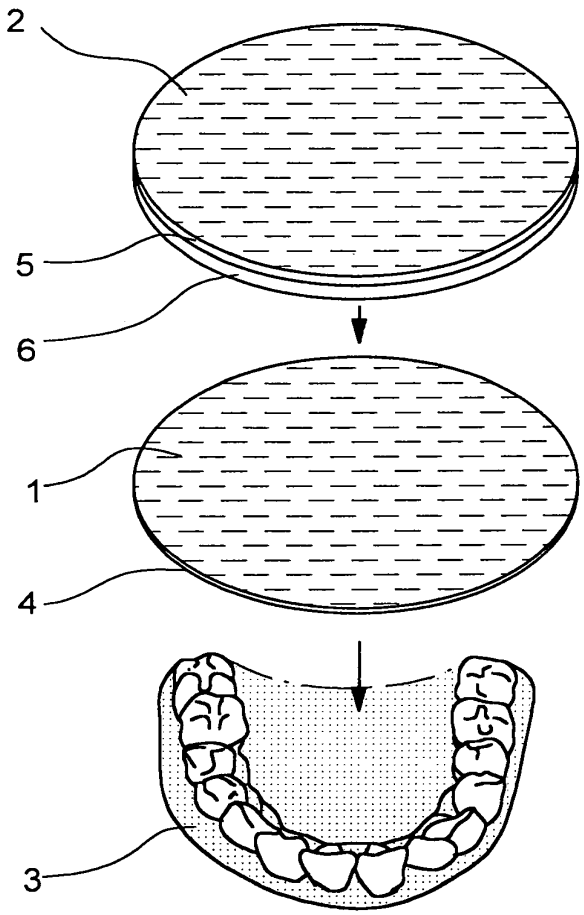


Fig. 1

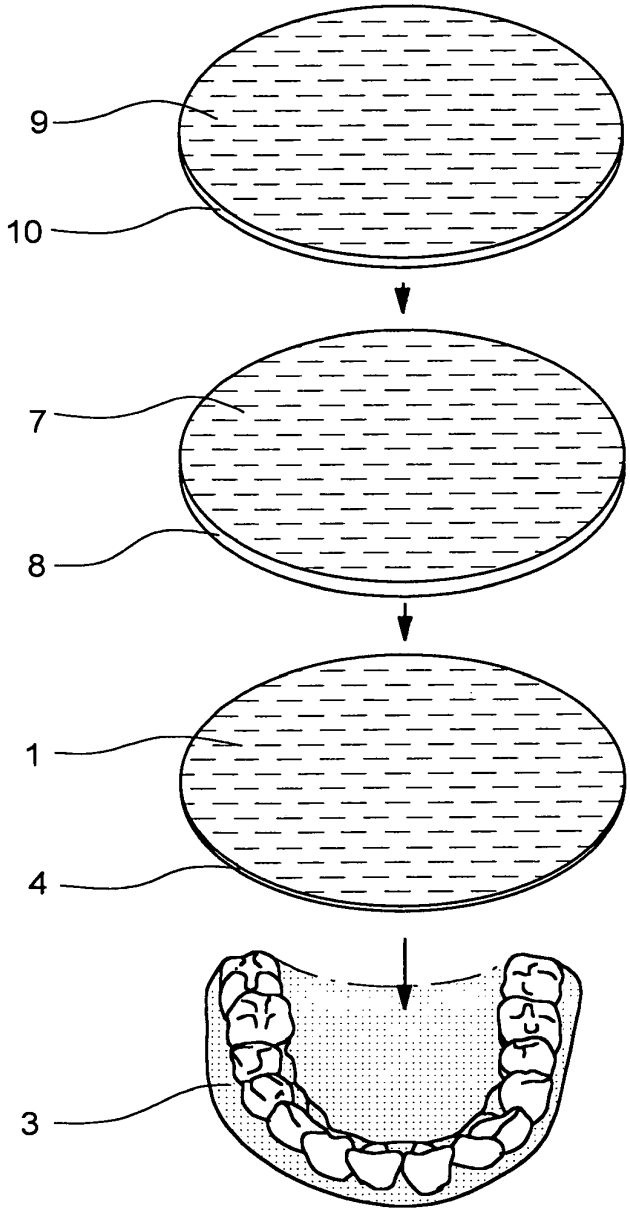


Fig. 2

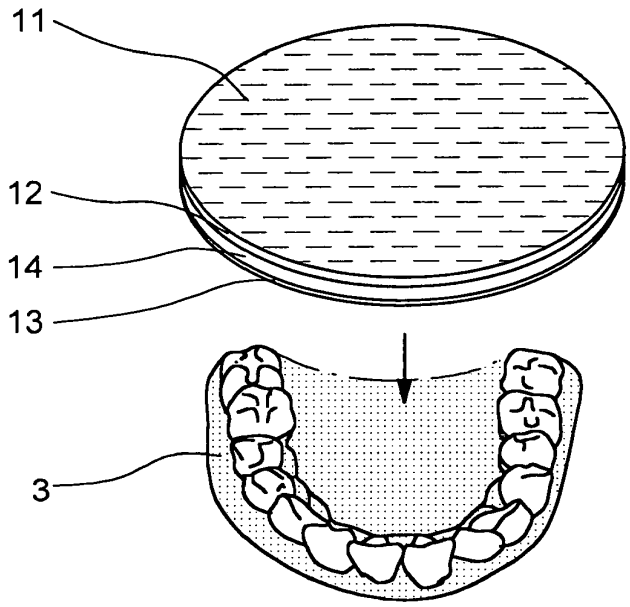


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/007480

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61C7/08 A61C19/06 A63B71/08 A61F5/56

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)
A61C A61F A63B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/209218 A1 (CHISHTI MUHAMMAD [US] ET AL) 21 October 2004 (2004-10-21) paragraphs [0043] - [0059], [0074]; figure 6 paragraph [0094]; figure 7	1,2,6-8, 11,13-15
X	AT 7 980 U1 (STEINBACH ROBERT [AT]) 15 December 2005 (2005-12-15) page 2, line 1 - page 3, line 10; figure 3	1,8,11
X	US 5 030 098 A (BRANFORD WILLIAM G [US]) 9 July 1991 (1991-07-09) column 2, lines 12-31; claim 1; figures 1,2	11,14,15
A		1-10

-/--

[X] Further documents are listed in the continuation of Box C. [X] 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
"E" earlier document but published on or after the international filing date
"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	Date of mailing of the international search report
9 Februar 2010	17/02/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ardhuin, Hélène

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/007480

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 765 324 A (LAKE JR JOHN R [US]) 23 August 1988 (1988-08-23) column 4, lines 23-38; figures 4-6 column 5, lines 14-21	11,15
X	WO 95/16488 A (SHOWA HATSUMEI KAISHA LTD [US]; GAGLIO THOMAS J [US]; SANTORIELLO LUIG) 22 June 1995 (1995-06-22)	11,13
A	page 8, line 26 - page 9, line 8; figures 6,8,9 page 11, line 14 - page 12, line 31	1-10
A	DE 296 21 578 U1 (SCHEU DENTAL CHRISTIAN [DE]) 6 March 1997 (1997-03-06) the whole document	
A	US 6 237 601 B1 (KITTELSEN JON D [US] ET AL) 29 May 2001 (2001-05-29) column 6, line 48 - column 7, line 47; figure 3	1,11

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/007480

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004209218 A1	21-10-2004	NONE	
AT 7980 U1	15-12-2005	NONE	
US 5030098 A	09-07-1991	NONE	
US 4765324 A	23-08-1988	NONE	
WO 9516488 A	22-06-1995	NONE	
DE 29621578 U1	06-03-1997	NONE	
US 6237601 B1	29-05-2001	NONE	

ClearCorrect Exhibit 1011, Page 826 of 890

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2009/007480

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61C7/08 A61C19/06 A63B71/08 A61F5/56

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61C A61F A63B

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2004/209218 A1 (CHISHTI MUHAMMAD [US] ET AL) 21. Oktober 2004 (2004-10-21) Absätze [0043] - [0059], [0074]; Abbildung 6 Absatz [0094]; Abbildung 7	1,2,6-8, 11,13-15
X	AT 7 980 U1 (STEINBACH ROBERT [AT]) 15. Dezember 2005 (2005-12-15) Seite 2, Zeile 1 - Seite 3, Zeile 10; Abbildung 3	1,8,11
X	US 5 030 098 A (BRANFORD WILLIAM G [US]) 9. Juli 1991 (1991-07-09) Spalte 2, Zeilen 12-31; Anspruch 1; Abbildungen 1,2	11,14,15
A		1-10

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
9. Februar 2010	17/02/2010

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Ardhuin, Hélène

Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2009/007480

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 4 765 324 A (LAKE JR JOHN R [US]) 23. August 1988 (1988-08-23) Spalte 4, Zeilen 23-38; Abbildungen 4-6 Spalte 5, Zeilen 14-21	11,15
X	WO 95/16488 A (SHOWA HATSUMEI KAISHA LTD [US]; GAGLIO THOMAS J [US]; SANTORIELLO LUIG) 22. Juni 1995 (1995-06-22)	11,13
A	Seite 8, Zeile 26 - Seite 9, Zeile 8; Abbildungen 6,8,9 Seite 11, Zeile 14 - Seite 12, Zeile 31	1-10
A	DE 296 21 578 U1 (SCHEU DENTAL CHRISTIAN [DE]) 6. März 1997 (1997-03-06) das ganze Dokument	
A	US 6 237 601 B1 (KITTELSEN JON D [US] ET AL) 29. Mai 2001 (2001-05-29) Spalte 6, Zeile 48 - Spalte 7, Zeile 47; Abbildung 3	1,11

ClearCorrect Exhibit 1011, Page 828 of 890

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2009/007480

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
US 2004209218	A1	21-10-2004	KEINE	
AT 7980	U1	15-12-2005	KEINE	
US 5030098	A	09-07-1991	KEINE	
US 4765324	A	23-08-1988	KEINE	
WO 9516488	A	22-06-1995	KEINE	
DE 29621578	U1	06-03-1997	KEINE	
US 6237601	B1	29-05-2001	KEINE	

ClearCorrect Exhibit 1011, Page 829 of 890

Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Patrick Michael Medley/John Macalagay
Attorney Docket Number:	22773-826.401

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt	
EFS ID:	41335366
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Patrick Michael Medley/John Macalagay
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.401
Receipt Date:	09-DEC-2020
Filing Date:	31-MAR-2017
Time Stamp:	12:57:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$260
RAM confirmation Number	E2020B9C58333768
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		22773-826-401_IDS_12-09-2020.pdf	324345 8e7b4f8cff73c79baff92bdb0aeeca9b99c43a08	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	4	
	Information Disclosure Statement (IDS) Form (SB08)		5	8	
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Information:					
2	Foreign Reference	WO2010043419A1_EFS.pdf	1039171 b5aa8e38c0ed4b3d7c970b83e9bf316c92dd0a17	no	24
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Information:					
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Warnings:					
Information:					
		Total Files Size (in bytes):	1393896		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	1748
Serial Number:	15/476,655	Examiner:	MONTIEL, CAROLINE
Filing or 371 (c) Date:	2017-03-31	**CONFIRMATION NO:**	**5936**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: December 09, 2020

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☐ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☐ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☒ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☒ a fee of $260.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $260.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* 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 or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $260.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.22773-826.401).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: December 09, 2020

By: /Patrick Medley/
Patrick Medley, Ph.D.
Reg. No. 74,735

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 107046

Electronic Acknowledgement Receipt	
EFS ID:	41335770
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Patrick Michael Medley/John Macalagay
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.401
Receipt Date:	09-DEC-2020
Filing Date:	31-MAR-2017
Time Stamp:	13:22:27
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	Non Patent Literature	LARSON_CanYouEstimate_1-5.pdf	555544 d286246d84ae8fc023c5437273e3b7f53902b231	no	5

Warnings:

Information:	
Total Files Size (in bytes):	555544

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.

New Applications Under 35 U.S.C. 111
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.
National Stage of an International Application under 35 U.S.C. 371
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.
New International Application Filed with the USPTO as a Receiving Office
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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

107046 7590 02/19/2021
Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER
MONTIEL, CAROLINE

ART UNIT	PAPER NUMBER
1748	

DATE MAILED: 02/19/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

TITLE OF INVENTION: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/19/2021

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.

ClearCorrect Exhibit 1011, Page 841 of 890

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)

107046 7590 02/19/2021
Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

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.

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.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

TITLE OF INVENTION: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/19/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
MONTIEL, CAROLINE	1748	264-016000

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.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 02/19/2021

Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
MONTIEL, CAROLINE	
ART UNIT	PAPER NUMBER
1748	

DATE MAILED: 02/19/2021

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. 15/476,655	Applicant(s) LI et al.	
	Examiner CAROLINE MONTIEL	Art Unit 1748	AIA (FITF) Status No

-- 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 11/13/2020.
   ☐ 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 20-41 . 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 11/13/2020; 12/9/2020.
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 _____.

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

DETAILED ACTION

1. The communication dated 11/13/2020 has been entered and fully considered.

2. Claims 20, 23, 31, 34, 37 and 39 have been amended. Claim 41 is new. Claims 20-41 are pending.

3. The present application is being examined under the pre-AIA first to invent provisions.

Allowable Subject Matter

4. Claims 21-41 are allowed.

5. The following is an examiner's statement of reasons for allowance:

The closest prior art of record is considered to be Desimone et al. (U.S. 7,641,828), hereinafter DESIMONE. DESIMONE teaches methods of making dental appliances for moving patient's teeth and providing a sheet comprising a hard polymer layer comprising co-polyester and a soft polymer layer. DESIMONE fails to teach, suggest or disclose a sheet comprising three or more polymer layers, the three or more polymer layers comprising a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and, a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D. One of ordinary skill in the art at the time of the effective filing date of the applicant's invention would not be reasonably motivated to modify the method of DESIMONE to achieve the claimed invention, and the applicant has done so for the benefit of producing appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, as taught in the instant specification [0007].

The applicant's affidavit was also found persuasive, in particular attention to the statement of "the appliances recited in the claims of the '665 application exhibit unexpectedly positive results over previously known appliances. These unexpected results are evidenced by clinical studies that were performed comparing the efficacy of orthodontic appliances as described and claimed in the '665 application with that of previously known appliances" [Affidavit: ¶ 3].

Any comments considered necessary 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."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CAROLINE MONTIEL whose telephone number is (571)272-2529. The examiner can normally be reached on MONDAY - FRIDAY 9:00 A.M. - 5:00 P.M.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ABBAS RASHID can be reached on (571) 270-7457. 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 https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.M./
Examiner, Art Unit 1748
/JACOB T MINSKEY/
Primary Examiner, Art Unit 1748

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61C 7/08	03/07/2019	CM
B32B 7/02	03/07/2019	CM
B29C 51/14	03/07/2019	CM
B32B 27/40	03/07/2019	CM
B32B 25/08	03/07/2019	CM
B32B 25/20	03/07/2019	CM
B32B 27/08	03/07/2019	CM
B32B 27/281	03/07/2019	CM
B32B 27/286	03/07/2019	CM
B32B 27/308	03/07/2019	CM
B32B 27/32	03/07/2019	CM
B32B 27/34	03/07/2019	CM
B32B 27/36	03/07/2019	CM
B32B 27/365	03/07/2019	CM
B29K 2995/0077	03/07/2019	CM
B32B 2250/24	03/07/2019	CM
B29L 2031/753	03/07/2019	CM
B29K 2067/00	03/07/2019	CM
B29K 2075/00	03/07/2019	CM
B29K 2995/0026	03/07/2019	CM
B29K 2995/007	03/07/2019	CM
B29K 2995/0082	03/07/2019	CM
B32B 2307/54	03/07/2019	CM
B32B 2250/03	03/07/2019	CM
B32B 2274/00	03/07/2019	CM
B32B 2307/412	03/07/2019	CM

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

B32B 2307/536	03/07/2019	CM
B32B 2535/00	03/07/2019	CM
B32B 2307/546	03/07/2019	CM
A61C 7/08 and keywords	11/20/2019	CM
B32B 7/02 and keywords	11/20/2019	CM
B29C 51/14 and keywords	11/20/2019	CM
B32B 27/40 and keywords	11/20/2019	CM
B32B 25/08 and keywords	11/20/2019	CM
B32B 25/20 and keywords	11/20/2019	CM
B32B 27/08 and keywords	11/20/2019	CM
B32B 27/281 and keywords	11/20/2019	CM
B32B 27/286 and keywords	11/20/2019	CM
B32B 27/308 and keywords	11/20/2019	CM
B32B 27/32 and keywords	11/20/2019	CM
B32B 27/34 and keywords	11/20/2019	CM
B32B 27/36 and keywords	11/20/2019	CM
B32B 27/365 and keywords	11/20/2019	CM
B29K 2995/0077 and keywords	11/20/2019	CM
B32B 2250/24 and keywords	11/20/2019	CM
B29L 2031/753 and keywords	11/20/2019	CM
B29K 2067/00 and keywords	11/20/2019	CM
B29K 2075/00 and keywords	11/20/2019	CM
B29K 2995/0026 and keywords	11/20/2019	CM
B29K 2995/007 and keywords	11/20/2019	CM
B29K 2995/0082 and keywords	11/20/2019	CM
B32B 2307/54 and keywords	11/20/2019	CM
B32B 2250/03 and keywords	11/20/2019	CM
B32B 2274/00 and keywords	11/20/2019	CM
B32B 2307/412 and keywords	11/20/2019	CM

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

B32B 2307/536 and keywords	11/20/2019	CM
B32B 2535/00 and keywords	11/20/2019	CM
B32B 2307/546 and keywords	11/20/2019	CM
A61C 7/08 and keywords	06/10/2020	CM
B32B (7/02; 27/40; 25/08; 25/20; 27/08; 27/281; 27/286; 27/308; 27/32; 27/34; 27/36; 27/365; 2250/24; 2307/54; 2250/03; 2274/00; 2307/412; 2307/536; 2535/00; 2307/546) and keywords	06/10/2020	CM
B29C 51/14 and keywords	06/10/2020	CM
B29K (2995/0077; 2067/00; 2075/00; 2995/0026; 2995/007; 2995/0082) and keywords	06/10/2020	CM
B29L 2031/753 and keywords	06/10/2020	CM
A61C 7/08 and keywords	02/10/2021	CM
B32B (7/02; 27/40; 25/08; 25/20; 27/08; 27/281; 27/286; 27/308; 27/32; 27/34; 27/36; 27/365; 2250/24; 2307/54; 2250/03; 2274/00; 2307/412; 2307/536; 2535/00; 2307/546) and keywords	02/10/2021	CM
B29C 51/14 and keywords	02/10/2021	CM
B29K (2995/0077; 2067/00; 2075/00; 2995/0026; 2995/007; 2995/0082) and keywords	02/10/2021	CM
B29L 2031/753 and keywords	02/10/2021	CM

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.

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

Search Notes		
Search Notes	**Date**	**Examiner**
See EAST search history	03/07/2019	CM
See EAST inventor search	03/07/2019	CM
See updated Inventor/Applicant EAST search	11/20/2019	CM
See updated EAST search history	11/20/2019	CM
See updated Inventor/Applicant search	06/10/2020	CM
See updated EAST search history	06/10/2020	CM
See updated Inventor/Applicant search	02/10/2021	CM
See updated EAST search history	02/10/2021	CM
Searched Google Patents, Espacenet, WIPO, Global Dossier	02/10/2021	CM

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61C	7/08 and keywords	02/10/2021	CM
B32B	(7/02; 27/40; 25/08; 25/20; 27/08; 27/281; 27/286; 27/308; 27/32; 27/34; 27/36; 27/365; 2250/24; 2307/54; 2250/03; 2274/00; 2307/412; 2307/536; 2535/00; 2307/546) and keywords	02/10/2021	CM
B29C	51/14 and keywords	02/10/2021	CM
B29K	(2995/0077; 2067/00; 2075/00; 2995/0026; 2995/007; 2995/0082) and keywords	02/10/2021	CM
B29L	2031/753 and keywords	02/10/2021	CM
Text search	See EAST text search history	02/10/2021	CM

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

CPC						
Symbol					Type	Version
A61C	/	7	/	08	F	2013-01-01
B32B	/	27	/	285	I	2013-01-01
B32B	/	25	/	08	I	2013-01-01
B32B	/	25	/	20	I	2013-01-01
B32B	/	27	/	08	I	2013-01-01
B32B	/	27	/	281	I	2013-01-01
B32B	/	27	/	286	I	2013-01-01
B32B	/	27	/	308	I	2013-01-01
B32B	/	27	/	32	I	2013-01-01
B32B	/	27	/	34	I	2013-01-01
B32B	/	27	/	36	I	2013-01-01
B32B	/	27	/	365	I	2013-01-01
B32B	/	27	/	40	I	2013-01-01
B32B	/	7	/	02	I	2013-01-01
B29C	/	51	/	14	I	2013-01-01
B32B	/	2323	/	04	A	2013-01-01
B32B	/	2323	/	10	A	2013-01-01
B32B	/	2367	/	00	A	2013-01-01
B32B	/	2371	/	00	A	2013-01-01
B32B	/	2375	/	00	A	2013-01-01
B32B	/	2377	/	00	A	2013-01-01
B32B	/	2555	/	00	A	2013-01-01
B32B	/	2250	/	03	A	2013-01-01
B32B	/	2274	/	00	A	2013-01-01
B32B	/	2307	/	412	A	2013-01-01
B32B	/	2307	/	536	A	2013-01-01
B32B	/	2307	/	54	A	2013-01-01
B32B	/	2307	/	546	A	2013-01-01
B32B	/	2535	/	00	A	2013-01-01
B32B	/	2250	/	24	A	2013-01-01
B29K	/	2067	/	00	A	2013-01-01

/CAROLINE MONTIEL/ Examiner, Art Unit 1748 (Assistant Examiner)	10 February 2021 (Date)	**Total Claims Allowed:** 22	
/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748 (Primary Examiner)	15 February 2021 (Date)	O.G. Print Claim(s) 20	O.G. Print Figure 1

U.S. Patent and Trademark Office — Part of Paper No.: 20210210

ClearCorrect Exhibit 1011, Page 853 of 890

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

CPC						
Symbol					Type	Version
B29K	/	2075	/	00	A	2013-01-01
B29K	/	2995	/	0026	A	2013-01-01
B29K	/	2995	/	007	A	2013-01-01
B29K	/	2995	/	0077	A	2013-01-01
B29K	/	2995	/	0082	A	2013-01-01
B29L	/	2031	/	753	A	2013-01-01

CPC Combination Sets							
Symbol					Type	Set	Ranking	Version
	/		/					

/CAROLINE MONTIEL/ Examiner, Art Unit 1748	10 February 2021	Total Claims Allowed:	
(Assistant Examiner)	(Date)	22	
/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748	15 February 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	20	1

U.S. Patent and Trademark Office — Part of Paper No.: 20210210

ClearCorrect Exhibit 1011, Page 854 of 890

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61C7/08	/	7	/	08
B32B27/28	/	27	/	28
B32B25/08	/	25	/	08
B32B27/08	/	27	/	08
B32B27/30	/	27	/	30
B32B27/34	/	27	/	34
B32B27/36	/	27	/	36
B32B27/40	/	27	/	40
B32B7/02	/	7	/	02
B29C51/14	/	51	/	14
B29K67/00	/	67	/	00
B29K75/00	/	75	/	00

NON-CLAIMED				
B32B25/20	/	25	/	20
B32B27/32	/	27	/	32
B29L31/00	/	31	/	00

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

/CAROLINE MONTIEL/ Examiner, Art Unit 1748 (Assistant Examiner)	10 February 2021 (Date)	Total Claims Allowed: 22	
/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748 (Primary Examiner)	15 February 2021 (Date)	O.G. Print Claim(s) 20	O.G. Print Figure 1

U.S. Patent and Trademark Office — Part of Paper No.: 20210210

ClearCorrect Exhibit 1011, Page 855 of 890

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/476,655	LI et al.
	Examiner	Art Unit
	CAROLINE MONTIEL	1748

☐ 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	9	28	20	37						
-	2	-	11	1	20	10	29	21	38						
-	3	-	12	2	21	11	30	22	39						
-	4	-	13	3	22	12	31	19	40						
-	5	-	14	4	23	13	32	14	41						
-	6	-	15	5	24	15	33								
-	7	-	16	6	25	16	34								
-	8	-	17	7	26	17	35								
-	9	-	18	8	27	18	36								

/CAROLINE MONTIEL/ Examiner, Art Unit 1748	10 February 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748	15 February 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	20	1

U.S. Patent and Trademark Office Part of Paper No.: 20210210

ClearCorrect Exhibit 1011, Page 856 of 890

Bibliographic Data

Application No: 15/476,655

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /CAROLINE MONTIEL/ (Examiner's Signature) | CM (Initials)

Title: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
03/31/2017	264	1748	22773-826.401
RULE			

APPLICANTS

ALIGN TECHNOLOGY, INC., San Jose, CA, UNITED STATES

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Craig PEHLERT, Lenox, MA, UNITED STATES

CONTINUING DATA

This application is a DIV of 13470681 05/14/2012 PAT 9655691

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

04/11/2017

STATE OR COUNTRY

UNITED STATES

ADDRESS

Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304
UNITED STATES

FILING FEE RECEIVED

$1,740

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-3763109	10-02-1973	WITSIEPE; W. et al.	
	002	US-3766146	10-16-1973	WITSIEPE; W. et al.	
	003	US-4346195	08-24-1982	HORNBAKER; Edwin D. et al.	
	004	US-4410595	10-18-1983	MATSUMOTO; Koichi et al.	
	005	US-4824723	04-25-1989	CAMPBELL; Richard W. et al.	
	006	US-20020146549	10-10-2002	KRANENBURG-VAN DIJK; Saskia I. et al.	
	007	US-20050100853	05-12-2005	TADROS; Safwat et al.	
	008	US-20090306327	12-10-2009	STEWART; Ray F. et al.	
	009	US-20110069134	03-24-2011	SAKAGAMI; Toshinori et al.	
	010	US-20120315484	12-13-2012	RIEDL; Josef et al.	
	011	US-20150374464	12-31-2015	STEWART; Ray F.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	JP-H06256630-A	09-13-1994	DENKI KAGAKU KOGYO KK., et al.	Abstract:	☒

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	02/04/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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.	T[2]
	001	Material Data Sheet of Ecdel 9966. 3 pages total (Year: 2020).	☐
	002	"Overview of Materials for PETG Copolyester" 2 pages (http://www.nnatweb.conn/search/DataSheet.aspx?MatGUID=4de1c85bb946406a86c52b688e3810d0&ckck=1) (webpage retrieved on 10/27/2020) (Year: 2020).	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	02/04/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

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Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Patrick Medley/	Date (YYYY-MM-DD)	2020-11-13
Name/Print	Patrick Medley, Ph.D.	Registration Number	74,735

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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.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		None			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-2010043419-A1	04-22-2010	HINZ LABOR FACHLABORATORIUM FU [DE], et al.	Abstract:	☒

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	02/04/2021

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Sheet 2 of 4

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Application Number	15/476,655
Filing Date	03-31-2017
First Named Inventor	LI; Chunhua
Art Unit	1748
Examiner Name	MONTIEL, CAROLINE
Attorney Docket Number	22773-826.401

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	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.	T[2]
	001	LARSON, Kent "Can You Estimate Modulus From Durometer Hardness for Silicones?" Dow White Paper, 2019 The Dow Chemical Company, Form No. 11-3716-01A S2D, pp. 1-5.	☐

Examiner Signature	/CAROLINE MONTIEL/	Date Considered	02/04/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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 2 hours 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, 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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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ 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 application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ 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 application, and, to the knowledge of the person signing the certification 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. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Patrick Medley/	Date (YYYY-MM-DD)	2020-12-09
Name/Print	Patrick Medley, Ph.D.	Registration Number	74,735

This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR1.14. This collection is estimated to take 1 hour 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

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).
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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 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.M./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	417,946	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/10 16:19
L2	9,427	L1 and (dental teeth)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/10 16:19
L3	125	L2 and (thermoplastic near5 polyurethane near5 elastomer "TPU") and co$1polyester	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/10 16:19
L4	37	L3 and (layer near10 (hardness durometer))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/10 16:19
S1	437	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/02/14 10:59
S2	939	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/02/14 10:59
S3	2,184	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR	US-PGPUB; USPAT; USOCR; EPO;	OR	ON	2019/02/14 11:26

		(("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	JPO; DERWENT			
S4	108,400	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S5	2,363	S4 and dental	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:36
S6	4,722	S4 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/14 11:37
S7	2	13/470,681.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/14 11:42
S8	4	("2009/0246724").URPN.	USPAT	OR	ON	2019/02/19 10:41
S9	108,672	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:42

S11	121	(dental teeth) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:43
S12	50	(dental teeth) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:45
S13	53	dental and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 10:47
S14	98	(oral dental) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:00
S15	40	(dental oral) and polymeric adj material and polymer adj layer and hard and soft and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:01
S16	2,480	(oral dental) and (braces retainers) and polymeric adj material	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:03
S17	18	(oral dental) and (braces retainers) and polymeric adj material and polymer adj layer and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/02/19 11:04
S18	3,542	(A61C7/00).IPCR.	US-PGPUB; USPAT	OR	OFF	2019/02/19 13:53
S19	124	S18 and layers and polymeric near5 material and (hardness hard durometer stiff stiffness) and sheet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 13:55
S20	821	S18 and (polyester co-polyester polycarbonate "thermoplastic polyurethane" polypropylene polyethylene polypropylene "polyethylene copolymer" acrylic "cyclic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2019/02/19 14:17

		block copolymer" polyetheretherketone polyamide "polyethylene terephthalate" "polybutylene terephthalate" polyetherimide polyethersulfone "polytrimethylene terephthalate")	DERWENT; IBM_TDB			
S21	201	S18 and ((styrenic adj1 block adj1 copolymer "SBC") "silicone rubber" "elastomeric alloy" (thermoplastic adj1 elastomer "TPE") (thermoplastic adj1 vulcanizate adj1 elastomer "TPV" adj1 elastomer) "polyurethane elastomer" "block copolymer elastomer" "polyolefin blend elastomer" "thermoplastic co-polyester elastomer" "thermoplastic polyamide elastomer")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:19
S22	125	S21 and S20	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/19 14:20
S23	81	soft adj1 polymer adj1 layer and hard adj1 polymer adj1 layer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/02/21 15:43
S24	172	("20010041320" | "20020006597" | "20030009252" | "20030139834" | "20030224311" | "20040128010" | "20040146670" | "20050055118" | "20070148608" | "20080299507" | "20090087808" | "20090239188" | "20090246724" | "20100055639" | "20150140300" | "20160228215" | "2467432" | "3407500" | "3600808" | "3660900" | "3683502" | "3738005" | "3860803" | "3916526" | "3922786" | "3950851" | "3983628" | "4014096" | "4195046" | "4253828" | "4324546" | "4324547" | "4348178" | "4478580" | "4500294" | "4504225" | "4505673" | "4526540" | "4575330" | "4575805" | "4591341" | "4609349" | "4611288" | "4656860" | "4663720" | "4664626" | "4676747" | "4742464" | "4755139" | "4763791" | "4791156" | "4793803" | "4798534" | "4836778" | "4837732" | "4850864" | "4850865" | "4856991" |	US-PGPUB; USPAT	OR	ON	2019/03/07 09:13

		"4877398" | "4880380" | "4889238" | "4890608" | "4935635" | "4936862" | "4937928" | "4941826" | "4964770" | "4975052" | "4983334" | "5011405" | "5017133" | "5024790" | "5027281" | "5035613" | "5055039" | "5059118" | "5100316" | "5121333" | "5125832" | "5128870" | "5130064" | "5131843" | "5131844" | "5139419" | "5145364" | "5176517" | "5184306" | "5186623" | "5257203" | "5273429" | "5278756" | "5328362" | "5338198" | "5340309" | "5342202" | "5368478" | "5382164" | "5395238" | "5431562" | "5440326" | "5440496" | "5447432" | "5452219" | "5454717" | "5456600" | "5474448" | "5518397" | "5528735" | "5533895" | "5542842" | "5549476" | "5562448" | "5587912" | "5605459" | "5607305" | "5614075" | "5621648" | "5645420" | "5645421" | "5655653" | "5683243" | "5692894" | "5725376" | "5725378" | "5733126" | "5740267" | "5742700" | "5799100" | "5800174" | "5823778" | "5848115" | "5857853" | "5866058" | "5879158" | "5880961" | "5880962" | "5934288" | "5957686" | "5964587" | "5971754" | "5975893" | "6015289" | "6044309" | "6049743" | "6062861" | "6068482" | "6099314" | "6123544" | "6152731" | "6183248" | "6190165" | "6217325" | "6217334" | "6244861" | "6309215" | "6315553" | "6322359" | "6350120" | "6382975" | "6398548" | "6402707" | "6482298" | "6524101" | "6554611" | "6572372" | "6629840" | "6705863" | "6722880" | "7641828" | "8235713" | "8496473" | "RE35169").PN.				
S25	4	"4791156".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2019/09/23 15:58
S26	112,431	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:05

		B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.				
S27	5,186	S26 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:06
S28	29	elongation near20 (2{d2} adj2 ("%" percent)) and S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:07
S29	3,073	elongation near20 (2{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:12
S30	1,879	elongation near20 (4{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:14
S31	2,816	elongation near20 (3{d2} adj2 ("%" percent))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:17
S32	6,273	S29 S30 S31	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S33	40	S27 and S32	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21
S34	29,226	modulus near20 psi	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:21

S35	1	S33 and S34	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 16:22
S36	7	("10052176" | "20080230938" | "20090130438" | "20170007362" | "6667101" | "9655691" | "9655693").PN.	US-PGPUB; USPAT	OR	ON	2019/09/23 16:24
S37	2	"2004146670".pn.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/23 17:12
S38	12	("20020192617" | "20030190576" | "20040170941" | "20070231765" | "20080020337" | "20190159870" | "20190183611" | "20190231484" | "6390812" | "6485298" | "6705861" | "7121825").PN.	US-PGPUB; USPAT	OR	ON	2019/09/23 17:18
S39	58,583	resin near20 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S40	47,502	resin near10 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S41	237,081	resin near10 polyurethane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S42	9,409	S40 and S41	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 09:58
S43	3	ISOPLAST near5 "2530" near10 (hardness durometer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/09/25 10:04
S44	472	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/09/25 10:17

S45	121,112	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 14:57
S46	5,358	S45 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 14:57
S47	36	elongation near20 (3{d2} adj2 ("%" percent)) and S46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:14
S48	5,358	S45 and (dental teeth tooth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:22
S49	36	elongation near20 (3{d2} adj2 ("%" percent)) and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:24
S50	30	elongation near20 (2{d2} adj2 ("%" percent)) and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:37
S51	2,379	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/12 15:40
S52	1,088	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2019/11/12 15:45
S53	485	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2019/11/12 15:48

S54	1,225	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	US-PGPUB; USPAT	OR	ON	2020/06/09 11:07
S55	2,536	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/09 11:07
S56	129,293	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/09 11:15
S57	5,836	S56 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/09 11:15
S58	547	((("ALIGN") near3 ("TECHNOLOGY") near3 ("INC"))).AS,AANM.	USPAT	OR	ON	2020/06/09 11:58
S59	7	("20080248438" | "20090298006" | "20110020761" | "6454565" | "6746757" | "7201575" | "7354270").PN.	US-PGPUB; USPAT	OR	ON	2020/06/10 09:03
S60	137,039	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/02/04 15:45
S61	6,333	S60 and (dental teeth)	US-PGPUB; USPAT; USOCR; EPO;	OR	ON	2021/02/04 15:45

			JPO; DERWENT			
S62	2,702	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/02/04 15:45
S63	23,605	((("LI") near3 ("Chunhua")) OR (("CHEN") near3 ("Yan")) OR (("PUDLEINER") near3 ("Heinz")) OR (("MEYER") near3 ("Klaus")) OR (("NICKEL") near3 ("Joerg")) OR (("PEHLERT") near3 ("Craig"))).INV.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/04 15:52
S64	273	S61 and (thermoplastic near5 polyurethane near5 elastomer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/02/04 16:58
S65	417,833	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/04 16:58
S66	9,419	S65 and (dental teeth)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/04 17:02
S67	282	S66 and (thermoplastic near5 polyurethane near5 elastomer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/04 17:06
S68	417,833	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or	US-PGPUB; USPAT;	OR	ON	2021/02/05 09:34

		B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S69	9,419	S68 and (dental teeth)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 09:34
S70	282	S69 and (thermoplastic near5 polyurethane near5 elastomer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 09:34
S71	418	S69 and (thermoplastic near5 polyurethane near5 elastomer "TPU")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 10:04
S72	34	elongation near20 (2{d2} adj2 ("%" percent)) and S71	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/02/05 10:26
S73	34	elongation near20 (2{d2} adj2 ("%" percent)) and S71	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 10:26
S74	2	S71 and (resin near10 (hardness durometer))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/02/05 10:29

			DERWENT; IBM_TDB			
S75	55	S71 and (layer near10 (hardness durometer))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 10:37
S76	125	S69 and (thermoplastic near5 polyurethane near5 elastomer "TPU") and co$1polyester	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 10:48
S77	37	S76 and (layer near10 (hardness durometer))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/02/05 10:49

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L5	32,863	(A61C7/08 or B32B7/02 or B29C51/14 or B32B27/40 or B32B25/08 or B32B25/20 or B32B27/08 or B32B27/281 or B32B27/286 or B32B27/308 or B32B27/32 or B32B27/34 or B32B27/36 or B32B27/365 or B29K2995/0077 or B32B2250/24 or B29L2031/753 or B29K2067/00 or B29K2075/00 or B29K2995/0026 or B29K2995/007 or B29K2995/0082 or B32B2307/54 or B32B2250/03 or B32B2274/00 or B32B2307/412 or B32B2307/536 or B32B2535/00 or B32B2307/546).cpc.	USPAT	OR	ON	2021/02/10 17:51
L6	1,984	5 and (dental teeth)	USPAT	OR	ON	2021/02/10 17:52
L7	31	6 and (thermoplastic near5 polyurethane near5 elastomer "TPU") and co$1polyester	USPAT	OR	ON	2021/02/10 17:52
L8	81	6 and (layer near10 (hardness durometer))	USPAT	OR	ON	2021/02/10 17:52

2/10/2021 6:00:48 PM
C:\Users\cmontiel\Documents\EAST\Workspaces\15476655.wsp

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

107046 7590 03/05/2021

Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
MONTIEL, CAROLINE	

ART UNIT	PAPER NUMBER
1748	

NOTIFICATION DATE	DELIVERY MODE
03/05/2021	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):

patentdocket@wsgr.com

Corrected ***Notice of Allowability***	**Application No.** 15/476,655	**Applicant(s)** LI et al.	
	Examiner CAROLINE MONTIEL	**Art Unit** 1748	**AIA (FITF) Status** No

-- 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 11/13/2020.
   ☐ 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 20-41 . 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 _____.

/C.M./ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

DETAILED ACTION

1. The communication dated 11/13/2020 has been entered and fully considered.

2. Claims 20, 23, 31, 34, 37 and 39 have been amended. Claim 41 is new. Claims 20-41 are pending.

3. The present application is being examined under the pre-AIA first to invent provisions.

Allowable Subject Matter

4. Claims 20-41 are allowed.

5. The following is an examiner's statement of reasons for allowance:

The closest prior art of record is considered to be Desimone et al. (U.S. 7,641,828), hereinafter DESIMONE. DESIMONE teaches methods of making dental appliances for moving patient's teeth and providing a sheet comprising a hard polymer layer comprising co-polyester and a soft polymer layer. DESIMONE fails to teach, suggest or disclose a sheet comprising three or more polymer layers, the three or more polymer layers comprising a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and, a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D. One of ordinary skill in the art at the time of the effective filing date of the applicant's invention would not be reasonably motivated to modify the method of DESIMONE to achieve the claimed invention, and the applicant has done so for the benefit of producing appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, as taught in the instant specification [0007].

The applicant's affidavit was also found persuasive, in particular attention to the statement of "the appliances recited in the claims of the '665 application exhibit unexpectedly positive results over previously known appliances. These unexpected results are evidenced by clinical studies that were performed comparing the efficacy of orthodontic appliances as described and claimed in the '665 application with that of previously known appliances" [Affidavit: ¶ 3].

Any comments considered necessary 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."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CAROLINE MONTIEL whose telephone number is (571)272-2529. The examiner can normally be reached on MONDAY - FRIDAY 9:00 A.M. - 5:00 P.M.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ABBAS RASHID can be reached on (571) 270-7457. 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 https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.M./
Examiner, Art Unit 1748

/JACOB T MINSKEY/
Primary Examiner, Art Unit 1748

Applicant-Initiated Interview Summary	**Application No.** 15/476,655	**Applicant(s)** LI et al.		
	Examiner CAROLINE MONTIEL	**Art Unit** 1748	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
CAROLINE MONTIEL	Examiner	Telephonic
LUIS PERLA	Attorney of Record	

Date of Interview: 02 March 2021

Issues Discussed:

Other

The Applicant called in regards to claims in the Notice of Allowance and to have it corrected to include the correct number of allowable claims.

/CAROLINE MONTIEL/ Examiner, Art Unit 1748	/JACOB T MINSKEY/ Primary Examiner, Art Unit 1748

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

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)

107046 7590 02/19/2021
Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

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.

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.

James Brady	(Typed or printed name)
/James Brady/	(Signature)
3/9/2021	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	03/31/2017	Chunhua LI	22773-826.401	5936

TITLE OF INVENTION: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/19/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
MONTIEL, CAROLINE	1748	264-016000

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 Wilson Sonsini
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: ALIGN TECHNOLOGY, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): San Jose, 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. 23-2415

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 /Luis Perla/ Date March 9, 2021

Typed or printed name Luis G. Perla, Ph.D. Registration No. 77,556

Electronic Patent Application Fee Transmittal

Application Number:	15476655
Filing Date:	31-Mar-2017
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Filer:	Luis Geovani Perla/James Brady
Attorney Docket Number:	22773-826.401

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	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt	
EFS ID:	42128852
Application Number:	15476655
International Application Number:	
Confirmation Number:	5936
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua LI
Customer Number:	107046
Filer:	Luis Geovani Perla/James Brady
Filer Authorized By:	Luis Geovani Perla
Attorney Docket Number:	22773-826.401
Receipt Date:	09-MAR-2021
Filing Date:	31-MAR-2017
Time Stamp:	13:59:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1200
RAM confirmation Number	E202139D59242465
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)	22773-826-401-Issue-Fee-Transmittal.pdf	126629 55f031d0783dbddea1eff620b1357856a988ca42	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30381 f6820494f078cee44f2914efdd7702a5a6c78e2c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	157010		

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.

New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/476,655	04/13/2021	10973613	22773-826.401	5936

107046 7590 03/24/2021

Align Technology, Inc. / WSGR
650 Page Mill Road
Palo Alto, CA 94304

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 150 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):

Chunhua LI, Cupertino, CA;
ALIGN TECHNOLOGY, INC., San Jose, CA;
Yan CHEN, Cupertino, CA;
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