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				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
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	311.	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).	
	312.	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).	
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	13/470,681
				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
Sheet	20	of	21	Attorney Docket Number	22773-826.201

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				Application Number	13/470,681
				Filing Date	May 14, 2012
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Sheet	21	of	21	Attorney Docket Number	22773-826.201

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	332.	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).	
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MANUFACTURE OF MOUTHPIECE FOR TEETH SET CORRECTION

Patent number:	JP4028359
Publication date:	1992-01-30
Inventor:	SHIMADA TAKEO; CHIHARA SHOICHI
Applicant:	MITSUBISHI PETROCHEMICAL CO
Classification:	
- international:	A61C7/08
- european:	
Application number:	JP19900134984 19900524
Priority number(s):	JP19900134984 19900524

Report a data error here

Abstract of **JP4028359**

PURPOSE:To permit easy installation of the title mouthpiece and prevent a specific tooth from being damaged, by using the mouthpiece in covering state on the whole teeth by preparing a plaster model for teeth set correction by correcting a teeth set plaster model which is prepared according to a patient's palate, and closely attaching and solidifying a softened thermoplastic polymer sheet on the model, and then demounting the solidified sheet. CONSTITUTION:A recessed teeth set model is made from a seal material according to a patient' s palate, and plaster is introduced into the recessed model, and a projecting teeth set plaster model is prepared, and correction is applied up to a corrected form on the basis of the plaster model, and a plaster model for teeth set correction is prepared. Then, a sheet-shaped thermoplastic polymer which possesses the superior strength and the elastomer characteristic such as ethylene-vinyl acetate copolymer is heat-softened and attached on the plaster model for teeth set correction, and further closely attached through heat shaping, and the teeth set of the model is correctly printed, and the thermoplastic polymer sheet is cooling-solidified to the normal temperature and demounted, thus a mouthpiece is obtained. Since the mouthpiece possesses rubber elasticity and is not so hard, the mouthpiece can be installed reasonably on the patient's teeth set, and since the compatibility to the tooth other than the corrected tooth is superior, the force applied onto the corrected tooth can be received in dispersion by the whole of the teeth.

Data supplied from the ***esp@cenet*** database - Worldwide

Reference A,D

⑲日本国特許庁(JP)　⑪特許出願公開

⑫公開特許公報(A)　平4−28359

⑤Int.Cl.⁵　識別記号　庁内整理番号　⑬公開　平成4年(1992)1月30日

A 61 C 7/08　7108−4C　A 61 C 7/00　M

審査請求 有　請求項の数 2 (全4頁)

⑭発明の名称　歯列矯正用マウスピースの製造法

⑳特　願　平2−134984

㉒出　願　平2(1990)5月24日

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㉔代理人　弁理士　佐藤　一雄　外2名

明　細　書

1．発明の名称

歯列矯正用マウスピースの製造法

2．特許請求の範囲

1．歯列不正患者より採取した歯列石膏模型を修正して歯列矯正用石膏模型を製作し、該歯列矯正用石膏模型に軟化した熱可塑性重合体シートを密着した後固化させて取り外すことを特徴とする歯列矯正用マウスピースの製造法。

2．熱可塑性重合体が、曲げ弾性率(ASTM−D747)800kg/cm²以下のものである請求項1に記載の歯列矯正用マウスピースの製造法。

3．発明の詳細な説明

〔発明の背景〕

<産業上の利用分野>

本発明は、歯牙に傷を付けることなく簡易に歯列の矯正を行なうことができる歯列矯正用マウスピースの製造法に関する。

<従来の技術>

従来、歯列の矯正は、一般に矯正を行なう歯牙に力を加えるために、他の正常な歯牙にワイヤー掛のための支具を装着して行なう方法が採用されている。

<発明が解決しようとする課題>

しかし、このような方法では、他の正常な歯牙をも傷を付け易いばかりか、一部の歯牙にのみ特に力が加わり易いことから、ワイヤー掛された歯牙が痛むといった欠点があった。

〔発明の概要〕

<要旨>

本発明者らは上記課題を解決するために鋭意研究を重ねた結果、従来の歯列矯正方法と全く異なる特殊なマウスピースを用いることによって他の正常な歯牙を傷付けること無く、歯牙に加える力を歯牙全体でこれを保持して、矯正する歯牙のみに特に力を加えることができるので、従来の矯正

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法と異なり簡易に矯正を行なうことができるとの知見を得て本発明を完成するに至った。

すなわち、本発明の歯列矯正用マウスピースの製造法は、歯列不正患者より採取した歯列石膏模型を修正して歯列矯正用石膏模型を製作し、該歯列矯正用石膏模型に軟化した熱可塑性重合体シートを密着した後固化させて取り外すことを特徴とするものである。

＜効果＞

本発明の歯列矯正用マウスピースの製造法によって製作された歯列矯正用マウスピースは、軟質材料を用いているので装着が容易であり、かつ歯牙全体に覆せて使用するので特定な歯牙を痛めることもない。また、はずして歯牙や口腔の中を滑めることも容易に出来るといった著しい効果を奏する。

〔発明の具体的説明〕

〔Ⅰ〕歯列矯正用石膏模型の製作

(1) 患者の歯列模型の製作工程

本発明の歯列矯正用マウスピースの製造法においては、先ず、歯列矯正を行なう患者の口蓋より、印象材を用いて凹型の歯列模型を製作し、この凹型の歯列模型に石膏を流し込んで患者の正確な歯列の凸型の歯列石膏模型を製作する。

この時凹型の歯列模型の作成に使用する印象材は、一般に歯科分野で用いられるものが使用でき、シリコーン印象材、寒天印象材、アルジネート印象材等が用いられる。また、凸型の歯列石膏模型に使用する石膏は、硬質石膏、又は超硬質石膏を用いるのがよい。

(2) 歯列矯正用石膏模型の製作工程

上記方法によって製作された患者の歯列の凸型の石膏模型をベースにして、最終的に、あるいは段階的に矯正されるべき形にまで修正を加えて歯列矯正用石膏模型を製作する。

このような歯列矯正用石膏模型は、患者の歯列石膏模型の矯正する歯牙の矯正するべき方向の力を加えたくない部所に肉盛りし、その反対側の力を加えたい部所を切削して修正を行なう。

切削に使用する道具は、石膏を切削することが

出来れば何を使用してもよいが、一般に技工用バーやハンドピースを用いて行なわれる。また肉盛りはコンポジットレジンやエポキシ樹脂等で行う。又肉盛りに使用する材料もその後の操作に耐えるだけの接着強度及び引張り強度があれば、どのようなものを使ってもよい。

〔Ⅱ〕歯列矯正用マウスピースの製作

(1) 熱可塑性重合体シートの熱成形

前記方法によって製作された歯列矯正用石膏模型に加熱によって軟化されたシート状の熱可塑性重合体を貼着し、さらに熱成形にて密着させて歯列矯正用石膏模型の歯列を正確に転写する。

ここで用いる熱可塑性重合体は、エラストマー特性及び強度の優れたもの、更には装着感の優れたものを用いる必要がある。

上記の条件を満足させる為に、使用する熱可塑性重合体は、曲げ弾性率（ＡＳＴＭ　Ｄ７４７）が８００kg／cm以下、好ましくは５０～５００kg／cmのものであることが望ましい。

このような条件を満足する材料としては、エチレン・酢酸ビニル共重合体、エチレン・アクリル酸エステル共重合体、エチレン・メタアクリル酸エステル共重合体、エチレン・α－オレフィン共重合体、ポリエチレン等のエチレン系樹脂のほかエチレン・プロピレンエラストマー、エチレン・プロピレン・ジエン化合物系エラストマー、スチレン・ブタジエン系（水添物も含む）エラストマー、ポリエステルエラストマー、ウレタンエラストマー、ポリブタジエン等がある。

これらの中でもエチレン系樹脂（特にエチレン・酢酸ビニル共重合体、エチレン・α－オレフィン共重合体、ポリエチレン）、スチレン・ブタジエン系エラストマーを用いることが好ましい。

これらは、単独で用いても或いは他の重合体と混合したり、積層して用いても、また、各種の添加剤を添加して用いてもよい。

このような添加剤としては、顔料、老化防止剤、成形改良剤、安定剤、紫外線防止剤、酸化防止剤、摩耗改良剤等がある。

また、該熱可塑性重合体シートの厚みは、一般

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に０．２５～３㎜、好ましくは０．３～１．５㎜、特に０．３～１㎜であることが好ましい。

前記熱成形の具体的な成形法としては、真空成形や圧空成形を行なうことが好ましいが、ブロー成形やスラッシュモールド成形を行なうこともできる。

該熱成形の成形条件は熱成形の方法及び熱可塑性重合体の種類によって異る。

望ましい熱成形である真空成形や圧空成形の場合には、前記熱可塑性重合体シートを軟化させる必要があるので、該シートを構成する素材のビカット軟化点（ＪＩＳ－Ｋ７２０６）以上、融点以下の温度にまで加熱される。

前記熱成形によって矯正された歯列の形状を正確に転写した熱可塑性重合体シートをそのまま常温附近の温度にまで冷却して固化し、歯型石膏模型より取り外し、歯周部分を目安に切断して形状を整えることによる凹型の歯列矯正用マウスピースが得られる。この場合の切断は歯周より３㎜程度内側でも外側でも良いが歯周に直接当たらない

方がよい。

このようにして製作された凹型の歯列矯正用マウスピースは矯正する歯の部分だけが咬合し難くなっているが、該マウスピースは５０～８００程度のゴム弾性を有しており、それほど硬くないので患者の歯列に無理なく装着することができる。また、矯正する歯牙以外の部分は各々の歯牙への適合性が良いので、矯正する歯牙へ与える力を歯牙全体で分散して受け止めることができる。

また、該マウスピースはそれほど硬度が高くないので、歯列矯正用石膏模型を傷つけることが無く、同一形状の歯列矯正用マウスピースを複数個製作できるし、この矯正歯列石膏模型をベースにして更に切削、肉盛りして修正を加えて、次の段階の矯正を行なうこともでき、このような操作を複数回繰り返してより正常な歯列に矯正することができる。

〔実験例〕

本発明の歯列矯正用マウスピースについて、更に具体的に説明するため、以下に実施例および比

較例の実験例を示す。

実施例１

歯列石膏模型の製作

上前歯２本の矯正を行う歯列不正患者の印象を、アルジネート印象材（スターミックス、日本歯研工業㈱製）を用いて作成し、そこに硬質石膏（ダイヤストーン、三菱鉱業セメント㈱製）を流して歯型石膏模型を作成した。

歯列矯正用石膏模型の製作

前記歯列石膏模型の前歯を技工用バーで１㎜の厚さで切削すると共に、切削した個所の反対側を、エポキシ樹脂系接着剤（コニシボンド、コニシ株式会社製）にて１㎜の厚さで肉盛りして歯列矯正用石膏模型を製作した。

熱可塑性重合体シートの製作

エチレン・酢酸ビニル共重合体樹脂（三菱ポリエチ－ＥＶＡ「Ｖ５０１Ｈ」、三菱油化㈱製、曲げ弾性率４００㎏／㎠、ビカット軟化点５４℃、融点９１℃）の厚さ０．５㎜、縦１５㎝、横１５㎝のプレスシートを吸収精密圧接器（スターバッ

ク三金工業㈱製）上に載置し、該プレスシートが８５℃の温度になる迄昇温した時に、前記歯列矯正用石膏模型に密着させて転写を行った。

上記の如く転写して成形した転写成形体をドライヤーの冷風で５分間冷却して固化させた。この転写成形体は石膏模型より容易にとり外せた。

マスウピースの製作

この凹状部分２と凸状部分３とを形成した転写成形体を歯列矯正用石膏模型の歯周部位より２㎜上部に合わせてハサミで切削して第１図に示すような上顎の歯列と下顎の歯列に分離して装着することができる上顎の歯列の歯列矯正用マウスピース１ａと下顎の歯列の歯列矯正用マウスピース１ｂとからなる歯列矯正用マウスピース１を作成した。この歯列矯正用マウスピース１を上記の矯正を行なう歯列不正患者に凹状部分２を歯列に被せて試したところ、容易に装着出来かつ、前歯２本に歯列の表面を覆う部分４の矯正の力が加わっていた。

前記歯列不正患者にこの歯列矯正用マウスピー

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スを１ケ月間装着した後に取り外し、上記歯列矯正用石膏模型を更に１mm切削し、その反対側の部位を１mm肉盛して修正を行ない、第２段階の歯列矯正用石膏模型を製作した。

そして、この第２段階の歯列矯正用石膏模型をベースにして再度熱可塑性重合体シートを密着させて、第２段階の歯列矯正用マウスピースを製作した。

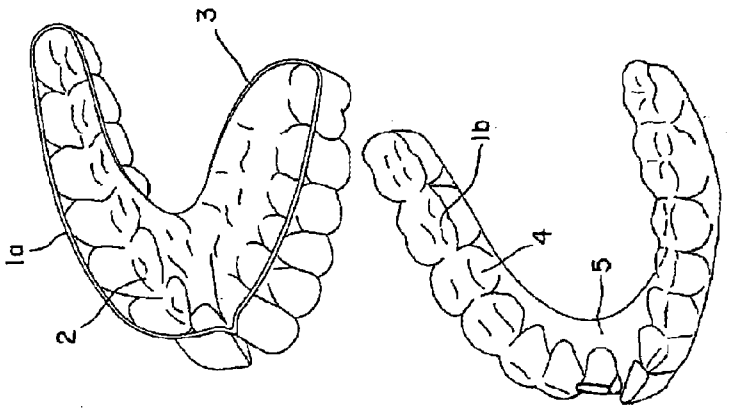
そして、この第２段階の歯列矯正用マウスピースを前記第１段階の歯列矯正を行なった歯列不正患者に装着したところ、装着が可能であった。これは前記第１段階の歯列矯正が十分に行なわれたことを示すもので、第２段階の歯列矯正に入ったことを意味するものである。

４．図面の簡単な説明

第１図は本発明実施例の歯列矯正用マウスピースの斜視図を表す。

１…歯列矯正用マウスピース、１ａ…上顎の歯列の歯列矯正用マウスピース、１ｂ…下顎の歯列の歯列矯正用マウスピース、２…凹状部分、３…凸状部分、４…歯列の表面を覆う部分、５…歯肉の表面を覆う部分。

出願人代理人　佐　藤　一　雄



第１図

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SHUSAKU YAMAMOTO

Appln. 11-504890
Align's Ref: AT-00003JP
Townsend's File No.: 018563-000120JP

(Translation)

Japanese Laid-Open Publication No. 4-28359

Laid-Open Publication Date: January 30, 1992
Japanese Application No. 2-134984
Filing Date: May 24, 1990
Inventors: T. SHIMADA, et al.
Applicant: Mitsubishi Yuka Kabushiki Kaisha

Specification

1. Title of the Invention
Method for producing an orthodontic mouthpiece

2. Claims

1. A method for producing an orthodontic mouthpiece, by which a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and then the softened thermoplastic polymer sheet is solidified and removed.

2. A method for producing an orthodontic mouthpiece according to claim 1, wherein the thermoplastic polymer has a flexure elasticity (ASTM-D747) of 800 kg/cm^2 or less.

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SHUSAKU YAMAMOTO

Appln. 11-504890
Align's Ref: AT-00003JP
Townsend's File No.: 018563-000120JP

3. Detailed Description of the Invention

[Background of the Invention]

<Field of the Invention>

The present invention relates to a method for producing an orthodontic mouthpiece for easily performing orthodontic treatment without damaging the teeth.

<Prior Art>

Conventionally, for orthodontic treatment, a method for attaching a tool for wiring normal teeth in order to apply a force to a tooth to be orthodontically-treated is generally used.

<Problems to be Solved by the Invention>

Such a method has problems in that the other normal teeth are likely to be damaged and the patient feels a pain in the wired teeth since a force is likely to be applied to a part of the teeth that are wired.

[Overview of the Invention]

<Summary>

The present inventors accumulated active studies in order to solve the above-described problems. As a result, the present inventors obtained the following knowledge and completed the present invention. By using a special mouthpiece which is completely different from that of conventional orthodontic methods, orthodontic treatment can be easily performed unlike conventional orthodontic

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methods. With the special mouthpiece, the force to be applied to the tooth to be orthodontically-treated can be held by all the teeth without damaging the other normal teeth, and the force can be especially applied only to the tooth to be orthodontically-treated.

According to the method for producing an orthodontic mouthpiece of the present invention, a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and the softened thermoplastic polymer sheet is solidified and removed.

<Effect>

The orthodontic mouthpiece produced by the method according to the present invention provides the following significant effects: the mouthpiece is formed of a soft material and thus is easily attached; the mouthpiece is applied to all the teeth and thus does not cause pain to a specific tooth; and in addition, the mouthpiece can be easily removed for washing the teeth and the palate.

[Specific Description of the Invention]

[I] Production of an orthodontic plaster cast

(1) Production process of a dentition model of a patient

According to a method for producing an orthodontic mouthpiece of the present invention, a concave dentition

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model is first produced from the palate of the patient for the orthodontic treatment using an impression material, and plaster is poured into the concave dentition model. Thus, an accurate convex dentition plaster cast of the patient is produced.

For producing the concave dentition model, any impression material generally used in dentistry is usable. For example, silicone impression materials, agar impression materials, and arginate impression materials are used. For the convex dentition plaster cast, it is preferable to use plaster, hard plaster or super-hard plaster.

(2) Production process of an orthodontic plaster cast

The convex dentition plaster cast of the patient produced by the above-mentioned method is used as a base and is modified into a final form or into an intermediate form to be further modified. Thus, an orthodontic plaster cast is produced.

The convex dentition plaster cast of the patient is modified to produce such an orthodontic plaster cast as follows: A portion to which a correcting force is not to be placed is bulged; and plaster is cut off from a portion on the opposite side, i.e., the portion to which a correcting force is to be placed.

For cutting, any tool which can cut plaster is usable. Generally, a bar or a hand piece used by dental technicians is used. For bulging, a composite resin, an

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epoxy resin or the like is used. For bulging, any material which has sufficient adhesive strength and tensile strength for withstanding the subsequent operations is usable.

[II] Production of an orthodontic mouthpiece

(1) Thermal molding of a thermoplastic polymer sheet

A thermoplastic polymer sheet which has been softened by heating is adhered to the orthodontic plaster cast produced by the above-described method, and more closely adhered thereto by thermal molding to accurately transfer the dentition of the orthodontic plaster cast.

The thermoplastic polymer used here needs to be superb in elastomer characteristics and in strength and also should be easily attachable.

In order to fulfill these conditions, the thermoplastic polymer used desirably has a flexure elasticity of 800 kg/cm^2 (ATSM D747) or less, preferably 50 to 500 kg/cm^2.

Materials fulfilling such conditions are: ethylene-based resins such as, for example, ethylene-vinyl acetate copolymer, ethylene acrylic acid ester copolymer, ethylene methacrylic acid ester copolymer, ethylene-α-olefin copolymer, and polyethylene; ethylene-propylene elastomer; ethylene-propylene-diene compound-based elastomer; styrene-butadiene-based elastomer (including materials with water added thereto); polyester

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elastomer; urethane elastomer, polybutadiene; and the like.

Among these materials, it is preferable to use ethylene-based resins (especially, ethylene-vinyl acetate copolymer, ethylene-α-olefin copolymer, polyethylene) or styrene-butadiene-based elastomer.

These materials may be used independently, or mixed or laminated with other polymers. Various additives may also be used.

Such additives include, for example, pigments, anti-aging agents, agents to enhance the molding, stabilizers, ultraviolet-preventive agents, anti-oxidants, and abrasion-preventive agents.

The thickness of the thermoplastic polymer sheet is generally 0.25 to 3 mm, preferably 0.3 to 1.5 mm, and especially preferably 0.3 to 1 mm.

Preferable specific thermal molding methods include vacuum molding and air pressure molding, but blow molding and slash molding may also be used.

The conditions for the thermal molding vary in accordance with the method of thermal molding and the type of thermoplastic polymer.

In the case where the preferable vacuum molding or air pressure molding is used, it is necessary to soften

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the thermoplastic polymer sheet. Therefore, the sheet is heated to a temperature which is higher than or equal to the vicat softening point (JIS-K7206) of the material forming the sheet and lower than or equal to the melting point of the material forming the sheet.

The thermoplastic polymer sheet having the orthodontically-treated dentition shape accurately transferred thereon by the above-described thermal molding is cooled to room temperature or to the vicinity thereof and solidified. The sheet is removed from the dentition plaster cast. The sheet is cut along the gum line and properly shaped. Thus, a concave orthodontic mouthpiece is obtained. The sheet may be cut along about 3 mm inner to or outer to the gum line, but it is preferable that the cutting line is not in direct contact with the gum line.

In the concave orthodontic mouthpiece produced in this way, only the teeth to be orthodontically-treated are difficult to fit. However, the mouthpiece has a rubber elasticity of about 50 to 800 and is not very hard, and therefore is easily attachable to the dentition of the patient. The portions other than the tooth to be orthodontically-treated are easily fit to the respective teeth. Thus, the force to be applied to the tooth to be orthodontically-treated can be dispersed and received by all the teeth.

The mouthpiece does not have a very high hardness, and thus does not damage the orthodontic plaster cast.

Therefore, a plurality of orthodontic mouthpieces of the same shape can be produced. It is also possible to perform the next orthodontic process, using such an orthodontic plaster cast as a base, by further modifying the cast with cutting and bulging. Such an operation can be repeated a plurality of times for straightening teeth into more normal dentition.

[Experimental examples]

The orthodontic mouthpiece according to the present invention will be more specifically described by way of experiments of examples and comparative examples.

Example 1

Production of a dentition plaster cast

An impression of a patient with malaligned dentition, whose two upper front teeth are to be orthodontically-treated, was produced using an alginate impression material (Starmix, produced by Nihon Shiken Corporation). Hard plaster (Diastone, produced by Mitsubishi Kogyo Cement Kabushiki Kaisha) was poured into the impression. Thus, a dentition plaster cast was produced.

Production of an orthodontic plaster cast

The upper front teeth of the dentition plaster cast were cut off by a thickness of 1 mm using a bar used by dental technicians, and a portion opposite to the portion which has been cut off was bulged by a thickness of 1 mm with an epoxy resin-based adhesive (Konishi Bond,

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produced by Konishi Co., Ltd.). Thus, an orthodontic plaster cast was produced.

Production of a thermoplastic polymer sheet

A pressed sheet having a thickness of 0.5 mm, a length of 15 cm and a width of 15 cm of an ethylene-vinyl acetate copolymer resin (Mitsubishi Polyethy-EVA "V501H", Mitsubishi Yuka Kabushiki Kaisha; flexure elasticity: 400 kg/cm^2, vicat softening point: 54°C, melting point: 91°C) was placed on an absorptive precision pressure-contact device (Starback, produced by Mitsugane Kogyo Kabushiki Kaisha). When the pressed sheet was heated to a temperature of 85°C, the pressed sheet was adhered to the orthodontic plaster cast for transference.

The transferred molded body obtained by the above-mentioned transference and molding was cooled for 5 minutes by cool air from a dryer and solidified. The transferred molded body was easily removed from the plaster cast.

Production of a mouthpiece

The transferred molded body having a concave portion 2 and a convex portion 3 was cut along a line 2 mm away from the gum line of the orthodontic plaster cast by scissors. Thus, as shown in Figure 1, an orthodontic mouthpiece 1 including an upper dentition orthodontic mouthpiece 1a and a lower dentition orthodontic mouthpiece 1b, which can be separately attached to the upper teeth and the lower teeth, was

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produced. The orthodontic mouthpiece 1 was tested for the above-mentioned patient with malaligned dentition for orthodontic treatment, such that the concave portion 2 covers the patient's dentition. The orthodontic mouthpiece 1 was easily attached, and the correcting force of a portion 4 covering the surface of the dentition was applied to the two front teeth.

After the patient with malaligned dentition wore the orthodontic mouthpiece for 1 month, the orthodontic mouthpiece was removed. The orthodontic plaster cast was modified by cutting it off by another 1 mm and bulging the opposite portion by 1 mm. Thus, a second stage orthodontic plaster cast was produced.

The second stage orthodontic plaster cast was used as a base, and another thermoplastic polymer sheet was adhered thereto. Thus, a second stage orthodontic mouthpiece was produced.

The second stage orthodontic mouthpiece was tested to the patient with malaligned dentition who had finished the first stage orthodontic treatment. The second stage orthodontic mouthpiece was attachable. This indicates that the first stage orthodontic treatment was fully performed, and that the patient was now in the second stage of orthodontic treatment.

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SHUSAKU YAMAMOTO

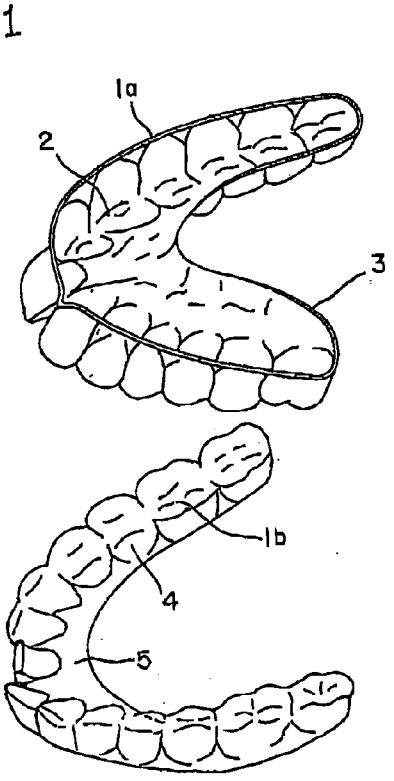
Appln. 11-504890
Align's Ref: AT-00003JP
Townsend's File No.: 018563-000120JP

4. Brief Description of the Drawings

Figure 1 represents a perspective view of an orthodontic mouthpiece according to an example of the present invention.

1 ... orthodontic mouthpiece; 1a ... upper dentition orthodontic mouthpiece; 1b ... lower dentition orthodontic mouthpiece; 2 ... concave portion; 3 ... convex portion; 4 ... portion covering the surface of the dentition; 5 ... portion covering the surface of gums.

Fig. 1



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METHOD OF PRODUCING DENTAL CORRECTION TREATING INSTRUMENT USING SILICON RESIN MATERIAL

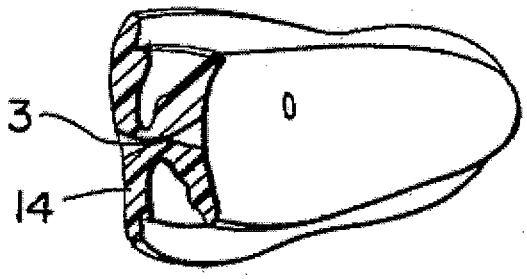
Patent number: JP53058191
Publication date: 1978-05-25
Inventor: YOSHII OSAMU
Applicant: YOSHII OSAMU;; MIURA FUJIO
Classification:
- international: A61C7/00
- european: A61C7/08; A61K6/093
Application number: JP19760132323 19761105
Priority number(s): JP19760132323 19761105

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US4505673 (A1)
US4504225 (A1)
GB1550777 (A)
FR2369828 (A1)
ES463897 (A)
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Abstract not available for JP53058191
Abstract of corresponding document: **US4504225**

Original models of plaster are obtained from impressions of the dentition of the upper and lower jaws of a patient with malocclusion. The teeth are then separated from the base of the models and reset in wax to a normal occlusion. The realigned teeth are fixed in place with wax, and impressions of the upper and lower models are taken to duplicate the rearranged models, forming working models made of plaster. The working models are mounted on an anatomic dental articulator and a wax occluding model is constructed of the new occlusion to cover both upper and lower arches. The working upper and lower models, together with the wax occluding model are buried in plaster in a split cast. The wax occluding model in the split cast is heated and the wax is melted and discharged out of the cast. Silicone resin is then placed into the impression of the occluding model and cured.



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⑲日本国特許庁　　⑪特許出願公開

公開特許公報　　昭53—58191

⑤1Int. Cl.²	識別記号	⑤2日本分類	庁内整理番号	⑷3公開　昭和53年(1978)5月25日
A 61 C 7/00		94 C 24	6335—39	

発明の数　2
審査請求　有

（全 6 頁）

⑤4シリコーン樹脂材を用いた歯科矯正治療器具の製作法

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⑵1特願　昭51—132323
⑵2出願　昭51(1976)11月5日
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明　細　書

1. 発明の名称

シリコーン樹脂材を用いた歯科矯正治療器具の製作法

2. 特許請求の範囲

1. 被不正咬合患者の上下顎の歯列を印象採得して石膏でオリジナル模型を製作し、次いでオリジナル模型上で個々の歯を1本づつ分割し、該分割歯を人為的に歯科矯正学上正しい位置に移動し、歯列全体を正常咬合に排列代えしてこれをワックスで固定し、この排列代えされた模型から再度上下顎の印象採得を行い石膏製の作業模型を上下顎別々に作成し、前記排列代えした模型から予め採取しておいたワックス製咬合型を上記作業模型に咬み合せ、この咬合型と作業模型との一塊になつたものを割型容器内の石膏中に埋没し、ついで容器内のワックス製咬合型を加熱して容器外へ溶融排出せしめ、この咬合型跡にシリコーン樹脂を注入又は充填したのち加熱することを特徴とするシリコーン樹脂材を用いた歯科矯正治療器具の製作法。

2. 被不正咬合患者の上下顎の歯列を印象採得して石膏でオリジナル模型を製作し、次いでオリジナル模型上で個々の歯を一本づつ分割し、該分割歯を人為的に歯科矯正学上正しい位置に移動し、歯列全体を正常咬合に排列代えしてこれをワックスで固定し、この排列代えされた模型から再度、上下顎の印象採得を行い石膏製の作業模型を上下顎別々に作成し、前記排列代えした模型から予め採得しておいたワックス製板体を上記作業模型に咬み合せ、この状態にて作業模型を石膏を用いて専用咬合器に固定し、ついで作業模型間に咬せてあるワックス製板体を温水にて溶融排出せしめ、この作業模型周辺にシリコーン樹脂を介在させてこれを作業模型に直接押付けて歯科矯正治療器具を末加硫シリコーン樹脂で成型し、ついでこれを加熱することを特徴とするシリ

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コーン樹脂材を用いた歯科矯正治療器具の製作法。

3. 発明の詳細な説明

従来から使用されている歯科矯正治療はアタッチメントを付着した金属バンドを歯に適合させセメントを用いて歯に固定し、これに金属線を通して歯を動かすものであつた。この場合矯正力（実際に歯を動かす応力）は主に金属線自身の弾力を利用したもので、一般には全帯環装置（マルチバンド）と呼び現在広く普及している矯正治療装置である。

しかしながらこの全帯環装置を用いる治療にあたつては一般に２０～２８歯に正確に金属バンドを歯に適合する技術や金属線を複雑に曲げるテクニック等が要求され、これには術者の長期に及ぶ教育並びに熟練と多大の労力を要し、また一方では患者に苦痛を与えるばかりでなく、２～３年という長期の矯正治療期間中には食片が付着してむし歯や歯周病等の疾患を併発することがしばしば認められ、かつ治療費も高くつ

(3)

くなどの欠点があつた。

本発明は金属線に代つてシリコーン樹脂の弾性を矯正力として利用することにより不正咬合を簡単に治療することができ、しかも取り外しが自由であるため患者に苦痛を与えず、夜間就寝時だけ使用すれば矯正治療が可能であるという矯正治療器具を簡単に製作することを目標に進められた。

まず口腔内という特殊かつ過酷な条件を充分にみたす弾性高分子材料の選出が行われ、その結果シリコーン樹脂（ケイ素樹脂）が理工学的及び臨床的立場より最良の効果をもたらす歯科矯正用弾性材料であることを実証した。即ち該材質は経時的に口腔内と同一の条件下で弾性が劣化せず、また破断応力も十分あり長期間変形しないというすぐれた理工学的性質があることが認められた。

その上シリコーン樹脂の硬化剤、触媒の種類並びに配合を変えることにより、成型樹脂の硬さが自由に変えられ、弱い力から強い力まで得

(4)

られるという臨床上の利点のほかに、無味無臭で高い透明度を維持し、生体に対する為害性もないと云う点は他のゴム材料にはない性質である。

なおシリコーン樹脂のほかポリウレタン樹脂も上記の諸性質を備えているが、シリコーン樹脂はポリウレタン樹脂と比較して硬化時間が短かく、かつ製作工程が簡単に行なえる利点があるので両者には著るしい差異が認められる。

本発明はこのようなシリコーン樹脂の特性を利用した矯正治療器具の製作法を提供するものである。

つぎに本発明について詳細に説明する。

第一の発明は被不正咬合患者の上下顎の歯列を印象採得して石膏でオリジナル模型を製作し、次いでオリジナル模型上で個々の歯を１本づつ分割し、該分割歯を人為的に歯科矯正学上正しい位置に移動し、歯列全体を正常咬合に排列代えしてこれをワックスで固定し、この排列代えされた模型から再度上下顎の印象採得を行い、

(5)

石膏製の作業模型を上下顎別々に作成し、前記排列代えした模型から予め採取しておいたワックス製咬合型を上記作業模型に咬み合せ、この咬合型と作業模型との一塊になつたものを割型容器内の石膏中に埋没し、ついで容器内のワックス製咬合型を加熱して容器外へ溶融排出せしめ、この咬合型跡にシリコーン樹脂を注入又は充填したのち加熱することを特徴とするシリコーン樹脂材を用いた歯科矯正治療器具の製作法であり、第二の発明は被不正咬合患者の上下顎の歯列を印象採得して石膏でオリジナル模型を製作し、次いでオリジナル模型上で個々の歯を一本づつ分割し、該分割歯を人為的に歯科矯正学上正しい位置に移動し、歯列全体を正常咬合に排列代えしてこれをワックスで固定し、この排列代えされた模型から再度、上下顎の印象採得を行い石膏製の作業模型を上下顎別々に作成し、前記排列代えした模型から予め採得しておいたワックス製板体を上記作業模型に咬み合せ、この状態にて作業模型を石膏を用いて専用咬合

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合器に固定し、ついで作業模型間に咬せてあるワックス製板体を温水にて溶融排出せしめ、この作業模型周辺にシリコーン樹脂を介在させてこれを作業模型に直接押付けて歯科矯正治療器具を末加硫シリコーン樹脂で成型し、ついでこれを加熱することを特徴とするシリコーン樹脂材を用いた歯科矯正治療器具の製作法である。

まず第一の発明は従来公知の印象材で上下顎の印象採得を行いオリジナル模型を作成する。この作成には、石膏を用いることが好ましく前記模型は咬合器などによつて正確に調節して行う。

つぎに被矯正歯列のオリジナル模型を咬合器に付着させ、その模型上で歯根方向から歯冠方向へ垂直に薄刃の鋸を用いて個々に歯を切断分割してこれを矯正学上正常な歯列に歯科用ワックスで固定しながら並べ代えた模型をつくり、これを再度印象採得して石膏製の作業模型を作成する。ここでワックスをまつたく用いない作業模型を作成する理由は、後に説明するように

(7)

咬合型跡（空洞部）は得ようとする矯正治療器具の正確な陰型となる。この咬合型跡にシリコーン樹脂を注入又は充填し、ついで割型容器を湯、熱風等で１００～１３０℃程度に加熱すると数分間でシリコーン樹脂が適度の弾性を保有しつつ重合（硬化）して定型体となる。

つぎに第二の発明では上記発明の割型容器の代わりに専用咬合器を用いるものであり、またワックス製咬合体の代わりにワックス製板体を用いる。

この作業模型を専用咬合器に取付固定したところで作業模型間のワックス製板体を温水にて溶融排出せしめ、作業模型上でこのワックス製板体位置に末加硫シリコーン樹脂を直接介在させてこれを押付けて歯科矯正器具を成型し加熱するものである。

第二の発明は第一のものと比較して精度はやや低下するが作業が容易となり短時間で歯科矯正器具を製作することができる特徴がある。

本発明によつて製作せられた矯正治療器具の

(9)

加熱してシリコーン樹脂を重合（硬化）させる場合、ワックスが融けて作業模型の形状が変形することを防止するためである。

なお正常な歯列となつた前記排列代えした模型からワックスにて上下顎の咬合型を正確に採取しておき、この咬合型を作業模型に咬み合せて係止する。

ついで第一の発明ではこの咬合型と作業模型の結合体を歯科用の割型容器に位置せしめ、石膏中に埋没せしめ型採りを行う。ここで割型容器を用いるのは、後にこの容器中にシリコーン樹脂を注入又は充填して得られる矯正治療器具の後処理，即ち治療器具の成型にともなうトリミングを省略するためである。

つぎにこの割型容器を加熱すると咬合型はワックス製であるため溶融し、これを容器外へ排出せしめることができ、一方作業模型は石膏製であるから割型容器内の石膏と一体となつて正確な位置を保持する。

したがつて割型容器内の石膏中に形成される

(8)

表面に注入型シリコーン樹脂液等を塗布すると、表面が平滑面となつて透明度の高い矯正治療器具が得られる。この樹脂を透明体とすることは患者の口腔内に装着した場合に、その効果つまり矯正経過が随時透視できる特徴があり、このことは術者にとつて正確な歯の移動を把握するために必要不可欠の条件である。

第一図は矯正すべき患者の不正咬合を印象採得し石膏を用いて製作したオリジナル模型の平面図で１は石膏で作られた歯を示す。

第二図はオリジナル模型より歯を分割した状態の個々の歯の正面図，第３図は正常歯列に排列代えした状態の平面図で２はこれらの歯の固定に用いたワックスを示す。第４図はシリコーン樹脂８を素材として完成した歯科矯正治療器具の平面図，第５図は同正面図で３は呼吸用通気孔，点線の歯は正常咬合に再排列した歯の凹型であり、この部分に被矯正患者の不正位置にある歯が挿入され、シリコーン樹脂が変形を起すとそこに樹脂の復元力が生じ不正咬合の歯を

(10)

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移動するための矯正力が生れる。

第6図は前図のA—A断面図、第7図は第4図のB—B断端面図で4は上顎の印歯を挿入する凹型、5は同じく下顎の印歯の凹型、第8図は矯正前後の比較図でイは矯正治療前、ロは矯正治療後を示し、6は上顎前歯、7は下顎前歯である。イ図は矯正治療前であるため上顎前歯唇側面及び下顎前歯舌側面に空隙が認められ、ロ図は治療後で樹脂の復元力から生じた矯正力で歯が移動したため空隙が認められない。

第9図は第一発明の実施例を示したものでイは割型容器9を分離した状態の断端面図、ロは割型容器の半部にシリコーン樹脂8を充填又は注入した状態の断端面図、ハは分離した割型容器を接合した状態の断端面図で10は割型容器の連結具を示す。

第10図は第二発明の実施例を示したものでイは専用咬合器11の平面図、ロは同側面図でワックス製板体を溶融排出せしめた状態、この状態位置で末加硫シリコーン樹脂を圧接し歯科

(11)

矯正器具を成型する。ハは末加硫シリコーン樹脂で作成した歯科矯正器具の側面図であり、このままこれを温水または熱風で硬化させると完成品になる。ニはイのC—C線断面図である。なお図中12は作業模型、14は歯科矯正治療器具である。

本発明で得られる歯科矯正治療器具は患者の歯型を基礎にして正常歯列模型を製作し、これを装着することによつて次第に矯正していくから歯及び歯周組織に無理を与えることなく矯正力が働き矯正治療が可能となる。

なおこの材質で成型した矯正治療器具は永久変形をせず経時的応力緩和がなく、硬さも自由に変えられ無味無臭で透明体で形成せられるので、矯正治療にすぐれた効果があるばかりでなく患者に取つては大変使い易いといつた利点が大きい。

特に本発明はポリウレタン樹脂を素材とする場合に比較して、樹脂を重合(硬化)させる時間がポリウレタンの場合は約10時間であるの

(12)

に対しシリコーンの場合は約20分という短時間であるから製作時間が極めて短縮でき、またポリウレタン樹脂で製作する場合、石膏中の水と反応して炭酸ガスを多量に発泡するために特殊な樹脂を用いて作業模型を製作しなければならず、その樹脂の熱硬化による収縮が大きな変形となつてあらわれる欠点があつたがシリコーン樹脂の場合は作業模型に石膏を使用出来るから変形も皆無であり、完成した矯正治療器具は精度の良いものとなる。

さらにポリウレタン樹脂を用いる場合は原液取扱いに危険が伴い、かつ脱泡攪拌工程が必要となり、この脱泡攪拌工程には真空ポンプが必要となり、またポリウレタンの発泡を防止するために高圧コンプレッサー並びに圧力釜を用いなければならず、更に成型には大型グラインダーも必要となる等、作業工程の煩雑さ及び特殊な機械を揃えなければならない不便があつたが、本発明はシリコーン樹脂を用いるため極めて安全であり、脱泡攪拌工程や研磨仕上げが不要と

(13)

となる等のすぐれた効果がある。

4. 図面の簡単な説明

第1図はオリジナル模型平面図、第2図は各歯の分割正面図、第3図はオリジナル模型を正常歯列に排列代えした模型の平面図、第4図は完成した矯正治療器具の平面図、第5図は同正面図、第6図は前図のA—A断面図、第7図は第4図におけるB—B断端面図、第8図は矯正前後の比較図でイは前、ロは後であり、第9図は第一発明の実施例でイは割型容器9を分離した状態の断端面図、ロは割型容器の中にシリコーン樹脂を充填した状態の断端面図、ハは分離した割型容器を接合した状態の断端面図、第10図は第二発明の実施例でイは専用咬合器の平面図、ロは上下顎石膏模型を固定するために必要なワックス板体を溶融排出せしめた状態の側面図、ハは作業模型の表面に末加硫シリコーン樹脂を圧接して歯科矯正治療器具を作成している状態の側面図、ニはハのC—C線断面図である。

1・・オリジナル模型　2・・ワックス

(14)

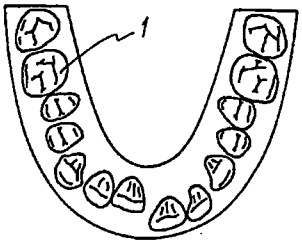
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3・・呼吸用通気孔　4、5・・凹型　6・・上顎前歯　7・・下顎前歯　8・・シリコーン樹脂　9・・割型容器　11・・専用咬合器　12・・作業模型　14・・歯科矯正治療器具

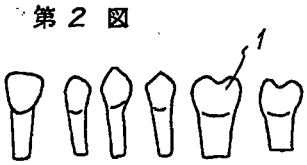
特許出願人　吉井　修
同　三浦不二夫
代理人　弁理士　寺田　止
同　松浦憲治

(15)

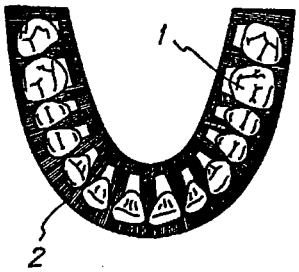
第1図



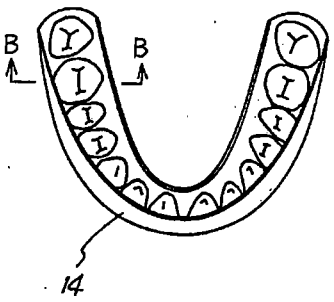
第2図



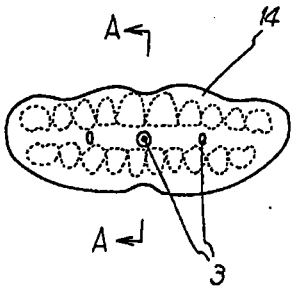
第3図



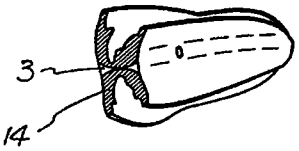
第4図



第5図



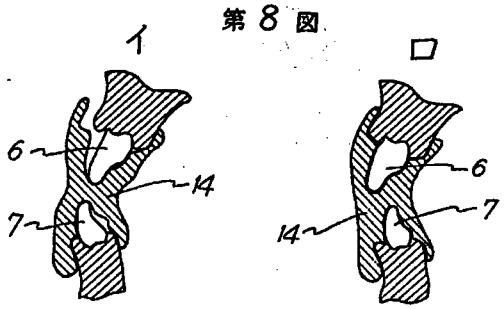
第6図



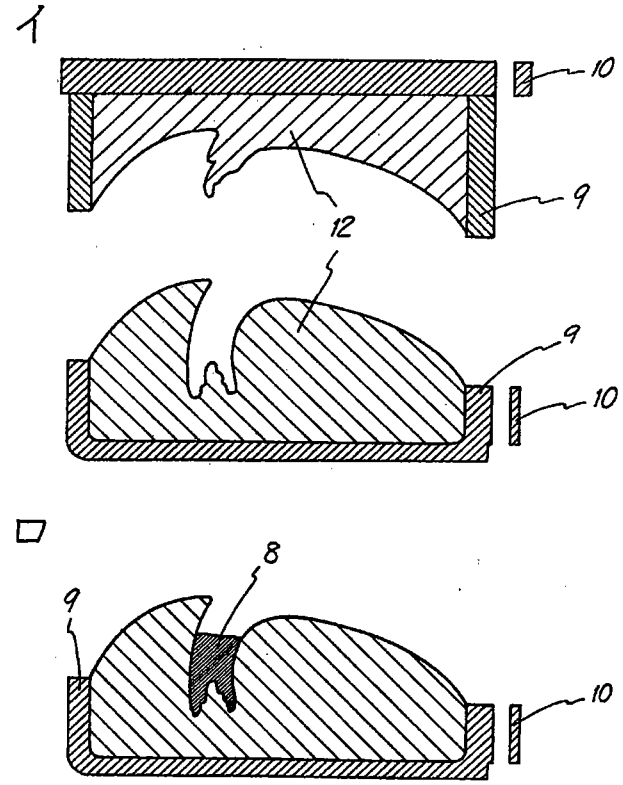
第7図



第8図

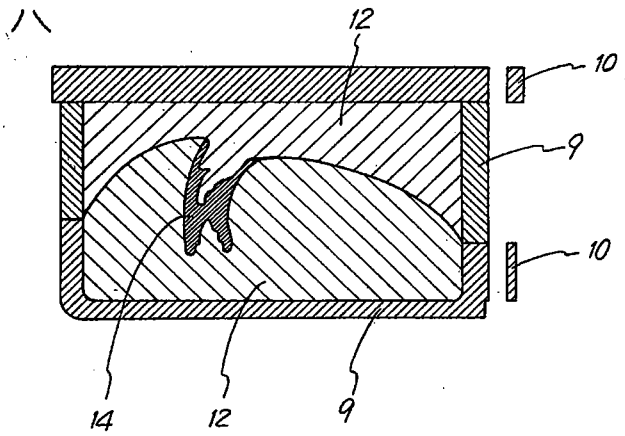


第9図

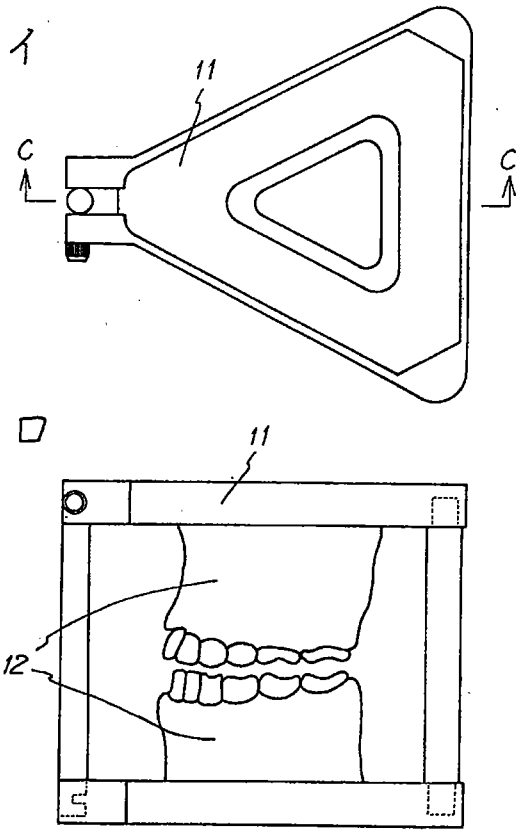


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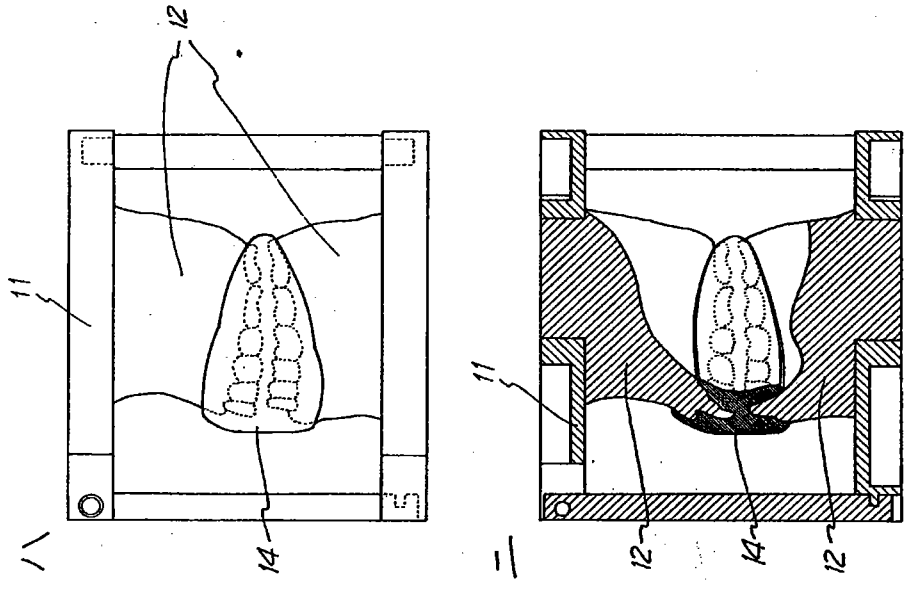
第9図



第10図



第10図



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Orthodontic treating device and method of manufacturing same

Patent Number: US4504225
Publication date: 1985-03-12
Inventor(s): YOSHII OSAMU [JP]
Applicant(s): YOSHII OSAMU [JP]
Requested Patent: AU3031677
Application Number: US19830531558 19830913
Priority Number(s): JP19760132323 19761105
IPC Classification: A61C7/00
EC Classification: A61C7/08, A61K6/093
Equivalents: AU517102, CA1121955, DE2749802, ES463897, FR2369828, GB1550777, JP53058191, US4505673

Abstract

Original models of plaster are obtained from impressions of the dentition of the upper and lower jaws of a patient with malocclusion. The teeth are then separated from the base of the models and reset in wax to a normal occlusion. The realigned teeth are fixed in place with wax, and impressions of the upper and lower models are taken to duplicate the rearranged models, forming working models made of plaster. The working models are mounted on an anatomic dental articulator and a wax occluding model is constructed of the new occlusion to cover both upper and lower arches. The working upper and lower models, together with the wax occluding model are buried in plaster in a split cast. The wax occluding model in the split cast is heated and the wax is melted and discharged out of the cast. Silicone resin is then placed into the impression of the occluding model and cured.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61C 13/00 | A1

(11) International Publication Number: WO 98/44865

(43) International Publication Date: 15 October 1998 (15.10.98)

(21) International Application Number: PCT/SE98/00493

(22) International Filing Date: 19 March 1998 (19.03.98)

(30) Priority Data:
9701309-8 10 April 1997 (10.04.97) SE

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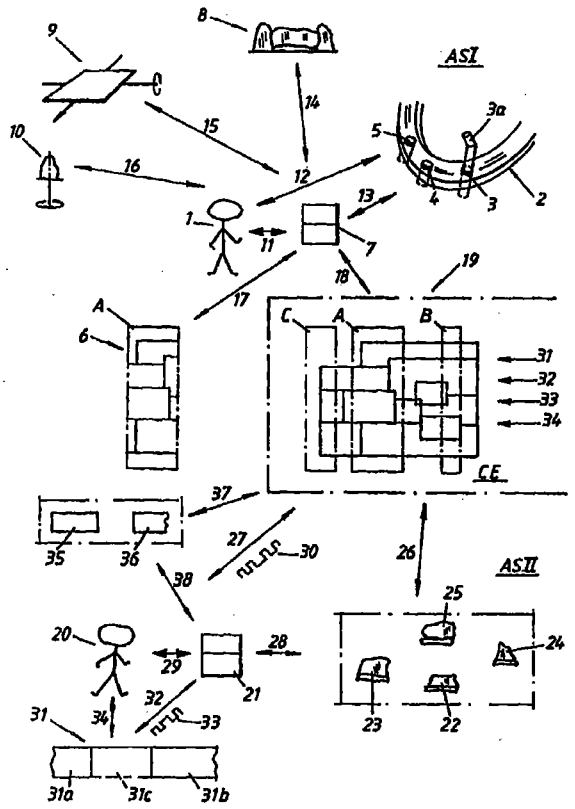
(81) Designated States: AU, CA, JP, NO, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
In English translation (filed in Swedish).

(54) Title: ARRANGEMENT AND SYSTEM FOR PRODUCTION OF DENTAL PRODUCTS AND TRANSMISSION OF INFORMATION

(57) Abstract

An operating site is used to assemble individually designed dental products, for example distancing pieces, bridges, etc. Each product consists of two or more structural elements. The operating site is provided with computer equipment which can reproduce a simulated model of the jaw, dentine, implant, etc., and structural elements applied to the model. The operating site is arranged to collate data in a query profile relating to part of the assembly. Members are included for transmitting query profile data via the network to the central unit. The central unit supplies information relating to the part in question. The information is sent to the operating site or to a production unit connected to the central unit for production of the part. A debiting system is arranged to indicate to the central unit or to the production site that the information or production, respectively, has been paid for.



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EE	Estonia	**LR**	Liberia	**SG**	Singapore		

TITLE

Arrangement and system for production of dental products and transmission of information.

TECHNICAL FIELD

The present invention relates to an arrangement which makes it possible, at an operating site, to assemble individually designed dental products, for example distancing pieces, bridges, etc. Each dental product can in this case be made up from two or more structural elements. Each operating site is arranged with computer equipment with which it is possible to reproduce a simulated model of the jaw, dentine, implant, etc., and structural elements applied to the model. By means of interaction with the user, it is possible to adapt the constructional design of the respective assembled product to the dental situation in question. The operating site can be connected to one or more central units via a telecommunications and/or computer network, via which the central unit receives data from the operating site.

The arrangement can also be set up to permit manufacture of dental products, or instruments for the latter, at a number of geographically distinct manufacturing sites, where the manufacturing procedure can be effected in a number of manufacturing stages.

The arrangement can also be set up so that, at one or more manufacturing sites, it is possible to control a manufacturing procedure for a dental product, or instrument for the latter, where the procedure comprises one or more subsidiary stages.

The arrangement can also be set up to assemble qualified constellations at a dental user site, for example with regard to dental situations, dental information, dental test products, etc. The user site has access to its own results or one or more presentation banks which can be subject to factual information relating to, for example, verifications,

adjustments, complementary additions, etc. The user site can in this case be connected to one or more central units via a telecommunications and/or computer network, via which the user site and the central unit are capable of exchanging information/ data.

The invention is also applicable to a system for supplying dental products and preferably dental information relating to the products and dental situations and, if appropriate, also for making instruments for production of the product. A number of users using the system and constituting user sites can be connected to one or more central units, included in the system, via a telecommunications and/or computer network. The respective user site can in this case be provided with computer equipment by means of which query profiles can be collated.

STATE OF THE ART

It is already known to use mechanical, computer-aided methods for production of dental products such as caps, bridges, etc. Plaster models and the jaw, tooth remains, etc. of the patient can be scanned with the aid of various methods by the dental technician/dentist. The scanned information can be compressed and fed to the computer equipment, in which the model or equivalent can be simulated and, in the computer environment, can undergo constructional and add-on functions in order to obtain an optimum tooth replacement or equivalent for the patient in question. The result obtained can constitute the basis for ordering the actual dental product from a centralized manufacturing site. An order can be sent in a known manner to the manufacturing site or production site in question, which manufactures the desired dental product and sends this back to the orderer, who can then continue his work preparing and fitting the dental product on the patient.

In this connection, it is known to prepare not only tooth caps in this way, but also pontics, titanium crowns and bridge parts.

The users or the customers on the system thus provide for the system a work station which includes a standard PC with modem (or ISDN connection). The work station can be fitted out in various ways. Thus, for example, it can be equipped with a scanner device of the Procera type with associated user program.

DESCRIPTION OF THE INVENTION

TECHNICAL PROBLEM

The manufacturing process entails, overall, a very complex technique which it is not possible for each user/customer to perform. There is, however, a need for each user or customer to be able, to a greater extent than has hitherto been possible, to be able to gain access in a technically simple manner to all or parts of the complete process structure or process technique in order to obtain support, at the user site or customer site, for his own constructional and testing work on the respective patient. It is essential in this respect that use of the system is possible in a technically simple manner which has been well proven in the sector. The main object of the invention is to solve these problems.

There is also a need for the user to be able to subscribe to certain functions (structures) in the dental complex manufacturing process, which is being constantly updated and refined. Thus, for example, constant developments are being made on the software side, with the systems user (dentist/dental technician) wishing to make use of these developments in their daily application, without too much work on updating requirements. The dentist/dental technician may require new reading and data compression systems and new hardware for these. By means of the invention, it is possible, in a simple manner, to have updating provided

and installed in the customer equipment in a more or less automatic way.

Different users may be specialists in different dental products and dental situations, cf. titanium and ceramic crowns and bridges, and they may wish to consult the complex system only within their specialist area. The invention solves this problem too.

Users who need to use the complex system only now and then can also obtain help in a simple manner in the form of basic information. Thus, for example, it may be useful for a user/customer to find out about existing and well-proven constructions in specific dental situations. His/her work is made easier with a main-type solution to the specific dental situation. This is achieved, inter alia, by means of the fact that the system can give statistics and examples of use in different situations on which the user/customer/patient can base his solution.

Colleges and other educational institutions can also use the system as an information source for different dental situations and dental presentations.

It is also expedient, when using distancing pieces on or for implants, for these to be designed individually. The individual preparation can be based on information from the system, and the ordering and manufacture of the individually designed distancing pieces can be done with the aid of the system.

For the system provider, it is important to have a secure and reliable debiting system which executes debits for function uses and function means from the system and dental products or parts thereof manufactured in the system and instruments for the said products or parts. The invention solves this problem too.

There is a need to be able to expand the available equipment at the respective user site or customer site, and it is therefore desirable, for example, to be able to introduce and use a free-standing CADD program. As new software and hardware is

developed, this too will be able to be connected to the work station, which in this way will be able to use the system to an even greater extent. There is therefore a need to be able to create a general IT-based dental platform (IT = information technology). In this way the customer can work with a Procerar station and send his work to a production unit via a network. The production unit then manufactures the component concerned and sends this to the customer. It will be possible to deal with all the administration in the given network. The invention solves this problem too.

The system will be able to be set up for a large number of work stations (customers). Thus, for example, the system will be able to be set up for several hundred work stations which will be able to be connected in stages without disrupting the rate of production of dental products and the delivery of information. Software used in the system will be able to be updated with minimal disruption to the production of dental products and delivery of information. This places special requirements on the coordination within the system. It additionally places requirements on the program constructions and how the programs are installed in the system. The invention is intended to solve these problems too.

There is therefore a requirement to be able to use routines for product modifications, which modification routines will be able to be used both for software and hardware. It is therefore expedient to be able to create a platform for comprehensive dental rehabilitation systems while at the same time being able to maintain the rate of development within the system. It is expedient in this case to be able to create a number of rules which mean that the routines in connection with the system are actually used. The invention also solves this set of problems.

SOLUTION

The feature which can principally be regarded as characterizing an arrangement used at an operating site to assemble individually designed dental products is that the operating site is arranged to collate data in a query profile relating to part of the assembly. The operating site is provided with members for transmitting query profile data via the network to the central unit. The latter is arranged, as a function of the received query profile data, to supply information relating to the part in question. This information can be sent to the operating site and/or can be set onwards to a production unit connected to the central unit, or included in the central unit, for production of the part. A further feature is that a debiting system is arranged to indicate to the central unit or to the production site that the information or production, respectively, has been paid for.

The query profile data can relate to queries on first information concerning the dental situation, which can relate to optimum design and fitting of the part concerned in the dental product in question. In one illustrative embodiment, the dental product can consist of a distancing arrangement on an implant. The distancing arrangement comprises an angled distancing part or other part which has on or more individual parameters, e.g. shape, position of rotation about the longitudinal axis of the implant, etc. The angled distancing part or the said other part is dependent on the individuality of the dental situation. In a further embodiment, the query profile data and the first information afford the possibility of interaction between the operating site's computer equipment, its user, and the central unit for production of one or more structures adapted to the respective dental situation. In a preferred embodiment, a number of operating sites or customer sites are connected to the central unit and its production unit or production units. The operating sites are in this case categorized

and each category subscribes to a relevant service which effects first information and/or product parts from the total range or offered range of the central unit and/or the production unit or production units. The first information can in this case relate to one or more computer program information items or computer programs for carrying out the said assembly. The query profile data of the respective operating site and the information sent from the central unit/respective production unit can preferably relate to user data and setting data for the scanner unit, measuring table, etc.

An arrangement used at a dental user site to assemble qualified constellations can principally be regarded as being characterized by the fact that the user site/customer site is arranged to collate data in a query profile relating to all or part of the constellation. The user site is in this case provided with members for transmitting query profile data via the network to the central unit. The central unit is arranged, as a function of the query profile data received, to supply factual information relating to the constellation or the constellations, which information can be sent back to the user site for acting on the said results or presentation bank/presentation banks. A further characteristic is that a debiting system is arranged to indicate to the central unit that the factual information sent out has been paid for.

In one embodiment, the factual information sent out consists of second information on manufacturing process(es) and/or statistics relating, for example, to the construction of different main types of dental products. In one embodiment, the central unit can also function as, or be connected to, one or more production units for production of dental products. The central unit and/or the respective production unit is arranged to utilize and store characteristic data on the dental products, data on the respective dental situation in which the respective dental product is being used, etc.

In a preferred embodiment, characteristic data thus utilized and stored and dental situations can be interrogated by means of the said query profiles from one or more user sites connected to the central unit and/or the respective production unit.

The respective query profile data and returned information concern characteristics or construction information on different types of dental crown configurations which have been the object of production in association with manufacture/production controlled or managed by the central unit. The said types form main types which can each be supplemented by one or more variants.

An arrangement to permit manufacture of dental products, or instruments for the latter, at a number of geographically distinct manufacturing sites where the manufacturing procedure is effected in a number of manufacturing stages, is principally characterized in that a central unit supplies moduled information items and means for carrying out the stages, in which the different modules can be assigned to the different manufacturing stages or parts thereof. The different manufacturing stages are capable of interrogating and/or are assigned in advance one or more of the said moduled information items and means in order to be able to carry out all or part of the manufacturing process by means of the called-up information items and means. Transmission members are arranged, as a function of the requested order for called-up information and means, to effect transmission of these on a computer and/or communications medium which connects the respective manufacturing site to the central unit. In this case too, a debiting system is arranged to credit the central unit with payment for used time, information and/or means.

In a preferred embodiment, the customers are categorized in such a way that a first category of customer can be assigned first information and means, a second category of customer can be assigned second

information and means, etc. The said information and means can comprise control information for operating equipment for one or more of the said manufacturing stages at the manufacturing site.

An arrangement used at one or more manufacturing sites to control a manufacturing procedure for a dental product, or instrument for this, where the manufacturing procedure comprises one or more subsidiary stages, can principally be regarded as being characterized by the fact that the control information for equipment effecting one or more manufacturing procedures or subsidiary stages thereof can be extracted by a selection procedure from an information and/or data bank located in a unit geographically separated from the respective manufacturing site. Extraction is in this case carried out by means of the selection made at the respective manufacturing site, and the selection made can be transferred via a computer and/or telecommunications medium to effect selection in the information and/or data bank at the central unit. As a function of the selection, the central unit transmits the selected information and/or means. At the manufacturing site, the selected information received is arranged to be included in or be converted to control information for the equipment in question. Here, once again, use is made of debiting equipment which credits the central unit with payment for used time, information and/or means.

A system in accordance with the above can be regarded as being characterized by the fact that the said central unit(s) comprise(s) one or more coordinating units which, via a first telecommunications and/or computer network or a second local telecommunications and/or computer network, is/are connected to one or more production units. The respective coordinating unit is in this case arranged to effect or participate in the assignment of the information flows coming from the user sites/customer sites via the first telecommunications and/or computer

network (query profile data). The respective production unit functions as order receiver for the respective dental product which the respective user site wishes to have produced.

In a preferred embodiment, the respective user site is equipped with functions for reading off the model or jaw, dentine, etc., of the patient. The reading result can be fed to the user site's computer equipment, and a query profile (systems user profile) effected by this means includes one or more tasks. The respective coordinating unit preferably functions as a connection station to a network (telecommunications and/or computer network) belonging to the system. Two or more coordinating units distribute the incoming query profile flow (systems user flow) and the flow of information coming from the coordinating units, which information, for example, will be controlled for access to different databases. The system capacity can be expanded by means of connection of further coordinating units and/or inclusion of more powerful computers in existing coordinating units and/or connection of several ISDN modems.

Further characteristics of the system will be evident from the subsequent system subclaims.

ADVANTAGES

The features proposed above provide a system and a user relationship characterized by economic application of the system from the viewpoint of the user sites/customers. Use is based on technology which is known per se, and which further affords simplified use procedures for the users, while maintaining economic advantages. The users, i.e. dentists/dental technicians, can make use of the advantages obtained through high manufacturing operations, involving substantial economic and technical outlay. By means of the fact that subsidiary functions, statistics, etc., are offered for sale in the large system, the developments in this system can benefit the users

against payment for only the desired use. Very considerable experience of manufactured products, product designs, etc., can be built into and stored in the system. The stored information can be used as basic information for the users and for statistical application in association with colleges and other institutions. In addition to offering accurate and exact products, the system provider can receive payment for continued development and research. The very substantial development of the databases in the coordinating units means that it is possible to follow everything that is going on in the system. Production can be constantly modified and administrative functions can be applied in the databases in order to facilitate the development work. Despite the information content being transferred in the proposed manner to the user sites/customers, the required accuracy of the products can be maintained. The required accuracy nowadays is about 2/100ths tolerance.

DESCRIPTION OF THE FIGURES

A presently proposed embodiment of an arrangement and a system according to the invention will be described hereinbelow with reference to the attached drawings, in which:

Figure 1 is an outline diagram showing the connection of two user sites/customers to a central unit, where the two users or customers represent different categories for use of different functions in the complex system at the central unit,

Figure 2 is an outline diagram showing the connection of the user site/customers to production units via a network of the Procera type,

Figure 3 shows, in a block diagram, the structure of a user site,

Figure 4 shows, in a block diagram, the structure of a coordinating unit in the network according to Fig. 2,

Figure 5 shows the flow of information, of query profile data from the user site, being received in a coordinating unit, and

Figure 6 shows databases in the production units and coordinating units connected to the databases and EQL database applications.

DETAILED EMBODIMENT

In Figure 1, a first user is indicated by 1. The user works, inter alia, with a model 2, in which implants 3, 4, 5 are arranged. In or on the implant 3 there is an angled distancing piece 3a which is individually designed for the patient/dental situation in question. The user 1 has a production resource 6. A user site for the user 1 is indicated by ASI. The user 1/user site ASI has access to computer equipment 7. The user 1 can also work with a dental product in the form of a dental bridge 8. In addition to the product resource 6 and other equipment, the user/user site can have access to levelling table 9 for production of the dental product, reading equipment 10, etc.

The manufacturing method for producing dental products in accordance with the above with the aid of the said equipment is already well known and will not be described here. However, the possibility of interaction between the user 1 and the computer equipment 7 is indicated symbolically by arrows 11. Interaction between user 1 and model 2 is indicated by arrows 12. The simulation and production of the model 2 in the computer equipment 7 is shown by arrows 13. The use and supply of information between the bridge part 8, levelling table 9 and scanning equipment 10 and the user 1 and computer equipment 7 are symbolized by arrows 14, 15 and 16. Relations and interaction between the computer equipment and the production resource 6 are symbolized by 17. A manufacturing and information supply site is indicated by CE, and transmission via a telecommunications and/or computer system between the user site ASI and the site CE is indicated by arrows

18. The site CE can be regarded as central equipment in relation to the user site.

In accordance with the invention, the user 1/user site ASI subscribes to or purchases information or orders products from the system 19 in the central unit CE. The system 19 is technically complex and includes manufacturing processes for production of titanium crowns, ceramic crowns, caps, bridges, statistics, programs, etc. The various functions, machinery, information, etc., can be categorized, and Figure 1 shows the categories A, B and C. In the present case, the user 1 has purchased or subscribed to information relating to category A, which information is used by the user 1 to assist in his work and make it more efficient. This work can involve producing an angled distancing piece 3a, in which work his purchased or subscribed information, data, programs, etc., can be used to produce an actual dental assembly 3 + 3a with the computer equipment 7. In accordance with the invention, he can obtain help in producing a dental bridge 8. He can also obtain control information on his levelling table 9 and/or information on reading of an actual product. In accordance with the concept of the invention, it is also possible, as a function of his constructional and test work, to make a product with the aid of the information obtained from the system 19, and the computer equipment 7, and to order the latter in the central unit CE.

Figure 1 also shows a second user site ASII with user 20. This user has, in corresponding manner, computer equipment 21. The user 20 may be interested in another type of information than that in the case of the user 1 described above. Examples of such information are statistics from different main types of dental crowns 22, 23, 24, 25. These statistics can be used as a basis for starting up dental fitting work in or on a patient. The statistics can also be used in different combinations and assessment situations. The acquisition of the statistics from the system 19 is

symbolized by arrows 26. The user 20 uses his computer equipment 21 to send a query profile via a connection (telecommunications and/or computer connection) which is symbolized by arrows 27. The input of statistics for the dental crowns in the computer equipment is symbolized by arrows 28. The interaction between the computer equipment and the user 20 is symbolized by arrows 29. The actual query profile which is generated by the user 20 with the aid of the computer equipment 21 is sent to the central unit CE in digital form, and such a query profile is symbolized by 30. The query profile triggers selection information 31, 32, 33 and/or 34 in the central unit CE. By means of the selection information, the information on the dental crowns 22, 23, 24 and 25 can be transmitted via an actual connection 26 or 27. The user 20 can, with the aid of the information in or from the system 19 in the central unit CE, build up an actual constellation 31 which can consist of previously known parts 31a and 31b, which the user 20 needs to supplement with factual information 31c from the system. The factual information can be transmitted from the computer equipment 21 via a connection which is symbolized by arrows 32. Alternatively, the factual information can be stored up and used in the computer equipment 21. Factual information is also transmitted in digital form and is symbolized by 33. The constellation construction which is carried out by the user 20 is symbolized by arrows 34. The user can also request program information 35, 36 from the system 19. Such program information, and its relation to the system, are symbolized by arrows 37. The transfer of the program to the computer equipment 21 is symbolized by arrows 38.

Figure 2 shows that the central unit CE can comprise different units, for example production units CE1, CE2 and CE3, and a network CE4 with associated coordinating units, which are described hereinbelow.

Figure 3 shows an example of the construction of a user site/customer ASI''. In accordance with the

above, the user site can include a process scanner/reader 39 of known type, for example a Procera scanner station. The scanner station can produce a query profile which is symbolized by 40. The query profile is generated with the aid of a CADD program known per se, for example the Procera CADE program. The program handles filling-in and ordering functions in a manner known per se. The user site ASI'' also includes a modem which can be of a type known per se. Thus, for example, a modem 40 of the ISDN type can be used. The modem connects the work station, or renders it connectable, to a connection symbolized by 42 in a computer network. The network part CE4 (cf. Figure 2) comprises a number of coordinating units. Figure 3 shows three coordinating units 43, 44, 45. The coordinating units form a common network with the production units CE1', CE2', CE3' (cf. Figure 2). The network connection is symbolized by 46. The information flow, when ordering a dental cap for example, can be described by the following work stages. Reading off the plaster model, filling-in of dental data, patient, tooth, ID type, type of work, etc., processing of data file in Procera CAD, filling-in of order form and dispatching of the order. The order is implemented by the equipment being coupled up to one of the Procera coordinating units. Here, the order is received, confirmed and sent onwards to one of the production units. The different customers (cf. the users 1 and 20 in Figure 1) can couple up to one of the said coordinating units and send their order on. The coordinating units provide the possibility of access to different databases, for example product registers or other product information, cf. below. There is also the possibility of providing ongoing information on the present order and previous orders.

Figure 4 shows a coordinating unit which in principle functions as a connection station to the Procera network. The purpose of several coordinating units is, on the one hand, to be able to distribute the

incoming information flow in the form of the said orders, and, on the other hand, to distribute the outgoing information flow, which can consist, for example, of access to different databases. As the flow of information increases, with new customers and services being added, the system capacity can be increased either by connection of several coordinating units or by equipping the respective coordinating unit with more powerful computers and more modem/ISDN connections. The coordinating unit is constructed as a local network. If several coordinating units are coupled together, these can be made to act as a common network. The local network 47 is an LAN (Local Area Network). In Figure 4, a transport server is shown by 48, and an ISDN connection arranged on the latter is shown by 49. Further servers are shown by 50, 51, 52 and 53. The server 52 is connected via ISDN connections 54 and 55 and modems 56, 57, 58 and 59. The server 53 is used as file server. The server 51 is coupled up as database motor. The server 52 constitutes an RLN server (Remote Lan Node). The latter server represents the respective client and forms the input and output channel of the coordinating unit.

Figure 5 shows the data flow in a production unit. Each event in the production unit is registered in different databases. The information in the databases is sent onwards to the coordinating unit or the coordinating units. The incoming order flow is shown by 60. The incoming connection is 61. Incoming orders are registered in block 62. 63 symbolizes a library for registration of incoming orders. Orders are registered in 64, and 65 indicates a data library. File preparations are made in 66, and 67 indicates a preparation library. 68 treats data on the milling process, and 69 indicates the flow registration. 70 symbolizes database applications, where a first application 71 indicates incoming data, a second application 72 indicates financial data, a third application 73 indicates data files, a fourth

application 74 indicates file preparations, a fifth application indicates production administration data, a sixth application 76 indicates milling or machining data, and 77 constitutes address information. The coordination between the incoming flow 60 and the database applications is achieved in a manner known per se and is shown by different connections. The database applications are connected to the coordinating unit via a transport server 78 which is provided with an output connection 79.

Figure 6 shows the construction of three different product units 80, 81 and 82. The product units are designed in essentially the same manner. The different production units can constitute different types of dental products, for example titanium bridges, ceramic crowns, etc. Each production database 80, 81 and 82 has a construction corresponding to the database constellation 70 in Figure 5. An input connection is indicated by 79' and a transport server by 83. At their outputs, the database parts 80, 81 and 82 are connected to a line system 84. Connected to the latter is a system for financial reporting 85, a system for specifications 86, a system for article indexing 87, a system for customer indexing 88, a system for client registration 89, a system for client database 90, and a system for production modifications 91.

Updating of the coordinating units is done by so-called data replication. Data replication is carried out so that one has several identical databases. These databases are updated by transferring only information which has been modified since the preceding update. By using this technique, it is possible to expand the system for several users and/or several applications without limit. The database applications 85-91 work using SQL (Structured Query Language). There are therefore copies of the databases from all the production units. The databases are constantly updated by means of data replication. The database applications can then take information from the production units'

databases. The system is expanded by creating more coordinating units. The said coordinating units then receive a complete set of databases.

The invention also relates to a method using one or more computers or computer units to generate a system protocol for the process of production of a dental product, for example all or parts of one or more dental crowns, one or more dental bridges, etc., or instruments for these. The system is generated on the basis of, inter alia, a construction of the product or instrument simulated at a customer site, which can be a dental practice, dental technician's workplace, etc., in a computer environment in a manner known per se. In this case, the computer environment has access to first data concerning a basic protocol relating to production of a basic variant of the dental product or instrument. A supplementary protocol is generated by means of second data generated as a function of the construction simulated at the customer site. In an interaction between the respective computer unit and user, the system protocol is generated on the basis of the said first and second information. The basic protocol can in this case be selected from among a number of existing basic protocols which represent different variants. The basic protocol variants can be produced as a function of statistics from previous treatments in accordance with the above. The system protocol can be produced at the central unit or at the respective customer site or at one or more of the customer sites. The respective customer site is debited by means of debiting equipment (cf. above) for use of the various data from the central unit.

The invention also relates to a method and arrangement using one or more computer units to generate a program for reproducing visually on the computer screen all or part of a product, for example all or part of one or more dental bridges, one or more dental crowns, etc., or instruments for these. The generation takes into account a construction simulated

at a customer site, for example at a dental clinic, dental technician's workplace etc., in a computer environment. The said computer environment is supplied with first data attributable to a basic program for reproduction and presentation on the computer screen of a basic variant of the dental product/instrument. The said computer environment is also supplied with second data attributable to an add-on program which permits addition of characteristics to the basic variant by interaction between the computer unit/computer units in question and one or more users. The said first and second data can be transmitted from the central unit to a customer site, and the content or use time of the data in question can be priced with the aid of debiting equipment.

The methods and arrangements described above can also be characterized by the fact that the transmission between a central unit and a customer site is effected wholly or partly via the internet, i.e. the international telecommunications and/or computer network. The invention also relates to an arrangement for a system for producing dental products, in which a number of customer sites (dentists, dental technicians, etc.) are served by one or more central units which supply the respective customer site with dental products, instruments for production of dental products, information on dental products, instruments, statistics, and the like. The arrangement is in this case characterized by a queuing facility which is arranged to provide the respective customer site with details on the delivery time of the requested product/instrument or information. The operation can then be accomplished as a function of an order or request from the customer site in a manner known per se. The information in question can include concrete time indications of the delivery.

The invention is not limited to the embodiment described above, but can be modified within the scope

of the attached patent claims and the inventive concept.

PATENT CLAIMS

1. Arrangement used at an operating site to assemble individually designed dental products, for example distancing pieces, bridges, etc., where each dental product can be made up from two or more structural elements and where each operating site is arranged with computer equipment designed to reproduce a simulated model of the jaw, dentine, implant, etc., and structural elements applied to the model, and, by means of interaction with the user, to permit a constructional design of the respective assembled product which is adapted to the dental situation in question, and where the operating site can be connected to one or more central units via a telecommunications and/or computer network, via which the central unit receives data from the operating site, characterized in that the operating site is arranged to collate data in a query profile relating to part of the assembly, in that the operating site is provided with members for transmitting query profile data via the network to the central unit, in that the central unit is arranged, as a function of the received query profile data, to supply information relating to the part in question, which information can be sent to the operating site and/or can be set onwards to a production unit connected to the central unit, or included in the central unit, for production of the part, and in that a debiting system is arranged to indicate to the central unit or to the production site that the information or production, respectively, has been paid for.

2. Arrangement according to Patent Claim 1, characterized in that the query profile data relates to queries on first information concerning the dental situation, for example first information on optimum design and fitting of the part concerned in the dental product.

3. Arrangement according to Patent Claim 1 or 2, characterized in that the dental product consists of a distancing arrangement for or on an implant, which distancing arrangement comprises an angled distancing part or other part which has on or more parameters, e.g. shape, position of rotation about the longitudinal axis of the implant, etc., and which is dependent on the individuality of the dental situation.

4. Arrangement according to Patent Claim 1, 2 or 3, characterized in that the query profile data and the first information afford the possibility of interaction between the operating site's computer equipment, its user, and the central unit for production of one or more structures adapted to the dental situation.

5. Arrangement according to any of the preceding patent claims, characterized in that a number of operating sites can be connected to the central unit and its production unit(s), and in that the operating sites are categorized and each category subscribes to a relevant service which effects first information and/or product parts from the total range or offered range of the central unit and/or the production unit(s).

6. Arrangement according to any of the preceding patent claims, characterized in that the first information relates to one or more computer program information items or computer programs for carrying out the assembly.

7. Arrangement according to any of the preceding patent claims, characterized in that the query profile data of the respective operating site and the information sent from the central unit/respective production unit relates to user data and setting data for the scanner unit, measuring table, etc.

8. Arrangement used at a dental user site to assemble qualified constellations, for example with regard to dental situations, dental information, dental test products, etc., where the user site has access to its own result or results or presentation bank(s) and can be subject to factual information relating to, for

example, verifications, adjustments with complementary additions, etc., where the user site can be connected to one or more central units via a first telecommunications and/or computer network, via which the site and the unit are capable of exchanging information/data, characterized in that the user site is arranged to collate data in a query profile relating to all or part of the constellation, in that the user site is provided with members for transmitting query profile data via the first network to the central unit, in that the central unit is arranged, as a function of the query profile data received, to supply factual information relating to the constellation(s), which information can be sent back to the user site for acting on the said results or presentation band(s), and in that a debiting system is arranged to indicate to the central unit that the factual information sent back has been paid for.

9. Arrangement according to Patent Claim 8, characterized in that the returned factual information relates to second information on manufacturing process(es) and/or statistics relating to dental products, dental situations, etc.

10. Arrangement according to Patent Claim 8 or 9, characterized in that the central unit also functions as, or is connected to, one or more production units for production of dental products and/or instruments for these, and in that the central unit and/or the respective production unit is arranged to manufacture, analyse and store characteristic data on the dental products, data on the respective dental situation in which the respective dental product is being used, etc., and in that characteristic data and dental situations thus manufactured and stored can be interrogated by means of the said query profile or the said query profiles from one or more user sites connected to the central unit and/or the respective production unit.

11. Arrangement according to Patent Claim 8, 9 or 10, characterized in that the respective query profile data and returned information concern characteristics or construction information on different types of dental crown configurations which have been the object of production in association with manufacture/ production controlled or managed by the central unit, and in that the said types form main types which can each be supplemented by one or more variants of the main type in question.

12. Arrangement to permit manufacture of dental products, or instruments for the latter, at a number of geographically distinct manufacturing sites where the manufacturing procedure can be effected in a number of manufacturing stages, for example reading off the product's or the instrument's inner and/or outer shapes, transformation and transmission of the respective read-off results, representation of the read-off result in a computer environment, input of adjustments and/or additions to the representation represented in the computer environment, physical production of the product or instrument from or with a blank, testing of the dental product on patient, etc., characterized in that a central unit supplies moduled information items and means for carrying out the stages, in which the different modules can be assigned to the different manufacturing stages or part thereof, in that the different manufacturing stages are capable of interrogating and/or are assigned in advance one or more of the said moduled information items and means in order to be able to carry out all or part of the manufacturing process by means of the called-up information items and means, in that transmission members are arranged, as a function of the requested order for called-up information, to effect transmission of these on a computer and/or telecommunications medium which connects the respective manufacturing site to the central unit, and in that debiting systems are arranged

to credit the central unit with payment for used time, information and/or means.

13. Arrangement according to Patent Claim 12, characterized in that the customers are categorized in such a way that a first category of customer(s) can be assigned first information and means, a second category of customer(s) can be assigned second information and means, etc.

14. Arrangement according to Patent Claim 12 or 13, characterized in that the information and means comprises control information for operating equipment for one or more of the said manufacturing stages at the manufacturing site.

15. Arrangement used at one or more manufacturing sites to control a manufacturing procedure for a dental product or instrument for this, where the manufacturing procedure comprises one or more subsidiary stages, for example reading-off the product's or instrument's inner and/or outer shapes, transformation and transfer of the respective read-off result, representation of the read-off result in a computer environment, input of adjustments and/or additions to the representation represented in the computer environment, physical production of the product or instrument from or with a blank, testing of the dental product on a patient, etc., characterized in that control information for equipment effecting one or more manufacturing procedures or subsidiary stages thereof can be extracted by a selection procedure from an information and/or data bank located in a unit geographically separated from the respective manufacturing site, in that extraction can be initiated by means of the selection made at the respective manufacturing site, in that the selection made can be transferred via a computer and/or telecommunications medium to effect selection in the information and/or data bank at the central unit, in that the central unit transmits the selected information/means to the requesting manufacturing site, in that the selected information

received at the last-mentioned manufacturing site is arranged to be included in or be converted to control information for the equipment in question, and in that debiting equipment is arranged to credit the central unit with payment for used time, information and/or means.

16. System for supplying dental products and preferably information relating to the products and dental situations and, if appropriate, instruments for production of the products, in which a number of users using the system and constituting user sites are connected to one or more central units, included in the system, via a first computer and/or telecommunications network, and the respective user site is provided with computer equipment by means of which the query profile can be collated, characterized in that the said central unit(s) comprise(s) one or more coordinating units which, via the first telecommunications and/or computer network or a second telecommunications and/or computer network, is/are connected to one or more production units, in that the respective coordinating unit is arranged to effect or participate in the assignment of the information flows coming from the user sites via the first telecommunications and/or computer network (query profiles/query profile data), and in that the respective production unit functions as order receiver for the respective dental product which the respective user site wishes to have produced.

17. System according to Patent Claim 16, characterized in that the respective user site is equipped with function(s) for reading off the model or jaw, dentine, etc., in different dental situations, in that the reading result can be fed to the user site's computer equipment, and in that a query profile (systems user profile) set up by this means also includes one or more of the following task functions: filling in of dental data, patient, tooth, identification of type of work, processing of data profile in the computer equipment, filling in of order

forms, and transmission of the order via the first telecommunications and/or computer network.

18. System according to Patent Claim 16 or 17, characterized in that the respective coordinating unit functions as a connection station to a network, telecommunications network and/or computer network belonging to the system, and in that two or more coordinating units allocate the incoming query profile flow (systems user flow) and the flow of information coming out of the coordinating units, which, for example, are to be given access to different databases.

19. System according to any of Patent Claims 16 to 18, characterized in that the system capacity can be expanded by connection of further coordinating units and/or fitting of more powerful computers in existing coordinating units and/or connection of several ISDN (Integrated Service Data Network) modems.

20. System according to any of Patent Claims 16 to 19, characterized in that the said first and/or second telecommunications and/or computer networks form(s) a local telecommunications and/or computer network in relation to the public telecommunications and/or computer network.

21. System according to any of Patent Claims 16 to 19, characterized in that the respective coordinating unit is provided with or is connected to a file server which functions as drive for the respective database used.

22. System according to any of Patent Claims 16 to 21, characterized in that the coordinating units can be updated with the aid of a data replication function which comprises two or more databases.

23. System according to any of Patent Claims 16 to 22, characterized in that all the production units work in essentially the same way, with possible differences in the product types that can be manufactured, differences in the machinery used, capacities, and/or the structure of the internal routines.

24. System according to any of Patent Claims 16 to 23, characterized in that the debiting and/or finance system used is arranged centrally in the overall system, and in that the respective production unit is arranged to generate a database register comprising financial database and/or production follow-up, etc.

25. System according to any of Patent Claims 16 to 24, characterized in that, in the respective production unit, incoming data can be received in an incoming registration member from which incoming data can be processed in an incoming data library, word register, data library, file preparation members, preparation library, milling process treatment, and final registration, and in that database applications include the organization of incoming files, finance, data files, file preparations, product administrations, milling treatment register and address functions.

26. System according to any of Patent Claims 16 to 25, characterized in that it comprises two or more production databases which receive data from a transport server which is linked to a digital line, in that the respective production database has files for file arrival, finance, data files, file preparations, product administrations, milling registration treatment, and addresses, in that the files in the said two or more production databases are connected via their outputs to a bus connection to which factual information on finance reports, specifications, article index, customer register, client registration, client databases, and production changes are connected.

27. System according to any of Patent Claims 16 to 26, characterized in that updating is performed by so-called downward compatibility, which will make it possible to minimize the rumber of program versions the system is working with, and in that the respective new or altered program is checked out according to a sequence on installation.

28. Method using one or more computer units to generate a system protocol for the process of

production of dental products, for example all or parts of dental crowns, dental bridges, etc., or instruments for these, where the system is generated on the basis of, inter alia, a construction of the product/instrument simulated at a customer site (dentist, dental technician, etc.) in a computer environment, characterized in that, in the said computer environment, first data is supplied concerning a basic protocol relating to production of a basic variant of the dental product/instrument, in that a supplementary protocol is generated by means of second data generated as a function of the construction simulated at the customer site, and in that, in an interaction between the computer unit(s) and a user, the system protocol is generated on the basis of the said first and second information.

29. Method according to Patent Claim 28, characterized in that the basic protocol in question is selected from among a number of existing (tried and tested, established) basic protocols which represent different basic variants.

30. Method according to Patent Claim 28 or 29, characterized in that the said first data is supplied by a central unit serving one or more customer sites, in that the said first data, or third data attributable to the first data, is transferred to the customer site concerned, preferably via a telecommunications and/or computer network, and in that a visual reproduction of the basic variant is presented on computer equipment (screen) located in the said computer environment at the customer site, in that the structural characteristics in question are added to the visual reproduction, which characteristics, in the computer equipment, bring about generation of the said second data or fourth data attributable to the second data.

31. Method according to Patent Claim 30, characterized in that the said second or fourth data is returned to the central unit which utilizes the said

second data, or the said second data generated from the said fourth data, to permit the said interaction.

32. Method according to Patent Claim 30, characterized in that the said second data or fourth data is used at the customer site to permit the interaction at the customer site.

33. Method according to Patent Claims 28 to 32, characterized in that debiting members are arranged to debit transmissions and/or use times of information and data which is transmitted from the central unit to the respective customer site.

34. Method using one or more computer units to generate a program for reproducing visually on the computer screen all or part of a dental product, for example all or part of dental crown(s), dental bridge(s), etc., or instruments for these, where the generation takes into account an instruction simulated at a customer site (dentist, dental technician, etc.) in the computer environment, characterized in that the said computer environment is supplied with first data attributable to a basic program for reproduction and presentation on the computer screen of a basic variant of the dental product/instrument, and in that the said computer environment is supplied with second data attributable to an add-on program which permits addition of characteristics to the basic variant by interaction between the computer unit(s) and user.

35. Method according to Patent Claim 34, characterized in that the said first and second data are transmitted from a central unit serving several customer sites via a telecommunications and/or computer network, and in that a debiting function is arranged to register use/use times of the data in question.

36. Method according to any of the preceding patent claims, characterized in that transmission between the central unit and the respective customer site served by the latter is effected wholly or partly via the internet, i.e. the international telecommunications and/or computer network.

37. Arrangement for a system for producing dental products, in which a number of customer sites (dentists, dental technicians) etc., are served by one or more central units which supply the respective customer site with dental products, instruments for production of dental products, information on dental products, instruments, statistics, and the like, characterized in that a queuing facility is arranged to provide the respective customer site with details on the delivery time of the requested product/instrument or information.

38. Arrangement according to Patent Claim 37, characterized in that the details include concrete time indications of the delivery.

Fig. 1

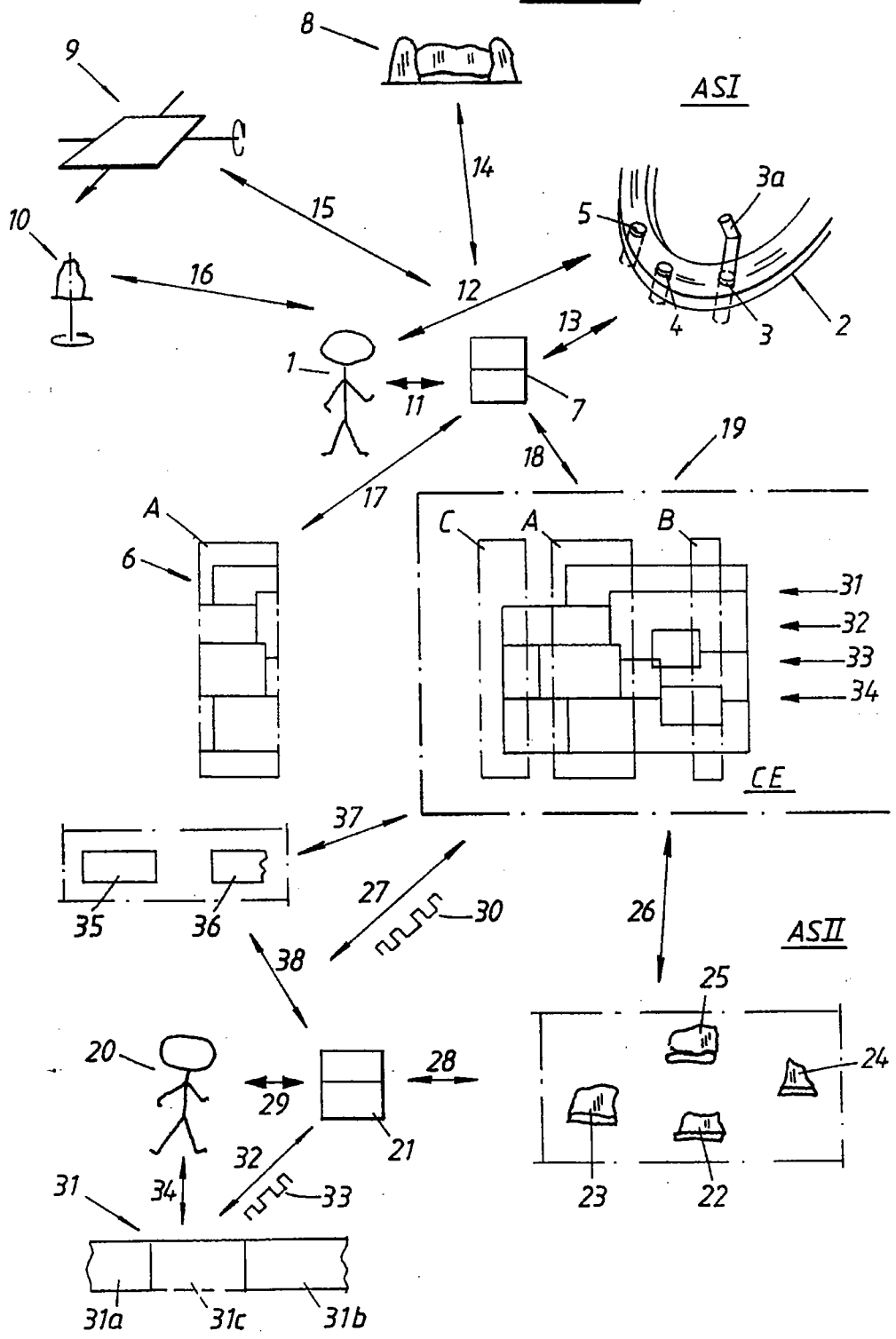

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Fig. 2

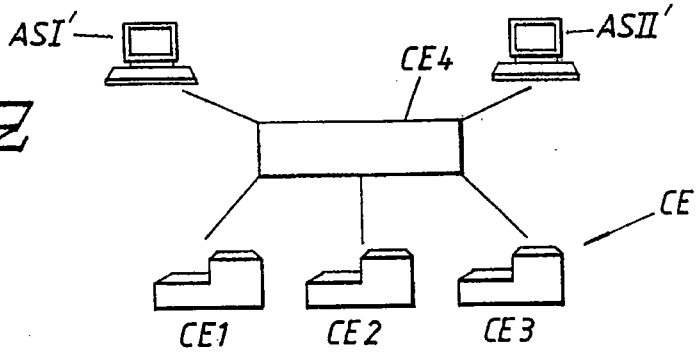


Fig. 3

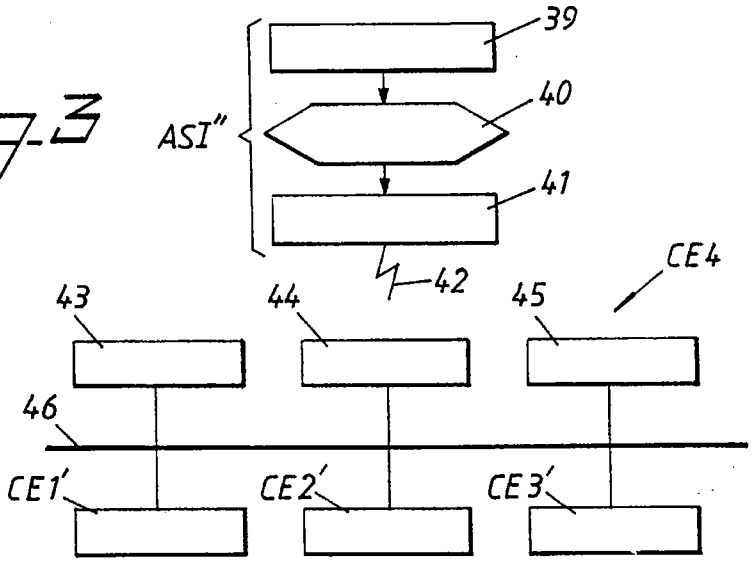
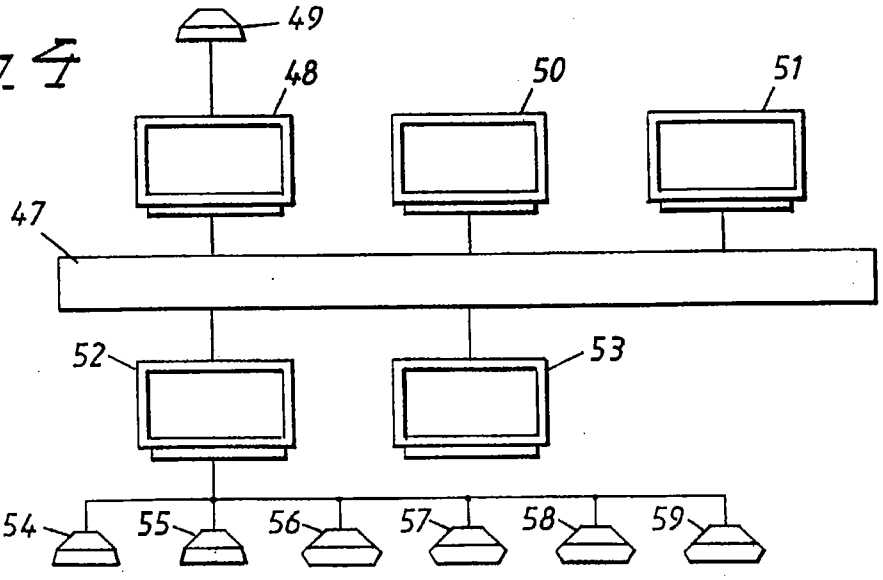


Fig. 4



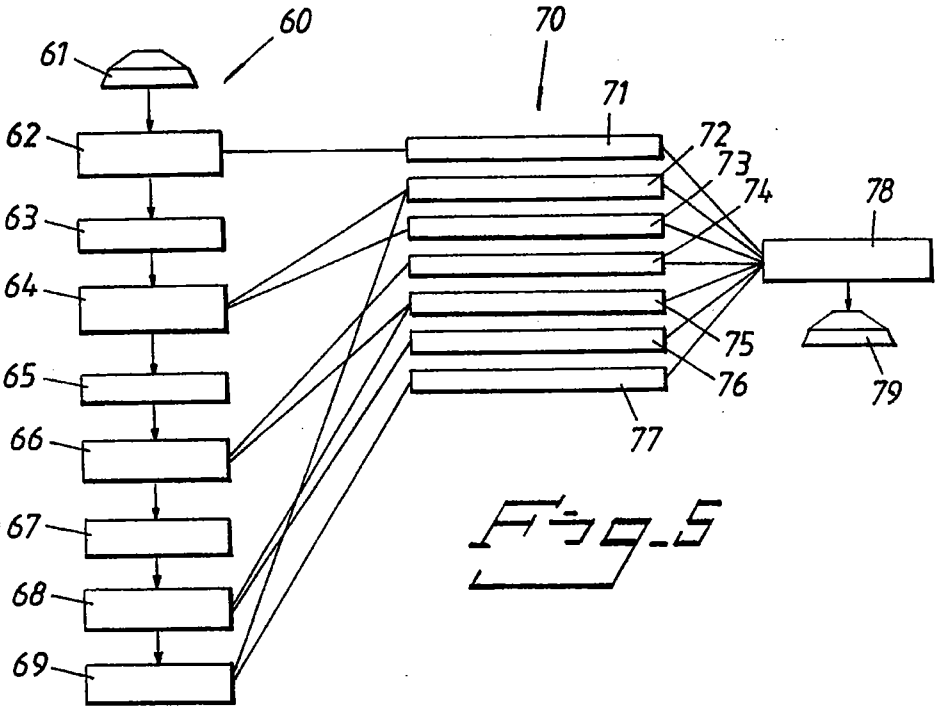

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Fig. 5

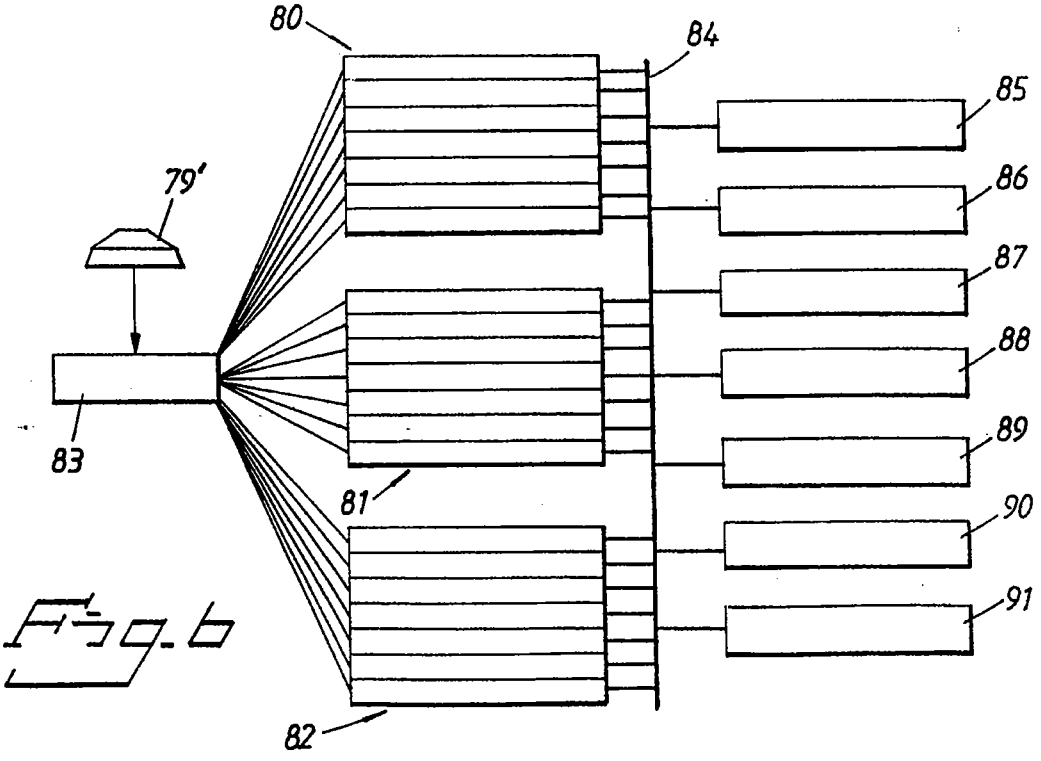

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Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/00493

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61C 13/00
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)

IPC6: A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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.
A	WO 9515731 A1 (NOBELPHARMA AB), 15 June 1995 (15.06.95) --	1-38
A	WO 9637163 A1 (SIEMENS AKTIENGESELLSCHAFT), 28 November 1996 (28.11.96) --	1-38

☐ 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" erlier 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
17 July 1998	21-07-1998
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Jack Hedlund Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/06/98

International application No.
PCT/SE 98/00493

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9515731 A1	15/06/95	AU 682083 B	18/09/97
		AU 1251695 A	27/06/95
		CA 2154478 A	15/06/95
		EP 0683647 A	29/11/95
		JP 8509150 T	01/10/96
		SE 502035 C	24/07/95
		SE 9304042 A	07/06/95
WO 9637163 A1	28/11/96	DE 19518702 A	28/11/96

Form PCT/ISA/210 (patent family annex) (July 1992)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number : **0 490 848 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number : **91850292.3**

(51) Int. Cl.[5] : **A61C 13/00**

(22) Date of filing : **22.11.91**

(30) Priority : **12.12.90 SE 9003967**

(43) Date of publication of application :
17.06.92 Bulletin 92/25

(84) Designated Contracting States :
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

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(54) A procedure and apparatus for producing individually designed, three-dimensional bodies usable as tooth replacements,prostheses, etc.

(57) A procedure for producing individually designed, three-dimensional bodies includes as part steps the identification of one or more shapes/forms (10) of one or more of said bodies (9). A first digital representation is formed by each respective identification. Respective representation is stored and processed possibly in a computer (20). The computer is activated for one or more read-outs via one or more ports (22) of one or more representations in processed or unprocessed form. In one or more machines for production of said bodies there are included one or more switch actuators. Each respective switch actuator is actuated in an activation function in which a blank and a device acting thereon are brought into coordination as a result of the actuation of the device by means of relevant read-out from the computer. During this actuation, the blank is allocated the relevant read-out form. The original representation of the form (10) may possibly be subjected to modification, e.g. supplementary modification. This modification can be performed by means of a computer (20), modification in the identification, machine setting, etc.

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TECHNICAL FIELD

The present invention relates to a procedure for producing individually designed, three-dimensional bodies intended to form at least parts of artificial replacements for teeth, dental bridges and joints; support parts for reconstruction of tissue build-up; and tools for producing whole or parts of such replacements and support parts, etc. The present invention also relates to apparatus for implementation of the procedure.

BACKGROUND ART

Using the procedure and apparatus according to the present invention, it will thus be possible to manufacture both an implant body as such and a tool part or parts employed in the production of the implant body. Production of a tool part for an implant body is relevant int al to the production of tooth sockets whose inner configuration must be adaptable with extreme accuracy to the tooth remains in question. In this case, electro-erosion is employed, in which it is necessary that the outer configuration of the tool part coincide with extreme accuracy (100 parts of 1 mm) to the outer configuration of each respective tooth remain. In such instance, it should also be noted that the tool parts (which, in the case of production of tooth crowns, consist of electrodes of graphite) are exposed to wear (primarily frontal wear) during the electro-erosion. The production of a tool part or parts is also relevant in the procedure for producing ceramic bodies which are linearly enlarged in relation to the replacement or support part and reduced in size by hard sintering in order to conform with extreme accuracy with the size of the replacement or the support part.

It is previously known in this art to transfer a configuration from a model to the implant body or the tool part herefor. By way of example, reference is made to the tracer milling cutter according to PCT application SE87/00194 (WO 87/06451). This tracer milling cutter employs a sensing needle which senses the configuration of the model in question, and hydraulically operating servo devices which transfer the movements sensed by the needle to the processing tools which forms the blank. The above-mentioned publication discloses in purely general terms that it is possible alternatively to employ a tracer milling cutter which operates with electric servo devices.

It is also previously known in the art to propose, in the above type of tracer milling cutter, apparatus which makes possible enlargement/reduction of the form of a sensed model.

It is also well known in the art to employ electro-erosion in the production of, for instance, tooth crowns/tooth sockets.

The prior art equipment imparts an extremely high degree of accuracy to the produced implant bodies which are usually characterized by unique, individual outer and/or inner configurations.

It is also previously known in the art to attempt to cast the individually shaped bodies. Casting of such bodies provides inferior surfaces and requires individually designed and shaped tools. This mode of approach must be regarded as inferior to the principles according to the present invention which are based on cutting or some other type of forming machining.

SUMMARY OF THE INVENTION

TECHNICAL PROBLEMS

In the production of implant bodies, there is a general need to be able to rationalize production of such implant bodies which must then be capable of displaying individually distinguished and also complex inner and/or outer configurations. The prior art equipment and procedures for this purpose are relatively slow, and in certain cases require the production of bodies of advanced design which cannot be achieved, or which can be achieved only with difficulty, using today's prior art equipment.

There is also a need in the art to be able to increase access to biocompatible material in connection with replacements and implant of support bodies in the human body. As a rule, such material is difficult to work with and must be capable of being employed in cost-effective and manufacture-efficient procedures and apparatus for the production of organic forms.

Hence, there is a need in the art to technically simplify the machines employed and their associated equipment, while still being able to utilize these more generally in the production of implant bodies. In this instance, the purely hydraulically operating equipment suffers from limitations and requires a relatively large machine park if all-round production of individual bodies and electro-erosion tools for these can be satisfied. Different machine variants are thus required for cases with or without enlargement/reduction function. Production of tooth sockets and tool parts for these also requires machine variants, since the tool parts must be designed with a wear allowance. The production of, for instance, complete teeth requires an additional machine variant. Those cases in which it is desired to build onto the produced form in relation to the form of the sensed model (as may be relevant in the production of a complete tooth/tooth part), would theoretically require one machine variant for each superstructure operation, which, in principle, would be impossible to satisfy with present-day tracer milling cutters that operate purely hydraulically.

The ideal is thus to be able to utilize a single machine variant in which it is possible to manufacture the desired implant body in response to controls

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which may be simply varied. In this instance, it must be possible to enter information on the configuration of the body in question either manually or automatically by read-off, copying, etc., whereafter the control equipment generates, in response to such information, the correct control signals to the machine which, in response to the generated control signals, produces the usually individually shaped body.

The hydraulically operating tracer milling cutter also suffers from drawbacks by not being capable of working sufficiently rapidly. The sensing needle must abut against the model with a certain force, the so-called reaction force. The model is usually made of plaster of Paris or other soft material, which limits the magnitude of the reaction force. On the other hand, the reaction force must be increased with increasing working speed in order-for the needle to be capable of following the contour, and the above-mentioned limitation in working speed will be readily perceived herefrom. In addition, the needle must be provided with a rounded tip (not a spiculated tip) in order for the model/plaster material not to be destroyed by the needle. This limits sensing accuracy in complicated shapes and it will readily be perceived that implant bodies of complex individual shapes cannot, for this reason, be manufactured with a sufficient degree of accuracy. The possibility of producing the implant body with complex shapes is also restricted by the fact that the axes of rotation of the rotary units cannot work above the rotary shaft of the blank because the above-mentioned axes of rotation are inclined at an angle in relation to each other. Such angular setting affords a number of advantages which it would be difficult to forego in the above-mentioned prior art tracer milling cutter.

The procedure and the apparatus according to the present invention are also intended to make possible the production of cavities in relevant blanks with a high degree of accuracy.

SOLUTION

The object of the present invention is to propose a procedure and apparatus which obviates at least the major part of the above-outlined drawbacks. That which may substantially be considered in thi context to characterize the procedure is, int al, that identification is included of one or more shapes on one or more of the above-mentioned bodies. In addition, a first respective digital representation of each respective identification is to be formed. Each respective first digital representation is provided in a storage and processing unit/computer. This hardware handles, for example by file and/or database processing, each respective first digital representation. This handling may possibly include the application, preferably via a terminal, of at least one piece of information with which actuation may be effectuated, e.g. shape change, size change, etc., in relation to each respective first representation with its respective information, in addition to which the generation of at least one second representation which differs from the relevant first representation may thus be realized in response to the above actuation. The storage and processing unit is activated to accomplish one or more readouts via one or more output ports of one or more of the first representations and one or more of the second representations, where applicable. Devices, switch actuators, positioning devices etc. which are included in one or more machines for production using one or more of the above-mentioned read-outs are controllable by means of each respective read-out or read-outs. Each respective actuator is actuated depending on its control in an actuation function where a blank and members acting thereon are brought into co-ordination with one another in consequence of actuation of the device by means of the relevant read-out, with a view to allocating to the blank the relevant read-out shape. Such actuation in relation to the first representation may be achieved by means of the above-mentioned second representation and/or change, e.g. additional change, in identification, machine setting, etc. In identification, additional change may thus be added, while in machine setting, adjustment or change of "errors" in the processing may be modified, etc.

In one embodiment, one or more models are produced of the above-mentioned bodies, identification being optionally executed with the aid of the shape or shapes of the model or models. Supplementary information or alternatively a description may be produced for each respective form of each respective model or body, and identification be effectuated with the aid of such description. The description may thus comprise description parts which respectively indicate co-ordinates, for example read-off angle of the body during read-off and position in a co-ordinate system for each respective read-off or plotting point. In one embodiment, use is made in the description of significances for the shape build-up. These significances may consist of predetermined codes characteristic of the build-up of the shape which form abbreviations or representations, hereinafter designated third representations, of or for the complete description parts. The information mass produced with the codes will, by such means, be considerably reduced in relation to the information mass of the complete description parts. The codes may be stored in the processing units (its host or associated memory), in which also these complete first and second representations are generated with the aid of codes on each respective deposition or loading occasion to the machine or machines.

In one embodiment, first and second data are entered in respect of a second shape associated with the model, the read-off or the copying, or possible differences in relation to the first shape in dimension

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and/or configuration which are to be present for the second shape in the memory hardware associated with the computer device, for example in the form of a PC, microprocessor, etc., which in turn is included in or connected to an electric control unit in which the above-mentioned controls are generated in the form or electric control signals. Furthermore, the novel procedure is characterized in that the electric control signals are based on/calculated in the computer hardware from relevant data of the above-mentioned first and second data and are fed to the movement-effectuating device which, in this instance, includes an electrically controlled servo device, switch actuator, etc., whose movement effectuation is executed by utilization of a slight inertia resistance in the movement-effectuating devices.

In an additional further development of the novel procedure according to the present invention, first information by means of which the above-mentioned first data may be generated is retrieved by a copier, for example, a dentist, a dental technician, etc., and transmitted by means of computer transfer or storage media to a central host unit which controls the production of implant bodies, and, at the central host unit, the above-mentioned first data is entered into the above-mentioned electric control unit/computer hardware on the basis of the first information. The computer transfer media may then preferably consist of a transmission line, e.g. a hooked-up and/or permanent connection in the general telecommunications network. Transmission and reception devices which preferably include modems are connected or connectible to the above-mentioned transmission line for transmission of the above-mentioned first information.

The above-mentioned second data in respect of different percentages in enlargement and reduction of the shape, different changes of the second shape in relation to the first shape, etc., are entered into the above-mentioned memory/computer hardware. The second data in question is selected for each respective production case, by means of actuation of terminal devices associated with or connected to the above-mentioned computer hardware. The rotary units are, or one of the rotary units is, controlled by the electric control unit to achieve an optimum production time in respect of machining speed and accuracy. In such instance, each respective longitudinally displaceable rotary unit is longitudinally displaced depending on the degree of complexity of the first shape. In such first portions of the first shape as represent a first part shape which permits a certain first maximum machining speed, each respective unit is longitudinally displaced at the first maximum machining speed. In such second portions of the first shape as represent a second part shape which permits a certain second maximum machining speed which differs from the first maximum machining speed, each respective unit is longitudinally displaced at the second maximum machining speed, and so on.

Further embodiments of the novel procedure according to the present invention are apparent from the appended description.

That which may substantially be considered as characterizing the novel apparatus according to the invention is, int al, that identification means are provided for identifying one or more shapes of one or more of the above-mentioned bodies. Means are also provided for forming a first digital representation of each respective identification. A storage and processing unit (computer) is operative to receive each respective first digital representation. The storage and processing unit is further operative to handle each respective first digital representation. Such handling may comprise set-up in a file or files or in a database or databases. The handling may also include the possible application (performable from a terminal associated with the storage and processing unit) of at least one item of information for actuation, e.g. shape change, size change, etc. in relation to each respective first representation with each respective item of information and generation of at least one second representation which differs from the relevant first representation in response to the above-mentioned actuation. The storage and processing unit is further operative to make possible read-out via one or more associated output ports, of one or more of the first representations and possibly one or more of the second representations, if applicable. Switch actuators/positioning devices are provided and are controllable by means of one or more of the above-mentioned read-outs. These devices are actuated in response to their controls in an actuation function in which a blank and one of the devices acting thereof are brought in to coordination as a result of the actuation of the device by means of the relevant read-out, and in which the blank is, by such means, allocated the relevant read-out shape. The novel apparatus may also be characterized in that, in cases where the above-mentioned actuation in relation to the first representation is to be present, such actuation is realized with the aid of the above-mentioned second representation and/or change which, in this instance, may consist of an additional change, in identification, machine setting, etc.

In one embodiment, the device generating the control signals includes an electric control unit which, in turn, comprises or is connected/connectible to computer means, e.g. a PC, microprocessor, etc., in whose associated memory equipment first and second data may be entered in respect of a second shape associated with the model, the read-out or the copy, or a difference in relation to the first shape in dimension and/or form which is to be present for the second shape. In addition, the apparatus is characterized in that the control unit generates, depending on relevant data on the above-mentioned first and second data,

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electric signals to the movement-effectuating device which, in this instance, includes or consists of an electrically controlled servo device, switch actuator, etc., with slight inertia resistance.

In yet a further embodiment, the apparatus is characterized in that the electric control unit is included in a distribution system for the transfer of first information by means of which the above-mentioned first data may be generated in the memory equipment/computer hardware. This distribution system includes, on the one hand, a number - preferably a plurality - of initiation or gathering stations for the above-mentioned first information, and, on the other hand, computer storage and/or computer transmission devices for the above-mentioned first information from these stations to a central or host station including the electric control unit and the armory equipment/computer hardware. The first items of information are converted into the above-mentioned first data in the memory equipment/computer hardware in connection with the transfer of the first items of information to the main station or, after intermediate storage or holding in the main station. The computer transmitting devices include transmitter and reception devices and transmission communication between the above-mentioned transmitting and receiving station. The transmission communications preferably include permanent and/or hook-up connections in the general telecommunications network, to which the above-mentioned transmitter and reception devices are connected/connectible.

In one preferred embodiment, the electric control unit is arranged to control one or both of the blank and tool supporting units for their mutual longitudinal displacement movements at speeds which are dependent upon the degree of complexity of the first shape, e.g. in complex shape portions of the first shape at a first speed, in less complex shape portions of the first shape at a second speed which exceeds the first speed, and so on.

In such first shapes or in such part portion of the first shape in which the machining device cannot operate above the axis of rotation of the blank because of the overall configuration of the first shape, the electric control unit controls each respective rotary unit so that machining in a given phase takes place during parts of a rotation turn for each respective rotary unit.

In one embodiment, the apparatus includes two or more pairs of rotary units in which each respective pair is included in its allocated machine or machine equipment part. In this instance, the electric control unit controls directly, or via sub-control units, the different unit pairs/machines/machine equipment parts on the basis of the same first shape/model/read-off/copy. A first pair of blank and tool-supporting units/a first machine/a first machine equipment part then shape a first blank which forms or is to form the implant body and which has an outer configuration corresponding to the outer configuration of the model, the read-off or the copy, or has been allocated the above-mentioned difference in relation to the outer configuration of the model/the read-off, or the copy. At least second and third pairs of blank and tool-carrying units/second and third machines/second and third machine equipment parts shape second and third blanks which form first and second tool parts in the form of electro-erosion devices intended for producing an inner shape of the implant body which then obtains a socket shape in its final form (cf. a tooth crown). The first tool part forms a rough production tool part which has been provided with frontal wear durability for compensating frontal wear in the electro-erosion. The second tool part forms a fine production tool part with close approximation to the second shape.

In one embodiment, the blank and tool-carrying units carry the blank and the processing device, respectively, with manifestly rigidly journalled shafts with a slight overhang between the part carrying the blank and the part carrying the processing device, respectively, and a shaft bearing/an immediately proximal shaft bearing.

ADVANTAGES

As a result of the above proposals, the processing time in the machine may be shortened five to tenfold of the time it takes to manufacture the implant body using the prior art tracer milling cutter. And yet, the principle of processing or correspondingly shaping manufacture can still be employed. The machine park may be simplified technically, and more complex shapes may be produced with the same degree of accuracy as previously applied to simpler shapes in employing the tracer milling cutter. Handling for transfer of model information or the like from the dentist/dental technician to the manufacturing unit may be considerably reduced and, for instance, it will be possible to utilize information transfer instead of physical package mailing in a simple manner via the public telecommunications network. Technical accuracy data in respect of the individual nature of the object is established by the dentist/dental technician, while superstructure parts/superstructure functions to the body may be applied by processing of data in the computer hardware on the basis of tests or experience. Different tests and experiments may, in each respective individual case, be conducted in order to obtain fully satisfactory results. The manufacturing process may be individually adapted to the transmitting stations and the resources of the main central station. In exact copying, for example, no other data need be employed. A number of machines can simultaneously be utilized for, for example, tooth crown production in which the production of the implant body proper is per-

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formed in a first machine, and graphite electrodes for subsequent electro-erosion can be produced in other machines. Enlargement and reduction functions of the produced body in relation to the model may be performed by simple pushbutton operations or manual activation. Seen as a whole, the overall throughflow time for an implant body can thus be substantially reduced. Alternatively, one or a few machines may be employed to produce bodies and programmings. The procedure and the apparatus are suitable for different types of chipforming machining, for example cutting machining, laser machining, etc.

The division of the sensing and machining functions of the mechanical tracer milling cutter into different locally placed units affords the above advantages in flexible production and machine park composition.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

One currently proposed embodiment of apparatus and a procedure performed using the apparatus will be described in greater detail hereinbelow, with particular reference to the accompanying Drawings, in which:

Fig. 1 schematically illustrates the production of three-dimensional implant bodies for living organisms;

Fig. 2 schematically illustrates a first embodiment of apparatus for read-off or sensing of a configuration of a three-dimensional body;

Fig. 3 schematically illustrates a second embodiment of apparatus for sensing a configuration of a body;

Fig. 4 schematically illustrates the information transfer via the telecommunications network of information from a sensing and storing side to a receiving and processing side;

Fig. 5 is a horizontal view showing one embodiment of a blank-supporting unit and a tool-supporting unit, the units being mutually longitudinallly displaceable along their longitudinal axes which, in this instance, are angled in relation to one another;

Fig. 6 is a side elevation showing parts of the apparatus according to Fig. 5; and

Fig. 7 is a side elevation showing a slightly modified embodiment of parts of the apparatus according to Fig. 5.

DETAILED EMBODIMENT

In Fig. 1, a number of sub-stations are indicated by reference letters A-I. In station 1 which is located at a dentist, doctor or other examiner, a model 1 is produced from, for example, a tooth 2 in a jaw 3. The model forms a prepared tooth which has been built up from a tooth remain 4 in the jaw. This model is produced by a model-producer (dentist, doctor, etc.) The model includes a metal or ceramic shell 5 and material 6 applied on this shell. The model includes an inner form 7 which corresponds to the outer form 8 of the tooth remain 4. From the model, a positive model 9 is produced which thus corresponds to the outer form 8 of the tooth remain 4. This positive model 9 is utilized in a second station B in which a read-off, description, identification, etc. is performed of the outer form 10 of the positive model. The positive model is disposed on or in read-off equipment 11 which may be of different type and operating principle. In Fig. 1, two principles are represented by reference numerals 11 and 12. The transfer from station A to station B is symbolized by arrows 13 and 14, respectively. The model 9 is disposed on a bracket 15 and can, by means thereof, be applied to the read-off device 11 which, in the illustrated case, comprises a rotary and displacing device 16. Moreover, the sensing device 11 includes a unit 17 sensing the form 10, this unit also being optionally designed or constructed on the basis of different principles. Rotation of the model 9 is symbolized by the arrow 18 and displacement by the arrow 19. By rotating and displacing the model 9 in a predetermined manner with simultaneous sensing of the surface 10 by means of the unit 17, a mathematical representation can be obtained with the aid of read-off signals i1 and control signals i2. The read-off signals depart from the unit 17 and the control signals 12 are impressed upon the rotary device 16. The sensing device 12 is controlled in a corresponding manner by means of the above-mentioned signals.

One station C includes a storage and processing unit 20 which may consist of a personal computer. Such a personal computer may be purchased on the open market. The personal computer comprises input and output ports 21 and 22. In addition, a CPU 23 is included, and memory devices 24, 25. A terminal 26 is provided for entering information i3 and accessing information i4. The above-mentioned control signal i2 is controlled from the CPU of the computer 20. The accessed information i1 is entered and received in the computer where the information is stored and processed. The accessed information from the unit 17 is obtained preferably in digital form, even though analog read-off may be carried out and converted into digital information in the computer. With the aid of the signals i1 and i2, there is thus generated for each respective read-off form 10, a first digital representation of each respective identification. The digital representation which is created as a result of the sensing is stored in memory devices 24 and/or 25. The personal computer handles the above-mentioned representation and sets this up in a a file or files or a database or databases. The information i3 is possibly entered for modification, e.g. form change, size change, etc., in relation to the first representation, with each respective item of information i3 and generation of at

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least a second representation which differs from the relevant first representation depending on the above-mentioned modification. The computer unit 20 is actuable for read-out of one or more of the above-mentioned representations and one such read-out is indicated in Fig. 1 by reference No. 27. The read-out 27 is transmitted to a station D which includes modem means 28 utilized for transferring the read-out on a line K permanently connected and/or connectible to the public telecommunications network. The digital signal departing from the modem is indicated by reference No. 29. This signal 29 is received in a receiver station E which includes a receiver modem 30 which is adjusted into harmony with the modem 28 and the communication line K. Such a data transfer effectuated by the modems 29 and 30 may consist of per se known type. By way of example, mention may be made that the "DATEL" leased line service can be utilized. Since the principles of this type of service are well known, they will not be described in greater detail here, it being merely ascertained that it operates with frequency shift keying and conforms with CCITT recommendations. Alternatively, the read-off 27 may be obtained on a diskette which may be loaded into and unloaded from the computer 20 and on which the read-out 27 may thus be transferred. This diskette may be transferred by an alternative route K' (by post) to the station E where the diskette has been represented by reference No. 32. The communication K is preferably of the type which effectuates series communication.

The memories 24, 25 in the computer 20 may consist of primary and secondary memories. The information in respect of the outer form 10 of the model 9 produced in the computer may be arranged in file or database. Such files or databases are entered in the secondary memory. The file or database contents, respectively, can be transferred to the working memory (the primary memory). Formation/editing of additional file or files, or data contents which represent varying or form-modified information items of the first information may be carried out with the aid of the second information item i3 and the file and database contents, respectively, which represent the outer form 10 of the model 9. The thus produced additional files or database contents, respectively may also be entered in the secondary memory. Hence, the read-outs 27 may represent both read-off form and modified form. Such editing may be performed using a processing form which operates on the basis of graphics. On the screen (not shown in detail) of the terminal 27, a graphic representation can in such instance be obtained. As file or database processing, use may be made of known protocol, and in this instance, mention may be made of the so-called transfer protocol PCPIP (U.S. navy) for file or database processing. On transfer from the secondary memory to the working memory, a processing program is activated which may consist of a conversion program which draws broken lines, angles, etc. with the aid of the information in the file or the database contents, respectively. By way of example of such programs, mention might here be made of POSTSCRIPT (for terminals), GKS (Graphic Kernel System) which effectuates editing of the additional files or data contents, respectively. GKS is a so-called editor.

A receiver station F of the information 33 received from the modem 30 (or the diskette 32) includes a second computer 34 of corresponding design to that of the computer 20. This computer also includes input and output ports 35 and 36, respectively. Moreover, a CPU 37 is included, and secondary and primary memories 38 and 39, respectively. The computer also includes a terminal 40 via which information i5 may be applied, and information i6 may be read off. The computer 34 controls the memory and control devices 41 and 42, respectively, which are included in a processing station G. The processing station in turn controls a machine park H which may comprise one or more machines 43, 44. In the machine park, the relevant individual bodies 45, 46 are manufactured which consist of implant bodies, support bodies, tools, etc. These bodies 45, 46 are finally treated in a station I which may include electro-erosion processes, material application processes, etc. In this embodiment, a memory 41a, 41b, 41c, 41d is each allocated, by the memory units, 41, their control unit 42a, 42b, 42c and 42d, respectively. Each control unit 42 isthen allocated to its machine/machine set. Thus, the unit 42a is allocated the machine 43, 42b the machine 44, and so on. Information 47 which is current on each occasion for execution by each respective machine 43, 44 is transferred from the computer 34 to the memories 41. Control of each respective machine is performed by each respective control unit 42. The items of information 47 to the memory and control units can be performed on BUS communication of per se known type (for example HE's BUS communication). Each respective control unit provides, for each respective machine, those sequences, movement patterns, etc. which are relevant in each machine.

Each respective machine includes a blank-carrying unit 48 and a tool-carrying unit 49, these units 48 and 49 being described in greater detail hereinbelow.

The blank-carrying unit is rotated by means of a motor 50 and is longitudinally displaced along its longitudinal axis by means of a motor 51. The tool-carrying unit is disposed to cause its pertinent processing tool 52 to abut, during ongoing processing, against the blank 53 rotated and longitudinally displaced by the unit 48. The longitudinal displacement movement of the unit 48 is disclosed by reference No. 54 and the rotational movement by reference No. 55. The longitudinal displacement movements of the unit 49 are indicated by reference No. 56. As will be apparent from the horizontal view according to Fig. 1, the longitudi-

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nal axes of the units 48 and 49 are disposed at an angle in relation to one another. In a more detailed embodiment (not shown), this angle may be varied with the aid of a symbolically intimated gear rim 57 which carries the unit 49. With the aid of a motor 58, the gear rim 57 is rotated and the above-mentioned angle between the units 48 and 49 can be varied by such means with the aid of a control signal to the motor 58. The above-mentioned control units 42 generate the signals to the motors 50, 51 and 58 and to a switch actuator/positioning device/electric servo included in the unit. In Fig. 1, a control signal to the motor 50 is indicated by reference No. i7, a control signal to the motor 51 by i8, a control signal to the motor 58 by i9, and a control signal to the device by i10.

The read-off form 10 of the model 9 can thus be modified if desired. Such modification information can be entered at different points in the identification and production chain. It is, thus, possible to apply to the model 9 a foil of a given thickness whichthen may represent the form modification. Similarly, the read-off function using the unit 17 may be influenced in the desired manner such that a enlargement of the form 10 takes place. Actuations such as these have been symbolized by a part 59 and arrows 60, 61 and 62. Actuation for modification may also be performed in station C with the aid of the above-mentioned second information i3. Such actuation for form modification, enlargement, etc. may also be performed in station F with the aid of the information i5. The above-mentioned actuation for form modification, enlargement, etc. may also be performed in the machines 43, 44. In this case, the modification is realized in that the error of the machine is adjusted manually and/or electrically. Such actuation has been symbolized in Fig. 1 by the cart 63 and the arrows 64 and 65. The equipment illustrated in Fig. 1 operates largely as follows. A model is produced in station A. One or more forms of the model or model 9 deriving from the model are sensed in station B with the aid of sensing equipment controlled from a computer in station C. This latter computer also prepares protocols/files/databases on such sensing. The stored information is possibly processed, and the information from stored or processed representations is read out from the computer unit. This read-out may be performed on command from the personal computer and/or on command from subsequent equipment. The read-out is transmitted via modem in the telecommunications network or its equivalent. The read-out is transferred via a communication connection to which receiver equipment is connected in a station E. The received information is stored and possibly processed in a station F which includes a computer unit which, in turn, controls memory and control units in a subsequent station G. The receiver units E qnd F may basically be connected to a plurality of stations A-D and, conservely, the stations A-D may be connected to different stations E-H (I). In this latter case, different tool parts and bodies may be made at geographically separate sites. For instance, sockets may be manufactured at one site, tools at another site, and so on. The computers 20 and 34 in the stations C and F can form master and slave relationships vis-á-vis one another. Information in a computer can be read off in another computer. The computer 34 may, for example, give priority to accessed information from a plurality od computers 20, and manufacture body/tool for information with the highest priority. The control unit 42 contain basic data for the basic functions of the machine park 43, 44, and data/information is fed to the memories 41 which is valid for each respective manufacturing occasion. Read-out and entry of information in the memory and control units may be preformed from the computer 34.

Figs. 2 and 3 each show their read-off principle, the principle illustrated in Fig. 2 relating to so-called capacitative indicators, and the principle according to Fig. 3 taking place by optical means. the capacitative indicator according to Fig. 2 fundamentally includes three permanent electrodes 66, 67 and 68, and one electrode 69 displaceable depending on the sensed form. Three capacitors may thus be considered as existing, namely one capacitor C1 between the electrodes 67 and 68, one capacitor C2 between the electrodes 68 and 69, and one capacitor C3 between the electrodes 66 and 69. The electrode 67 is connected to a frequency 70 which may be of the order of magnitude of 1 mHz. The voltage caused by the frequency will be divided up between the capacitors C1 and C2 in relation to their inherent capacitances. The variation will be performed in response to the longitudinal displacement position of the displaceable electrode in relation to the electrode 67 and 68. The capacitance of the capacitor C is constant over the measurement area because of the fact that the electrode 66 is constantly covered by the electrode 69. At one connection terminal 71 to the electrode, it will thus be possible to sense a voltage which exists on the electrode 69 at each respective relevant position, and this voltage will always be proportional to the longitudinal displacement of the electrode 69. In one embodiment, the electrodes may be designed as cylinders in which the electrodes 66, 67 and 68 are thoroughly insulated from one another and the electrode 69 is in the form of a rod of conductive material which is displaceable within the cylinders. The indicator is connected to an electric converter which gives the digital representation i1′ on its output (cf. Fig. 1). The displaceable rod 69/the electrode extends towards the model 9′ and abuts against the outer form 10′ of the model. The above-mentioned sensing takes place depending on the rotation 18′ of the model about the longitudinal axis 73 and the longitudinal displacement 19′ along the longitudinal axis 73. The electrode or rod 69 is urged against the model 9′ by means of a counter spring 74 which may actuate the sensing device 75

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towards the surface of the model 9′ with a predetermined abutment force.

The sensing principle according to Fig. 3 operates by so-called non contact sensing of the triangulation type using laser light. In this case, a laser source 76 is included, as well as light emitting means 77. The departing laser beam 78 is reflected against the surface 10″ of the model 9″. The model 9″ is rotated and longitudinally displaced along its axis of rotation in a manner corresponding to that of Fig. 2. The surface 10″ reflects the laser light 78 and the reflected light has been indicated by reference No. 78′. The unit includes receiver means 79 (lens) which refracts the impinging light towards a detector surface 80. The detector (not shown in detail) emits signals in response to the angles of the incoming light 78′. By such means, a digital signal corresponding to the form can be generated on the output of the unit 81 (cf. Figs. 1 and 2). This type of indicator is commercially available in a plurality of makes and, by way of example, mention may be made of the indicator from Nippon Automation CO LTD, Japan, of the type "Laser Analog Sensor LAS 5010". Fundamentally, the indicator operates such that a light beam is generated by the light source 76 and is focussed by an optical system 77 against the surface 10″. The spot arising on the surface is observed by the detector 79, 80 consisting of optics 79, a detector surface 80 and a positional-sensing circuit (not shown in detail), e.g. a so-called CCD detector (CCD = Charge Coupled Device). Such circuits are well-known in the art and will not be described in greater detail here.

In Fig. 4, reference No. 82 indicates a telecommunications system in which the selector matrix has been symbolized by reference No. 83 and control means (register etc.) by reference No. 84. The transmitting and receiving sides 85 and 86, respectively, are connected to the telecommunications system 82 as subscribers. Each respective subscriber installation 85, 86 includes a modem 87, 88 (cf. 28, 30 in Fig. 1). Each respective installation may include telephone sets 89 and 90, respectively, and connections of PCs 91 and 92, respectively, or corresponding storage and processing devices (cf. the computers 20 and 34 in Fig. 1).

Figs. 5-7 show the blank and tool-supporting units 48′ and 49′, respectively, in greater detail. There are extreme demands on flexurally rigid support of the movable parts in the units. This is because the materials which are to undergo cutting processing are generally extremely hard (extreme processing forces). In addition, such processing must take place with a high degree of sensitivity and exactness. In Fig. 5, the switch actuator of the unit 49′ has been indicated by reference No. 93. The switch actuator must be of the type which is electrically controllable with the aid of the above-mentioned signals which are primarily intended to be of the digital type. In one embodiment, the switch actuator may consist of an electrically controlled hydraulic valve which is disposed to be rapidly capable of controlling an oil flow. The switch actuator includes a return-connected position sensor in its cylinder and is disposed to be capable of generating a counterforce which is necessary in the cutting process. It must further be able to effectuate variations of an order of magnitude of 20 Hz with a manifestly high degree of accuracy which gives the contemplated manufacturing accuracy in the body in question. This accuracy is of the order of approx. 0.01 mm. The switching force must be large in the switch actuator and the mass which is to be displaced by the above-mentioned 20 Hz is of the order of approx. 4 kg. As example of a switch actuator which is applicable in this context, mention may be made of a hydraulic switch actuator of the MOOG brand, type hydraulic cylinder E 851 and an associated electrically switchable valve of the E 769 type. Alternatively, use may be made of a worm gear device as described in connection with Fig. 7 and including a worm gear of SKF make together with a brushless DC motor of, for instance the type MOOG D 313-002A. As an alternative to this motor, use may be made of another rapid acceleration motor. Given that the function and construction of the switch actuator 93 are per se known, this will not be described in greater detail here. The unit 49′ also includes a milling spindle 94 which displays a longitudinally displaceable rotary spindle 95 which is journalled with extreme flexural rigidity with the aid of a ball screw 96. Forwardly, the rotary spindle is provided with an anchorage 97 for a tool 98. As an example of applicable tools, mention may be made of a milling tool. The piston of the cylinder 93 is designated by reference No. 99, and the spindle 95 is actuated from the piston via a transmission section 100 which includes an angularly inclined portion 101 which projects into a recess 102 in an actuation portion 103 for the spindle 95. The portion 102 actuates the actuation portion 103 in the recess 102 via a ball bearing 104. The spindle is actuated from the actuation portion 103 at its rear regions. At its forward regions, the spindle is rigidly journalled by means of the ball screw 96 along a portion which constitutes approximately half of the total extent of the spindle. This total extent is indicated by reference L, and the above-mentioned portion by reference 1. The longitudinal displacement movements of the spindle along its longitudinal axis 105 are disclosed by the arrows 106. In the figure, the tool 98 has been shown in two different longitudinal displacement positions, the outer longitudinal displacement position having been shown by broken lines with reference No. 98′. The rotary portion 107 in the unit 48′ is also journalled in an extremely flexural rigid manner. The rotary portion 107 carries, at its end, chuck means 108. The blank 109 is fixedly clampable in the chuck means 108 by means of a bracket 110. In addition to its rotary mo

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vement about its longitudinal axis 111, the portion 107 is longitudinally displaceable along its longitudinal axis 111. The blank 109 is shown in two different positions, the outer position being indicated by reference No. 109'. In this latter position, the above-mentioned co-operation takes place with the tool 98. The rotary portion 107 is journalled in a block 112 via a sliding bearing which is formed by a recess in the block 112. This sliding bearing is of manifest length, and has a length which is at least half of the length of the portion 107. The portion 107 is disposed with a relatively extremely slight overhang or extremely slight projecting portion 113 from the end surface 112a of the block. The chuck means 108 is permanently secured in the rotary portion 107 in a per se known manner. The axes 106 and 111 make an obtuse angle α which is preferably selected within the range of between 30 and 60° and, in the illustrated case, is approx. 45°. In accordance with the above, this angle may be varied within an angular range not specified more closely here, for example an angular range of between 10 and 80° or less. Rotation of the portion 107 is performed by means of the motor 52'. In this instance, the motor is selected so as to be able to give high speeds of rotation of the rotary portion 107, e.g. speeds of up to 60,000 rpm. The longitudinal displacement in the direction of the arrows 114 of the portion 107 is realized with the aid of the motor 51'. At the end 115 of the portion 107, a screw 116 is non-rotationally secured, the thread of the screw co-operating with an internal thread in a recess in a block 117. The screw 116 is rotary by means of the motor 51' such that it can be threaded into or out of the recess in the block 117. The portion 107 is, in this instance, disposed to accompany the longitudinal, displacement movement of the screw depending on the rotary movements of the screw. The rotary movements of the motors 51' and 52', respectively, are transmitted to the screw and the part 107, respectively, by belt drive 118 and 119, respectively. The screw is fitted with a rotationally fixed wheel 120, and the motor with a drive wheel 121 across which wheels 120 and 121 the belt 118 is laid. Correspondingly, the portion 108 has a non-rotationally disposed belt wheel 122, and the motor 52' a drive wheel 123, over which wheels 122 and 123 the belt 119 is laid. The blocks 112 and 117 are fixedly secured in a frame 124. The recess with the thread which corresponds to the outer thread of the screw is disposed in a bushing-like device 125. The motors 51' and 52' are disposed on a plate 126 which accompanies the longitudinal displacement movement of the portion 107. The motor 51' may rotate at a speed of between 0,5 and 5 rpm. The motors 51' and 52' may consist of stepping motors whose speed is divided into 400 steps. The pitch of the screw 116 is of approx. 2 mm/turn. At its end 115, the unit is journalled in a fork journal. Two ball bearings 127, 128 are included in this fork bearing. The belt 119 and the belt wheel 122 extend into the space between the fork portions 129 and 130.

Fig. 7 shows a switch actuator in the form of a worm gear device (cf. 93 in Fig. 5). This so-called worm gear servo includes per se known parts and will not, for thesee, be described in detail here. The servo includes a brushless DC motor 130 or servo motor. A worm 131 is rotated in either direction by the motor. A milling spindle 132 is longitudinally displaced in its longitudinal direction along its longitudinal axis 133 depending on rotation of the screw 131. The spindle 132 is journalled in a bearing bracket 134 with rolling bearing arrangement 135. The motor and the bearing bracket are disposed in a block 136. The moving parts are protected by a selector arrangement 137, 138 and 139. This design is also characterized by a high degree of rapidity and extreme switching force. A tool 140 is secured in the end of the spindle. The stations A-D and the stations E-I may form first and second stations disposed on the transmitting and receiving side, respectively, of a communication connection K.

The present invention should not be considered as restricted to the embodiment described above by way of example, many modifications being conceivable without departing from the spirit and scope of the inventive concept as herein disclosed and defined in the appended claims.

Claims

1. A procedure for producing individually designed, three-dimensional bodies (45, 46) intended to form at least parts of artificial replacements for teeth, dental bridges and joints; support parts for reconstruction of tissue build-up; and tools for producing whole or parts of such replacements and support parts, etc., **characterized by the steps of** identifying one or more forms of one or more of said bodies, forming a first digital representation (i1) of each respective identification, providing each respective first digital representation in memory devices (24, 25) associated with or included in a storage and processing unit (computer), handling, e.g. set-up in a file or files or in a database or databases, in the storage and processing unit of each respective first digital representation, said handling possibly including the application, for example via a terminal (26) associated with the storage and processing unit, of at least one item of information to the storage and processing unit (20) for actuation, e.g. form modification, size modification, etc., in relation to each respective first representation with each respective item of information, and generation of at least a second representation which differs from the relevant first representation depending on said actuation, activation of the storage and

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processing unit for one or more read-outs via one or more output ports of one or more of the first representations and the possible second representations, controlling one or more switch actuators/positioners (93) included in one or more machines (43, 44) for production by means of one or more of said read-outs; wherein each respective device, depending on its control, is actuated in an actuation function where a blank and a device acting thereon is brought into co-ordination because of the actuation of the device by means of relevant read-out and in which the blank is thus allocated the relevant read-out form; and wherein in cases where said actuation in relation to the first representation is to exist, such actuation is realized with the aid of said second representation and/or modification, e.g. supplementary modification, in the identification, machine setting, etc.

2. The procedure as claimed in Claim 1, **wherein** the production of one or more models of said bodies (6) and said identification are performed with the aid of the form(s) of the model(s), and/or production of a,description of each respective form of each respective model (9) or body, and wherein identification is performed with the aid of the description, said description including description parts which each respectively disclose co-ordinate indications (read-off angle of the body during read-off and position in one co-ordinate system) for each respective read-off point.

3. The procedure as claimed in Claim 1 or 2, **wherein** the description is allocated significances for form build-up, said significances consisting of predetermined codes characteristic of the build-up of the form and creating abbreviations or representations, here designated third representations, of the complete description parts and there forming an information mass which is substantially reduced in relation to the information mass of the complete description parts, and/or wherein the codes are stored in the processing unit and wherein complete first and second representations therein are generated with the aid of said codes.

4. The procedure as claimed in any one of the preceding claims, **wherein** application of the first information via an input port (21) to first memory means (secondary memory) arranged in file or database of the first information, transmission to working memory of relevant file or database content, respectively, formation (editing) by introduction of a second item of information from the terminal (26) and with the aid of the transferred file or database content, respectively, of further file(s) or database content, respectively, representing varied or form-modifying third information items of the first information, storage in the first memory (secondary memory) of said additional file(s) or said database contents, respectively, read-out, by activation of the terminal (26) request from each respective machine (43, 44), etc., of one or more said first and third items of information.

5. The procedure as claimed in any one of the preceding claims, **wherein** transition to user-friendly treatment form, e.g. a treatment form which operates on the basis of graphics in which editing may be carried out with the aid of a graphic representation on a screen, in connection with the transfer of each respective file or database content to the working memory (24), and/or wherein, on application of the first information, a program is activated for file or database processing, and/or wherein, on transfer from the first memory to the working memory, a processing program is activated which effectuates editing of the additional files or database contents, respectively, and/or wherein the file or database content, respectively, transferred to the working memory is recycled and restored in the first memory device.

6. The procedure as claimed in any one of the preceding Claims, **wherein** for making possible, by means of model, read-off or other copying, the production of implant bodies, e.g. tooth replacements, tooth crowns, prostheses, construction parts of prostheses etc. in biocompatible and mechanically durable material, e.g. titanium, ceramics, plastic, etc. two units (48, 49) are mutually longitudinally displaceable along their longitudinal axes which are preferably obliquely inclined in relation to one another, the first unit carrying a blank (53) from which the implant body or a tool part for these is produced, and the second unit carries a processing device (52) acting on said blank, in connection with its longitudinal axes (105, 114) and the mutual longitudinal displacement movements of the units are effectuated by a movement effectuating device which, depending on controls from a device generating controls, is actuated such that the blank is allocated, by the processing device, a first form associated with the implant body or tool part, respectively, wherein first and second data in respect of a second form or possible differences in relation to the first form in dimension and/or a form which is to exist for the second form are entered in memory equipment associated with computer means (20), e.g. personal computer, microprocessor, etc. included in or associated with an electric control unit in which the controls

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are generated in the form of electric control signals, and wherein the electric control signals are based on/calculated in the computer unit from relevant data of said first and second data and are entered into the movement-effectuating device whichthen includes an electrically controlled servo device, switching means (93), etc., whose movement effectuation is executed by the utilization of a slight inertia resistance in the movement-effectuating devices.

7. The procedure as claimed in any one of the preceding claims, **wherein** first information by means of which said first data may be generated is produced at a copier, e.g. a dentist, dental technician, etc., and transmitted by means of data conveying or data storing media to a central unit (E-I) which caters for production, and wherein said first data is, at the central unit, entered in said electric control unit/computer device on the basis of the first information items, and/or wherein said data conveying medium includes a transmission line (K), e.g. a hooked-up and/or permanent communication in the public telecommunications network (82), and wherein transmitter and reception devices (91, 92) which preferably include modems, are disposed connectible to said transmission line for transfer of the first information, and/or wherein said second data in respect of different percentages in enlargement and reduction of the second form, different form modifications of the first form in relation to the second form, etc., are entered in said memory equipment/computer device (20), and wherein the relevant second data is selected by means of actuations of terminal devices (26, 40) associated with or connected to said computer devices (20, 34).

8. The procedure as claimed in any one of the preceding Claims, **wherein** the blank and tool-carrying units (48, 49), or one of the blank and tool-carrying units is controlled by the electric control unit for obtaining an optimum manufacturing time in respect of machining speed and accuracy, and wherein each respective rotary unit is in such instance longitudinally displaced depending on the complexity of the first or second form such that, in such first portions of the first or second form, respectively, as represent a first part form which permits a certain first maximum machining speed or unit, respectively, is longitudinally displaced at the first maximum machining speed, in such second portions of the first or second form, respectively, as represent a second part form which permits a certain second maximum machining speed which differs from the first maximum machining speed, unit, respectively, is longitudinally displaced at the second maximum machining speed, and so on.

9. Apparatus for realizing the procedure as claimed in Claim 1 for producing individually designed, three-dimensional bodies (45, 46) intended to form at least parts of artificial replacements for teeth, dental bridges and joints; support parts for reconstruction of tissue build-up, and tools for producing whole or parts of such replacements and support parts, etc., **wherein** identification means (11, 12) are provided for identifying one or more forms of one or more of said bodies (9), wherein means are provided for forming a first digital representation of each respective identification, wherein a storage and processing unit (computer) receives each respective first digital representation in memory devices (23, 25) associated therewith, wherein the storage and processing unit handles, e.g. sets up a file (files) or database (databases) for each respective first digital representation, said handling optionally including the application, e.g. via a terminal (26) associated with the storage and processing unit, of at least one item of information to the storage and processing unit for actuation, e.g. form modification, size modification, etc., in relation to each respective first representation with each respective item of information, and generation of at least a second representation which differs from the relevant first representation depending on said actuation, wherein said storage and processing unit is actuable for obtaining one or more readouts via one or more output ports (22) of one or more of the first representations and the possible second representations, wherein one or more switch actuators/positioning devices are disposed controllable by means of one or more of said readouts, wherein each respective device, depending on its control, is actuable in an actuation function in which a blank (53) and a device (52) acting thereon may be brought into co-ordination with each other as a result of the actuation of the device by means of relevant read-out, and in which the blank is by such means allocated the relevant read-out form, and wherein said identification means, machine or machines, etc., are actuable for realizing/occasioning a second representation and/or modification which differs from the first representation.

10. The apparatus as claimed in Claim 9, **wherein** for realizing production, by means of model, read-off or other copy, of tools, replacement, support body in the form of implant body, e.g. tooth replacement, tooth crow, prosthesis, construction part for prosthesis, etc., in biocompatible and mechanically durable/hard material, e.g. titanium, ceramics, etc., there are included two blank and

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tool-carrying units (48, 49) which are mutually longitudinally displaceable along their axes of rotation which are preferably inclined at an angle in relation to one another, said first unit (48) being disposed to carry a blank, from which the implant body or a tool part for these may be produced, and the second unit (49) is disposed to carry a processing device (52) by means of which the blank is formable, and movement-effectuating means depending on controls from a device generating the controls, to realize mutual longitudinal displacement movements for the units so that the processing device allocates to the blank a first form associated with the implant body or tool part, respectively, wherein the device generating the controls includes an electric control unit (42) which comprises or is connected/connectible to computer means, e.g. a personal computer, microprocessor, etc., in whose associated memory devices first and second data may be entered in respect of a second form relating to the model, the read-off or the copy, or a difference in relation to the first form, respectively, in dimension and/or form which is to exist for the second form, and wherein the control unit, depending on relevant data from said first and second data generate electric signals to the movement-effectuating device whichthen includes or consists of electrically controlled servo devices, switch actuators, etc., with slight inertia resistance.

11. The apparatus as claimed in Claim 9 or 10, **wherein** the electric control unit is included in a distribution system for transfer of first information, by means of which said first information, by means of which said first data may be generated in the memory equipment/computer device (20), said distribution system including a number, preferably a plurality, of initiation or gathering devices for said first information, and data storing and/or data transmitting/data transferring devices for said first information from said stations to a central station including the electric control unit and memory equipment/computer device, said first information being converted into said first data in the memory equipment/computer device in connection with transfer of the first information to the central station or after a short or lengthy intermediate storage in the central station (E-I), wherein the data transmitting devices include transmitter and receiver means (28, 30) and transfer communications between said transmitting and receiving stations, respectively, and wherein said transfer communication includes permanent and/or hook-up connections in the public telecommunications network to which said transmitter and receiver means are connected/connectible via modems, and/or wherein said electric control unit is operative to control the one or both of the rotary units for their mutual longitudinal displacement movements at speeds which are dependent upon the complexity of the form in question, e.g. in complicated form portions of the form in question at a first speed, in less complicated form portions of the form in question at a second speed which exceeds the first speed, and so on, and/or wherein in such forms in question or in such part forms of forms in question in which the processing device cannot operate above the axis of rotation of the blank because of the total configuration of the form in question, the electric control unit controls each respective rotary unit such that processing in certain phases takes place only under a part of a rotation turn for each respective rotary unit, and/or wherein it includes two or more pairs of rotary units where each respective pair is included in a machine or machine part allocated thereto, and wherein the electric control unit controls, directly or via subordinate control units, the different unit pairs/machines/machine equipment parts on the basis of the same model/read-off/copy.

12. The apparatus as claimed in Claim 11, **wherein** the first pair of rotary units/a first machine/a first machine equipment part shapes a first blank which forms or is to form the implant body and which has an outer configuration which corresponds to the outer configuration of the model/the read-off/or the copy, or has been allocated said difference in relation to the outer configuration of the model/the read-off/the copy, and wherein at least second and third pairs of rotary units/second and third machines/second and third machine equipment parts shape second and third blanks, respectively, which form first and second tool parts in the form of electro-erosion devices intended for the production of an inner configuration of the implant body which then obtains socket form in its final configuration, cf. tooth crown, which first tool part forms a rough production part which has been provided with frontal wear durability for compensation of frontal wear in electro-erosion and which second tool part forms a fine production tool part with close association to the second form.

13. The apparatus as claimed in any one of Claims 9-12, **wherein** said units (48) carry the blank or processing device, respectively, with manifest flexurally rigidly journalled shafts with slight overhang between a part supporting the blank or processing device, respectively, and an axle bearing/an immediately proximal axle bearing.

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14. The apparatus as claimed in any one of Claims 9-13, **wherein** a first station (A-D) includes description, storage and transmission functions, and wherein a second station (E-H) includes receiving and processing functions, and wherein each respective station includes computer devices (C and F) connected or connectible to each respective end of a communication connection (K, K') uniting the stations.

15. The apparatus as claimed in any one of Claims 10-14, **wherein** a computer device (34) is disposed to control one or more machines by control information relating to speed of the blank-carrying unit, mutual longitudinal displacement movements of the units carrying blank and tool.

16. The apparatus as claimed in any one of Claims 10-14, **wherein** the units carrying blank and tool are disposed at mutual angular adjustment between their longitudinal axes, and/or wherein the angular adjustment is variable by means of manual or electric adjustment.

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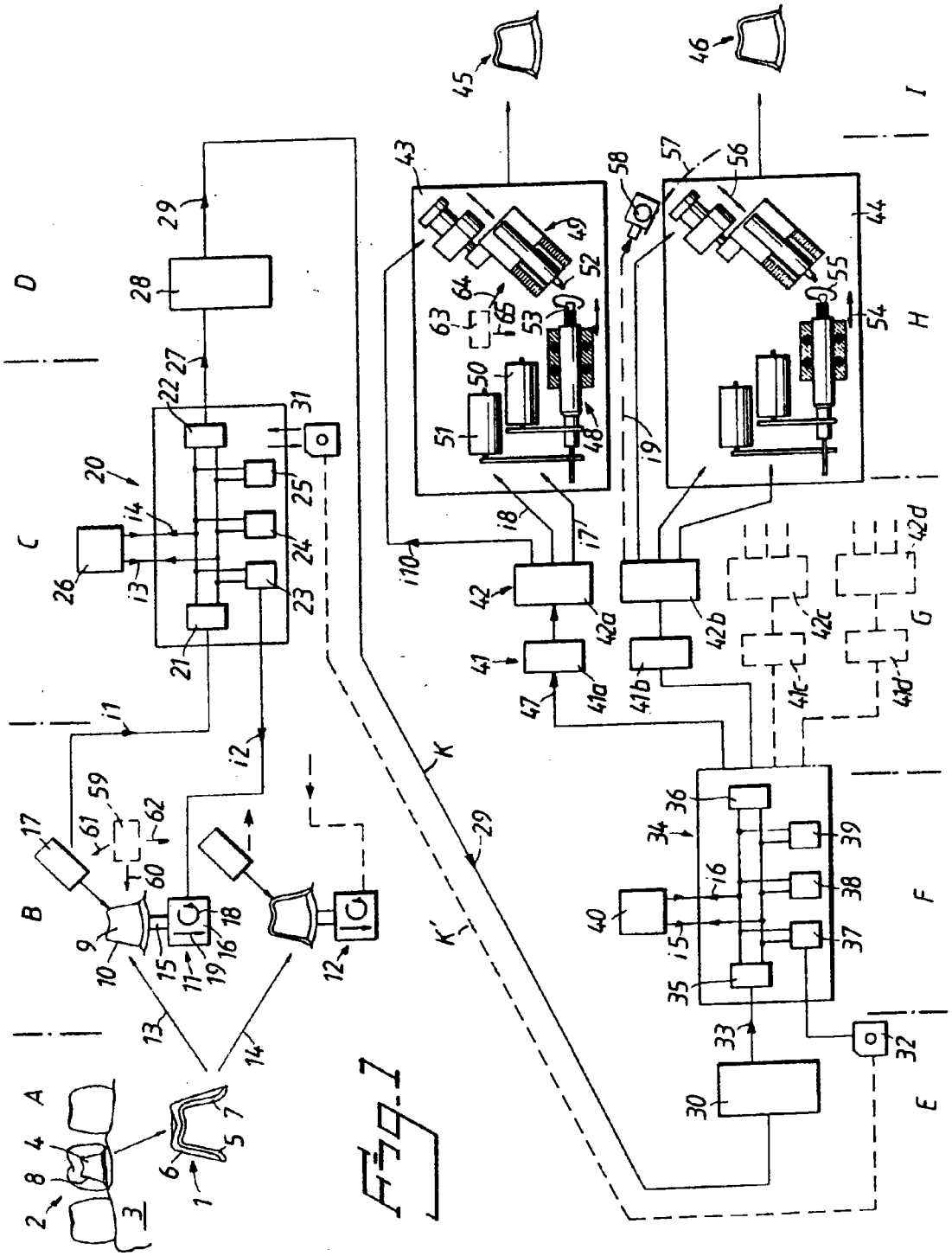


Fig. 1

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Fig. 2

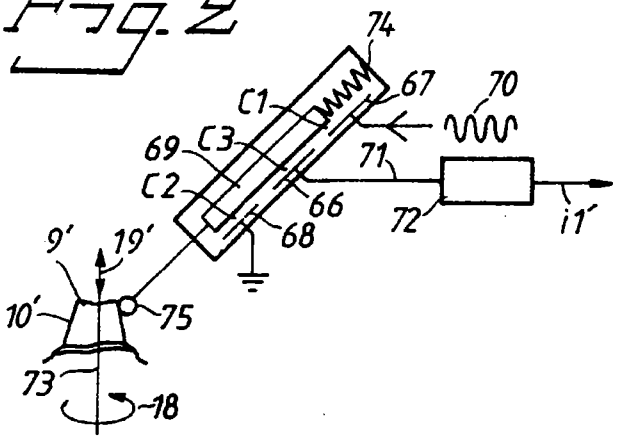


Fig. 3

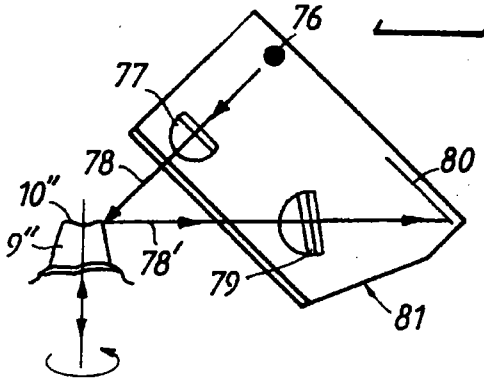
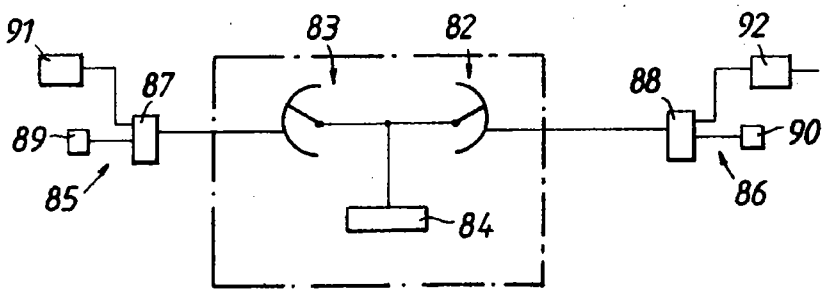


Fig. 4



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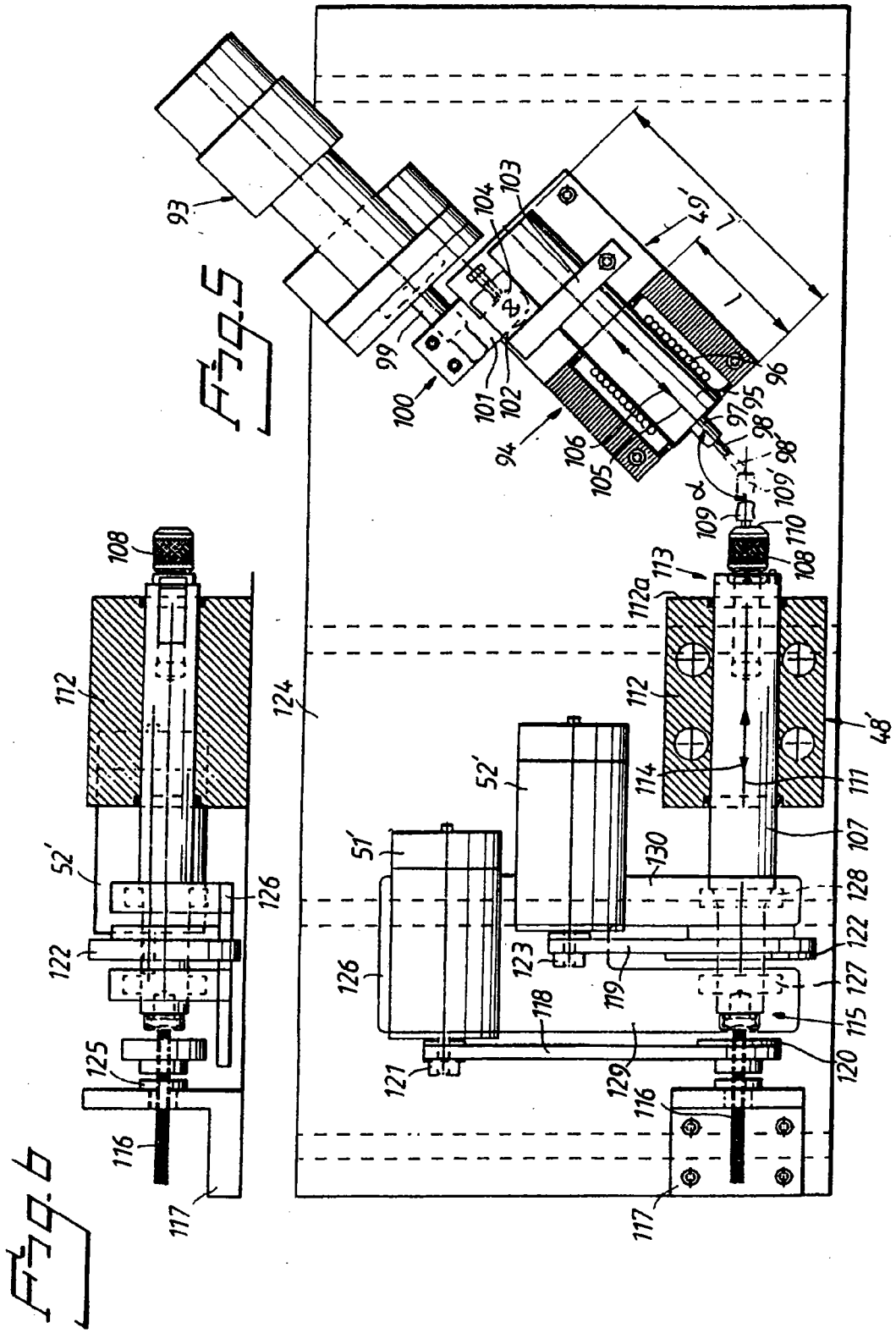
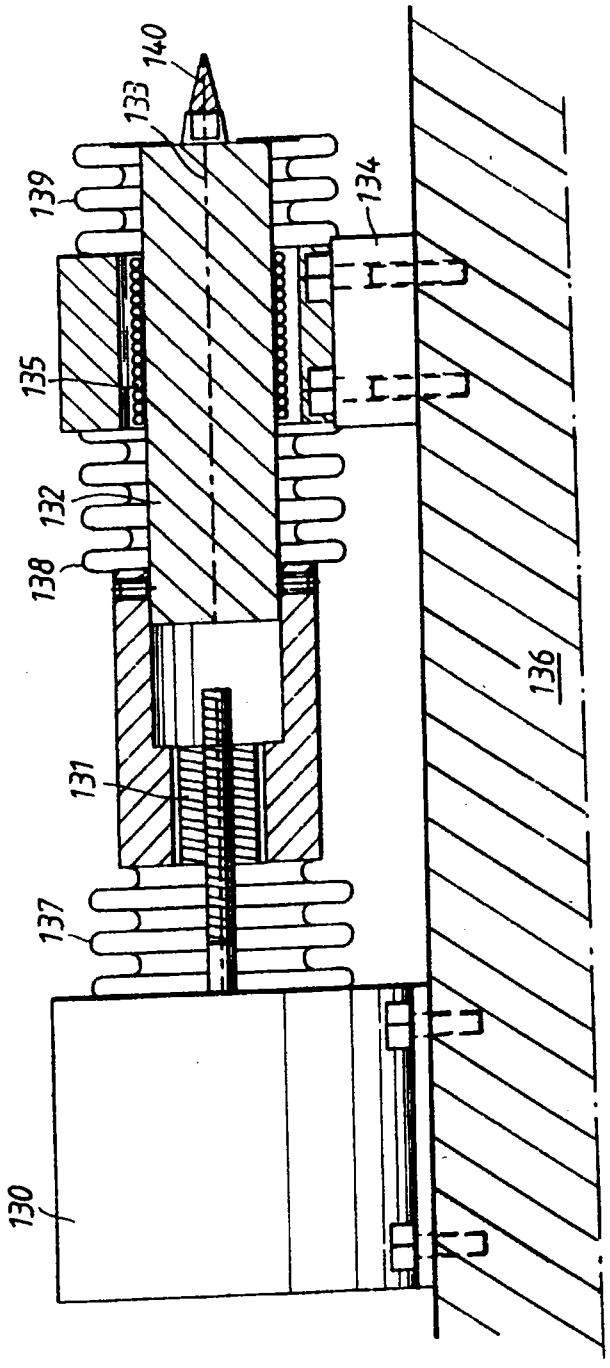


Fig.5

Fig.6

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Фиг. 7



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Device for taking impressions by optical means, particularly for the automatic shaping of dental prostheses

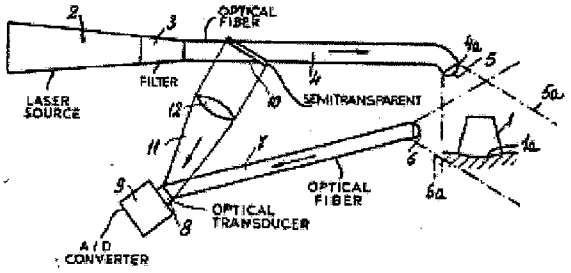
Patent number: EP0091876
Publication date: 1983-10-19
Inventor: DURET FRANCOIS
Applicant: DURET FRANCOIS (FR); MICHALLET E EPOUSE DURET (FR); TERMOZ CHRISTIAN (FR)
Classification:
- international: A61C5/10; A61C9/00; A61C19/04
- european: A61C5/10; A61C13/00C1; A61C19/04; G05B19/42B2
Application number: EP19830420065 19830414
Priority number(s): FR19820006707 19820414

Also published as:
US4611288 (A1)
JP58187802 (A)
FR2525103 (A1)

Cited documents:
EP0040165
EP0025911
EP0054785
EP0033492
FR2121483

Abstract not available for EP0091876
Abstract of corresponding document: **US4611288**

Dental prostheses, such as crowns, inlays or dentures are produced automatically based upon an optical impression taken of the oral region wtih nontraumatic radiation. The reflected waves are transformed into numerical data which is used directly to operate a numerically controlled machine in the fabrication process. The process is pertinent to other medical applications as well.



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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Numéro de publication: **0 091 876**
A1

(12) # DEMANDE DE BREVET EUROPEEN

(21) Numéro de dépôt: **83420065.1**

(22) Date de dépôt: **14.04.83**

(51) Int. Cl.³: **A 61 C 5/10**
A 61 C 9/00, A 61 C 19/04

(30) Priorité: **14.04.82 FR 8206707**

(43) Date de publication de la demande:
19.10.83 Bulletin 83/42

(84) Etats contractants désignés:
AT BE CH DE FR GB IT LI LU NL SE

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(54) **Dispositif de prise d'empreinte par des moyens optiques, notamment en vue de la réalisation automatique de prothèses.**

(57) Ce dispositif comprend des moyens émetteurs d'ondes lumineuses (2, 3), des moyens optiques (4, 5) dirigeant ces ondes sur l'objet à analyser (1), et des moyens optiques récepteurs (6, 7) dirigeant les ondes réfléchies sur un capteur (8) associé à un convertisseur analogique-numérique (9). On obtient ainsi, sous forme de signaux numériques, une représentation de la forme de l'objet (1) dans les trois dimensions de l'espace. Ces signaux sont analysés et traités pour commander automatiquement une machine-outil à commande numérique qui réalisera une prothèse exactement adaptée. Application : en art dentaire, confection automatique d'une prothèse du type couronne s'adaptant sur un moignon de dent (1) constituant l'objet analysé.

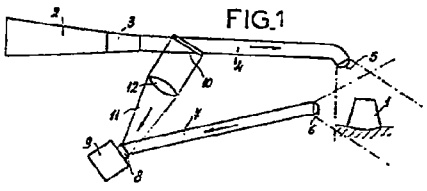


FIG.1

EP 0 091 876 A1

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"Dispositif de prise d'empreinte par des moyens optiques, notamment en vue de la réalisation automatique de prothèses"

La présente invention se rapporte à un dispositif de prise d'empreinte par des moyens optiques, notamment en vue de la réalisation automatique d'une prothèse, et encore plus particulièrement la réalisation de prothèses telles que les couronnes utilisées en art dentaire, cette application n'étant toutefois pas limitative, en ce sens que le dispositif est aussi utilisable pour l'établissement d'un diagnostic odontologique qui n'est pas suivi de la confection d'une prothèse.

Très peu d'études ont, jusqu'à présent, eu pour objet la prise d'une empreinte par des moyens optiques, dans le domaine de l'art dentaire, et les réalisations concrètes sont actuellement inexistantes. On peut citer le brevet US N° 3 861 044 (SWINSON), document décrivant un procédé qui consiste, pour faire l'empreinte d'une cavité creusée dans une dent et réaliser un insert (ou "inlay") destiné à se loger dans la cavité, en la séquence d'opérations suivante :

- préparation de la dent défectueuse ;
- réalisation d'une représentation photographique de la dent avec sa cavité ;
- transfert d'un signal représentatif de l'image photographiée à une machine-outil commandée automatiquement ;
- remplissage de la dent préparée avec de la cire ;
- réalisation d'une nouvelle représentation photographique de la dent, cette fois remplie de cire ;
- transfert d'un signal représentatif de la nouvelle image photographique à la machine-outil commandée automatiquement ;
- fonctionnement automatique de la machine-outil à partir des signaux précédents, afin d'usiner un insert dentaire de forme adaptée ;
- mise en place de l'insert dans la cavité de la dent.

Cette technique arbitraire, telle qu'elle est décrite dans le document auquel il est ici fait référence, présente de nombreux inconvénients ainsi que des insuffisances diverses :

1. Une image photographique ordinaire ne peut représenter qu'en deux dimensions l'objet dont la forme est à analyser. Si l'on veut reconstituer par ce procédé les trois dimensions de l'espace, il faut réaliser un grand nombre de photographies, par exemple de l'ordre du millier au minimum, avec une précision de 100 microns, pour chaque élément

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à analyser.

2. Il n'est pas précisé quelle est la nature des signaux transmis, supposés représentatifs des images photographiques réalisées, et en particulier si ces signaux sont analogiques ou numériques. Or un usinage automatique ne peut se faire qu'au moyen d'une machine-outil à commande numérique, et dans le cas considéré l'on ne voit donc pas concrètement comment la machine pourra effectuer un travail déterminé, ni surtout un positionnement strict de la pièce à usiner, à partir d'images photographiques traduites en des signaux de nature indéfinie.

3. Dans le procédé évoqué, le praticien doit remplir la cavité de cire. Cette technique est possible pour les inserts, mais inapplicable à d'autres types courants de prothèses pour dents, notamment les couronnes, ce qui exclut bien évidemment ce genre d'applications.

4. De plus, le remplissage de cire et son utilisation constituent une sorte de prise d'empreinte par moulage ; le procédé exige ainsi des opérations matérielles sur la dent à traiter et ne peut s'assimiler à une prise d'empreinte complète par des moyens purement optiques ; le temps de mise en oeuvre reste donc également important. Enfin, le second signal photographique, obtenu à partir de ce remplissage de cire, est toujours aussi imprécis (reconstitution des trois dimensions ?), et cette imprécision se répercute évidemment sur le résultat final obtenu.

La présente invention remédie à ces inconvénients, en fournissant des moyens d'analyse en trois dimensions, adaptés à toutes applications odontologiques et médicales, en précisant les moyens permettant d'analyser l'image et de fournir un signal directement utilisable par une machine-outil à commande numérique, ceci d'une manière très rapide tout en offrant une possibilité de vérification de la qualité d'analyse, et en permettant l'usinage automatique d'une prothèse complète uniquement à partir de l'empreinte optique réalisée et d'algorithmes de travail, sans aucune intervention intermédiaire en bouche ou sur une autre partie du corps devant recevoir la prothèse, les moyens fournis étant économiquement intéressants dans la mesure où ils comportent un large champ d'application et apportent un gain effectif de temps et de main-d'oeuvre.

A cet effet, la présente invention a pour objet un dispositif de prise d'empreinte par des moyens optiques, notamment en vue de la réalisation automatique de prothèses, ce dispositif comprenant essentiellement, en combinaison, des moyens émetteurs d'ondes lumineuses ou

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acoustiques non traumatisantes, des moyens pour diriger lesdites ondes sur la partie du corps, telle qu'emplacement de dent, à analyser, des moyens récepteurs des ondes lumineuses ou acoustiques réfléchies par cette partie du corps, dirigeant lesdites ondes sur un capteur associé à un convertisseur analogique-numérique, permettant d'obtenir sous forme de signaux numériques une représentation de la forme, dans les trois dimensions de l'espace, de la partie du corps à analyser, et des moyens d'analyse et de traitement des signaux numériques obtenus, notamment en vue de la commande automatique d'une machine-outil à commande numérique pour l'usinage d'une prothèse, telle qu'une prothèse dentaire adaptée exactement à la partie du corps analysée.

Le dispositif selon l'invention permet de saisir toutes les caractéristiques de forme de la zone à analyser par des moyens de nature purement "optique", en excluant l'analyse photographique, le terme "optique" incluant ici aussi bien l'utilisation d'ondes typiquement optiques que l'utilisation d'ondes acoustiques, du moment que ces ondes permettent de réaliser directement une analyse en trois dimensions, et ne sont bien entendu pas traumatisantes pour les tissus de la partie analysée du corps du patient. Le capteur et le convertisseur utilisés doivent correspondre au type d'ondes mis en oeuvre, et l'ensemble doit permettre de relever des détails de forme avec une précision suffisante, par exemple inférieure ou égale au millimètre.

Dans le cas d'utilisation d'ondes de lumière cohérente, le dispositif comprend avantageusement une source laser, au moins une fibre optique et une lentille pour diriger le faisceau incident vers la partie du corps à analyser, au moins une autre lentille et une autre fibre optique pour recueillir le faisceau réfléchi et le diriger sur le capteur associé au convertisseur analogique-numérique, et un système optique tel qu'à miroir semi-transparent et lentille, dirigeant en outre sur ledit capteur un faisceau de référence, pour une analyse par interférence ondulatoire. La source laser, le capteur et le convertisseur se placent ainsi dans un boîtier extérieur à la bouche, où se produit l'interférence, ce boîtier étant relié par les fibres optiques à une tête d'analyse mobile, de faibles dimensions, amenée dans la bouche du patient. En variante, le montage peut comprendre une seule fibre optique guidant à la fois le faisceau incident et le faisceau réfléchi, et il est possible aussi de supprimer toute fibre optique, si la tête d'analyse inclut la source d'éclairage et le capteur,

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avec les lentilles toujours nécessaires et est raccordée par des liaisons purement électriques avec un boîtier extérieur incluant l'alimentation électrique et le convertisseur analogique-numérique.

Une méthode particulière évitant le dépouillement de l'hologramme ou sa lecture consiste à utiliser un laser émettant deux rayons de longueurs d'onde légérement différente presque simultanément ou simultanément par le passage optique non linéaire (au travers de cristaux minéraux ou organiques), dans des pulsions brèves ou des intensités faibles en continu. Ceci permet la création de "courbes de niveau" analysables par un logiciel classique de squelettisation.

Dans le cas d'utilisation de lumière non cohérente, on peut toujours recourir à des fibres optiques mais le montage devra comprendre en outre, pour permettre l'analyse par interférométrie holographique, des trames de repérage, associées respectivement à la source émettrice et au capteur, et des moyens permettant de déterminer ou de fixer la distance entre les moyens optiques de la tête d'analyse et un plan de référence lié à la partie du corps à analyser. Une première solution, dite "dynamique", consiste à placer sur la tête d'analyse un émetteur-récepteur d'ultra-sons ou d'infra-rouge déterminant la distance au plan de référence au moment précis où est réalisé l'éclairage pour l'analyse.Une seconde solution, dite "statique", consiste à prévoir sur la tête d'analyse un repère de longueur connue, destiné à reposer sur un point de la partie du corps à analyser.

On peut envisager par ailleurs l'utilisation de fibres optiques à gradient d'indice, pour simplifier voire supprimer toutes les lentilles se trouvant vers l'objet ou la caméra. Ce système est applicable tant en lumière cohérente qu'en lumière non cohérente.

Des systèmes de miroirs, et des optiques plus ou moins "larges", permettent l'analyse de zones plus ou moins étendues, pouvant posséder des faces orientées différemment les unes des autres, ou des faces qui ne peuvent être directement éclairées et/ou observées.

Le capteur, atteint par le faisceau réfléchi et aussi éventuellement par un faisceau de référence, est avantageusement du type photosenseur à transfert de charge, notamment un photosenseur du type CCD matriciel, ou encore un tube vidicon modifié. L'intérêt du photosenseur CCD sur le système vidicon est qu'il fournit une analyse plan par plan ; par contre le nombre de niveaux de gris y est inférieur, actuellement.

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Afin de ne pas surcharger les moyens de traitement des données, l'analyse se fait en fixant les coordonnées suivant deux dimensions, par exemple en des points correspondant à des intervalles de 20 µ, et en ne faisant varier que les coordonnées suivant la troisième dimension de l'espace.

Suivant un mode de réalisation, des moyens de stockage de l'information sont insérés entre le capteur et le convertisseur analogique-numérique proprement dit, lequel délivre vers les moyens de traitement des signaux de sortie "point par point", transformés par une interface pour leur adaptation aux moyens de traitement numérique, des moyens de visualisation des données saisies étant en outre prévus, en liaison avec les moyens de stockage précités.

La visualisation doit être de préférence prévue, pour information et vérification, afin de pouvoir apprécier si l'empreinte optique réalisée est totale, précise, exploitable et prise sur un travail préparatoire (taille d'un moignon de dent) effectué correctement. Plus particulièrement la visualisation est avantageuse avant conversion analogique-numérique, afin de limiter le champ d'action (suppression des informations jugées inutiles) et vérification de la qualité de la saisie des données. La visualisation de l'image sous sa forme obtenue après conversion analogique-numérique est aussi utile, pour apprécier ligne par ligne la précision des données. Le choix de la meilleure image, à retenir pour le traitement numérique ultérieur, poura être manuel et facilité par une visualisation interactive, ou même être entièrement automatique.

Le traitement numérique, préalable à la réalisation d'une prothèse, doit dans le cas pris ici pour exemple d'une couronne dentaire tenir compte encore d'autres données que les seules caractéristiques géométriques du moignon de dent, déterminées comme résultat de l'analyse optique, et à cet effet les moyens d'analyse et de traitement comprennent encore, de préférence :

- des moyens de détermination et de prise en compte de l'enveloppe, ou volume à l'intérieur duquel doit s'inscrire la dent reconstituée ;

- des moyens de détermination et de prise en compte de l'occlusion, statique et dynamique ;

- éventuellement, des moyens de détermination et de prise en compte des couleurs ou teintes de dents.

Plus particulièrement, l'enveloppe de la prothèse, considérée

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comme un volume limité par 6 plans, peut être obtenue par détermination :

a) des zones de contact des dents voisines,

b) des plans tangents à l'arcade ou déterminés sur le côté symétrique, pour les faces vestibulaires ou linguales,

c) des limites inférieures du moignon analysé en bouche, pour le plan inférieur, et

d) du plan supérieur en fonction d'une analyse mathématique issue soit de l'étude des zones d'usure de l'ensemble du maxillaire, soit du déplacement réel de la mandibule.

Dans le cas d'application de l'invention à la confection automatique de prothèses mobiles, l'occlusion réelle pourra être déterminée non seulement par la prise d'empreinte optique mais encore par une analyse faciale et buccale du patient sur lequel on aura préalablement placé un certain nombre de repères buccaux, évitant une étude de l'articulation temporaux-maxillaire par le moyen classique, très coûteux, de l'articulateur.

L'occlusion pourra être déterminée par repérage des maxillaires supérieur et inférieur, prises d'empreinte optique séparées des deux maxillaires, réalisation d'une claie optique antérieure des repères des deux maxillaires, et réunion des deux maxillaires grâce à leurs repérages au niveau de la claie.

La réalisation automatique de la prothèse, telle que notamment couronne, passe par les étapes suivantes, exploitant les opérations d'analyse et de détermination diverses exposées précédemment :

1. Réalisation de la partie interne de la prothèse, en fonction essentiellement de l'empreinte optique réalisée, avec modification éventuelle des données brutes selon le type de fixation (espace souhaité pour le ciment, ou fixation sans joint par élasticité du métal), selon la position de l'axe d'insertion, ou selon les imperfections non corrigées de la taille du moignon.

2. Adaptation d'une forme extérieure théorique, stockée en mémoire, à l'enveloppe précédemment déterminée, et ajustage de cette forme selon la détermination faite de l'occlusion.

3. Choix du mode d'usinage et du matériau, tenant compte entre autres de la détermination préalable de couleur ou teinte.

Les outils doivent évidemment être adaptés aux dimensions et aux courbures des pièces prothétiques à confectionner, dont l'ébauche

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devra être fixée rigidement de manière à éviter les vibrations et à fournir un point de référence lors de l'usinage. Les principes connus de programmation, de repérage, et d'asservissement pour l'utilisation des machines-outils à commande numérique s'appliqueront sans difficultés, l'usinage s'effectuant de préférence sous contrôle visuel de ses différentes phases par les moyens de visualisation mentionnés plus haut.

Pour une précision recherchée de 50 microns, l'on peut estimer à 5 minutes le temps nécessaire à l'usinage d'une couronne ; la réalisation complète d'une couronne, incluant la prise d'empreinte optique, le traitement des données et l'usinage lui-même, ne devrait pas dépasser une durée totale de 15 minutes, alors que le temps nécessaire est actuellement de l'ordre d'une semaine, avec plus de 3 heures de travail effectif de dentiste et de prothésiste, en se référant au procédé classique de la "cire perdue". Le temps réel de travail est donc divisé par 12, et le temps séparant la prise d'empreinte de la pose de la prothèse est divisé par 600, tout en améliorant les conditions biologiques et physiologiques de l'opération puisque le patient pourra repartir avec sa dent reconstituée 15 mm après la fin de la taille.

De toute façon, l'invention sera mieux comprise à l'aide de la description qui suit, en référence au dessin schématique annexé représentant, à titre d'exemples non limitatifs, quelques formes d'exécution de ce dispositif de prise d'empreinte, notamment en vue de la réalisation de prothèses, et illustrant diverses applications de ce dispositif :

Figure 1 est une vue très schématique d'une première forme de réalisation de la partie optique du dispositif selon l'invention, utilisant une source de lumière cohérente ;

Figure 2 montre un détail de la tête d'analyse optique, dans un mode de réalisation particulier ;

Figure 3 est une vue d'ensemble des moyens permettant la prise d'empreinte optique, selon le principe de la figure 1, dans un agencement particulier ;

Figure 4 est un schéma de principe de la partie optique du dispositif selon l'invention, utilisant une source de lumière non cohérente ;

Figures 5,6 et 7 sont des vues d'ensemble des moyens permettant la prise d'empreinte optique, dans divers agencements adaptés à une source de lumière non cohérente ;

Figures 8 et 9 sont des schémas de systèmes optiques de

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prise d'empreinte, utilisant en outre des miroirs ;

Figure 10 montre le système optique du dispositif selon l'invention, appliqué à l'analyse des arcades ;

Figures 11,12 et 13 sont des vues de détail du système optique de figure 10, muni de divers moyens d'appui ;

Figure 14 est un schéma-bloc de la partie du dispositif réalisant la prise d'empreinte, dans le cas d'utilisation d'ondes échographiques ;

Figure 15 est un schéma-bloc des moyens de réception des ondes réfléchies, de conversion analogique-numérique et de visualisation interactive du dispositif, pour l'obtention de l'empreinte optique traduite numériquement, dans le cas d'utilisation d'un capteur du type "photosenseur CCD" ;

Figure 16 est une vue en plan illustrant la détermination de plusieurs des plans définissant l'enveloppe d'une couronne à réaliser ;

Figure 17 montre le principe d'adaptation de la forme extérieure d'une couronne, déterminée théoriquement, à la forme et à la position du moignon analysées par la prise d'empreinte optique ;

Figure 18 illustre, dans le cas d'application à une prothèse mobile, la définition des plans et surfaces d'enveloppe ;

Figure 19 est un schéma expliquant le positionnement relatif des empreintes supérieure et inférieure intervenant dans la détermination de l'occlusion réelle ;

Figure 20 est un organigramme relatif à la détermination de l'occlusion ;

Figure 21 est un organigramme relatif à l'exploitation de repères et autres capteurs, pour la prise en compte de la pathologie de l'articulation temporaux-maxillaire ;

Figure 22 est un organigramme relatif à la définition des caractéristiques d'une prothèse dentaire fixe, à sa réalisation et à son adaptation, à partir de prises d'empreintes optiques ;

Figure 23 est un organigramme relatif à la définition des caractéristiques d'une prothèse dentaire mobile, et à sa réalisation, dans le cas d'une prothèse avec antagoniste ;

Figure 24 est un organigramme des fonctions complémentaires, à réaliser dans le cas d'une prothèse dentaire mobile sans antagoniste;

Figure 25 est un schéma-bloc du principe d'usinage automatique d'une prothèse et de contrôle d'usinage, par le dispositif objet de l'inven-

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tion ;

Figure 26 montre les formes à usiner pour la réalisation d'une couronne ;

Figure 27 montre les formes à usiner pour la réalisation d'une prothèse avec pivot de fixation ;

Figures 28,29 et 30 sont des schémas définissant les données géométriques fondamentales, pour l'usinage d'une couronne ;

Figures 31,32 et 33 illustrent l'usinage du flanc d'une couronne, au moyens d'outils de fraisage de diverses formes ;

Figure 34 est un schéma illustrant l'opération d'usinage du fond d'une couronne ;

Figure 35 est une vue très schématique de la machine d'usinage à commande numérique ;

Figure 36 représente, enfin, une ébauche de couronne, la figure 37 indiquant la section de son tenon de fixation.

Les figures 1 à 13 sont relatives à diverses formes de réalisation de la partie optique, permettant une analyse en trois dimensions, par interférométrie, des détails de forme et dimension d'un objet qui, dans les premiers exemples, est un moignon de dent taillé (1), destiné à recevoir une couronne.

La figure 1 montre que dans ce but l'on peut utiliser un laser (2), comme source de lumière cohérente, qui après avoir traversé un filtre (3) est dirigée, par une première fibre optique (4), vers la zone du moignon (1) à analyser. Le faisceau d'ondes incident est dispersé sur la zone à analyser par une lentille (5), fixée à l'extrémité de la fibre optique (4). Une autre lentille (6) concentre le faisceau réfléchi, pour le recueillir dans une seconde fibre optique (7) qui le dirige sur un capteur (8), associé à un convertisseur analogique-numérique (9). Un miroir semi-transparent (10), interposé sur le trajet du faisceau incident, dévie une fraction de ce dernier pour obtenir un faisceau de référence (11), qu'une autre lentille (12) concentre sur le capteur (8).

Pour capter le faisceau d'ondes réfléchi, la tête d'analyse (13) c'est-à-dire la partie de l'appareil amenée à l'intérieur de la bouche à proximité de la zone à analyser peut posséder deux lentilles réceptrices (6' et 6''), fixées respectivement aux extrémités de deux fibres optiques (7' et 7'') qui guident le faisceau réfléchi, divisé ici en deux fractions (voir figure 2). Deux faces opposées du moignon (1) peuvent être ainsi

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analysées simultanément. La tête d'analyse (13) est munie d'une poignée de tenue (14) et raccordée par les fibres optiques (4 et 7), à un boîtier (15) situé à l'extérieur de la bouche et renfermant la source émettrice (2) ainsi que le capteur (8) et le convertisseur (9), ce qui permet d'utiliser un laser performant (voir figure 3).

Chacune des fibres optiques (4et 7,ou7' et 7"), doit être gainée pour éviter tous risques oculaires.

La figure 4 illustre le principe d'un appareil n'utilisant pas une source de lumière cohérente. Les moyens émetteurs d'ondes, désignés dans leur ensemble par le repère (16), comprennent ici une source lumineuse (17) par exemple à halogène, un condensateur de lumière (18), une trame de repérage (19) et un objectif (20). Les moyens récepteurs d'ondes, désignés dans leur ensemble par le repère (21), comprennent un objectif (20a), une trame de repérage (19a) et le capteur (8), toujours associé au convertisseur analogique-numérique. Les deux trames de repérage (19 et 23), par exemple du type "micro moiré", doivent avoir un pas connu à 10^{-3} mm près au minimum. Le nombre de franges ou quadrillage doit être déterminé avec précision (de 1mm à 10^{-3} mm, la valeur idéale étant 10^{-2} mm). La distance séparant les deux centres optiques doit être connue à 0,5 mm près, et la focale doit être connue au mm près. Ces différents facteurs sont fixés et définis constructivement. Le "moiré" peut présenter, pour l'analyse des dents, un problème de réflexion, dû à ce que la lumière incidente est de type blanche. Pour éviter ceci, on travaillera dans une gamme d'ondes ne correspondant à aucune couleur présente dans la bouche, en plaçant par exemple un filtre permettant de travailler dans le bleu ou le vert, ou entre le vert et le bleu. Il reste à déterminer ou fixer la distance séparant le plan d'analyse du capteur (8) du plan de référence, à situer toujours en dessous du rebord inférieur de la future couronne, cette dernière distance devant être connue au mm près. Une solution consiste à fixer, sur la tête d'analyse (13), un pointeau (22) de longueur convenablement choisie, destiné à prendre appui sur le moignon de dent (1) à analyser, comme le montre la figure 5 représentant un montage pratique correspondant au principe de la figure 4, et utilisant des fibres optiques (4,7',7") ainsi que des lentilles (5,6',6") comme dans le cas précédent d'une source de lumière cohérente.

Un autre montage possible est illustré par la figure 6, où une seule fibre optique (23), portant une lentille (24) à son extrémité

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munie du pointeau (22), guide simultanément le faisceau incident et le faisceau réfléchi, ce dernier étant renvoyé par un miroir semi-transparent (25) sur le capteur (8) associé au convertisseur (9).

Les fibres optiques peuvent être aussi supprimées, comme montré sur la figure 7, en réalisant une tête d'analyse (13) incluant la source lumineuse (17) et le capteur (8), sur lesquels sont directement montés les lentilles respectives (5 et 6). Cette tête (13) est raccordée par des liaisons électriques (26 et 27) à une alimentation électrique (28) et au convertisseur analogique-numérique (9), appartenant à un boîtier extérieur (29).

Comme le montre la figure 8, un système de deux miroirs (30 et 31), ajouté au système optique réalisé selon les principes décrits précédemment, permet de dévier le faisceau incident, et le faisceau réfléchi, de manière à permettre l'analyse de la face de l'objet (1) opposée au côté directement accessible par la source (17) et le capteur (8). En variante, comme illustré par la figure 9, la combinaison d'une source lumineuse (17) d'un unique miroir (32) et de deux capteurs (8' et 8"), associés respectivement à des convertisseurs analogique-numérique (9' et 9"), permet l'analyse simultanée de deux faces opposées de l'objet (1).

Alors que l'objet (1) à analyser était jusqu'ici supposé de faibles dimensions, les figures 10 et suivantes montrent comment le système optique peut être adapté à l'analyse d'une zone plus étendue, comprenant en l'occurence l'arcade supérieure (33) et/ou l'arcade inférieure (34), pour procéder à une analyse de ces arcades en vue de situer l'ensemble de la prothèse dans le milieu buccal. Les principes de réalisation de l'appareil restent inchangés : un boîtier (15) est relié, par une fibre optique (4), à une lentille (5) diffusant le faisceau incident, tandis que d'autres lentilles (6' et 6") sont fixées au point de départ des fibres optiques (7' et 7") qui guident les faisceaux réfléchis. L'optique doit être plus "large", et le pointeau (22), lorsqu'il est recouru à cette solution en cas d'utilisation d'ondes non cohérentes, doit être adapté à l'optique et au point d'appui choisi. Ainsi peut être réalisé un appui palatin (voir figure 11) ou un appui dentaire (figure 12), ou encore éventuellement un appui vestibulaire (non représenté). Dans le même but de situer la prothèse dans son environnement, est encore réalisable une analyse de l'occlusion, frontale ou latérale, avec un élément d'appui vestibulaire

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(22 ou 22a) - voir figure 13, ainsi qu'une analyse de la face, réalisée après avoir placé sur le patient un certain nombre de repères faciaux. Des repères peuvent être notamment placés sur les dents (incisives et prémolaires), à la base du maxillaire inférieur, et au niveau du condyle ou du trou auditif, pour réaliser une analyse dynamique, avec mouvements progressifs de la mâchoire (mouvements en occlusion et extrêmes).

Dans les applications médicales de haute chirurgie, les informations numériques peuvent être obtenues à partir d'une analyse radiologique reconstituée en trois dimensions, ou par couplage sur scanner, ou par corrélation vectorielle sur image radiographique, ou encore par échographie. S'il est certain que l'on peut admettre l'échographie pour l'obtention de l'empreinte optique d'une forme dentaire, en variante des solutions décrites précédemment, l'utilisation d'ondes échographiques est intéressante surtout dans la détermination du contour d'un organe. Comme le montre la figure 14, le générateur d'ondes échographiques (35), dirigées vers l'objet (1) à analyser, doit être piloté par une horloge (36) fournissant une base de temps, et la réception des signaux réfléchis par le capteur (8), associé au convertisseur (9), s'effectue par l'intermédiaire d'un traducteur (37) et/ou d'un amplificateur (38).

Dans la mesure où l'information est prise séparément par plusieurs capteurs, il est nécessaire d'associer les images entre elles. Pour cela on peut réaliser un positionnement par rapport à un élément de référence, tel que le pointeau (22), ou encore par rapport à la circonférence la mieux captée. C'est seulement à la suite d'une telle opération de superposition que l'on peut être certain d'avoir déterminé la totalité de la forme. Pour cela il suffit d'étudier l'"espace-point", c'est-à-dire de vérifier si l'espace entre deux points est constant. Si ce n'est pas le cas, il y a insuffisance d'information.

La correction sera effectuée en rejoignant les points les plus extrêmes en respectant la courbure des points les plus voisins, le nombre de points déterminant cette courbure étant fonction de la précision de la méthode.

Une autre modification consiste à augmenter les valeurs en fonction des exigences de l'insertion de la prothèse (petites contre-dépouilles) et des propriétés physiques des ciments de scellement utilisés. Si l'on emploie des métaux "à mémoire", cette dernière opération devient inutile.

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La figure 15 représente plus en détail les moyens de réception des ondes réfléchies et de conversion analogique-numérique, permettant une analyse optique rapide et répétitive, avec visualisation simultanée pour permettre le choix de la meilleure image. Le capteur (8), recevant le faisceau réfléchi par l'objet à analyser, est ici un photosenseur du type CCD matriciel, délivrant une information qui est stockée en (39) avant de parvenir au convertisseur analogique-numérique proprement dit (9), ces différentes parties ayant toutes leurs alimentations spécifiques indiquées en (40). Le convertisseur (9) est raccordé à un circuit de sortie (41), relié par une interface (42) au calculateur (43). De plus, des moyens de visualisation (44), réalisés sous la forme d'un écran moniteur "vidéo", de préférence avec image en couleur, sont reliés de façon interactive aux circuits de stockage (43), pour contrôler le transfert d'informations vers le convertisseur (9).

Le système d'analyse avec photosenseur CCD, dont le principe est donné par la figure 15, nécessite d'avoir au minimum 100 niveaux de gris avec un système "anti-blowing", pour obtenir suffisamment d'information. Les coordonnées "x" et "y" sont données automatiquement dans le plan. Elles sont corrigées ultérieurement en fonction de la focale d'analyse utilisée, et de l'éloignement du point considéré par rapport à l'axe optique. La coordonnée "z" est le résultat d'une transforméedu type Fourier, en ondes cohérentes comme en ondes non cohérentes (avec utilisation d'une trame de repérage dans ce dernier cas). Les algorithmes mathématiques à utiliser ici sont actuellement connus.

Tous les moyens décrits jusqu'à présent permettent l'obtention d'une empreinte optique en trois dimensions notamment d'un moignon de dent (1), et sa traduction sous une forme numérique exploitable par des moyens de traitement automatique de l'information. Ce traitement numérique doit, en considérant l'application à la réalisation automatique d'une couronne, prendre encore en considération d'autres facteurs, théoriques et réels.

En particulier, comme le montre la figure 16, doit être déterminée l'enveloppe de la future couronne (45), c'est-à-dire le volume à l'intérieur duquel celle-ci doit s'inscrire. Ce volume est défini par des plans, entre autres un plan antérieur (46) et un plan postérieur (47), théoriquement tangents aux dents adjacentes (48 et 49), aux points de contact avec la dent à reconstituer, et dont la détermination pratique peut prendre

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en compte des facteurs correctifs, dûs aux mouvements physiologiques et au diastème. Le volume en question est aussi délimité par un plan latéral palatin ou lingual (50), et par un plan latéral vestibulaire (51), tangents, l'un et l'autre aux dents antérieure (48) et postérieure (49) ; ici également peuvent intervenir des facteurs correctifs, liés au type de dent à reconstituer, ces facteurs pouvant être dégressifs par exemple dans le cas d'une incisive latérale supérieure. Pour définir complétement l'enveloppe, sensiblement parallélèpipédique, dans laquelle s'inscrit la couronne théorique, il reste encore à définir un plan inférieur, donné par la limite singulaire de la couronne, tracé automatiquement ou manuellement sur moniteur, et un plan supérieur ou occlusal, déterminé en occlusion et défini comme le plan passant par le point le plus élevé de la surface occlusale de la dent antagoniste ou, en cas d'absence de cette dernière, par la limite supérieure des dents antérieure et postérieure.

Pour affiner la détermination du plan supérieur, on propose ici une méthode de détermination de la cinématique mandibulaire :

En faisant une empreinte de la mandibule avec précision, il est possible de déterminer les facettes d'usure de chaque dent. Ces facettes correspondent aux plans de glissement de la mandibule sur le maxillaire supérieur. Ces facettes sont donc l'empreinte des mouvements mandibulaires. En les étudiant dans leur ensemble il est connu depuis longtemps que l'on peut reconstituer les mouvements avec une totale exactitude.

Pour repérer ces zones il suffit de faire serrer les deux maxillaires. Les points de contacts se trouvent forcément sur ces facettes. Si ces plans se retrouvent sur chaque dent et correspondent entre eux, ce sont forcément les plans d'usure de la mandibule. Connaissant mathématiquement les interrelations entre surface d'usure et mouvements mandibulaires de ces facettes, on connaîtra les mouvements sans être obligé de faire une étude dynamique des mouvements des repères les uns par rapport aux autres.

De la même manière il découlera automatiquement le plan supérieur de l'enveloppe. En appliquant à ce plan les règles connues de l'occlusion, ne seront retenus comme zone de contact dent antagoniste-couronne que les points du type tripodisme, "long centric" ou autre stabilisant l'arcade, permettant la mastication et permettant des déplacements normaux de la mandibule.

L'on obtient ainsi six plans, auxquels doivent être tangentes les diverses faces extérieures d'une couronne théorique, pouvant être désormais entièrement déterminée en partant d'une forme de dent théorique mise en mémoire, ou en partant de l'analyse de la dent symétrique existante après correction "gauche-droite". Au cas éventuel où la dent était intacte avant l'opération de taille, il suffirait de réaliser une empreinte optique avant la taille et une empreinte optique après la taille. Pour un ensemble correspondant à plusieurs dents, il suffit de diviser l'espace considéré en une pluralité d'enveloppes unitaires.

Une fois déterminée la forme extérieure de la couronne théorique, il convient de l'adapter, comme l'illustre la figure 17, à la forme et à la position du moignon de dent (1). L'opération consiste à faire coïncider le bord inférieur (A) de la couronne (45), situé dans le plan inférieur de l'enveloppe, avec le contour (8) du moignon (1), en respectant une épaisseur minimale de matière (e) au point le plus bas. Pour cela, le profil extérieur théorique de la couronne (45') subit une correction progressive, lui conservant une allure de courbe régulière tout en lui permettant de joindre la zone de contact avec les dents adjacentes (48 et 49), d'une part, et la limite inférieure désirée, d'autre part.

En ce qui concerne la limite supérieure, une première correction à effectuer consiste à centrer la gouttière de la dent théorique sur la ligne générale des gouttières des dents de l'arcade. Une deuxième correction est celle d'occlusion statique ; elle représente une adaptation aux surfaces occlusales des dents antagonistes telle que (52) - figure 17, saisie par des moyens décrits plus loin. Une troisième correction consiste à faire un lissage mathématique en incluant la surface obtenue à l'ensemble des arcades en occlusion et en induisant des mouvements latéraux et antéro-postérieurs effectuant un lissage des données. Il est à noter que l'enveloppe peut être déterminée aussi par l'adjonction d'une coiffe déformable sur le moignon (1), le plan supérieur ou occlusal étant dans ce cas analysé en trois dimensions après avoir demandé au patient d'effectuer tous les mouvements nécessaires.

Dans le cas d'une prothèse mobile, comme le montre la figure 18, la définition de l'enveloppe est partiellement différente : on distingue toujours un plan inférieur (53), un plan supérieur (54) et un plan postérieur (55), mais les plans latéraux et antérieur sont réunis en une seule surface enveloppe incurvée (56), qui sera déterminée comme étant sensiblement

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tangente à la crête gingivale, et toutefois espacée de celle-ci de quelques millimètres, cet espacement étant fonction de la partie la plus vestibulée de la prothèse (bord libre des incisives ou rebord de la résine...). La limite inférieure de la surface (56) devra être fixée à une profondeur non traumatisante, fonction de l'empreinte optique définissant le plan inférieur (53). Au moment de la prise de cette empreinte, il sera souhaitable de faire jouer les muscles buccaux pour que son intersection avec la surface (56) ne soit pas traumatisante. Le plan postérieur (55) sera déterminé par les éléments anatomiques situant la limite théorique d'une prothèse (tubérosité rétro-molaire, trigône,...). Enfin, le plan supérieur (54), c'est-à-dire le plan d'occlusion de la prothèse résultera directement de la détermination de l'occlusion réelle, décrite ci-après en référence aux figures 19 et suivantes.

Dans ce but, s'il existe encore des contacts dentaires, l'on réalise des empreintes optiques des arcades supérieure (33) et inférieure (34), comme déjà décrit plus haut, ainsi que des empreintes optiques antérieure et latérales définissant des "claies" antérieure (57) et latérales (58). Ensuite l'on procède à l'ajustement des empreintes supérieure et inférieure l'une par rapport à l'autre, les claies permettant le positionnement mathématique exact d'un maxillaire par rapport à l'autre, d'où obtention de l'occlusion "statique".

S'il n'existe pas d'antagoniste, dans le cas d'une prothèse fixe, on se reportera au cas traité précédemment, alors que pour une prothèse mobile (complète) on procédera comme décrit plus haut, en déclenchant la prise d'empreinte de la claie de préférence au pied pour bien fixer les rapports inter-maxillaires au bon moment.

Pour la détermination de l'occlusion "dynamique", les mouvements des mâchoires peuvent être enregistrés selon un mode opératoire sensiblement identique, par analyse faciale du patient sur lequel on aura placé un certain nombre de repères buccaux. Si cette analyse faciale se fait en rayons X, il suffit d'avoir trois repères radio-opaques, liés aux maxillaires et visibles à la prise d'empreinte optique. S'il s'agit de repères émetteurs, il faut que la table d'analyse soit sensible à la longueur d'onde d'émission, et que ces repères soient visibles à la prise d'empreinte optique. S'il s'agit de repères classiques, il faut qu'ils soient visibles à tout moment durant l'analyse des mouvements. Dans chaque cas, les repères doivent être fixes à quelque 100 µ près, entre le début et la

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fin de l'analyse. Si ces repères ne sont que intra-buccaux, il faut qu'ils soient visibles à tout instant durant l'analyse des mouvements.

L'organigramme de la figure 20 illustre l'exécution de cette dernière opération, effectuée en réalisant un contrôle par les moyens de visualisation (44).

Dans tous les cas sains, cette analyse évite une étude directe de l'articulation temporaux-maxillaire. Dans les cas pathologiques, il sera cependant judicieux d'adjoindre des moyens d'étude musculaire (tension,...) et d'étude de cette articulation, le processus à suivre étant illustré par l'organigramme de la figure 21. Dans ce dernier cas, on utilisera pour les repères internes et externes un système de fixation endo-buccal sur dent ou sur gencive, collant ou à ventouse, et après enregistrement des mouvements faciaux des points externes, on prendra deux empreintes optiques, l'une avec les points de repère, l'autre pour la prothèse elle-même. Il suffit alors de positionner mathématiquement les empreintes l'une par rapport à l'autre, en ne retenant que les repères. Les mouvements faciaux permettront de donner les mouvements des mandibules dans l'espace. L'étude de l'articulation temporaux-maxillaire permettra de suivre le cas pathologique par rapport à l'occlusion, et de chercher une meilleure occlusion. La même remarque peut être faite pour l'étude musculaire.

En variante, on peut aussi appliquer ici la méthode des facettes d'usure expliquée précédemment, et retrouver ainsi mathématiquement tous les mouvements de la mandibule sans avoir à les étudier de façon dynamique.

En ce qui concerne la détermination des couleurs, la teinte d'une dent sera évaluée par un procédé connu de thermographie, en utilisant en particulier un récepteur à infrarouge à grande ouverture ou en suscitant un éclairement infrarouge. Les couleur déterminées automatiquement seront adressées, après visualisation (en couleur réelle), à la mémoire puis au stock de dents. Cette même détermination peut induire la fabrication automatique de surfaces esthétiques (inclusions automatiques de couches successives de résine ou céramique, suivie de cuissons automatiques de dents).

L'organigramme de la figure 22 résume l'ensemble des opérations relatives à la définition des caractéristiques d'une prothèse fixe, à sa réalisation et à son adaptation, à partir de prises d'empreintes opti-

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ques et autres données obtenues par les moyens précédents. Des exemples concrets de fabrication de prothèses fixes, notamment couronnes, seront décrits plus loin.

On s'intéressera, auparavant, aux principes de fabrication de prothèses mobiles, en considérant tout d'abord une prothèse mobile avec antagoniste.

Dans ce cas, les informations devant être reçues sont : l'empreinte optique des deux maxillaires, les claies frontale et latérales, les mouvements généraux des maxillaires. On effectue les opérations comme suit :

- On prend l'empreinte optique des deux maxillaires et des claies. Après les avoir visualisées et choisi la meilleure image, on effectue la conversion analogique-numérique, et l'on stocke les résultats. Il est nécessaire de bien faire jouer les muscles pour que la limite inférieure de la surface enveloppe incurvée (56) soit exacte.

- On fait une détermination d'occlusion statique et dynamique pour limiter encore plus le volume enveloppe.

- Un appel à la mémoire théorique ou le tracé manuel sur moniteur permettra de proposer un tracé de prothèse sur ce type de maxillaire et dans l'enveloppe considérée.

- Un appel à la mémoire théorique permettra le choix des dents selon le même principe que pour une prothèse fixe (adaptation à l'occlusion, aux mouvements mandibulaires, à la teinte).

- Pour des raisons esthétiques, l'usinage sera séparé pour les dents d'une part et la plaque d'autre part.

- On adoptera un système de fixation usiné sur la plaque et dont les contreparties seront usinées sur les dents. Le type de fixation choisi doit être stable et démontable. La fixation sera automatique ou manuelle.

- Une étude échographique peut permettre de connaître les zones de décharge (épaisseur gingivale).

Chacune de ces étapes sera contrôlée à tout moment et corrigée éventuellement sur l'écran moniteur de visualisation, comme le montre l'organigramme de la figure 23 qui résume l'ensemble des opérations. Le système de repérage d'usinage sera précisé plus loin.

Pour la fabrication d'une prothèse mobile sans antagoniste, les opérations sont sensiblement identiques mais nécessitent une évaluation

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plus exacte de la position de repos musculaire de la bouche, puis de celle de l'occlusion. Pour cette raison, il est ici proposé un système identique au précédent, à l'exception de fonctions complémentaires illustrées par l'organigramme de la figure 24, pour opérer une analyse plus stricte au niveau de l'occlusion :

- Analyse de la position de repos avec l'aide de capteurs musculaires et d'une analyse de l'articulation temporaux-maxillaire.

- Réduction de 2mm par exemple de la position obtenue, donnant la position d'occlusion.

- Réunion théorique des deux maxillaires sur cette dernière position.

S'il reste des dents servant de support pour la prothèse à fabriquer, le calculateur déterminera l'axe d'insertion idéal, offrant le maximum de stabilité, comme résultante de l'ensemble des axes dentaires pris séparément. Dans la mesure où l'insertion est impossible, il y aura positionnement d'attachement sur les dents les plus responsables. Enfin le calculateur choisira, pour le tracé des crochets ou le point d'ancrage des attachements, la meilleure situation.

En orthopédie dento-faciale, l'empreinte optique permet de traiter réellement l'étude des moulages de façon automatique. Elle permet d'aboutir à un diagnostic, et à la proposition d'un traitement dent par dent en associant les données radiographiques, échographiques et thermographiques. En faisant l'empreinte optique de l'arcade et des maxillaires, on pourra faire un calcul automatique des constantes servant au diagnostic. En faisant une empreinte de la face, de façon automatique on en déterminera les constantes faciales fondamentales. En associant l'empreinte optique buccale et faciale à l'analyse musculaire et radiographique, il en découlera une automatisation du diagnostic puis du traitement, chose qui était impossible jusqu'à présent. Compte tenu de l'empreinte optique des maxillaires, et des empreintes radiologiques des dents prises séparément, il y aura usinage automatique des crochets de traction des dents à déplacer et de leurs points de fixation sur les dents ou sur une prothèse mobile. En faisant une empreinte optique chaque année à un même enfant, le diagnostic se fera automatiquement l'année où l'intervention deviendra nécessaire. Enfin, en prévoyant les résultats de façon empirique, il sera possible de contrôler chaque étape du traitement.

Dans le domaine de la dentisterie opératoire, plutôt que d'utili_

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ser la photographie (selon le procédé du brevet US N° 3 861 044 signalé dans l'introduction), le dispositif selon la présente invention permet de réaliser une empreinte optique, donnant directement une image en trois dimensions, sans utiliser le support intermédiaire qu'est la photographie et en stockant au contraire directement l'information, moyennant seulement une conversion analogique-numérique. Pour déterminer le volume utile de l'obturation à réaliser, on procédera comme pour une prothèse, mais d'une façon plus rapide :

- 1er temps : détermination du volume
- 2ème temps : détermination des plans enveloppes (cavités composées)
- 3ème temps : détermination de l'occlusion statique et dynamique
- 4ème temps : usinage de l'insert (ou "inlay") d'obturation.

Le mode opératoire est donc identique à celui de la réalisation d'une prothèse fixe. Le volume de la chambre pulpaire sera évalué de la même façon afin de calibrer les instruments.

En paradontologie, les moyens d'investigation proposés par la présente invention permettent de résoudre le diagnostic "articulation temporaux-maxillaire/muscle/articulé dentaire", mais aussi celui de la dent par rapport à son support osseux. Dans le premier cas, après avoir fait un repérage de l'articulé occlusal, on y associe la position du condyle dans la cavité glénoïde et l'état de tension musculaire. On saura ainsi s'il existe une dissymétrie articulaire ou musculaire, ou toute autre pathologie liée à cet ensemble. Dans le cas du diagnostic dentaire, on déterminera par échographie ou par xérographie le contour osseux par rapport au contour dentaire et muqueux, et l'on mesurera la mobilité dentaire par empreintes optiques successives.

En chirurgie, les moyens techniques selon la présente invention seront utilisables pour situer très exactement la position d'une dent incluse (échographie).

En implantologie. si la cavité est dégagée, il sera logique d'effectuer une prise d'empreinte optique localisée, comme décrit précédemment. Si la cavité est d'une accessibilité difficile, on aura recours à l'échographie ou à la radiographie, sous différents angles. Le tout permettra d'usiner des implants adaptés très exactement à la cavité taillée, en supprimant les implants préfabriqués.

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Pour les implants juxta-osseux comme en haute chirurgie, on procédera à une visualisation en échographie, aux rayons X ou en onde pénétrante, afin de repérer les contours osseux exacts, puis on dessinera la pièce sur moniteur. Cette pièce permettra donc de fixer parfaitement les éléments éventuellement fracturés, de guider le geste du chirurgien et de réaliser la pièce avant l'ouverture de la plaie.

Le système de programmation et de communication avec l'opérateur doit évidemment être adapté à la nature des informations traitées (formes définies numériquement), en permettant la visualisation, le contrôle et la sauvegarde du travail, essentiellement en utilisant un pupitre avec clavier alphanumérique et de commande de fonctions, ainsi qu'un écran de visualisation et des moyens graphiques interactifs, permettant de "manipuler" l'image : translation, changement d'échelle, rotation,... Les données seront traitées rapidement, en "temps réel", tout en permettant de stocker le travail effectué, pour la constitution du fichier "clients" et l'exécution d'autres tâches de gestion du cabinet dentaire ou médical. Les images à traiter et les formes à usiner se ramènent essentiellement à des surfaces et volumes. Les surfaces complexes seront définies comme une fraction d'interpolation d'un réseau de points et de courbes, sur lesquels des contraintes transversales de tangence et de courbure seront imposées. Les volumes complexes devront dériver de volumes polyédriques imposés par les limites de l'enveloppe optique et par les possibilités d'insertion de la pièce prothétique. Une dernière fonction moins abstraite sera la préparation de l'usinage par commande numérique, à partir des éléments stockés dans la mémoire, avec contrôle permanent, l'opérateur n'ayant pas à choisir le travail car il sera présélectionné (fonctions réduites).

Le schéma-bloc de la figure 25 résume le principe d'usinage automatique d'une prothèse et de contrôle d'usinage.

Plus particulièrement, deux types d'usinage sont à envisager, dans le domaine de la prothèse et de la dentisterie opératoire, à savoir l'usinage du support et l'usinage de la ou des pièces esthétiques. L'usinage du support doit s'adapter aux surfaces existantes, telles que celles du moignon, déterminées par les moyens exposés précédemment. La partie en contact avec la bouche suivra les règles connues. Pour la partie supérieure, plusieurs possibilités sont offertes :

Comme montré en haut de la figure 26, si le matériau utilisé

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est esthétiquement et biologiquement acceptable, le support est usiné en fonction de toutes les données à prendre en considération, pour constituer lui-même la totalité de la couronne (45) à réaliser, s'adaptant sur le moignon (1).

Le support (59) peut aussi, comme montré au bas de la figure 26, comporter des points de fixation (60), usinés pour la mise en place d'une pièce esthétique (61) qui viendra recouvrir exactement le support (59), l'ensemble constituant la couronne (45).

Dans le cas d'un moignon (1) trop réduit, le support (59) peut encore comporter un pivot de fixation (62), éventuellement fileté, comme le montre la figure 27.

Les points de fixation, tels que (60), peuvent être : des axes très rigides de dimensions déterminées avec précision, sur lesquels viendront se fixer des éléments avec formes d'ancrage complémentaires (en ciment, métal...) - des boutons-pressions, amortis,... attachements pouvant se fixer sur l'axe rigide et supportant l'élément esthétique - des systèmes de vissage - des moyens de collage.

En chirurgie et en orthopédie dento-faciale, l'usinage peut concerner en outre des points de fixation de ressorts, ou un moule réalisé à la suite d'une étude en chirurgie esthétique.

Le travail d'usinage consiste à modéliser par référence à des géométries de forme. On peut, en premier lieu, modéliser par référence à des géométries simples les formes de dents, à partir de la reconnaissance des formes de leurs projections dans deux plans distincts ; cette méthode éviterait la reconstruction point par point du volume dans l'espace, éliminant ainsi une technique lourde et inutile pour l'usinage par commande numérique.

Aux données purement géométriques de l'objet à usiner (coordonnées en trois dimensions), s'ajouteront les paramètres suivants : nature du matériau (désigné par un numéro si le choix est possible) - numéro de l'outil - séquence de fraisage ou autre usinage - vitesse de l'outil - cote d'avance/retour rapide - cote d'arrosage - fin de programme. Les coordonnées seront déterminées de manière relative plutôt que de manière absolue. La machine explorera les informations en rafales pour les distribuer. Les procédés d'usinage utilisables seront :

- le fraisage,
- l'électro-érosion par générateur à impulsions et électrode

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fine,

- l'électrochimie pour rectification et perçage,

- l'électro-formage pour dépôt sur forme maîtresse (parties esthétiques),

- l'usinage chimique, notamment pour la réalisation de prothèses amovibles par la technique du masque,

- les ultra-sons et la haute énergie (laser) : opérations de finition, nettoyage, soudure, voire d'usinage proprement dit.

L'usinage consiste essentiellement à enlever de la matière d'une pièce afin de lui donner les formes idéales recherchées. Dans le cas présent, il s'agit de générer des programmes de commande numérique permettant de réaliser l'intérieur et l'extérieur de la prothèse, et aussi d'utiliser des outils et des orientations et trajectoires d'outils géométriquement adaptés à cette application ainsi qu'au matériau de la pièce. Plus particulièrement, dans le cas pris ici pour exemple d'une couronne à réaliser, par utilisation d'une micro-fraiseuse, les données géométriques nécessaires à la génération des programmes d'usinage se divisent en trois secteurs principaux :

- La base de la couronne est un contour fermé (63), constitué de segments de droite (D) et de demi-cercles (C) tangents (voir figure 28). Le rayon du plus petit cercle (C) sera toujours supérieur à celui de l'outil au niveau du plan de joint.

- Le flanc de la couronne s'appuie sur le contour précédent (63), et présente une dépouille angulaire variable (α ou β) - voir figure 29.

- Le fond de la couronne sera constitué exclusivement d'un assemblage de plans adjacents (64), et ne présentera pas de partie en contre-dépouille (voir figure 30). Ce fond est délimité, sur son périmètre, par le flanc (65) de la couronne. Le raccordement flanc-fond sera d'un rayon égal à celui du bout sphérique de l'outil, et il en sera de même pour tout diamètre rentrant.

Le choix des outils doit être fait en fonction de la forme et des dimensions de la couronne à usiner. Pour l'usinage du flanc (65), on utilise un outil conique (66), de demi-angle au sommet égal à l'angle de dépouille à obtenir, avec un bout sphérique (67) de rayon égal au rayon de raccordement au fond. Si le demi-angle au sommet de l'outil n'est pas égal à l'angle de dépouille, on est obligé de réaliser un usinage en

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bout d'outil (68), en multipliant le nombre de passes d'usinage du flanc. Les plans de fond (64) définissent les limites de plongée de l'outil (66 ou 68) - voir figures 31,32 et 33.

Pour l'usinage du fond de la couronne, un outil (69) à bout sphérique, de rayon égal au rayon de raccordement du fond, sera nécessaire. L'usinage du fond se fera plan par plan, avec passes linéaires et parallèles délimitées par les plans adjacents et/ou par le flanc de la couronne. Pour réaliser un programme général, il faut convenir d'une forme type du contour du plan de base et du nombre de plans de fond (64), ainsi que de leur disposition relative (voir figure 34).

Une schéma de principe de la machine d'usinage à commande numérique (70) est donné par la figure 35, sur laquelle (71) désigne la zone où s'effectue le travail suivant les trois coordonnées (x,y et z). De part et d'autre de la machine proprement dite (70), sont disposés des magasins (72 et 73) permettant respectivement le choix du matériau à usiner et le choix de l'outil. La machine (70) comporte, en association avec ces magasins, un bras (74) de prise des matériaux, et un bras (75) de changement d'outil, permettant les transferts entre les deux magasins (72 et 73) et la zone de travail (71).

On disposera d'un ensemble d'ébauches de couronnes (76) - voir figure 36, que le calculateur sélectionnera en fonction du volume et autres caractéristiques de la couronne (45) à réaliser. Chaque ébauche (76) est munie d'un tenon de fixation (77), pour son immobilisation totale sur la machine. Dans ce but, la section du tenon (77) sera par exemple rectangulaire (voir figure 37).

Enfin, les copeaux résultant du fraisage pourront être recyclés par fonderie, pour un nouvel usinage.

Comme il va de soi, l'invention ne se limite pas aux seules formes d'exécution de ce dispositif de prise d'empreinte qui ont été décrites ci-dessus, à titre d'exemples ; elle en embrasse, au contraire, toutes les variantes de réalisation et d'application fondées sur les mêmes principes. En particulier :

- La fonction du capteur (8) peut être effectuée en temps différé par la corrélation vectorielle entre deux images radiographiques ou photographiques, prises sous des angles différents.

- Le convertisseur analogique-numérique (9), réalisé sous la forme d'un microprocesseur, peut être incorporé à l'ensemble endo-

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buccal, dans un dispositif similaire à celui de la figure 7.

- Il est possible d'utiliser une première fibre optique de section circulaire pour guider le faisceau incident, et une seconde fibre optique de section annulaire, entourant la première, pour guider le faisceau réfléchi, au lieu de fibres optiques juxtaposées.

- Dans le système optique, il est possible d'utiliser non seulement des miroirs, mais aussi des prismes en association avec les fibres optiques, pour permettre une observation latérale dans des parties de la bouche d'accessibilité difficile.

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REVENDICATIONS

1. Dispositif de prise d'empreinte par des moyens optiques, notamment en vue de la réalisation automatique de prothèses, et encore plus particulièrement la réalisation de prothèses telles que les couronnes utilisées en art dentaire, caractérisé en ce qu'il comprend essentiellement, en combinaison, des moyens émetteurs d'ondes lumineuses ou acoustiques non traumatisantes (2,17), des moyens pour diriger lesdites ondes (4,5) vers la partie du corps, telle qu'emplacement de dent, à analyser, des moyens récepteurs (6,7) des ondes lumineuses ou acoustiques réfléchies par cette partie du corps, dirigeant lesdites ondes sur un capteur (8) associé à un convertisseur analogique-numérique (9), permettant d'obtenir sous forme de signaux numériques une représentation de la forme, dans les trois dimensions de l'espace, de la partie du corps à analyser, et des moyens d'analyse et de traitement (39 à 44) des signaux numériques obtenus, notamment en vue de la commande automatique d'une machine-outil à commande numérique (70) pour l'usinage d'une prothèse, telle qu'une prothèse dentaire (45), adaptée exactement à la partie du corps analysée (1).

2. Dispositif selon la revendication 1, caractérisé en ce qu'il comprend une source de lumière cohérente (2), au moins une fibre optique (4) et une lentille (5) pour diriger le faisceau incident vers la partie du corps à analyser, au moins une autre lentille (6) et une autre fibre optique (7) pour recueillir le faisceau réfléchi et le diriger sur le capteur (8) associé au convertisseur analogique-numérique (9), et un système optique tel qu'à miroir semi-transparent (10) et lentille (12), dirigeant en outre sur ledit capteur (8) un faisceau de référence (11), pour une analyse par interférence ondulatoire.

3. Dispositif selon la revendication 1, caractérisé en ce qu'il comprend en outre, dans le cas d'utilisation d'une source de lumière non cohérente (17), et pour permettre l'analyse par interférométrie holographique, des trames de repérage (19,19a) associées respectivement à la source émettrice (17) et au capteur (8), et des moyens (22) permettant de déterminer ou de fixer la distance entre les moyens optiques de la tête d'analyse (13) et un plan de référence lié à la partie du corps à analyser (1).

4. Dispositif selon la revendication 3, caractérisé en ce que l'analyse est effectuée dans une gamme d'ondes ne correspondant à aucune couleur présente dans la bouche, notamment en associant la source de

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lumière (7) à un filtre permettant par exemple de travailler dans le bleu ou le vert, ou entre le bleu et le vert.

5. Dispositif selon la revendication 3 ou 4, caractérisé en ce qu'est placé, sur la tête d'analyse (13), un émetteur-récepteur d'ultra-sons ou d'infra-rouge, déterminant la distance au plan de référence, au moment précis où est réalisé l'éclairage par la source (17).

6. Dispositif selon la revendication 3 ou 4, caractérisé en ce qu'est prévu, sur la tête d'analyse (13), un repère de longueur connue (22), destiné à reposer sur un point de la partie du corps à analyser (1).

7. Dispositif selon l'une quelconque des revendications 1 à 6, caractérisé en ce que la source (2,17), le capteur (8) et le convertisseur analogique-numérique (9) sont placés dans un boîtier extérieur (15), relié par des fibres optiques (4,7) à la tête d'analyse (13), telle qu'une tête apte à être amenée dans la bouche d'un patient.

8. Dispositif selon la revendication 7, caractérisé en ce que la tête d'analyse (13) possède deux lentilles réceptrices (6',6") fixées respectivement aux extrémités de deux fibres optiques (7',7") qui guident le faisceau réfléchi, divisé en deux fractions, pour analyser simultanément deux faces opposées de la partie du corps (1).

9. Dispositif selon l'une quelconque des revendications 1 et 3 à 6, caractérisé en ce qu'il comporte une fibre optique unique (23), portant à son extrémité une lentille (24), qui guide à la fois le faisceau incident et le faisceau réfléchi, ce dernier étant renvoyé par un miroir semi-transparent (25) sur le capteur (8) associé au convertisseur (9).

10. Dispositif selon l'une quelconque des revendications 1,3,4 et 5, caractérisé en ce que la tête d'analyse (13) inclut la source d'éclairage (17) et le capteur (8), avec les lentilles respectives (5,6) montées directement, cette tête (13) étant raccordée par des liaisons électriques (26,27) avec un boîtier extérieur (29) incluant l'alimentation électrique (28) et le convertisseur analogique-numérique (9).

11. Dispositif selon l'une quelconque des revendications 1 à 10, caractérisé en ce que le système optique est complété par un ou des miroirs (30,31,32) pour l'analyse simultanée de deux faces opposées de la partie du corps (1).

12. Dispositif selon l'une quelconque des revendications 1 à 11, caractérisé en ce que le capteur (8) atteint par le faisceau réfléchi, et aussi éventuellement par un faisceau de référence (11), est du type

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photosenseur à transfert de charge, et plus particulièrement un photosenseur du type CCD matriciel.

13. Dispositif selon la revendication 12, caractérisé en ce que des moyens de stockage de l'information (39) sont insérés entre le capteur (8) et le convertisseur analogique-numérique proprement dit (9), lequel délivre vers les moyens de traitement (43) des signaux de sortie "point par point" (41), transformés par une interface (42) pour leur adaptation aux moyens de traitement numérique (43), des moyens de visualisation (44) des données saisies étant en outre prévus, en liaison avec les moyens de stockage (39) précités.

14. Dispositif selon l'une quelconque des revendications 1 à 13, caractérisé en ce que les moyens d'analyse et de traitement comprennent encore des moyens de détermination et de prise en compte de l'enveloppe ou volume (46,47,50,51,53 à 55) à l'intérieur duquel doit s'inscrire la prothèse (45) à usiner.

15. Dispositif selon la revendication 14, caractérisé en ce que l'enveloppe de la prothèse (45) est obtenue par détermination :

a) des zones de contact (46,47) des dents voisines (48,49) ;

b) des plans (50,51) tangents à l'arcade ou déterminés sur le côté symétrique, pour les faces vestibulaires ou linguales ;

c) des limites inférieures du moignon (1) analysé en bouche, pour le plan inférieur, et

d) du plan supérieur en fonction d'une analyse mathématique issue soit de l'étude des zones d'usure de l'ensemble du maxillaire, soit du déplacement réel de la mandibule.

16. Dispositif selon la revendication 14, caractérisé en ce que sont prévus des moyens de correction automatique de la forme extérieure théorique de la prothèse (45') inscrite dans l'enveloppe précitée, en fonction de données résultant de l'analyse optique, telles que la forme du moignon de dent (1) dans le cas de réalisation d'une couronne.

17. Dispositif selon l'une quelconque des revendications 1 à 16, caractérisé en ce que les moyens d'analyse et de traitement comprennent encore des moyens de détermination de l'occlusion, statique et dynamique.

18. Dispositif selon la revendication 17, caractérisé en ce que l'occlusion est déterminée par repérage des maxillaires supérieur (33) et inférieur (34), prises d'empreinte optique séparées des deux maxillaires, réalisation d'une claie optique antérieure (57) des repères des deux maxil-

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laires, et réunion des deux maxillaires grâce à leurs repèrages au niveau de la claie.

19. Dispositif selon l'une quelconque des revendications 1 à 18, caractérisé en ce que les moyens d'analyse et de traitement comprennent encore des moyens de détermination et de prise en compte des couleurs ou teintes de dents.

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FIG_1

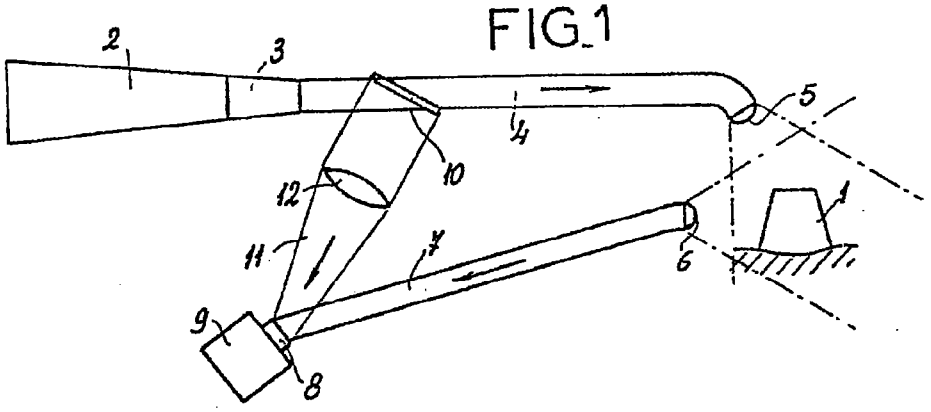


FIG_2

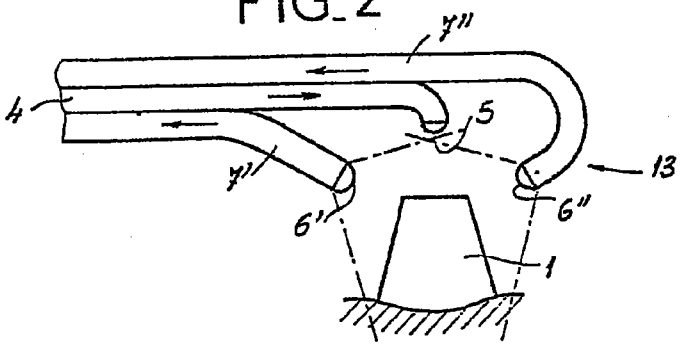


FIG_3

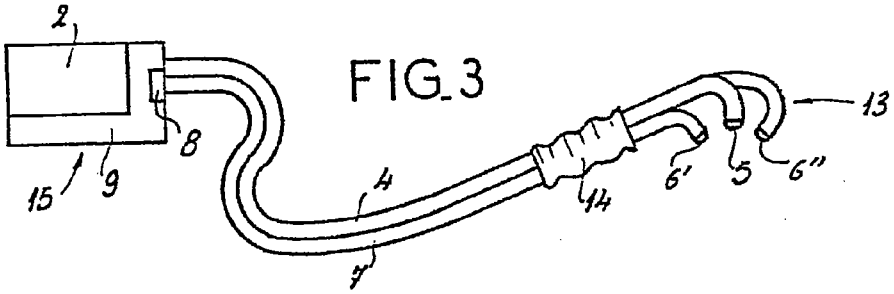
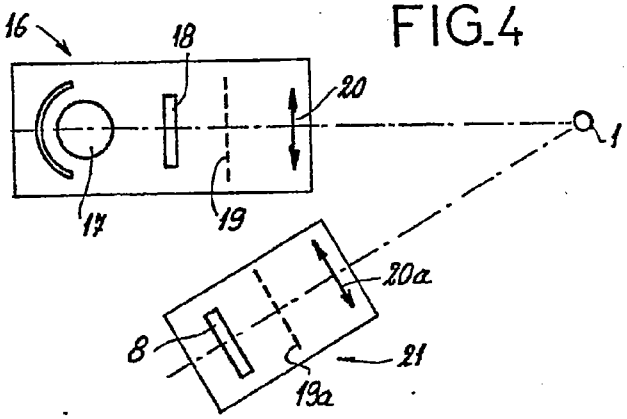


FIG_4



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FIG_5

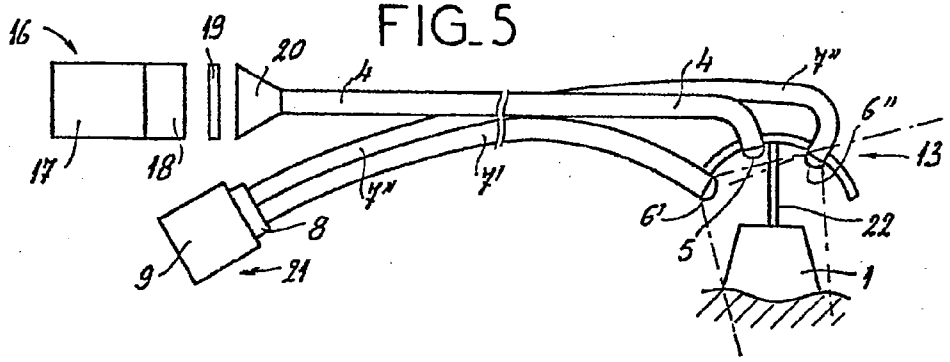


FIG_6

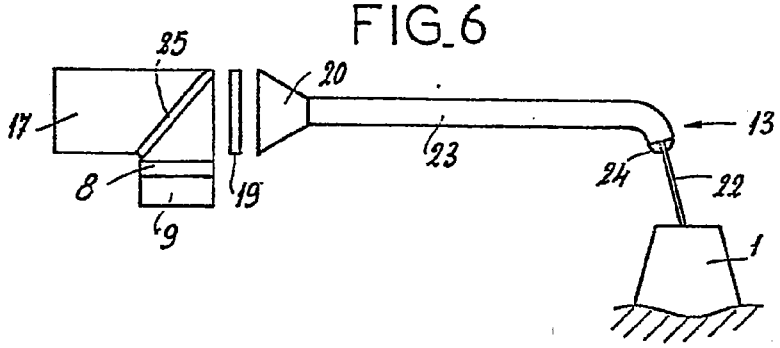


FIG_7

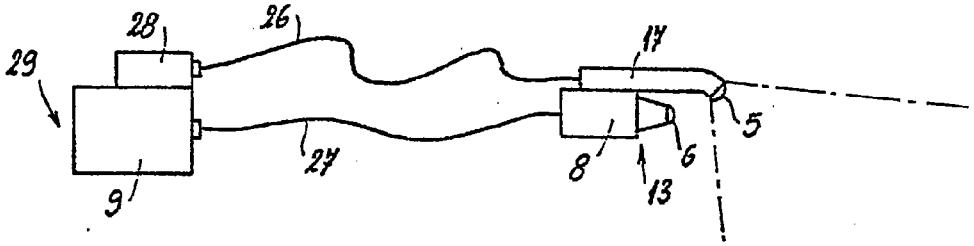


FIG_8

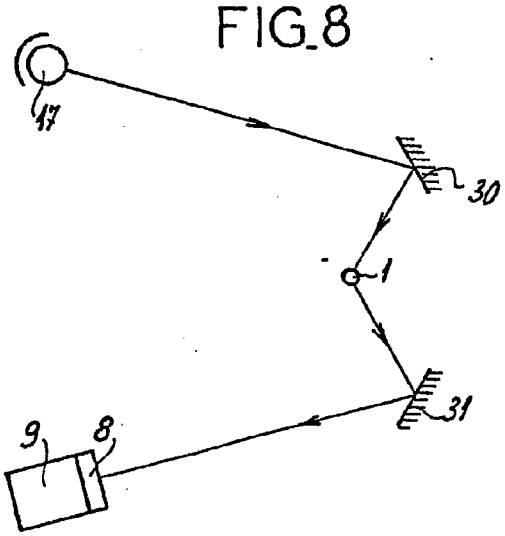


FIG_9

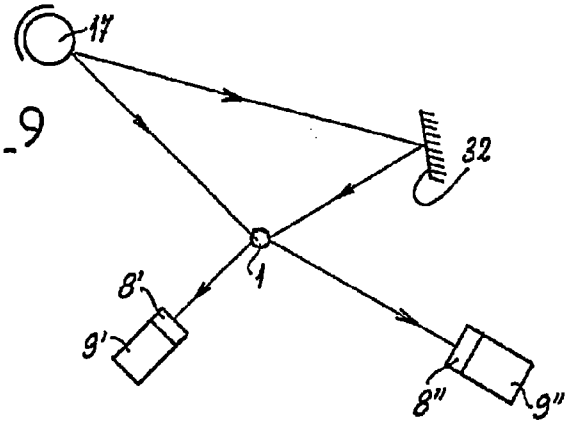


FIG_10

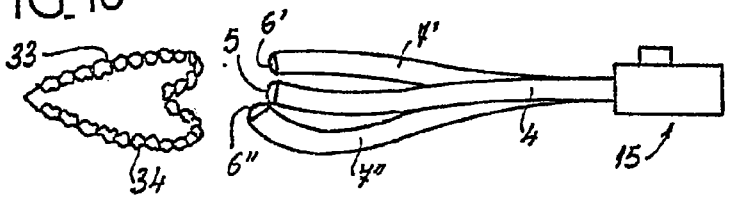


FIG_11

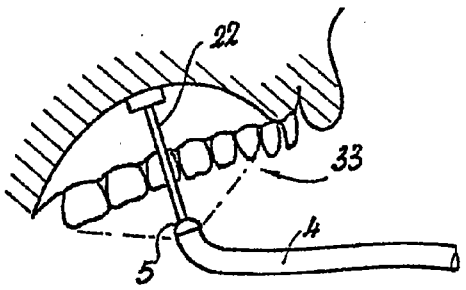


FIG_12

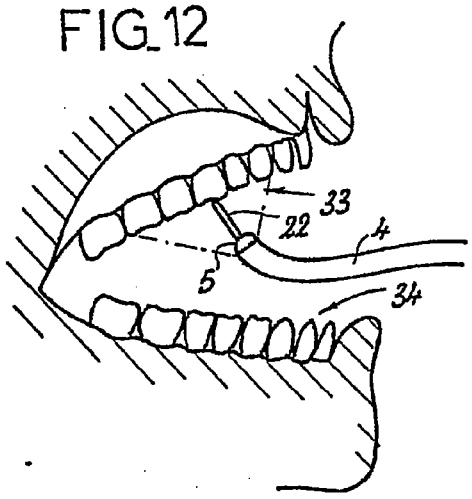
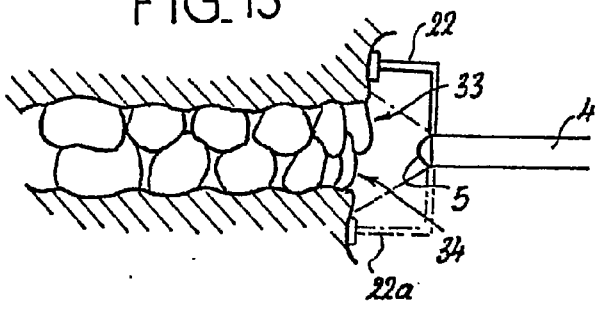


FIG_13



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FIG_14

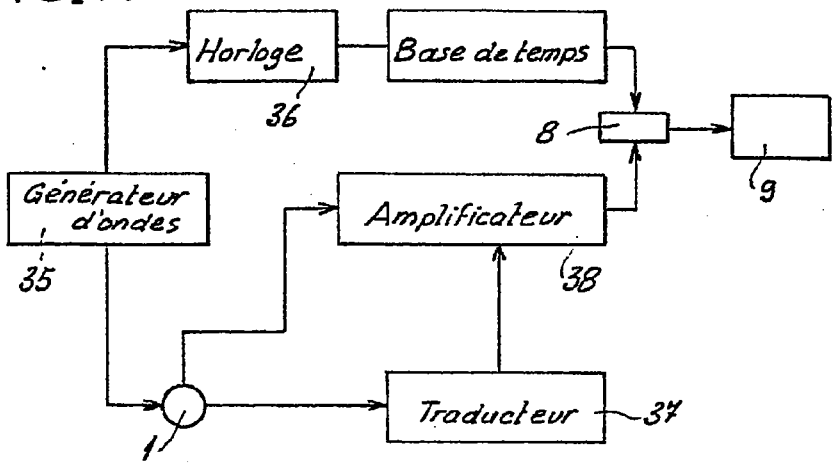


FIG_15

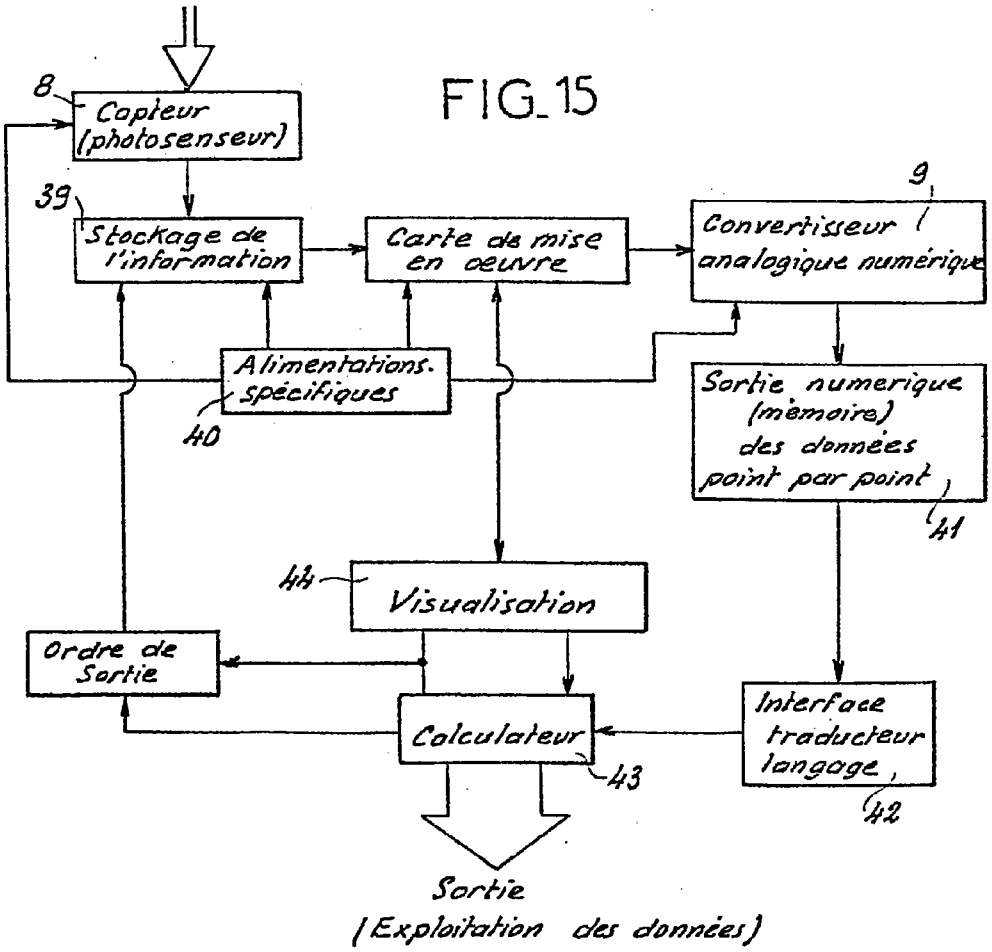


FIG.16

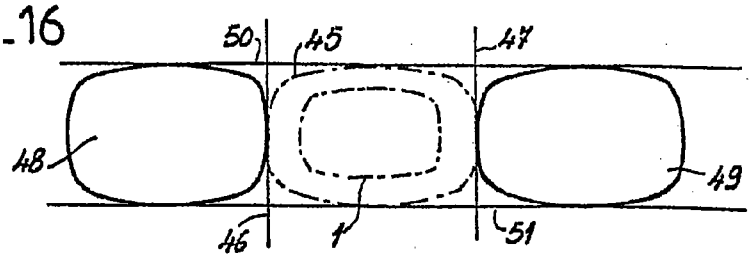


FIG.17

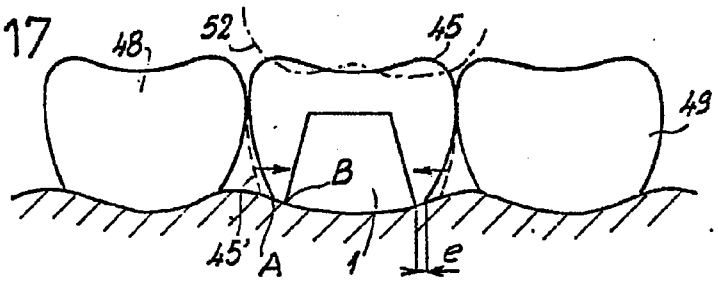


FIG.18

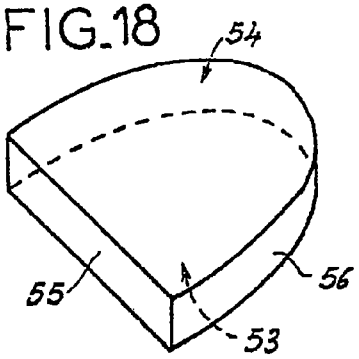


FIG.19

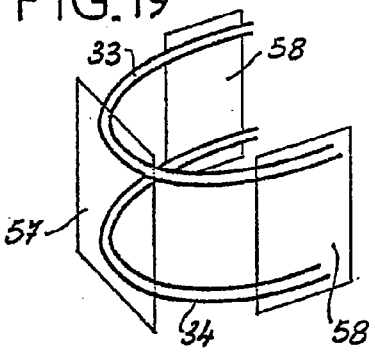
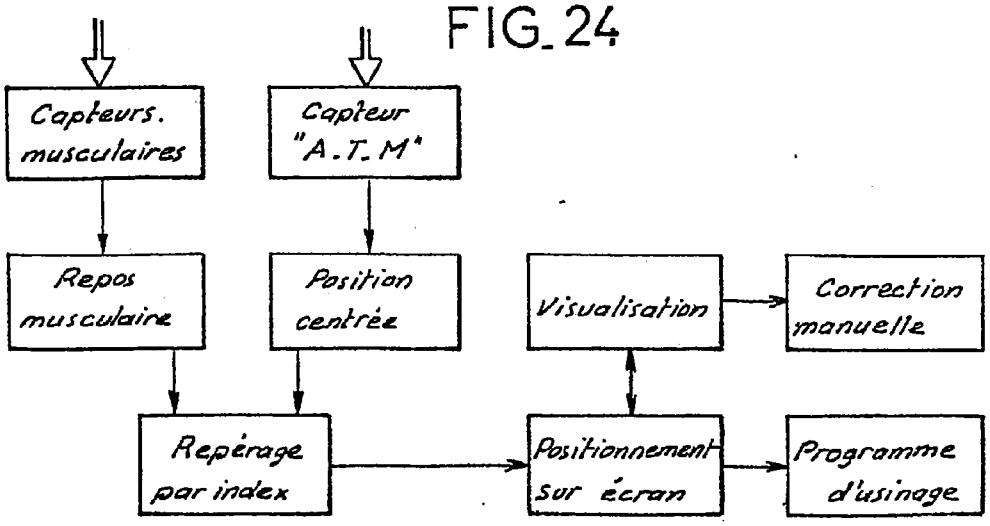
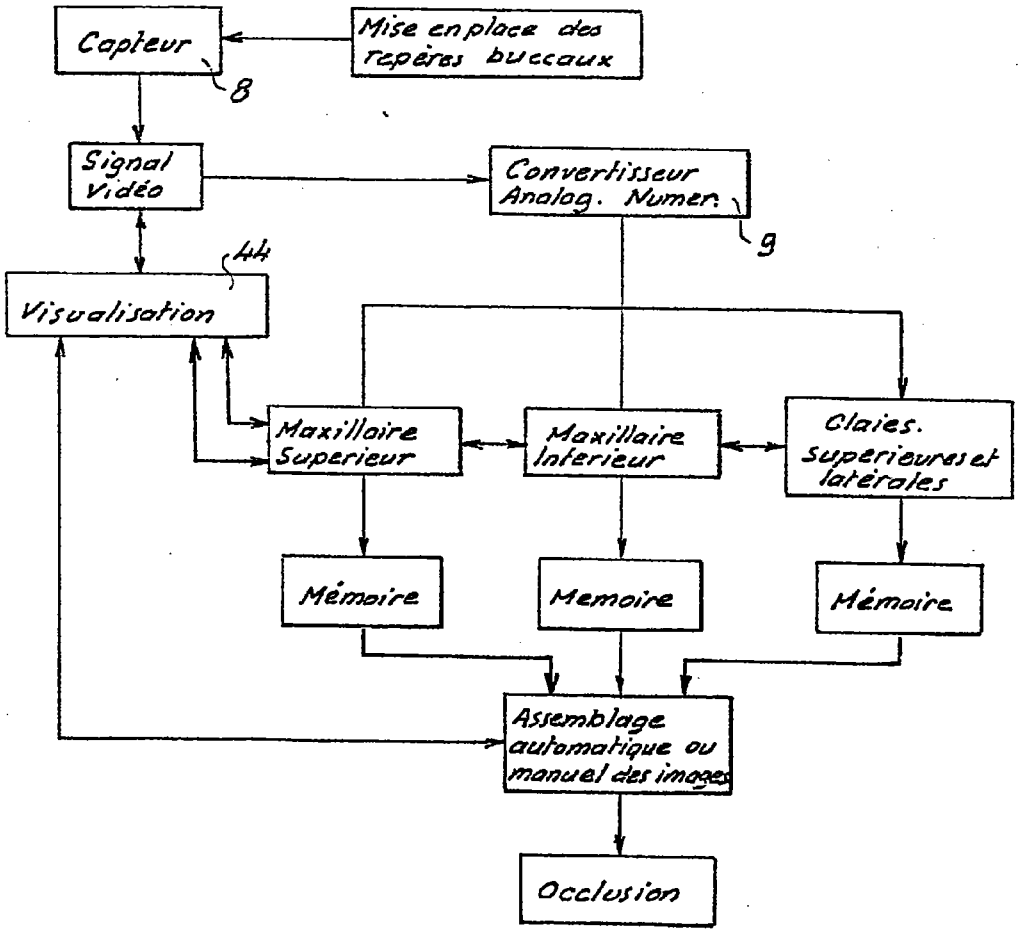


FIG.24



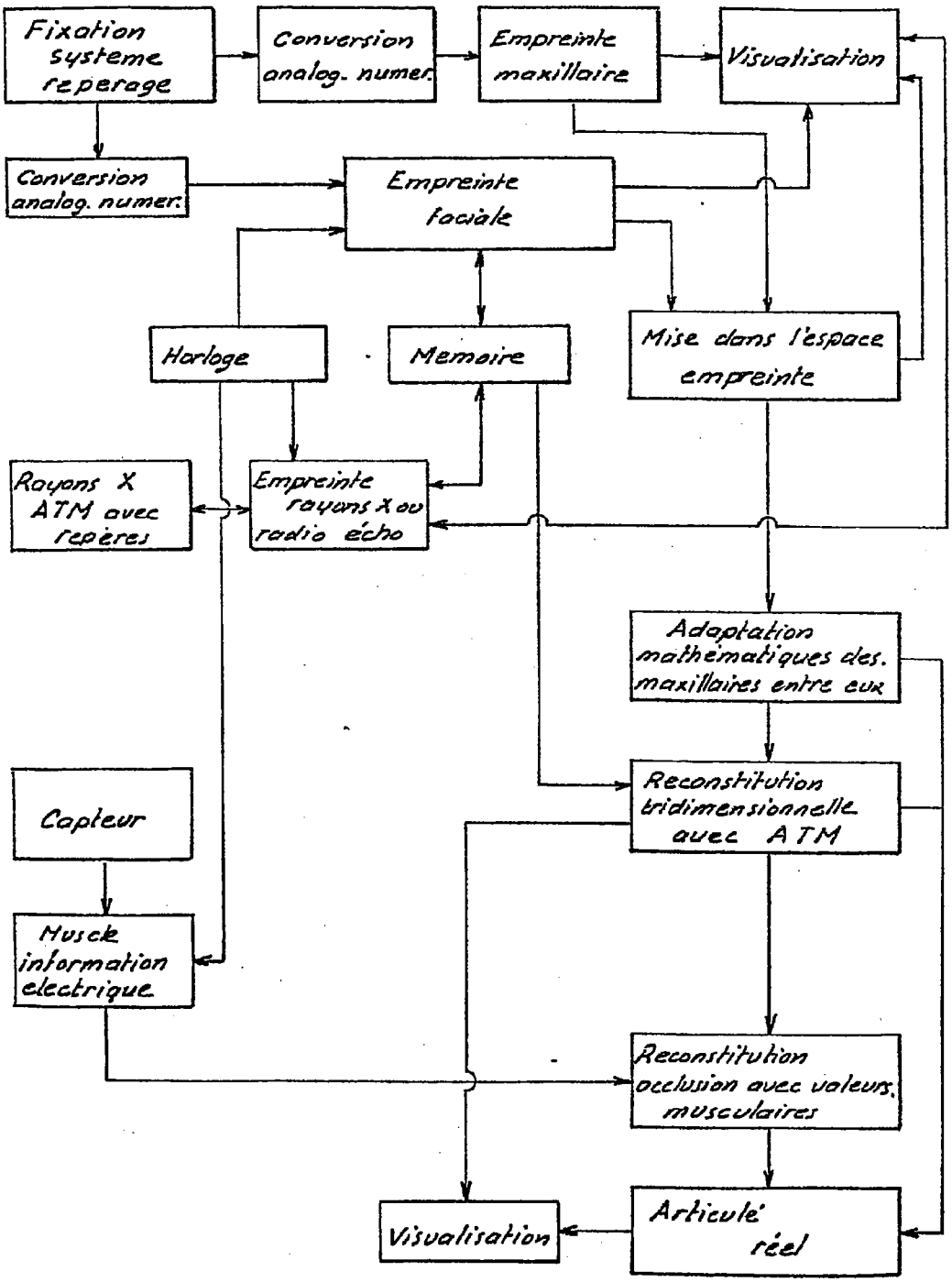
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FIG.20



0091876

FIG.21



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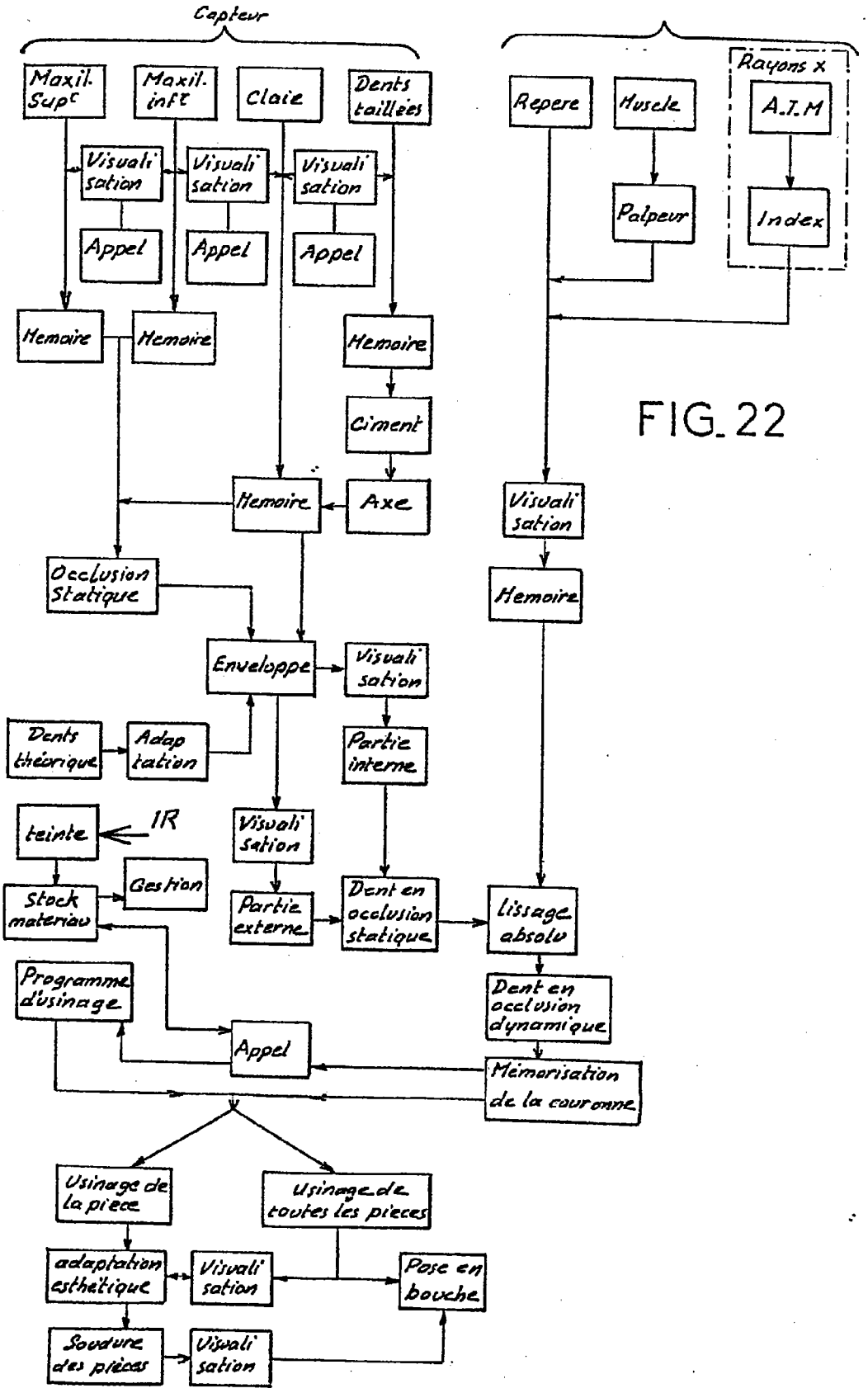


FIG. 22

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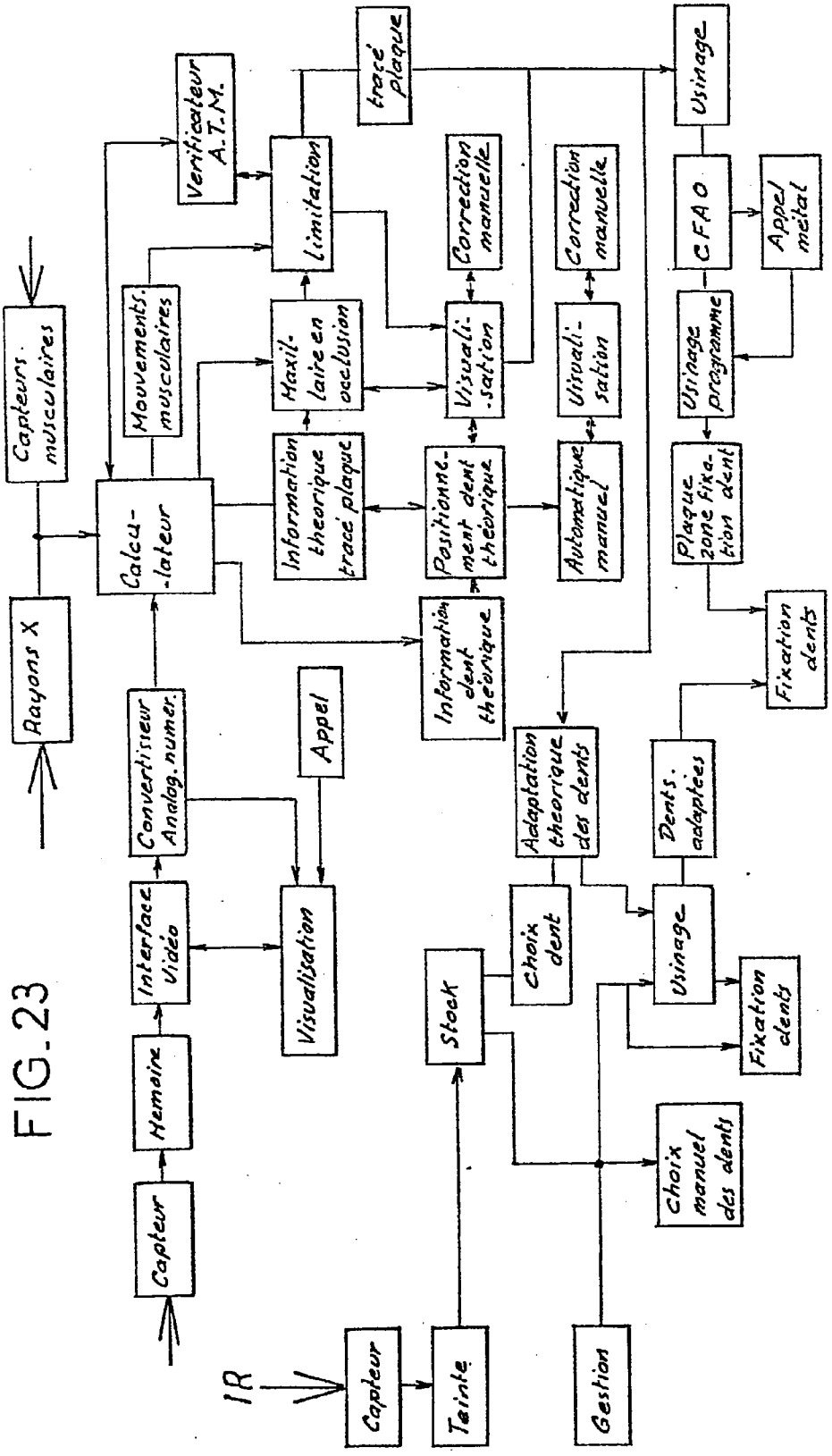

Capteurs musculaires
Rayons X
Calcu-lateur
Mouvements musculaires
Vérificateur A.T.M.
Limitation
Tracé plaque
Usinage
Maxil-laire en occlusion
Information théorique tracé plaque
Correction manuelle
Visuali-sation
CFAO
Appel métal
Usinage programme
Positionnement dent théorique
Automatique manuel
Plaque zone fixation dent
Information dent théorique
Fixation dents
Convertisseur Analog. numer.
Appel
Interface Vidéo
Visualisation
Adaptation théorique des dents
Dents adaptées
Hemeine
Capteur
Stock
Choix dent
Usinage
Fixation dents
Choix manuel des dents
IR
Capteur
Teinte
Gestion

FIG. 23

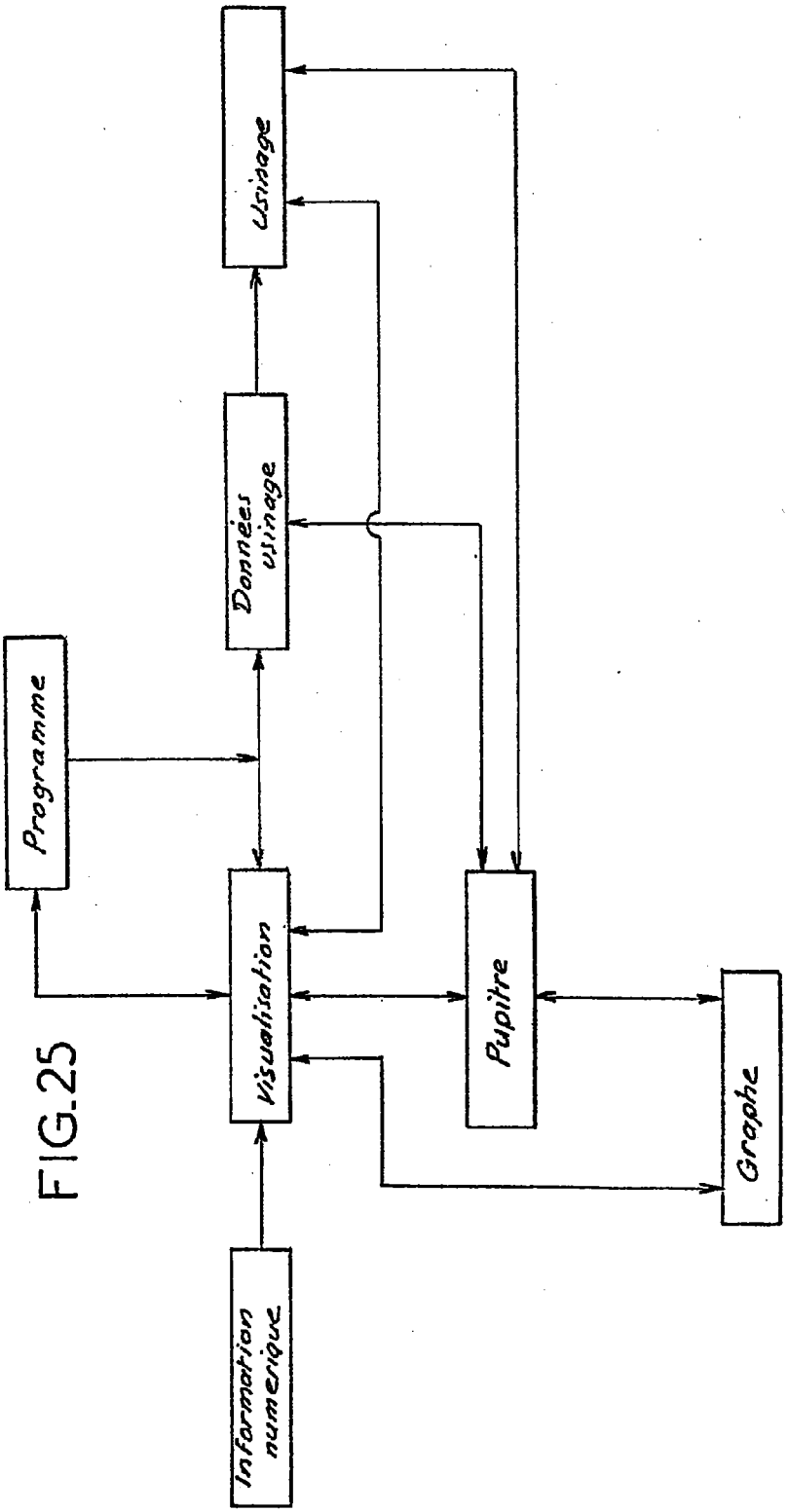

Usinage
Données usinage
Programme
Visualisation
Pupitre
Graphe
Information numérique

FIG.25

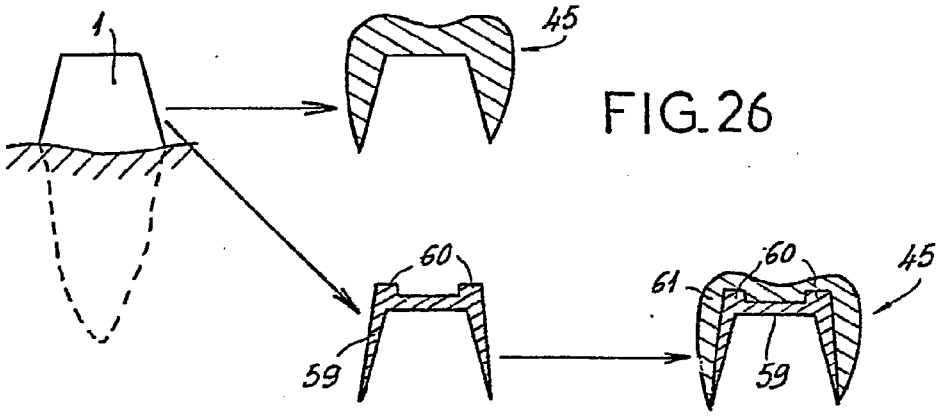


FIG.26

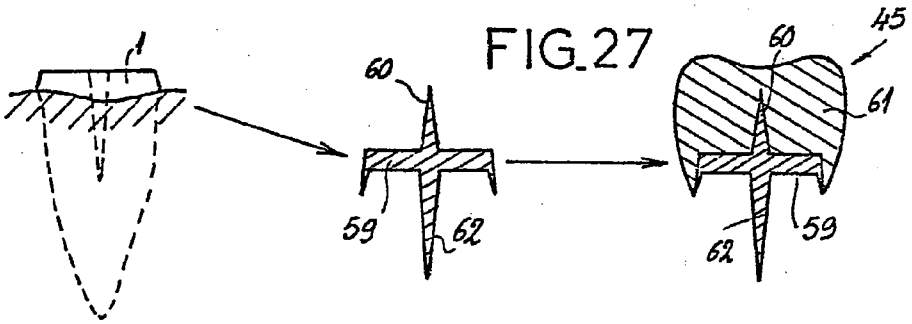


FIG.27

FIG.28

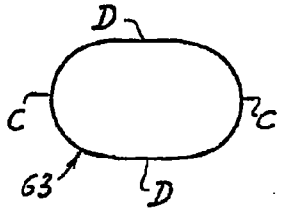


FIG.29

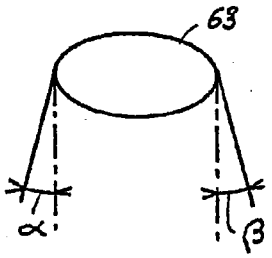


FIG.30

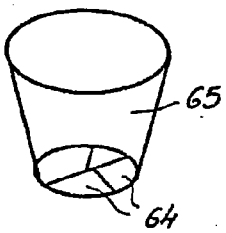


FIG_31

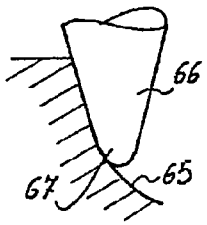


FIG_32

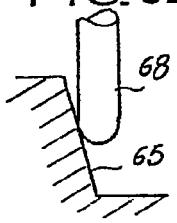


FIG_33

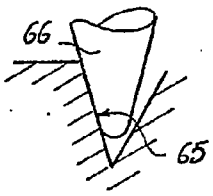


FIG_34

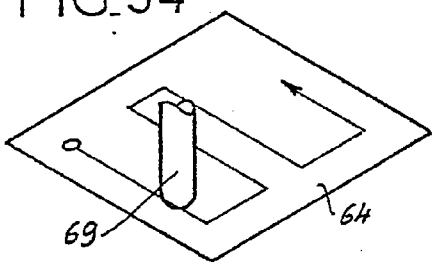


FIG_35

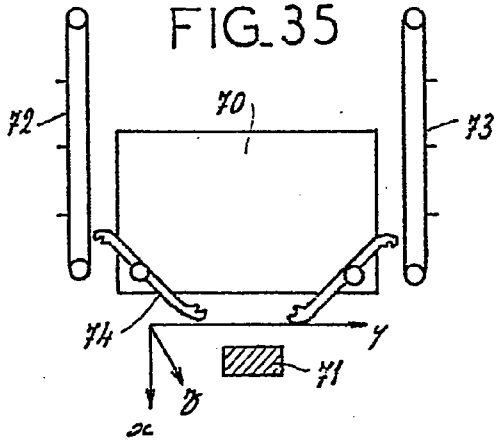


FIG_36

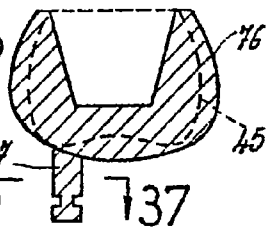
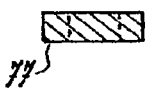


FIG_37



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RAPPORT DE RECHERCHE EUROPEENNE

Numéro de la demande

EP 83 42 0065

DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	Revendication concernée	CLASSEMENT DE LA DEMANDE (Int. Cl. ³)
X	EP-A-0 040 165 (TERMOZ) * Page 3, lignes 5-37; page 4, lignes 8-24 *	1,2,13,14,16	A 61 C 5/10 A 61 C 9/00 A 61 C 19/04
X	EP-A-0 025 911 (HEITLINGER) * Page 13, ligne 31 - page 15, ligne 5; revendication 4; figures 1-3 *	1,7,13,16	
P,Y	EP-A-0 054 785 (MORMANN) * Revendication 1; figures 1,4 *	1	
Y	EP-A-0 033 492 (BECKER) * Revendication 1; figure 6 *	1	DOMAINES TECHNIQUES RECHERCHES (Int. Cl. ³)
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Le présent rapport de recherche a été établi pour toutes les revendications

Lieu de la recherche	Date d'achèvement de la recherche	Examinateur
LA HAYE	09-06-1983	DURAND-SMET J.E.J.S.

CATEGORIE DES DOCUMENTS CITES

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Electronic Acknowledgement Receipt

EFS ID:	13400827
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Vernon A. Norviel/Steven Dieu (MIRO)
Filer Authorized By:	Vernon A. Norviel
Attorney Docket Number:	22773-826.201 (022900US)
Receipt Date:	02-AUG-2012
Filing Date:	14-MAY-2012
Time Stamp:	11:29:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

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		Total Files Size (in bytes):	92737949		

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Electronic Acknowledgement Receipt

EFS ID:	13400690
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Vernon A. Norviel/Steven Dieu (MIRO)
Filer Authorized By:	Vernon A. Norviel
Attorney Docket Number:	22773-826.201 (022900US)
Receipt Date:	02-AUG-2012
Filing Date:	14-MAY-2012
Time Stamp:	11:18:16
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.)
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28	Non Patent Literature	Z-GAO-3-D-element-267.pdf	401591 bf9c9af79c95bb7f03d8a46229e9eb692d0f81e8	no	6
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Information:					

29	Non Patent Literature	Z-GIM-ALLDENT-Das-dux-system.pdf	130254 4adff5eccc16261cdd800bd53f2e9fa39fc81c56	no	2
Warnings:					
Information:					
30	Non Patent Literature	Z-GOTTLIEB-JCO-interviews-390.pdf	1456775 f8c93557b086e3aee8785a8d5aa74ce5d4b37f4d	no	21
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Information:					
31	Non Patent Literature	Z-GRAYSON-New-methods-1990.pdf	417056 ea1bc1df1bdca491660fa5573423e1d1adc806b5	no	3
Warnings:					
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32	Non Patent Literature	Z-GUESS-Computer-treatment-262.pdf	1132027 27b5f0ebeb878777c564331c016739377a028175	no	11
Warnings:					
Information:					
33	Non Patent Literature	Z-HEAVEN-Computer-based-17.pdf	796720 3f97abf36236ee767d29370a23b097478485e5cd	no	3
Warnings:					
Information:					
34	Non Patent Literature	Z-HIGHBEAM-Simulating-stress-1996.pdf	140183 c10a4548ad43902dd7ffc898b642687a63b58e85	no	2
Warnings:					
Information:					
35	Non Patent Literature	Z-HIKAGE-Integrated-orthodontic-248.pdf	2799512 61fa540c68cfd9c5031e0ed68836b0b4d6c9fc06	no	56
Warnings:					
Information:					
36	Non Patent Literature	Z-HOFFMAN-Role-of-375.pdf	4616306 0097a93ab4ab42fa0f7da4eef39b837de6a59eee	no	23
Warnings:					
Information:					
37	Non Patent Literature	Z-HOJJATIE-Three-dimensional-1157.pdf	572590 e8e8f04e6191be80b820eb8222b0af8f0be0f269	no	10
Warnings:					
Information:					

38	Non Patent Literature	Z-HUCKINS-CAD-CAM-96.pdf	98055 3bc1b326bacd3b8def27813e0b6e7ec68648ce86	no	1
Warnings:					
Information:					
39	Non Patent Literature	Z-Important-tip-about-wearing-1998.pdf	46522 340a2832fe869b21695cc4662c61b3a8fe5b3df6	no	1
Warnings:					
Information:					
40	Non Patent Literature	Z-Inside-the-ADA-286.pdf	1411918 3039c1a3cf11f60c743c55534d1e8a7b98acd62f	no	9
Warnings:					
Information:					
41	Non Patent Literature	Z-JCO-interviews-459-1994.pdf	789378 eb8cc6cdb5a807d275aff43995351e05fb98a4e1	no	14
Warnings:					
Information:					
42	Non Patent Literature	Z-JCO-interviews-819-1983.pdf	1195122 24c006982a08e971fb69e1d665185d3c2c13c78f	no	19
Warnings:					
Information:					
43	Non Patent Literature	Z-JERROLD-The-problem-478.pdf	247348 213460c6855c8b07584675786249eb1a9d4b0cd5	no	5
Warnings:					
Information:					
44	Non Patent Literature	Z-JONES-An-assessment-85.pdf	493613 e009d93ddc7c6e776651de4e4cef902144f91261	no	10
Warnings:					
Information:					
45	Non Patent Literature	Z-JP-FABER-Computerized-interactive-36.pdf	465810 139652252abf4b216de00c6d1ecdd548dd957a7e	no	6
Warnings:					
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46	Non Patent Literature	Z-KAMADA-Construction-of-1982.pdf	856658 d28516253841da77323d15300fbbc0565fb1d546	no	28
Warnings:					
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47	Non Patent Literature	Z-KANAZAWA-Three-dimensional-1298.pdf	473549 8b4e653af57a0fd53fcbd21c7fe33ee8e6069b71	no	6
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Information:					
48	Non Patent Literature	Z-KESLING-The-philosophy-297.pdf	373829 fdcd21b043f3daf4df3d8cedf987333f939e5d0b	no	6
Warnings:					
Information:					
49	Non Patent Literature	Z-KESLING-Coordinating-the-285.pdf	492258 1f1cc962bcf019aa013e6e360f14929f1bd5a46a	no	8
Warnings:					
Information:					
50	Non Patent Literature	Z-KAMADA-Case-reports-11.pdf	642704 0333ab43190df705129d4b06e6d881f2b7caf4b0	no	20
Warnings:					
Information:					
51	Non Patent Literature	Z-KLEEMAN-The-speed-673.pdf	920375 07b8b512ca1666a5c26df2826836b548a6dbe7b4	no	8
Warnings:					
Information:					
52	Non Patent Literature	Z-KOCHANEK-Interpolating-splines-33.pdf	640437 77af1aff1d1c0e24fc3d60e715ade91d42d635cd	no	9
Warnings:					
Information:					
53	Non Patent Literature	Z-KUNII-Articulation-simulation-181.pdf	709919 8488f62405d5670e0ced1a36020caef1d84829d3	no	8
Warnings:					
Information:					
54	Non Patent Literature	Z-KURODA-Three-dimensional-365.pdf	531182 e66065bdaea56b0ee4953cf100571c908e637a09	no	5
Warnings:					
Information:					
55	Non Patent Literature	Z-LAURENDEAU-A-computer-vision-453.pdf	499672 53462babf653afe4a83458868d556955110a44c2	no	9
Warnings:					
Information:					

56	Non Patent Literature	Z-LEINFELDER-A-new-703.pdf	508063 e776fb6e5a7454cf74fb17ae7b1dcf95d3f82242	no	5
Warnings:					
Information:					
57	Non Patent Literature	Z-MANETTI-Computer-aided-370.pdf	1687370 6009829137fa3e27079c72fcfd94212ae7fd2a62	no	8
Warnings:					
Information:					
58	Non Patent Literature	Z-MCCANN-Inside-the-286.pdf	904121 f775a5baaaef6dd7aa3dd709e64ec5dba78cf946	no	9
Warnings:					
Information:					
59	Non Patent Literature	Z-MCNAMARA-Invisible-retainers-570.pdf	407944 bf0ebc18a99eba68c8f15486195871316f41e3e7	no	11
Warnings:					
Information:					
60	Non Patent Literature	Z-MCNAMARA-Orthodontic-and-347.pdf	3226062 3382eb655e5a3baf0e7255a107f6e0f6a771cd32	no	11
Warnings:					
Information:					
		Total Files Size (in bytes):	47039028		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	13400848
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Vernon A. Norviel/Steven Dieu (MIRO)
Filer Authorized By:	Vernon A. Norviel
Attorney Docket Number:	22773-826.201 (022900US)
Receipt Date:	02-AUG-2012
Filing Date:	14-MAY-2012
Time Stamp:	11:30:57
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	Z-YOSHII-Research-on-112.pdf	2157229 8070485a9904375eb8961a5786e32f67cba6115f	no	40

Warnings:	
Information:	

2	Non Patent Literature	Z-YOSHII-Research-on-146.pdf	3206858 0d26f89b3a4a27b13a50beac3098f2a0ea16d886	no	43
Warnings:					
Information:					
3	Non Patent Literature	Z-You-may-be-a-candidate.pdf	164196 7dce50f5fa113ccb979dfe5b8c32ad7fa1817cfe	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	5528283	

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.

PLUS Search Results for S/N 13470681, Searched Mon Sep 24 14:58:49 EDT 2012

The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

6790035 69
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BIB DATA SHEET

CONFIRMATION NO. 5655

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/470,681	05/14/2012	433	3732	22773-826.201 (022900US)

APPLICANTS

Chunhua Li, Cupertino, CA;
Yan Chen, Cupertino, CA;

**** CONTINUING DATA ***************************

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****
05/24/2012

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☐ No	/JUSTIN R O'DONNELL/ Examiner's Signature	☐ Initials	CA	8	29	3

ADDRESS

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

TITLE

MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

FILING FEE RECEIVED		
1920	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Notice of References Cited	Application/Control No. 13/470,681	Applicant(s)/Patent Under Reexamination LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,024,790 A	06-1991	Grossman et al.	264/16
*	B	US-2009/0246724 A1	10-2009	Chen et al.	433/6
*	C	US-8,235,713 B2	08-2012	Phan et al.	433/6
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 10/10/2012

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

EXAMINER	
O'DONNELL, JUSTIN R	
ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
10/10/2012	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	Justin O'Donnell	3732	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *02 August 2012 and 17 July 2012*.

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 *27 September 2012*; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-29* is/are pending in the application.

5a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-19* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☒ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *14 May 2012* 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).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/02/2012*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a dental appliance and orthodontic system for positioning a patient's teeth, classified in class 433, subclass 6.

II. Claims 20-29, drawn to a method of making a dental appliance for positioning a patient's teeth, classified in class 264, subclass 16.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as injection molding.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:

a. the inventions require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries);

b. the inventions have acquired a separate status in the art in view of their different classification;

c. the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

d. the prior art applicable to one invention would not likely be applicable to another invention;

e. the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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

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

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Chris Kuyper on 27 September 2012 a provisional election was made without traverse to prosecute the invention of group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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

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

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information Disclosure Statement

1. The listing of references in the specification (namely: 6,450,807) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be

submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

2. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Drawings

3. The drawings are objected to for the following reasons:

- As required by 37 CFR 1.83(a), the drawings must show every feature of the invention specified in the claims. Therefore, the hard polymer layer comprising at least two layers of claims 4 and 15, and the at least one of the first soft polymer layer and the second soft polymer layer comprising at least two layers of claims 8 and 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
- The character of the lines in Figs. 5-8 is such that the abovementioned figures have unsatisfactory reproduction characteristics. See 37 CFR 1.84(l)-(m), (q).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that

the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract is objected to because it does not convey that which is new in the art and what is applicant's invention.

5. The abstract is objected to because it contains less than 50 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1-19 are indefinite because it is unclear what polymeric materials would be encompassed by the terms “hard” and “soft”. The hardness of a material is a quantitative measure generally defined by its resistance to plastic deformation, and depending upon the type of material, may be tested in a variety of different ways. Further specificity is required.

- Claims 5, 9, 10 are indefinite because the words “thickness in the 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” (claim 5), “thickness in a range from about 25 µm to about 100 µm, about 30 µm to about 90 µm, or about 35 µm to about 80 µm” (claim 9), “thickness of about 500 µm to about 1200 µm, about 550 µm to about 1100 µm, or about 600 µm to about 1000 µm” (claim 10) do not specifically point out the metes and bounds of the claims. There are broader and narrower ranges in the same claims. See MPEP 2173.05 (c).
- Claim 9 is indefinite because it is not clear whether "the soft polymer layer" refers to "a first soft polymer layer" or "a second soft polymer layer" set forth in line 5 of claim 1. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 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. Claims 1-5, 10, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 2009/0246724 A1).

Chen discloses an orthodontic system including a plurality of incremental tooth position adjustment appliances (100) having teeth receiving cavities (102) shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force

to the patient's teeth, where the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement ([0014]-[0015] line 5), and where at least one of the appliances includes a hard polymer layer (150, Fig. 5) disposed between a first soft polymer layer (outer 152) and a second soft polymer layer (inner, tooth-facing 152) ([0036] lines 8-10, 13-16: outer layer 152 may have…lower glass transition temp than inner layers 150; layers with lower glass transition temp may be the softer segment… layers with higher glass transition temp may be harder segment).

Regarding claims 2, 3, 4, 5, 10, 14, and 15, the hard polymer layers (Fig. 5: two inner layers 150) include a layer of a polycarbonate ([0036] lines 5-7), and includes a thickness in the range from about 400 µm to about 1100 µm ([0031] lines 5-6: at 10 mil per layer, the two inner layers in Fig. 5 have combined thickness of 20 mil = 508 µm). 10. The combined hard and soft polymer layers (Fig. 5) include a thickness of about 500 µm to about 1200 µm (4 x 10 mil = 40 mil = 1016 µm).

Claim Rejections - 35 USC § 103

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

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

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6-9, 12, 16, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen, in view of Grossman et al. (US 5,024,790).

Chen discloses the invention substantially as claimed above, including that at least one of the first and second soft polymer layers includes two layers ([0033] lines 1-3), but does not disclose that each of the first soft polymer layer and the second soft polymer layer independently includes 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; that each of the first soft polymer layer and the second soft polymer layer independently includes 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; that at least one of the first soft polymer layer and the second soft polymer layer includes at least two layers, and where 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; that the soft polymer layer includes a thickness in a range from about 25 µm to about 100 µm, about 30 µm to about 90 µm, or about 35 µm to about 80 µm; that the first soft polymer layer and the second soft polymer layer each independently include 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%.

Grossman teaches a soft polymer layer (10, Fig. 4) which is made to conform to a tooth surface (crown 16), the layer including a thermoplastic elastomer with a thickness in the range of 12.7 µm to 50.8 µm, and an elongation in the 100-1000% range (column 4 lines 15-30; where 1 mil = 25.4 µm). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Chen soft layers using the Grossman material, as Grossman states in column 4 lines 7-10 that this material makes it possible to construct a highly flexible layer which can faithfully conform to the extremely irregular surfaces of a dental shape.

9. Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen.

Chen discloses the invention substantially as claimed above, but does not disclose that the hard polymer layer includes 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%. However, the instant disclosure does not describe these parameters as contributing any unexpected result to the appliance. As such, these parameters are deemed matters of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of Chen et al. (US 2009/0246724).

The differences between instant claims 1 and 13, and patented claims 1, 2, and 6 are twofold. First, patented claim 6 contains the additional limitation of "wherein at least one of the appliances comprises a shell having a different geometry than that of at least one other appliance in the system, and wherein at least two different appliances of the system have different elastic moduluses and hardnesses with respect to each other", and is thus more specific, in effect making the invention of patented claim 6 a “species” of the “generic” invention of instant claim 13. It has been held that the generic invention is “anticipated” by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). The second difference between the claims is that patented claim 6 does not specify that the hard polymer layer (patented claims: the first polymeric material with an elastic modulus greater than the second polymeric material) is disposed between a first soft polymer layer and a second soft polymer layer.

Chen discloses an appliance which includes a hard polymer layer (150, Fig. 5) disposed between a first soft polymer layer (outer 152) and a second soft polymer layer (inner, tooth-facing 152). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify claim 6 of U.S. Patent No. 8,235,713 to include the

Chen layers, as Chen states in [0012] and [0032] that the combination of layers with differing glass transition temperatures allows the appliance to transition from a deformed and/or relaxed shape to an original shape upon an application of an external stimulus, thereby extending the useful lifespan of the dental appliance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Justin O'Donnell whose telephone number is (571)270-5131. The examiner can normally be reached Monday-Friday, 10:30-8:30.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Cris Rodriguez, at* (571) 272-4964**. 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.

/Justin O'Donnell/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012							
	1	÷	✓							
	2	÷	✓							
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S21	608	433/6.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 21:38
S22	478	433/18.ccls.	US-PGPUB; USPAT; USOCR;	OR	OFF	2012/09/29 21:38

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S23	909	433/24.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 21:38
S24	344	US-2467432-$.DID. OR US-20020006597-$.DID. OR US-20030009252-$.DID. OR US-20030139834-$.DID. OR US-20030224311-$.DID. OR US-20040128010-$.DID. OR US-20050055118-$.DID. OR US-3407500-$.DID. OR US-3600808-$.DID. OR US-3660900-$.DID. OR US-3683502-$.DID. OR US-3738005-$.DID. OR US-3860803-$.DID. OR US-3916526-$.DID. OR US-3922786-$.DID. OR US-3950851-$.DID. OR US-3983628-$.DID. OR US-4014096-$.DID. OR US-4195046-$.DID. OR US-4253828-$.DID. OR US-4324546-$.DID. OR US-4324547-$.DID. OR US-4348178-$.DID. OR US-4478580-$.DID. OR US-4500294-$.DID. OR US-4504225-$.DID. OR US-4505673-$.DID. OR US-4526540-$.DID. OR US-4575330-$.DID. OR US-5017984-$.DID. OR US-4575805-$.DID. OR US-4591341-$.DID. OR US-4609349-$.DID. OR US-4611288-$.DID. OR US-4656860-$.DID. OR US-4663720-$.DID. OR US-4664626-$.DID. OR US-4676747-$.DID. OR US-4742464-$.DID. OR US-4755139-$.DID. OR US-4763791-$.DID. OR US-4793803-$.DID. OR US-4798534-$.DID. OR US-4836778-$.DID. OR US-4837732-$.DID. OR US-4850864-$.DID. OR US-4850865-$.DID. OR US-4856991-$.DID. OR US-4877398-$.DID. OR US-4880380-$.DID. OR US-4889238-$.DID. OR US-4890608-$.DID. OR US-4935635-$.DID. OR US-4936862-$.DID. OR US-4937928-$.DID. OR US-4941826-$.DID. OR US-4964770-$.DID. OR US-4975052-$.DID. OR US-4983334-$.DID. OR US-5011405-$.DID. OR US-5017133-$.DID. OR US-5027281-$.DID. OR US-5035613-$.DID. OR US-5055039-$.DID. OR US-5059118-$.DID. OR US-5100316-$.DID. OR US-5121333-$.DID. OR US-5125832-$.DID. OR US-5128870-$.DID. OR US-5130064-$.DID. OR US-5131843-$.DID. OR US-5131844-$.DID. OR US-5139419-$.DID. OR US-5145364-$.DID. OR US-5176517-$.DID. OR US-5184306-$.DID. OR US-5186623-$.DID. OR US-5257203-$.DID. OR US-5273429-$.DID. OR US-5278756-$.DID. OR US-5328362-$.DID. OR US-5338198-$.DID. OR US-5340309-$.DID. OR US-5342202-$.DID. OR US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 21:38

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S25	523	264/16.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 21:38
S26	298	264/17.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 21:38
S27	150	264/18.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 21:38
S28	3037	S20 S21 S22 S23 S24 S19 S25 S26 S27	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 21:38
S29	16	S18 and S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 21:39
S30	117	invisalign invis$align	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 22:42
S31	94	S30 and "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 22:43
S32	749	align.as.	US-PGPUB; USPAT;	OR	ON	2012/09/29 22:43

			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S33	333	S32 and "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 22:43
S34	8	"5024790"	USPAT	OR	OFF	2012/09/29 23:03
S36	697	(appliance aligner aligning) with ((first near2 layer) and (second near2 layer)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:04
S37	4	S36 and align.as.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:05
S38	11	("3311977" | "4055895" | "4370129" | "4799884" | "4983334" | "5203695" | "5746221" | "5865619" | "5947724" | "6171107").PN. OR ("8235713").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/29 23:11
S39	29	("4150485" | "4253828" | "4370129" | "4983334" | "5022855" | "5536168" | "5607300" | "5645420" | "5951291" | "5975893").PN. OR ("6454565").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/29 23:11
S40	43	("4150485" | "4253828" | "4370129" | "4983334" | "5022855" | "5536168" | "5607300" | "5645420" | "5951291" | "5975893").PN. OR ("6454565").URPN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/29 23:13
S41	30220	aligner (orthdontic near2 appliance)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:13
S42	111893	(stiff$2 hard$2) near2 layer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:14
S43	56178	(soft$2) near2 layer	US-PGPUB; USPAT; USOCR;	OR	ON	2012/09/29 23:14

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S44	7794	S42 with S43	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:14
S45	1	S44 with S41	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:14
S46	2	11/227810.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/29 23:19

EAST Search History (Interference)

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	13/470,681
				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
Sheet	1	of	21	Attorney Docket Number	22773-826.201

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
	1.	US 2,467,432	04/19/1949	Kesling	
	2.	US 2002/0006597 A1	01/17/2002	Andreiko et al.	
	3.	US 2003/0009252 A1	01/09/2003	Pavlovskaia et al.	
	4.	US 2003/0139834 A1	07/24/2003	Nikolskiy et al.	
	5.	US 2003/0224311 A1	12/04/2003	Cronauer	
	6.	US 2004/0128010 A1	07/01/2004	Pavlovskaia et al..	
	7.	US 2005/0055118 A1	03/10/2005	Nikolskiy et al.	
	8.	US 3,407,500	10/29/1968	Kesling	
	9.	US 3,600,808	08/24/1971	Reeve	
	10.	US 3,660,900	05/09/1972	Andrews	
	11.	US 3,683,502	08/15/1972	Wallshein.	
	12.	US 3,738,005	06/12/1973	Cohen	
	13.	US 3,860,803	01/14/1975	Levine	
	14.	US 3,916,526	11/04/1975	Schudy	
	15.	US 3,922,786	12/02/1975	Lavin	
	16.	US 3,950,851	04/20/1976	Bergersen	
	17.	US 3,983,628	10/05/1976	Acevedo	
	18.	US 4,014,096	03/29/1977	Dellinger	
	19.	US 4,195,046	03/25/1980	Kesling	
	20.	US 4,253,828	03/03/1981	Coles et al.	
	21.	US 4,324,546	04/13/1982	Heitlinger et al.	
	22.	US 4,324,547	04/13/1982	Arcan et al.	
	23.	US 4,348,178	09/07/1982	Kurz	
	24.	US 4,478,580	10/23/1984	Barrut	
	25.	US 4,500,294	02/19/1985	Lewis	
	26.	US 4,504,225	03/12/1985	Yoshii	
	27.	US 4,505,673	03/19/1985	Yoshii	
	28.	US 4,526,540	07/02/1985	Dellinger	
	29.	US 4,575,330	03/11/1986	Hull	

Examiner Signature	/Justin O'Donnell/	Date Considered	09/30/2012

*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.

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	13/470,681
				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
Sheet	2	of	21	Attorney Docket Number	22773-826.201

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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
	30.	US 4,575,805	03/11/1986	Moermann et al.	
	31.	US 4,591,341	05/27/1986	Andrews	
	32.	US 4,609,349	09/02/1986	Cain	
	33.	US 4,611,288	09/09/1986	Duret et al.	
	34.	US 4,656,860	04/14/1987	Orthuber et al.	
	35.	US 4,663,720	05/05/1987	Duret et al.	
	36.	US 4,664,626	05/12/1987	Kesling	
	37.	US 4,676,747	06/30/1987	Kesling	
	38.	US 4,742,464	05/03/1988	Duret et al.	
	39.	US 4,755,139	07/05/1988	Abbatte et al.	
	40.	US 4,763,791	08/16/1988	Halverson et al.	
	41.	US 4,793,803	12/27/1988	Martz	
	42.	US 4,798,534	01/17/1989	Breads	
	43.	US 4,836,778	06/06/1989	Baumrind et al.	
	44.	US 4,837,732	06/06/1989	Brandestini et al.	
	45.	US 4,850,864	07/25/1989	Diamond	
	46.	US 4,850,865	07/25/1989	Napolitano	
	47.	US 4,856,991	08/15/1989	Breads et al.	
	48.	US 4,877,398	10/31/1989	Kesling	
	49.	US 4,880,380	11/14/1989	Martz	
	50.	US 4,889,238	12/26/1989	Batchelor	
	51.	US 4,890,608	01/02/1990	Steer	
	52.	US 4,935,635	06/19/1990	O'Harra,	
	53.	US 4,936,862	06/26/1990	Walker et al.	
	54.	US 4,937,928	07/03/1990	van der Zel	
	55.	US 4,941,826	07/17/1990	Loran et al.	
	56.	US 4,964,770	10/23/1990	Steinbichler et al.	
	57.	US 4,975,052	12/04/1990	Spencer et al.	
	58.	US 4,983,334	01/08/1991	Adell	

Examiner Signature	/Justin O'Donnell/	Date Considered	09/30/2012

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	59.	US 5,011,405	04-31-1991	Lemchen	
	60.	US 5,017,133	05/21/1991	Miura	
	61.	US 5,027,281	06/25/1991	Rekow et al.	
	62.	US 5,035,613	07/30/1991	Breads et al.	
	63.	US 5,055,039	10/08/1991	Abbatte et al.	
	64.	US 5,059,118	10/22/1991	Breads et al.	
	65.	US 5,100,316	03/31/1992	Wildman	
	66.	US 5,121,333	06/09/1992	Riley et al.	
	67.	US 5,125,832	06/30/1992	Kesling	
	68.	US 5,128,870	07/07/1992	Erdman et al.	
	69.	US 5,130,064	07/14/1992	Smalley	
	70.	US 5,131,843	07/21/1992	Hilgers et al.	
	71.	US 5,131,844	07/21/1992	Marinaccio et al.	
	72.	US 5,139,419	08/18/1992	Andreiko et al.	
	73.	US 5,145,364	09/08/1992	Martz et al.	
	74.	US 5,176,517	01/05/1993	Truax	
	75.	US 5,184,306	02/02/1993	Erdman et al.	
	76.	US 5,186,623	02/16/1993	Breads et al.	
	77.	US 5,257,203	10/26/1993	Riley et al.	
	78.	US 5,273,429	12/28/1993	Rekow et al.	
	79.	US 5,278,756	01/11/1994	Lemchen et al.	
	80.	US 5,328,362	07/12/1994	Watson et al.	
	81.	US 5,338,198	08/16/1994	Wu et al.	
	82.	US 5,340,309	08/23/1994	Robertson	
	83.	US 5,342,202	08/23/1994	Deshayes	
	84.	US 5,368,478	11/29/1994	Andreiko et al.	
	85.	US 5,382,164	01/17/1995	Stern	
	86.	US 5,395,238	03/07/1995	Andreiko et al.	
	87.	US 5,431,562	11/11/1995	Andreiko et al.	

Examiner Signature	/Justin O'Donnell/	Date Considered	09/30/2012

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				Application Number	13/470,681
				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
Sheet	4	of	21	Attorney Docket Number	22773-826.201

U.S. PATENT DOCUMENTS

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	88.	US 5,440,326	08/08/1995	Quinn	
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	90.	US 5,447,432	09/05/1995	Andreiko et al.	
	91.	US 5,452,219	09/19/1995	Dehoff et al.	
	92.	US 5,454,717	10/03/1995	Andreiko et al.	
	93.	US 5,456,600	10/10/1995	Andreiko et al.	
	94.	US 5,474,448	12/12/1995	Andreiko et al.	
	95.	US 5,518,397	05/21/1996	Andreiko et al.	
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	102.	US 5,605,459	02/25/1997	Kuroda et al.	
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	118.	US 5,823,778	10/20/1998	Schmitt et.al.	
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	120.	US 5,857,853	01/12/1999	van Nifterick et al.	
	121.	US 5,866,058	02/02/1999	Batchelder et al.	
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				Art Unit	3732
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	151.	US 6,482,298	11/19/2002	Bhatnagar	
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	164.	DE 69327661 T	07/20/2000	Andreiko et al.		
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	166.	EP 0299490 A2 (in German with English abstract)	01/18/1989	Steinbichler et al.		
	167.	EP 0376873 A2	07/04/1990	Shafir		
	168.	EP 0490848 A2	06/17/1992	Andersson et al.		
	169.	EP 0541500 A1	05/12/1993	Andersson et al.		

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	188.	ALEXANDER et al., "The DigiGraph Work Station Part 2 Clinical Management," JCO, pp. 402-407 (July 1990	
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	195.	BARTELS, et al., An Introduction to Splines for Use in Computer Graphics and Geometric Modeling, Morgan Kaufmann Publishers, pp. 422-425 (1987).	

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				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
Sheet	10	of	21	Attorney Docket Number	22773-826.201

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				Application Number	13/470,681
				Filing Date	May 14, 2012
				First Named Inventor	Chunhua Li
				Art Unit	3732
				Examiner Name	Unassigned
Sheet	16	of	21	Attorney Docket Number	22773-826.201

NON PATENT LITERATURE DOCUMENTS			
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	276.	MCNAMARA et al., Orthodontic and Orthopedic Treatment in the Mixed Dentition, Needham Press, pp. 347-353 (January 1993).	
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	321.	VAN DER ZEL, "Ceramic-Fused-to-Metal Restorations with a New CAD/CAM System," Quintessence Int., 24(11):769-778 (1993	
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

Amendments to the Claims:

Please amend claims 1, 5, 9, 10, and 13; and withdraw claims 20-29 as set forth below. This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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.

2. (Original) 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. (Original) 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. (Original) 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. (Currently Amended) The dental appliance of claim 1, wherein the hard polymer layer ~~comprises~~ has a thickness in a range from ~~about~~ 400[[tm]] μm to ~~about~~ 1100[[gm]] μm~~, about 450 tm to about 1000 gm, about 500 tm to about 900 gm, or about 550 tm to about 750 gm~~.

6. (Original) 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. (Original) 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. (Original) 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. (Currently Amended) The dental appliance of claim 1, wherein at least one of the first soft polymer layer ~~comprises~~ and the second soft polymer layer has a thickness in a range from ~~about~~ 25[[tm]] μm to ~~about~~ 100[[gm]] μm~~, about 30 tm to about 90 gm, or about 35 gm to about 80 gm~~.

10. (Currently Amended) The dental appliance of claim 1, wherein the hard polymer layer, the first soft polymer layer and the second soft polymer layer combined ~~comprises~~ has a thickness of ~~about~~ 500[[tm]] μm to ~~about~~ 1200[[gm]] μm~~, about 550 tm to about 1100 gm, or about 600 tm to about 1000 gm~~.

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

13. (Currently Amended) 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 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 being greater that each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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.

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

28. (Withdrawn) 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. (Withdrawn) 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.

Amendments to the Specification:

Please replace the Abstract with the following amended Abstract:

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

Please replace paragraph **[0025]** with the following amended paragraph:

Paragraph **[0025]** is amended as follows:

[0025] 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.

Amendments to the Drawings:

The attached sheets of drawings include changes to Figs 2 and 5-8.

Attachments: Replacement Sheets

REMARKS

This paper is responsive to the Non-Final Office Action mailed October 10, 2012. Claims 1, 5, 9, 10, and 13 have been amended. Claims 20-29 have been withdrawn from further consideration by the examiner. Support for the amendments can be found in the specification as originally filed. Accordingly, no new matter has been added. Reconsideration in view of the amendments and the following remarks is respectfully requested.

Election/Restrictions

The Examiner issued a group restriction requirement stating that the application claims distinct inventions as follows:

I. Claims 1-19, drawn to a dental appliance and orthodontic system for positioning a patient's teeth, classified in class 433, subclass 6; and

II. Claims 20-29, drawn to a method of making a dental appliance for positioning a patient's teeth, classified in class 264, subclass 16.

Applicants confirm the provisional election of **Group I**, corresponding to claims 1-19.

Objections to the Drawings

The drawings stand objected to under 37 CFR 1.83(a). Specifically, it is indicated in the Office Action that the drawings should show that the hard polymer layer and at least one of the first and second soft polymer layers can include at least two layers (see claims 4, 8, 15, and 17). Also, that the character of the lines in FIGS. 5-8 is such as to cause unsatisfactory reproduction characteristics.

Revised FIGS. 2 and 5-8 are submitted herewith to overcome these objections. The revisions to FIG. 2 are supported in the specification as filed (*e.g.*, see paragraph [0025] lines 19-21; paragraph [0029] lines 25-28 on page 9 and lines 3-5 on page 10).

Accordingly, withdrawal of the objections to the drawings is respectfully requested.

Objections to the Abstract

The Abstract stands objected for the reasons set forth on page 8 of the Office Action. Applicants have submitted an amended Abstract to overcome the objection to the Abstract.

Accordingly, withdrawal to the objection to the Abstract is respectfully requested.

Claim Rejections – 35 USC § 112

Claims 1-19 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is stated in the Office Action that it is unclear what polymeric materials would be encompassed by the terms "hard" and "soft" and as such, further specificity is required. Claims 5, 9, and 10 stand rejected for reciting broader and narrow ranges in the same claims. And claim 9 stands rejected as indefinite because it is not clear whether "the soft polymer layer" refers to the "first soft polymer layer" or the "second polymer layer" set forth in claim 1.

Independent claims 1 and 13 have been amended to further specify that the hard polymer layer has an elastic modulus that exceeds the elastic modulus of each of the first and second soft polymer layers, thereby providing further specificity with regard to the recited layers. Additionally, claims 5, 9, and 10 have been amended to address the above-noted issues.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 1-19 under 35 U.S.C. 112 is respectfully requested.

Claim Rejections – 35 USC § 102 and § 103

Claims 1-5, 10 and 13-15 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by *Chen et al.* (US 2009/0246724). Claims 6-9, 12, 16, 17 and 19 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over *Chen*, in view of *Grossman et al.* (US 5,024,790). And claims 11 and 18 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over *Chen*.

Without conceding the merit of the rejections, the claims have been amended to expedite prosecution. It is respectfully submitted that the cited references, either alone or in any combination, fail to disclose or suggest all elements recited in the claims, thereby precluding

rejections based on anticipation and/or obviousness. Additionally, the proposed combination of *Chen* in view of *Grossman* cannot be used to render claims obvious because the proposed modification of *Chen* would render *Chen* unfit for its intended purpose. (see **MPEP 2143.01 V.**)

Amended claim 1 recites:

> 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,
>
> wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and
>
> wherein 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.

Claim 1 recites elements similar to elements recited in claim 6 – specifically a list of materials that at least one of the first soft polymer layer and the second soft polymer layer can include. As acknowledged on page 11 and 12 of the Office Action, *Chen* fails to disclose such elements. Claim 1 also recites "*... wherein 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.*"

Grossman fails to remedy the above-noted deficiencies of *Chen*. *Grossman* discloses a method of applying a surface glaze to a dental construct in which a glazing material is associated with a carrier that is highly flexible and removable. The carrier and associated glazing is forced onto the dental construct using differential pressure and then the carrier is removed, thereby leaving the glazing applied to the dental construct. (Abstract). The carrier (organic film 10 shown in FIGS. 1, 4, 5, and 6) of *Grossman* is identified in the Office Action as corresponding to the first and second soft polymer layers recited in claim 1. The carrier of

Grossman, however, is disclosed as being relatively soft – see col. 2 lines 45 in which the film 10 of *Grossman* is disclosed as having a 100% secant modulus of less than 1000 psi. Accordingly, *Grossman* fails to disclose *"... wherein 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"* as recited in claim 1. Accordingly, claim 1 is allowable over the cited references at least for the cited references, either alone or in combination, failing to disclose all the elements recited in claim 1.

Moreover, the proposed combination of *Chen* to utilize the film 10 of *Grossman* cannot be used to render the claims obvious because such a modification of *Chen* would render *Chen* unfit for its intended purpose. (see **MPEP 2143.01 V.**). *Chen* discloses a multilayer dental appliance in which an external stimulus is applied to transition the appliance from a first shape to a second shape. (see, *e.g.*, FIG. 6). In the cited portion of *Chen* (paragraph [0036]), material layers having different glass transition temperatures are heated over the lower of the glass transition temperatures such that the corresponding layer gets softer, thereby allowing the shape of the appliance to change. In contrast, *Grossman* merely discloses the film 10 as being highly flexible and as such would not inherently undergo the significant change in stiffness in response to an external stimulus as disclosed in *Chen* and would therefore not enable the resulting change in shape disclosed in *Chen*.

Claims 2-12 depend from claim 1 and are therefore also allowable over the cited references for the same reasons as for claim 1, as well as on their own merits. Claim 13 recites elements similar to the above-noted claim 1 elements, and is therefore also allowable over the cited references for the same reasons as for claim 1, as well as on its own merits. Claims 14-19 depend from claim 13 and are therefore also allowable over the cited references for the same reasons as for claim 13, as well as on their own merits.

Accordingly, withdrawal of the rejection of claims 1-19 under 35 U.S.C. 102(b) and 103(a) is respectfully requested.

Double Patenting

Claims 1 and 13 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly obvious over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of *Chen et al.* (US 2009/0246724).

The obviousness-type double patenting rejection is acknowledged and will be addressed upon final resolution of the claims, *e.g.*, by filing a terminal disclaimer, if necessary.

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: January 8, 2013

/Mark T. McMcMaster/

Mark T. McMaster
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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 January 8, 2013

WILSON SONSINI GOODRICH & ROSATI

By: /Monica Leigh/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chunhua Li Application No.: 13/470,681 Filed: May 14, 2012 For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS Customer No. 107046	Confirmation No. 5655 Examiner: Justin R. O'Donnell Art Unit: 3732 AMENDMENT

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

Commissioner:

In response to the Non-Final Office Action mailed October 10, 2012 please enter the following amendments and remarks:

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

Amendments to the Claims are reflected in the listing of claims, which begins on page 4 of this paper.

Amendments to the Drawings begin on page 12 of this paper and include attached replacement sheets.

Remarks begin on page 13 of this paper.

An **Appendix** including amended drawing figures is attached following page 17 of this paper.

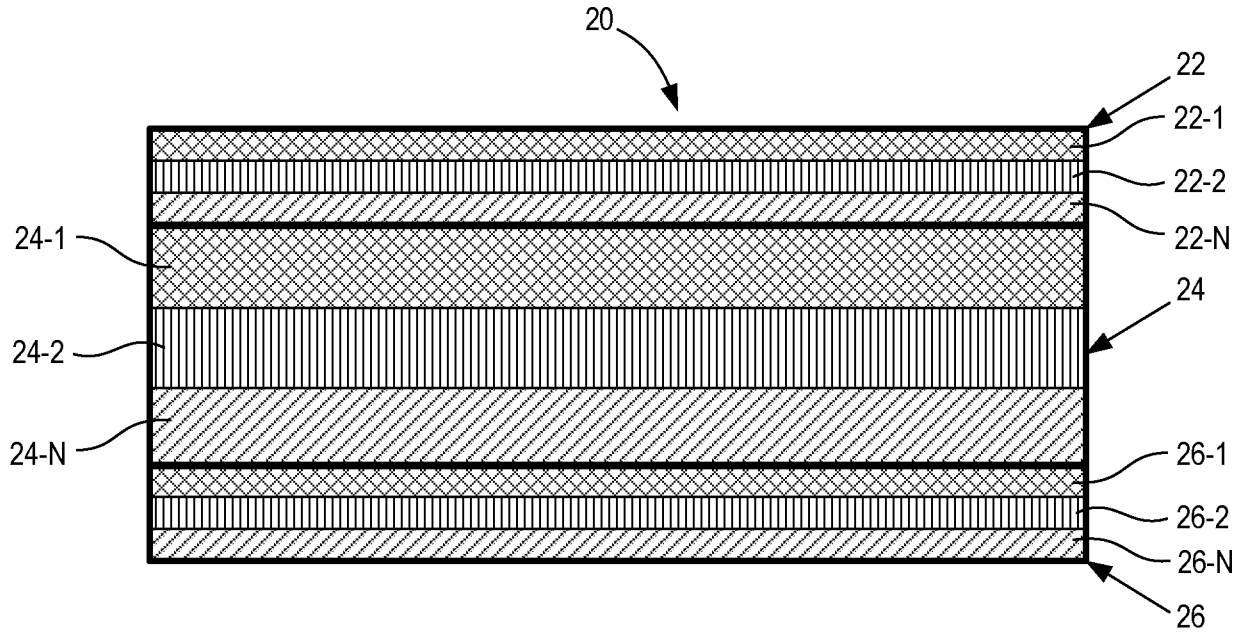


FIG. 2

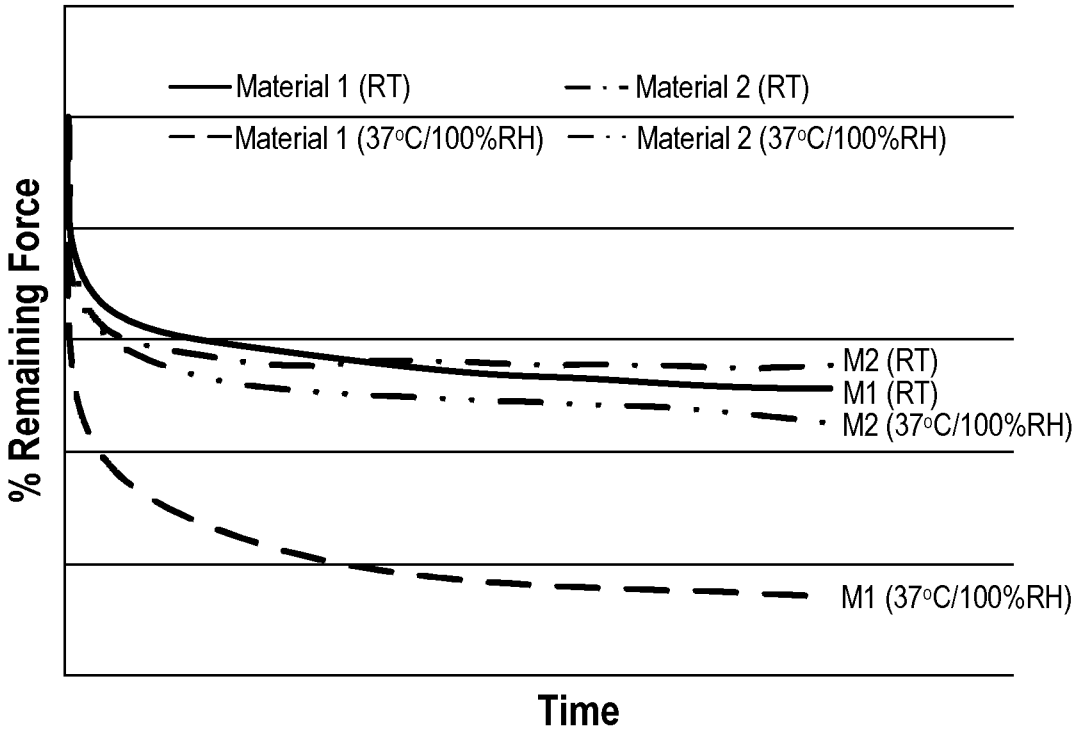

Material 1 (RT)
Material 2 (RT)
Material 1 (37°C/100%RH)
Material 2 (37°C/100%RH)
% Remaining Force
M2 (RT)
M1 (RT)
M2 (37°C/100%RH)
M1 (37°C/100%RH)
Time

FIG. 5

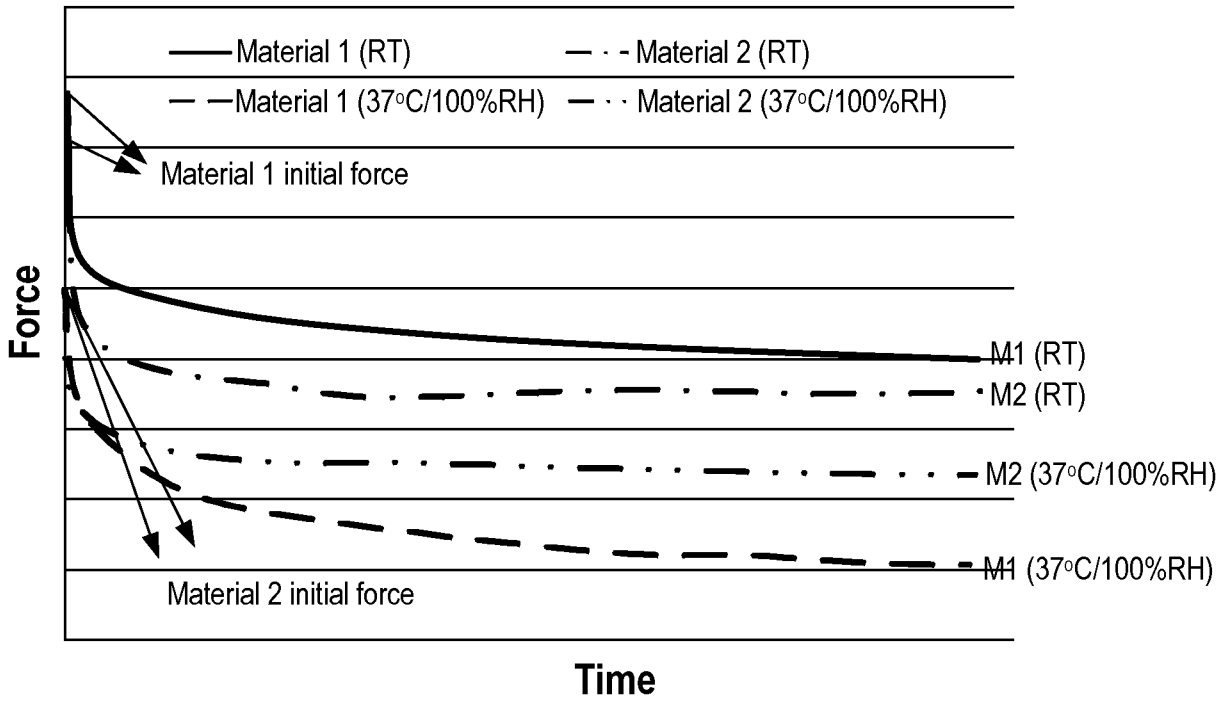

Material 1 (RT)
Material 2 (RT)
Material 1 (37°C/100%RH)
Material 2 (37°C/100%RH)
Material 1 initial force
Force
M1 (RT)
M2 (RT)
M2 (37°C/100%RH)
M1 (37°C/100%RH)
Material 2 initial force
Time

FIG. 6

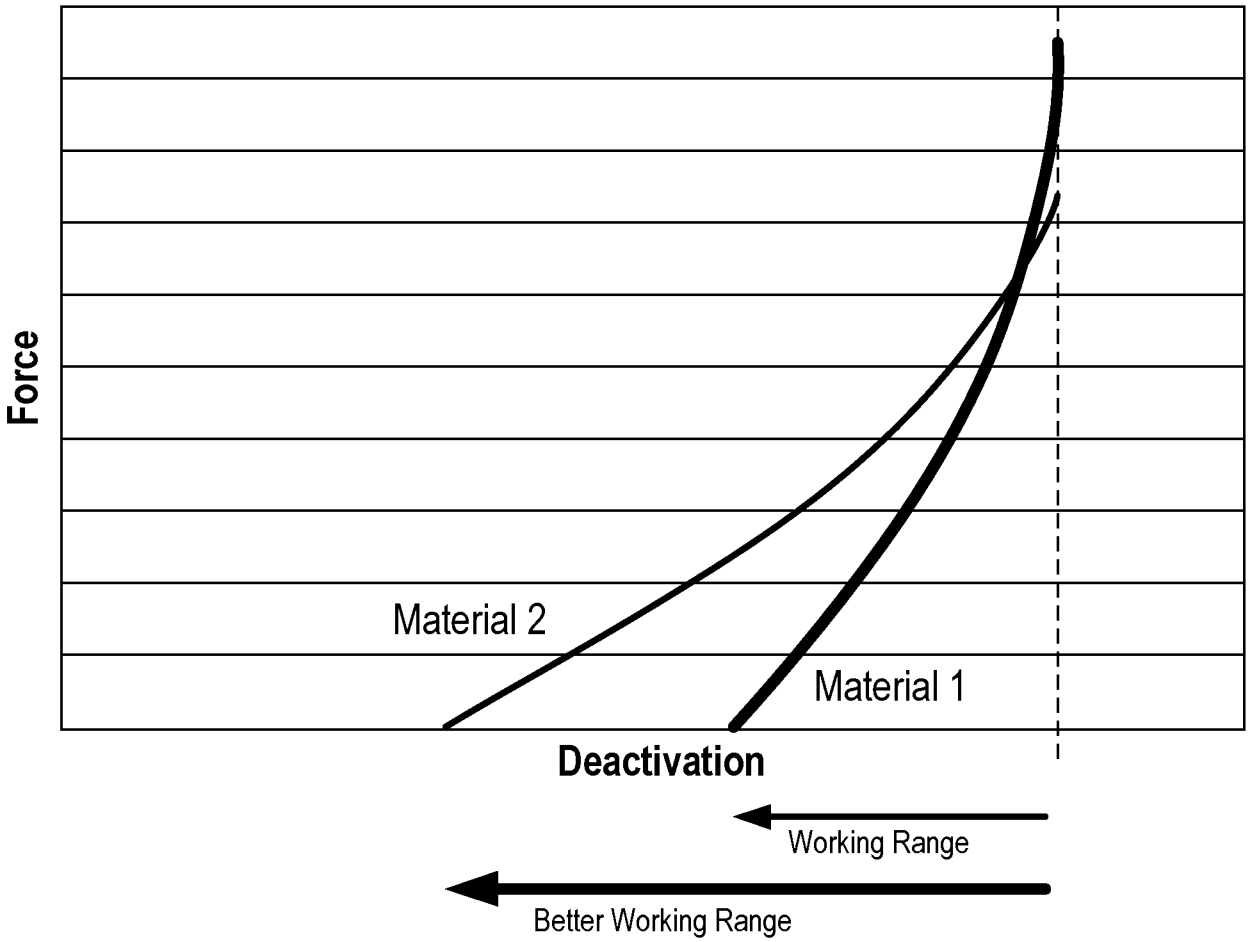

Force
Material 2
Material 1
Deactivation
Working Range
Better Working Range

FIG. 7

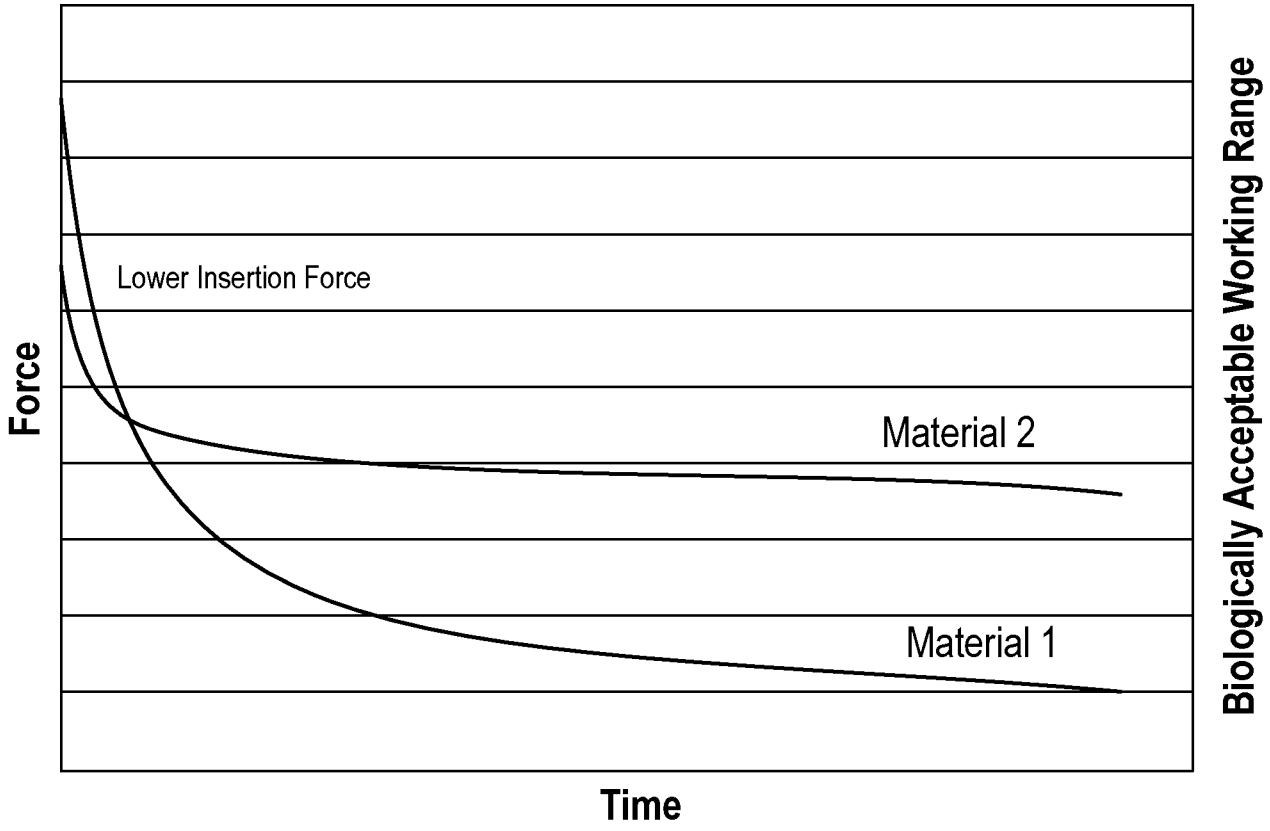

Force
Lower Insertion Force
Material 2
Material 1
Time
Biologically Acceptable Working Range

FIG. 8

Please replace paragraph **[0029]** with the following amended paragraph:

Paragraph **[0029]** is amended as follows:

[0029] 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 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.

Electronic Acknowledgement Receipt

EFS ID:	14644737
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Mark T. McMaster/Monica Leigh
Filer Authorized By:	Mark T. McMaster
Attorney Docket Number:	22773-826.201
Receipt Date:	08-JAN-2013
Filing Date:	14-MAY-2012
Time Stamp:	16:16:29
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		2013_01-08_Amd_Drawings_22773_826_201.pdf	227157 647e9f62a849d3ccec15ad988e204094848e2e31	yes	22

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	3
	Claims	4	11
	Applicant Arguments/Remarks Made in an Amendment	12	17
	Drawings-only black and white line drawings	18	22
Warnings:			
Information:			
	Total Files Size (in bytes):	227157	

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/SB/06 (07-06)
Approved for use through 1/31/2007. 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	Filing Date	☐ To be Mailed
13/470,681	05/14/2012	

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	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 01/08/2013	(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))	* 29	Minus	** 29	= 0	X $ =		OR	X $62=	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $250=	0
☐ 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	0

AMENDMENT	(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".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/STELLA LITTLE/

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.

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107046 e 2013-01-18

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

Paper No.

Application No.:	**13/470,681**	**Date Mailed:**	**2013-01-18**
First Named Inventor:	Li, Chunhua,	Examiner:	O'DONNELL, JUSTIN R
Attorney Docket No.:	22773-826.201	Art Unit:	3732
Confirmation No.:	5655	Filing Date:	2012-05-14

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

Commissioner for Patents

PTO-90c (Rev.08-06)

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 13/470,681	Applicant(s) LI ET AL.
		Art Unit 3998

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

The amendment document filed on *08 January, 2013* is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other _____.
- ☒ 2. Abstract:
  - ☒ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other _____.
- ☐ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☐ E. Other: _____.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4): For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period if the non-compliant amendment is an** after-final amendment or an amendment filed after allowance, or a drawing submission (only) If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1 to 4 are checked, the correction required is only the corrected section of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable /STELLA LITTLE/ Telephone No: (571)272-4365

Amendments to the Specification:

Please replace paragraph **[0025]** with the following amended paragraph:

Paragraph **[0025]** is amended as follows:

[0025] 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.

Please replace paragraph **[0029]** with the following amended paragraph:

Paragraph **[0029]** is amended as follows:

[0029] 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 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.

REMARKS

This paper is responsive to the Notice of Non-Compliant Amendment mailed January 18, 2013. Specifically, the amendments to the abstract are presented on a separate sheet. Additionally, the previously submitted amended paragraphs [0025] and [0029] are resubmitted herewith. Reconsideration in view of the foregoing amendments, as well as in view of the amendments and remarks in the related amendment filed January 8, 2013, is respectfully requested.

Objections to the Specification

The Abstract stands objected to for the reasons set forth on page 8 of the Office Action mailed October 10, 2012 and the Notice of Non-Compliant Amendment mailed January 18, 2013. Applicants have submitted an amended Abstract on a separate sheet to overcome the objections.

Accordingly, withdrawal of the objection to the Abstract is respectfully requested.

CONCLUSION

In view of the foregoing and the related amendment filed January 8, 2013, 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: February 12, 2013

/Mark T. McMaster/

Mark T. McMaster
Registration No. 62,078

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

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on February 12, 2013

WILSON SONSINI GOODRICH & ROSATI

By: /Monica Leigh/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chunhua Li Application No.: 13/470,681 Filed: May 14, 2012 For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS Customer No. 107046	Confirmation No. 5655 Examiner: Justin R. O'Donnell Art Unit: 3732 RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

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

Commissioner:

In response to the Notice of Non-Compliant Amendment mailed January 18, 2013, please enter the following amendments and remarks.

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

Amendments to the Specification begin on page 3 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Abstract:

Please replace the Abstract with the following amended Abstract:

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

Electronic Acknowledgement Receipt

EFS ID:	14941652
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Mark T. McMaster/Monica Leigh
Filer Authorized By:	Mark T. McMaster
Attorney Docket Number:	22773-826.201
Receipt Date:	12-FEB-2013
Filing Date:	14-MAY-2012
Time Stamp:	17:14:06
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		2013_02_12_RESP_NOTICE_NON_COMPLIANT_AMD.pdf	100133 58d8016c791ef6afc316edca71bc9dae5b11a9c5	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Abstract	2	2
	Specification	3	4
	Applicant Arguments/Remarks Made in an Amendment	5	6

Warnings:	
Information:	
Total Files Size (in bytes):	100133

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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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO
Updated	All	9/10/2013	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO
Updated EAST search	9/10/2013	JO

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S62	968	264/16,17,18.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/09/10 23:23
S61	2158	433/2,6,18,24.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/09/10 23:23
S60	2	"7641828".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 20:05
S59	94	S55 and S56	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:57
S58	7	S55 same3 S56	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:56
S57	2	S55 same S56	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:55
S56	288413	brace aligner orthodonti$2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:55
S55	5410	S50 same S51	US-PGPUB;	OR	ON	2013/09/10

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			19:51
S52	2357	S50 with S51	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:51
S51	147900	(tensile elastic young$2) near2 modulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:51
S50	507474	(silicon$2 near2 rubber) (elastomer$2 near2 (blend alloy)) "tpv" "tpe" ((thermoplastic polyurethane) near2 elastomer) (polyolefin near2 blend) (block near copolymer) (thermoplastic near2 (elastomer vulcanizate co$polyester polyamide))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/09/10 19:49
S49	130	invisalign	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/26 17:48
S47	799	align.as.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/26 17:48

EAST Search History (Interference)

<This search history is empty>

9/10/2013 11:25:04 PM
C:\Users\jodonnell\Documents\EAST\Workspaces\13470681.wsp

Notice of References Cited	Application/Control No. 13/470,681	Applicant(s)/Patent Under Reexamination LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,641,828 B2	01-2010	DeSimone et al.	264/129
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Boedeker.com. Polycarbonate specifications [retrieved on 10 September 2013]. Retrieved from the Internet: http://www.boedeker.com/polyc_p.htm
	V	Lubrizol.com. Isoplast 2530 data sheet [retrieved on 10 September 2013]. Retrieved from the Internet: http://www.lubrizol.com/Medical/TDS/Isoplast-2530.pdf
	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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 09/25/2013

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

EXAMINER	
O'DONNELL, JUSTIN R	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
09/25/2013	PAPER

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.

Office Action Summary	Application No. 13/470,681	Applicant(s) LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	AIA (First Inventor to File) 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *12 February 2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-29* is/are pending in the application.

5a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-19* 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 *08 January 2013* 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/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☒ Other: *NPL documents*.

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

In the amendment filed 08 January 2013, claims 1, 5, 9, 10, 13 are amended, claims 2-4, 6-8, 11-12, and 14-19 are original. Claims 1-19 will be examined in accordance with abovementioned amendments.

Information Disclosure Statement

2. The listing of references in the specification (namely: 6,450,807) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Drawings

4. The drawings were received on 08 January 2013. While these drawings are approved, several of the reference characters in Replacement Fig. 2 do not appear in the amended specification.

5. The drawings are objected to for the following reasons:

- Figure 2 includes the following reference characters not mentioned in the description: **24-1**, **24-2, 24-N**. See 37 CFR 1.84(p)(5).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The amendment to the specification filed 08 January 2013 is acceptable.

Claim Rejections - 35 USC § 103

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

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

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2009/0246724 A1), in view of DeSimone et al. (US 7,641,828 B2), as evidenced by Boedeker (see attached) and Lubrizol (see attached).

Chen teaches an orthodontic system including a plurality of incremental tooth position adjustment appliances (100) having teeth receiving cavities (102) shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, where the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement ([0014]-[0015] line 5), and where at least one of the appliances includes a hard polymer layer (150, Fig. 5) having a hard polymer layer elastic modulus (375,000 psi; see 'Unfilled' column in the attached Polycarbonate Specifications) disposed between a first soft polymer layer (outer 152) having a first soft polymer layer elastic modulus and a second soft polymer layer (inner, tooth-facing 152) having a second soft polymer layer elastic modulus, the hard polymer layer elastic modulus being greater than each of the first soft polymer layer elastic

modulus and the second soft polymer layer elastic modulus ([0036] lines 8-10, 13-16: outer layer 152 may have…lower glass transition temp than inner layers 150; layers with lower glass transition temp may be the softer segment… layers with higher glass transition temp may be harder segment); where at least one of the first and second soft polymer layers includes two layers ([0033] lines 1-3).

Chen does not teach that the at least two layers of at least one of the first and second soft polymer layer independently includes 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, a polyester elastomer, or a combination thereof; and that the first and second soft polymer layer each independently include 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 ℃ 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 a multilayer polymer dental positioning appliance (claim 1: first and second transparent materials), which includes a soft layer of polyurethane elastomer (col. 10 ll. 14-16: ISOPLAST 2530; softer than hard layer formed from materials in col. 7 ll. 27-35) having a soft layer elastic modulus (2300 MPa, or 333,586.8 psi; see attached ISOPLAST 2530 technical data sheet). It would have been obvious to

one of ordinary skill in the art at the time of invention to make the Chen soft polymer layers using the DeSimone material in order to reinforce the appliance with a layer having excellent chemical resistance, high heat, low moisture sensitivity, toughness, and dimensional stability (col. 10 ll. 17-20).

With respect to claims 2-5, 10, 11, 14, and 15, Chen teaches that the hard polymer layers (Fig. 5: two inner layers 150) include a layer of a polycarbonate ([0036] lines 5-7) having a tensile and flexural modulus greater than 150,000 psi (respectively 320,000 and 375,000 psi; see 'Unfilled' column in the attached Polycarbonate Specifications)) thickness in a range from 400 µm to 1100 µm ([0031] lines 5-6: at 10 mil per layer, the two inner layers in Fig. 5 have combined thickness of 20 mil = 508 µm); and that the combined hard and soft polymer layers (Fig. 5) have a thickness of 500 µm to 1200 µm (4 x 10 mil = 40 mil = 1016 µm).

With respect to claim 9, Chen does not teach at least one of the first and second soft polymer layer as having a thickness in a range from 25 µm to 100 µm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to select a soft polymer layer having a thickness from 25 to 100 µm because Applicant has not disclosed this parameter as contributing any unexpected result to the appliance. One of ordinary skill in the art, furthermore, would have expected Chen's appliance and applicant's invention to perform equally well with either the layer taught by Chen or the claimed layer having a thickness from 25 to 100 µm because both layers would perform the same function of providing an aligner appliance with a combined modulus sufficient to grab hold of and reposition teeth.

Therefore, it would have been prima facie obvious to modify Chen to obtain the invention as specified in claim 9, as such a modification would have been considered a mere design consideration, which fails to patentably distinguish over the prior art of Chen.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of Chen et al. (US 2009/0246724).

The differences between instant claims 1 and 13, and patented claims 1, 2, and 6 are twofold. First, patented claims 1, 2, and 6 contain the additional limitations of

"wherein at least one of the appliances comprises a shell having a different geometry than that of at least one other appliance, and wherein at least two different appliances of the system have different elastic moduluses and hardnesses; and a first appliance consisting entirely of the first material; and a second appliance consisting entirely of the second material," and is thus more specific, in effect making the invention of patented claim 6 a "species" of the "generic" invention of instant claims 1 and 13. It has been held that the generic invention is "anticipated" by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). The second difference between the claims is that patented claim 6 does not specify that the hard polymer layer (patented claims: the first polymeric material with an elastic modulus greater than the second polymeric material) is disposed between a first soft polymer layer and a second soft polymer layer.

Chen teaches an appliance which includes a hard polymer layer (150, Fig. 5) disposed between a first soft polymer layer (outer 152) and a second soft polymer layer (inner, tooth-facing 152). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify claim 6 of U.S. Patent No. 8,235,713 to include the Chen layers, as Chen states in [0012] and [0032] that the combination of layers with differing glass transition temperatures allows the appliance to transition from a deformed and/or relaxed shape to an original shape upon an application of an external stimulus, thereby extending the useful lifespan of the dental appliance.

Response to Arguments

9. Applicant's arguments filed 08 January 2013 have been fully considered but they are not persuasive. Applicant argues that the prior art of Chen and Grossman do not teach the claimed first and second soft polymer layer having a flexural modulus greater than 35,000 psi. However, it is noted that the prior art of DeSimone has been cited to teach the claimed limitation. The applicant's arguments are therefore moot.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** 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 mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Justin O'Donnell whose telephone number is (571)270-5131. The examiner can normally be reached Monday-Friday, 10:30-8:30.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Cris Rodriguez, at* (571) 272-4964**. 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.

/Justin O'Donnell/
Examiner, Art Unit 3732

/HEIDI M EIDE/
Primary Examiner, Art Unit 3732

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	✓						
	4	÷	✓	✓						
	5	÷	✓	✓						
	6	÷	✓	✓						
	7	÷	✓	✓						
	8	÷	✓	✓						
	9	÷	✓	✓						
	10	÷	✓	✓						
	11	÷	✓	✓						
	12	÷	✓	✓						
	13	÷	✓	✓						
	14	÷	✓	✓						
	15	÷	✓	✓						
	16	÷	✓	✓						
	17	÷	✓	✓						
	18	÷	✓	✓						
	19	÷	✓	✓						
	20	÷	N	N						
	21	÷	N	N						
	22	÷	N	N						
	23	÷	N	N						
	24	÷	N	N						
	25	÷	N	N						
	26	÷	N	N						
	27	÷	N	N						
	28	÷	N	N						
	29	÷	N	N						

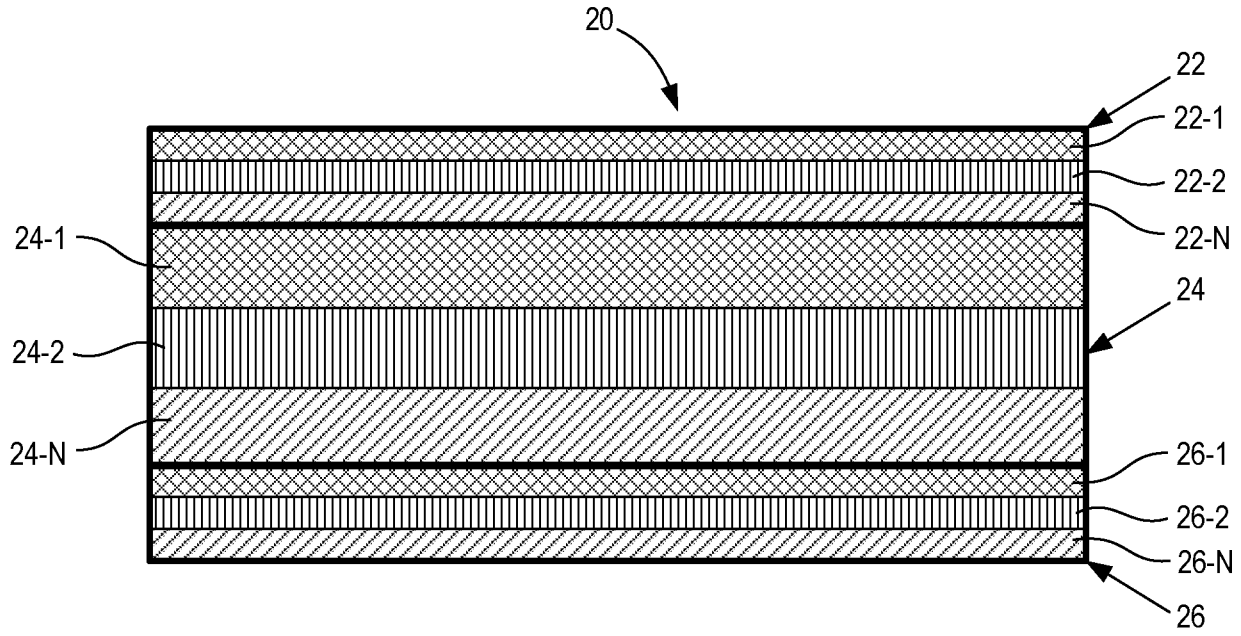


FIG. 2

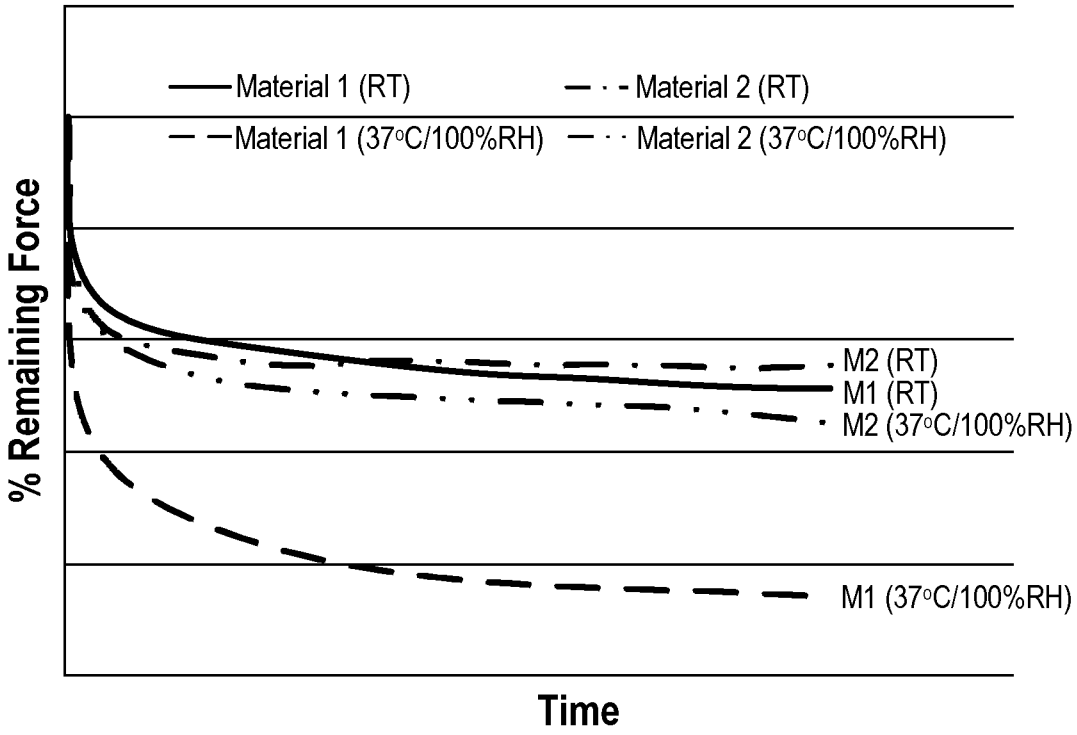

Material 1 (RT)
Material 2 (RT)
Material 1 (37°C/100%RH)
Material 2 (37°C/100%RH)
% Remaining Force
M2 (RT)
M1 (RT)
M2 (37°C/100%RH)
M1 (37°C/100%RH)
Time

FIG. 5

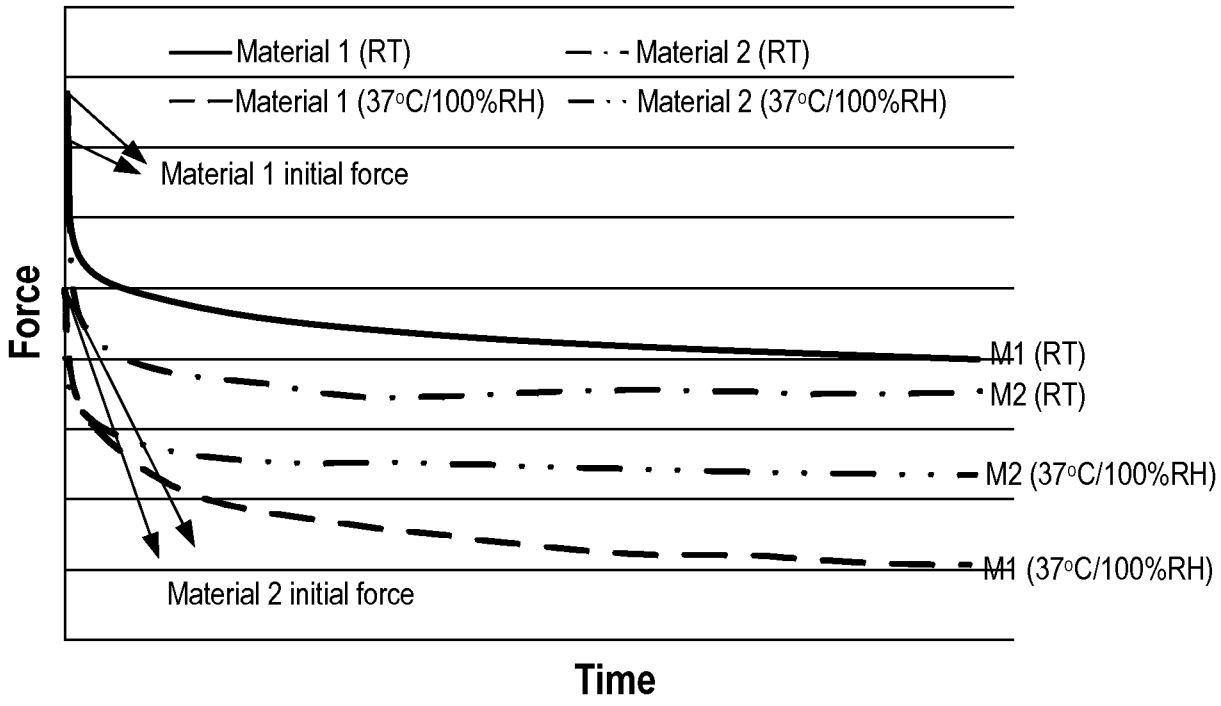

Material 1 (RT)
Material 2 (RT)
Material 1 (37°C/100%RH)
Material 2 (37°C/100%RH)
Material 1 initial force
Force
M1 (RT)
M2 (RT)
M2 (37°C/100%RH)
M1 (37°C/100%RH)
Material 2 initial force
Time

FIG. 6

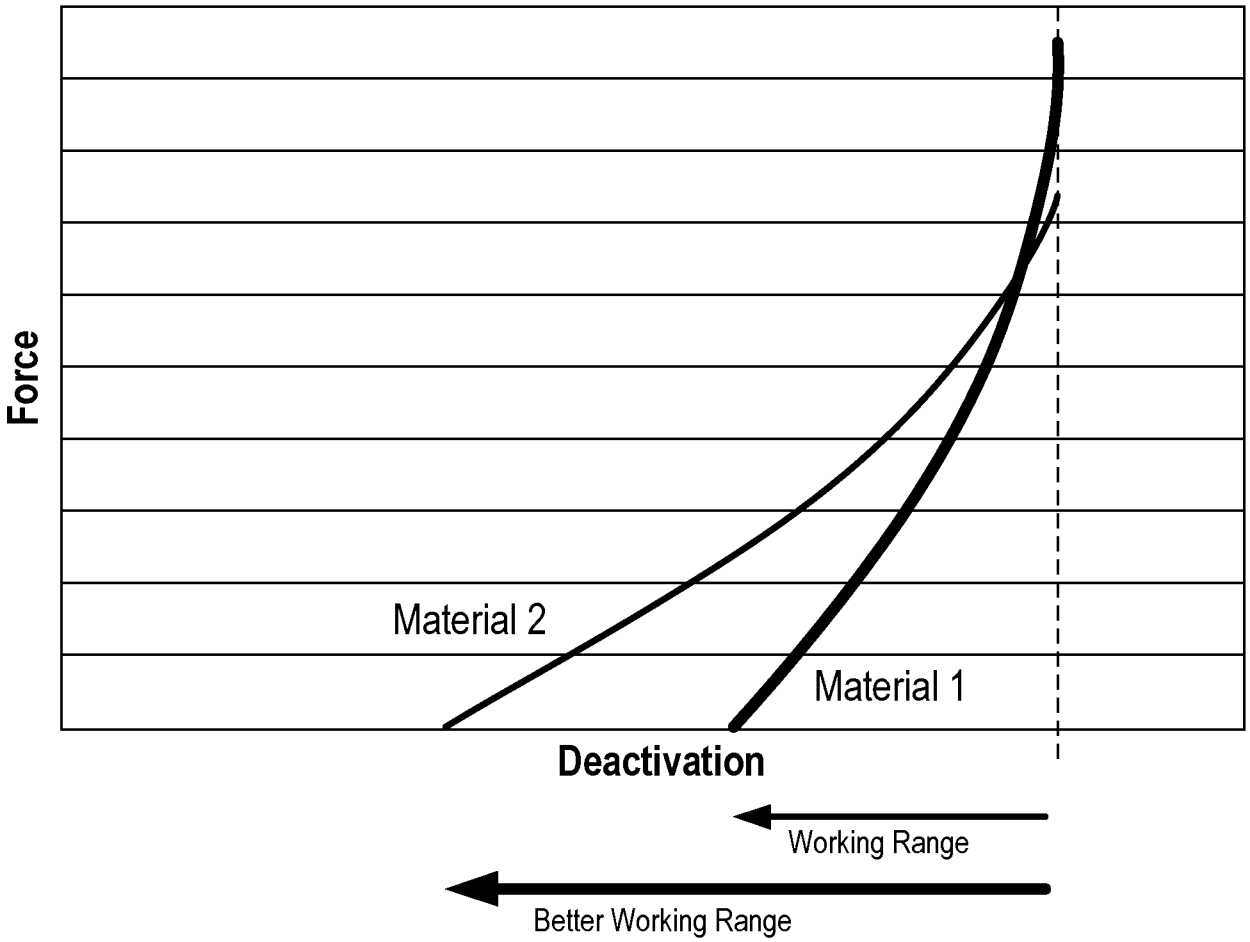

Force
Material 2
Material 1
Deactivation
Working Range
Better Working Range

FIG. 7

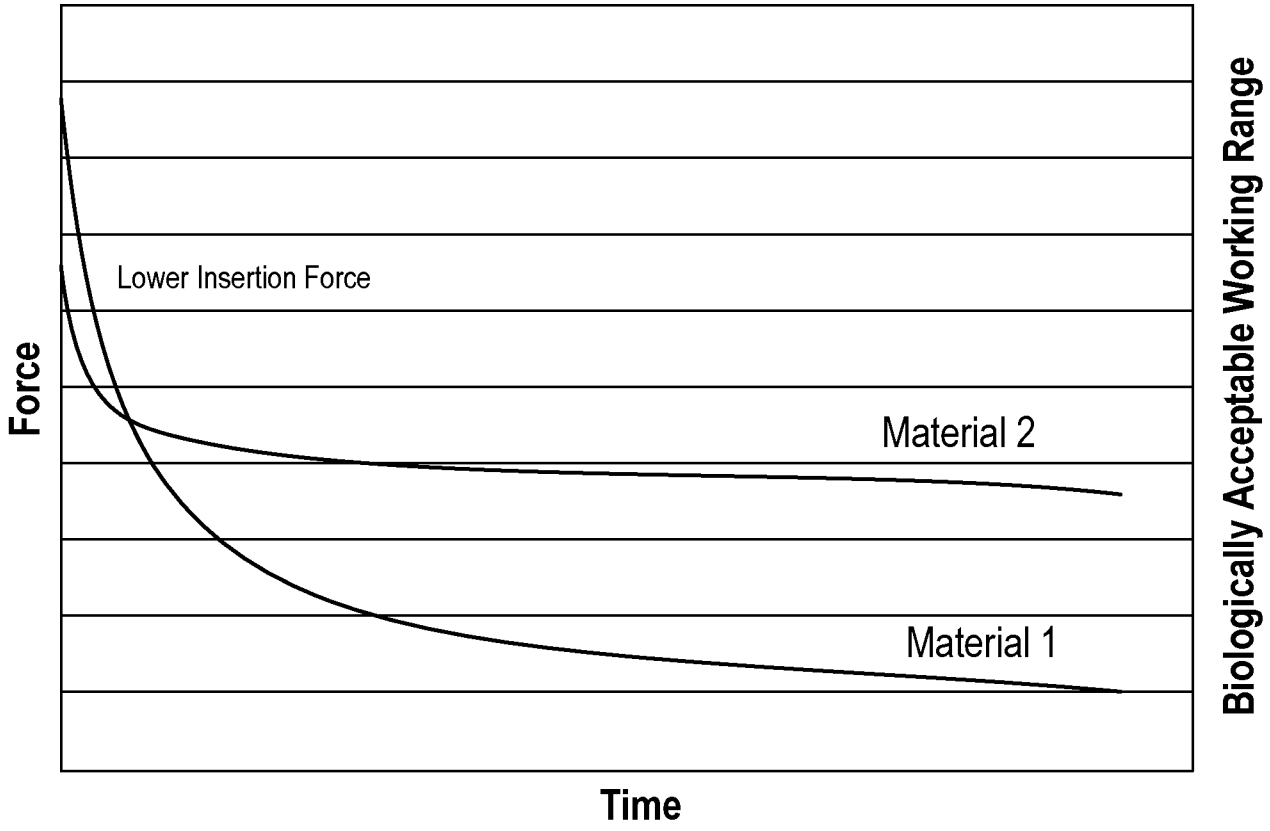

Force
Lower Insertion Force
Material 2
Material 1
Time
Biologically Acceptable Working Range

FIG. 8

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/470,681	05/14/2012	Chunhua Li	22773-826.201

CONFIRMATION NO. 5655

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

PUBLICATION NOTICE

OC00000064983767

Title:MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

Publication No.US-2013-0302742-A1
Publication Date:11/14/2013

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 Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, 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 http://pair.uspto.gov/. 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

REMARKS

Claims 1-29 are pending in the present application. Claims 2-4, 6-8, and 14-17 have been amended. Claims 20-29 stand withdrawn. Support for the amendments can be found in the specification as originally filed – accordingly, no new matter has been added. Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

Information Disclosure Statement

Applicants thank the Examiner for indicating that a reference listed in the specification (U.S. Patent 6,450,807) has not been considered by the Examiner due to not being listed on an Information Disclosure Statement (IDS).

U.S. Patent 6,450,807 is a continuation of PCT/US98/12861, which corresponds to WIPO Publication No. WO 98/58596, which was previously cited on the IDS filed August 2, 2012, (cite no. 185).

Objections to the Drawings

The drawings stand objected to under 37 CFR 1.84(p)(5). It is asserted in the Final Office Action that replacement figure 2 includes reference characters (specifically 24-1, 24-2, and 24-N) not mentioned in the amended specification.

Applicants respectfully direct the Examiner's attention to amended paragraph [0025], which was submitted in Applicants' prior response and was amended to include reference numbers 24-1, 24-2, and 24-N.

Accordingly, withdrawal of the objections to the drawings is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1-19 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over *Chen et al. (US 2009/0246724)* in view of *DeSimone et al., US 7,641,828)*, as evidenced by *Boedeker* and *Lubrizol*.

Applicants respectfully traverse the rejections. The cited references fail to disclose or suggest all the elements recited in the claims, thereby precluding the establishment of a *prima facie* case of obviousness.

Claim 1 recites:

> 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus***,
>
> wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and
>
> wherein ***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***.
>
> (***emphasis*** added)

Chen, while representing a considerable advancement in the art of orthodontics, fails to disclose all the elements recited in claim 1. *Chen* discloses a dental appliance that includes a shape memory material configured to restore the shape of the dental appliance upon application of an external stimulus. (*Chen* Abstract). Referring to paragraph [0032], *Chen* discloses an example embodiment having multiple layers including polycarbonate layers and PVC layers. The polycarbonate layers are identified in the Final Office Action as corresponding to the hard polymer layer recited in claim 1. Polycarbonate, however, has an elastic modulus less than that of PVC. In contrast, claim 1 recites in part that "... *the hard polymer layer elastic*

modulus being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus ...". Accordingly, the polycarbonate layer in *Chen* cannot correspond to the hard polymer layer recited in claim 1.

DeSimone fails to rectify the false basis upon which the rejection of claim 1 is based. *DeSimone* discloses methods of making a removable dental appliance that include forming a sheet of transparent crystalline polymeric material into a shell having teeth receiving cavities. The polymeric material may be annealed at a temperature above its glass transition temperature or cured to enhance characteristics of the polymeric material. (*DeSimone* Abstract). *DeSimone* is cited in the Final Office Action as teaching a multilayer polymer dental positioning appliance that includes a soft layer of polyurethane elastomer. The Final Office Action states:

> It would have been obvious to one or ordinary skill in the art at the time of the invention to make the Chen soft polymer layers using the DeSimone material in order to reinforce the appliance with a layer having excellent chemical resistance, high heat, low moisture sensitivity, toughness, and dimensional stability (col. 10 ll. 17-20).

As noted above, however, the polycarbonate layer of *Chen* is the soft layer – not the hard layer in *Chen*. Accordingly, the rejection of claim 1 is based on a false premise and is therefore not based on a rational basis required to support an obviousness rejection. Thus, claim 1 is not rendered obvious by the proposed modification of *Chen* in view of *DeSimone*.

Claims 2-12 depend from claim 1 and are therefore also allowable over the cited references for the same reasons as for claim 1, as well as on their own merits. Claim 13 recites elements similar to the above-noted claim 1 elements, and is therefore also allowable over the cited references for the same reasons as for claim 1, as well as on its own merits. Claims 14-19 depend from claim 13 and are therefore also allowable over the cited references for the same reasons as for claim 13, as well as on their own merits.

Accordingly, for the rationale set forth above, withdrawal of the rejection of claims 1-19 under 35 U.S.C. 103(a) is respectfully requested.

Double Patenting

Claims 1 and 13 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly obvious over claims 1, 2, and 6 of *Phan et al., (US 8,235,713)* in view of *Chen et al., (US 2009/0246724)*.

The rejection is acknowledged and will be addressed upon final resolution of the claims by, e.g., filing a terminal disclaimer, if necessary.

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 25, 2013

/Mark T. McMaster/

Mark T. McMaster
Registration No. 62,078

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Electronic Acknowledgement Receipt

EFS ID:	17501486
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Mark T. McMaster/Shannon Worden
Filer Authorized By:	Mark T. McMaster
Attorney Docket Number:	22773-826.201
Receipt Date:	25-NOV-2013
Filing Date:	14-MAY-2012
Time Stamp:	20:54:53
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		2013_11_25_AMDAF_22773_826_201.pdf	222559 85e8a6adea78808687613251 4a71f76ed8142b0b	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	9
	Applicant Arguments/Remarks Made in an Amendment	10	13
Warnings:			
Information:			
	Total Files Size (in bytes):	222559	

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 November 25, 2013

WILSON SONSINI GOODRICH & ROSATI

By: /Shannon Worden/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5655
Chunhua Li	
Application No.: 13/470,681	Examiner: Justin R. O'Donnell
Filed: May 14, 2012	Art Unit: 3732
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	AMENDMENT AFTER FINAL
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 September 25, 2013 please enter the following amendments and remarks:

Amendments to the Claims are reflected in the listing of claims, which begins on page 4 of this paper.

Remarks begin on page 10 of this paper.

Amendments to the Claims:

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

Listing of Claims:

1. (Previously Presented) 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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.

2. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) 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. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Currently Amended) 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. (Currently Amended) 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.

ClearCorrect Exhibit 1010, Page 1040 of 1447

8. (Currently Amended) 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. (Previously Presented) The dental appliance of claim 1, wherein at least one of the first soft polymer layer and the second soft polymer layer has a thickness in a range from 25 μm to 100 μm.

10. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer, the first soft polymer layer and the second soft polymer layer combined has a thickness of 500 μm to 1200 μm.

11. (Original) 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. (Original) 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 modulus of greater than about 35,000 psi, and a light transmission

between 400 nm and 800 nm of greater than about 75%.

13. (Previously Presented) 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 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 being greater that each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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.

14. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) 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. (Original) 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. (Original) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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

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

28. (Withdrawn) 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. (Withdrawn) 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.

DO NOT ENTER: /J.O./

11/27/2013

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on November 25, 2013

WILSON SONSINI GOODRICH & ROSATI

By: /Shannon Worden/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5655
Chunhua Li	
Application No.: 13/470,681	Examiner: Justin R. O'Donnell
Filed: May 14, 2012	Art Unit: 3732
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	AMENDMENT AFTER FINAL
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 September 25, 2013 please enter the following amendments and remarks:

Amendments to the Claims are reflected in the listing of claims, which begins on page 4 of this paper.

Remarks begin on page 10 of this paper.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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P.O. Box 1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 12/04/2013

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

EXAMINER	
O'DONNELL, JUSTIN R	
ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
12/04/2013	PAPER

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.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 13/470,681	**Applicant(s)** LI ET AL.	
	Examiner Justin O'Donnell	**Art Unit** 3732	**AIA (First Inventor to File) Status** No

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

THE REPLY FILED 25 November 2013 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed: .
    Claim(s) objected to: .
    Claim(s) rejected: 1-19.
    Claim(s) withdrawn from consideration: 20-29.

/Cris L. Rodriguez/ Supervisory Patent Examiner, Art Unit 3732	/Justin O'Donnell/ Examiner, Art Unit 3732

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Continuation of 3. NOTE:
The amendments to delete the polycarbonate, cyclic block copolymer, polypropylene and polyethylene copolymer, styrenic block copolymer, polyurethane elastomer, and block copolymer elastomer materials changes the scope of claims 2-4, 6-8, and 14-17, raising new issues which require further consideration.

Continuation of 11. does NOT place the application in condition for allowance because: In response to applicant's argument that the polycarbonate layer in Chen cannot correspond to the hard polymer layer in claims 1 and 13, the examiner respectfully disagrees. In [0036] lines 5-7, Chen states that inner layer 150 may be made from polycarbonate, and states in lines 8-16 that the inner layer 150 may have a higher glass transition temperature (and therefore be harder) than the outer layer 152. The soft outer layer 152 of Chen is then modified in view of de Simone to be made from a polyurethane elastomer. The evidence of Boedeker and Lubrizol was provided to support the examiner's position with respect to the material properties of polycarbonate (Boedeker: modulus=375,000 psi) and polyurethane elastomer (Lubrizol: modulus=333586.8 psi). The combination of Chen/de Simone thus meets the claim 1 and 13 limitations of a hard polymer layer disposed between first and second soft polymer layers.

It is also noted that applicant is arguing against the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The rejection of claims 1 and 13 is not based solely on the referenced Chen embodiment, but rather on the combination of Chen and de Simone.

ClearCorrect Exhibit 1010, Page 1050 of 1447

Electronic Acknowledgement Receipt

EFS ID:	17731258
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Mark T. McMaster/Kim Helenius
Filer Authorized By:	Mark T. McMaster
Attorney Docket Number:	22773-826.201
Receipt Date:	20-DEC-2013
Filing Date:	14-MAY-2012
Time Stamp:	17:20:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1200
RAM confirmation Number	8410
Deposit Account	232415
Authorized User	

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 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		2013_12_20_RCE_SUPP_AMDAF_22773_826_201.pdf	268674 15fb420a5a22b807cdc3896b58c67165d652589c	yes	16

Multipart Description/PDF files in .zip description

Document Description	Start	End
Request for Continued Examination (RCE)	1	2
Supplemental Response or Supplemental Amendment	3	3
Claims	4	11
Applicant Arguments/Remarks Made in an Amendment	12	16

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30141 74640a6c730185e0c9557c809dec54212b095de6	no	2

Warnings:

Information:

Total Files Size (in bytes):	298815

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

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New International Application Filed with the USPTO as a Receiving Office

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Electronic Patent Application Fee Transmittal

Application Number:	13470681
Filing Date:	14-May-2012
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Filer:	Mark T. McMaster/Kim Helenius
Attorney Docket Number:	22773-826.201

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

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($)
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
		Total in USD ($)		**1200**

Amendments to the Claims:

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

Listing of Claims:

1. (Currently Amended) 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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 and a hardness of about 60A to about 85D.

2. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) 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. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) The dental appliance of claim 1, wherein at least one of

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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. (Previously Presented) The dental appliance of claim 1, wherein at least one of the first soft polymer layer and the second soft polymer layer has a thickness in a range from 25 μm to 100 μm.

10. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer, the first soft polymer layer and the second soft polymer layer combined has a thickness of 500 μm to 1200 μm.

11. (Original) 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. (Original) 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 modulus of greater than about 35,000 psi, and a light transmission between 400 nm

and 800 nm of greater than about 75%.

13. (Currently Amended) 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 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 being greater that each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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 and a hardness of about 60A to about 85D.

14. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) 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. (Original) 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

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

28. (Withdrawn) 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. (Withdrawn) 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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on December 20, 2013

WILSON SONSINI GOODRICH & ROSATI

By: /Kim Helenius/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chunhua Li Application No.: 13/470,681 Filed: May 14, 2012 For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS Customer No. 107046	Confirmation No. 5655 Examiner: Justin R. O'Donnell Art Unit: 3732 SUPPLEMENTAL AMENDMENT AFTER FINAL

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

Commissioner:

In response to the Final Office Action mailed September 25, 2013, and the Advisory Action mailed December 4, 2013, please enter the following amendments and remarks. A Request for Continued Examination (RCE) accompanies this response.

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

Remarks begin on page 10 of this paper

REMARKS

Claims 1-29 are pending in the present application. Claims 1-4, 6-8, and 13-17 have been amended. Claims 20-29 stand withdrawn. Support for the amendments can be found in the specification as originally filed – accordingly, no new matter has been added. Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

Information Disclosure Statement

Applicants thank the Examiner for indicating that a reference listed in the specification (U.S. Patent 6,450,807) has not been considered by the Examiner due to not being listed on an Information Disclosure Statement (IDS).

U.S. Patent 6,450,807 is a continuation of PCT/US98/12861, which corresponds to WIPO Publication No. WO 98/58596, which was previously cited on the IDS filed August 2, 2012, (cite no. 185).

Objections to the Drawings

The drawings stand objected to under 37 CFR 1.84(p)(5). It is asserted in the Final Office Action that replacement figure 2 includes reference characters (specifically 24-1, 24-2, and 24-N) not mentioned in the amended specification.

Applicants respectfully direct the Examiner's attention to amended paragraph [0025], which was submitted in Applicants' prior response and was amended to include reference numbers 24-1, 24-2, and 24-N.

Accordingly, withdrawal of the objections to the drawings is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1-19 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over *Chen et al.* (US 2009/0246724) in view of *DeSimone et al.,* (US 7,641,828), as evidenced by *Boedeker* and *Lubrizol.*

Without conceding the merit of the rejections, the claims have been amended to expedite prosecution. It is respectfully submitted that the cited references, either alone or in combination, fail to disclose or suggest all the elements recited in the claims, thereby precluding the establishment of a *prima facie* case of obviousness.

Claim 1 recites:

> 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus***,
>
> wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and
>
> wherein ***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 and a hardness of about 60A to about 85D***.
>
> (***emphasis*** added)

Chen, while representing a considerable advancement in the art of orthodontics, fails to disclose all the elements recited in claim 1. *Chen* discloses a dental appliance that includes a shape memory material configured to restore the shape of the dental appliance upon application of an external stimulus. (*Chen* Abstract). Referring to paragraph [0032], *Chen* discloses an example embodiment having multiple layers including polycarbonate layers and PVC layers. The

polycarbonate layers are identified in the Final Office Action as corresponding to the hard polymer layer recited in claim 1. Polycarbonate, however, has an elastic modulus less than that of PVC. In contrast, claim 1 recites in part that "... *the hard polymer layer elastic modulus being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus* ...". Accordingly, the polycarbonate layer in *Chen* cannot correspond to the hard polymer layer recited in claim 1.

DeSimone fails to rectify the false basis upon which the rejection of claim 1 is based. *DeSimone* discloses methods of making a removable dental appliance that include forming a sheet of transparent crystalline polymeric material into a shell having teeth receiving cavities. The polymeric material may be annealed at a temperature above its glass transition temperature or cured to enhance characteristics of the polymeric material. (*DeSimone* Abstract). *DeSimone* is cited in the Final Office Action as teaching a multilayer polymer dental positioning appliance that includes a soft layer of polyurethane elastomer. The Final Office Action states:

> It would have been obvious to one or ordinary skill in the art at the time of the invention to make the Chen soft polymer layers using the DeSimone material in order to reinforce the appliance with a layer having excellent chemical resistance, high heat, low moisture sensitivity, toughness, and dimensional stability (col. 10 ll. 17-20).

As noted above, however, the polycarbonate layer of *Chen* is the soft layer – not the hard layer in *Chen*. Accordingly, the rejection of claim 1 is based on a false premise and is therefore not based on a rational basis required to support an obviousness rejection.

Moreover, claim 1, as amended, further recites that at least one of the soft layers has a hardness of about 60A to about 85D. In contrast, the Examiner supplied technical data sheet for ISOPLAST 2530 lists an R scale Rockwell hardness of 121, which is significantly harder than 85D. Thus, claim 1 is not rendered obvious by the proposed modification of *Chen* in view of *DeSimone*.

Claims 2-12 depend from claim 1 and are therefore also allowable over the cited references for the same reasons as for claim 1, as well as on their own merits. Claim 13 recites elements similar to the above-noted claim 1 elements, and is therefore also allowable over the cited references for the same reasons as for claim 1, as well as on its own merits. Claims 14-19 depend

from claim 13 and are therefore also allowable over the cited references for the same reasons as for claim 13, as well as on their own merits.

Accordingly, for the rationale set forth above, withdrawal of the rejection of claims 1-19 under 35 U.S.C. 103(a) is respectfully requested.

Double Patenting

Claims 1 and 13 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly obvious over claims 1, 2, and 6 of *Phan et al.,* (US 8,235,713) in view of *Chen et al.,* (US 2009/0246724).

The rejection is acknowledged and will be addressed upon final resolution of the claims by, e.g., filing a terminal disclaimer, if necessary.

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,

Date: December 20, 2013

/Mark T. McMaster/

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Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	13/470,681	Filing Date	2012-05-14	Docket Number (if applicable)	22773-826.201	Art Unit	3732
First Named Inventor	Chunhua Li			Examiner Name	Justin R. O'Donnell		

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 (07-09)
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Signature of Registered U.S. Patent Practitioner			
Signature	/Mark T. McMaster/	Date (YYYY-MM-DD)	2013-12-20
Name	Mark T. McMaster	Registration Number	62078

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.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/470,681	Filing Date 05/14/2012	☐ 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	12/20/2013	(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))	* 29	Minus	** 29	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	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		(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))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ 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.
** 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
/DAWN BREWER/

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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Notice of References Cited	Application/Control No. 13/470,681	Applicant(s)/Patent Under Reexamination LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,791,156 A	12-1988	Hostettler, Fritz	528/76
*	B	US-2010/0055639 A1	03-2010	Lewis et al.	433/39
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*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
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014					
	1	÷	✓	✓	✓					
	2	÷	✓	✓	✓					
	3	÷	✓	✓	✓					
	4	÷	✓	✓	✓					
	5	÷	✓	✓	✓					
	6	÷	✓	✓	✓					
	7	÷	✓	✓	✓					
	8	÷	✓	✓	✓					
	9	÷	✓	✓	✓					
	10	÷	✓	✓	✓					
	11	÷	✓	✓	✓					
	12	÷	✓	✓	✓					
	13	÷	✓	✓	✓					
	14	÷	✓	✓	✓					
	15	÷	✓	✓	✓					
	16	÷	✓	✓	✓					
	17	÷	✓	✓	✓					
	18	÷	✓	✓	✓					
	19	÷	✓	✓	✓					
	20	÷	N	N	N					
	21	÷	N	N	N					
	22	÷	N	N	N					
	23	÷	N	N	N					
	24	÷	N	N	N					
	25	÷	N	N	N					
	26	÷	N	N	N					
	27	÷	N	N	N					
	28	÷	N	N	N					
	29	÷	N	N	N					

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 01/15/2014

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

EXAMINER	
O'DONNELL, JUSTIN R	
ART UNIT	PAPER NUMBER
3732	
MAIL DATE	DELIVERY MODE
01/15/2014	PAPER

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.

Office Action Summary	Application No. 13/470,681	Applicant(s) LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	AIA (First Inventor to File) 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 *20 December 2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-29* is/are pending in the application.

5a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-19* 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 *08 January 2013* 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: _____.

1. The present application is being examined under the pre-AIA first to invent provisions.

Request for Continued Examination

2. 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 20 December 2013 has been entered.

Claim Rejections - 35 USC § 103

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 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

4. Claims 1, 2, 3, 4, 5, 9, 10, 11, 12, 13, 14, 15, 18, 19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2009/0246724 A1), in view of DeSimone et al. (US 7,641,828 B2), as evidenced by Boedeker (previously cited), Lubrizol (previously cited), and Hostettler (US 4,791,156).

Chen teaches an orthodontic system including a plurality of incremental tooth position adjustment appliances (100) having teeth receiving cavities (102) shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, where the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement ([0014]-[0015] line 5), and where at least one of the appliances includes a hard polymer layer (150, Fig. 5; [0036] ll. 5-7: polycarbonate) having a hard polymer layer elastic modulus disposed between a first soft polymer layer (outer 152) having a first soft polymer layer elastic modulus and a second soft polymer layer (inner, tooth-facing 152) having a second soft polymer layer elastic modulus, the hard polymer layer elastic modulus being greater than each of the

first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus ([0036] lines 8-10, 13-16: outer layer 152 may have…lower glass transition temp than inner layers 150; layers with lower glass transition temp may be the softer segment… layers with higher glass transition temp may be harder segment); where at least one of the first and second soft polymer layers includes two layers ([0033] lines 1-3).

Chen does not teach that the at least two layers of at least one of the first and second soft polymer layer independently includes 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, a polyester elastomer, or a combination thereof; and that the first and second soft polymer layer each independently include 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 ℃ 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 a multilayer polymer dental positioning appliance (claim 1: first and second transparent materials), which includes a soft layer of polyurethane elastomer (col. 10 ll. 14-16: ISOPLAST 2530; softer than hard layer formed from materials in col. 7 ll. 27-35) having a soft layer elastic modulus. It would have been

obvious to one of ordinary skill in the art at the time of invention to make the Chen soft polymer layers using polyurethane elastomer as taught by DeSimone in order to reinforce the appliance with a layer having excellent chemical resistance, high heat, low moisture sensitivity, toughness, and dimensional stability (col. 10 ll. 17-20).

To support the examiner's position with respect to the above rejection of claims 1 and 13, applicant is directed to the previously cited Boedeker and Lubrizol documents, and to the newly cited Hostettler reference. The Boedeker document contains a table with typical properties of polycarbonate, with the "Unfilled" column stating that the flexural modulus of polycarbonate is 375,000 psi. The Lubrizol document shows that the flexural modulus of ISOPLAST 2530 (polyurethane elastomer) is 2300 MPa, or 333,586.8 psi, while the Hostettler reference shows that soft polyurethane elastomers used in dental prostheses have a hardness of not greater than about 65A (col. 2 ll. 38-44). As combined, the materials of Chen (hard polycarbonate) and deSimone (soft polyurethane elastomer) thus meet the claims 1 and 13 limitations of a hard polymer layer disposed between first and second soft polymer layers, where the first and second soft polymer layers each has a flexural modulus greater than about 35,000 psi and a hardness of about 60A to about 85D.

With respect to claims 5, 10, 11, 12, 18, 19, Chen teaches that the hard polymer layer has a thickness in a range from 400 µm to 1100 µm ([0031] lines 5-6: at 10 mil per layer, the two inner layers in Fig. 5 have combined thickness of 20 mil = 508 µm), a tensile and flexural modulus greater than 150,000 psi (respectively 320,000 and 375,000 psi; see 'Unfilled' column in the previously cited Boedeker evidence), that the

combined hard and soft polymer layers (Fig. 5) have a thickness of 500 µm to 1200 µm (4 x 10 mil = 40 mil = 1016 µm); that the first and second soft polymer layers each independently have a flexural modulus of greater than 35,000 psi (333,586.8 psi; see previously cited Lubrizol evidence).

With respect to claims 2, 3, 4, 14, 15, Chen/deSimone teach that the hard polymer layer includes at least two layers (Chen: Fig. 5: two inner layers 150), but do not specifically teach that the hard layers are independently selected from a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate. However, deSimone teaches that hard layers may be made from polyester, thermoplastic polyurethane, acrylic, polyamide, or polyetherimide (col. 6 ll. 47-59), polyethylene terephthalate, or polybutylene terephthalate (col. 7 ll. 24-31) may be used for hard layers (col. 6 ll. 47-59: polymeric materials with high glass transition temperatures). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/deSimone hard polymer layer to include the materials taught by deSimone, as deSimone states that polyester blends in order to improve the strength, chemical resistance, and tendency of the appliance to creep.

With respect to claim 9, Chen does not teach at least one of the first and second soft polymer layer as having a thickness in a range from 25 µm to 100 µm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to select a soft polymer layer having a thickness from

25 to 100 µm because Applicant has not disclosed this parameter as contributing any unexpected result to the appliance. One of ordinary skill in the art, furthermore, would have expected Chen's appliance and applicant's invention to perform equally well with either the layer taught by Chen or the claimed layer having a thickness from 25 to 100 µm because both layers would perform the same function of providing an aligner appliance with a combined modulus sufficient to grab hold of and reposition teeth.

5. Claims 6, 7, 8, 16, 17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen in view of DeSimone as evidenced by Boedeker, Lubrizol, and Hostettler as applied to claims 1 and 13 above, and further in view of Lewis et al. (US 2010/0055639 A1).

Chen/deSimone teach the invention substantially as claimed and discussed above, including that at least one of the first and second soft polymer layers includes two layers (Chen: [0033] lines 1-3), but do not specifically teach that the at least two layers are independently selected from the group consisting of a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a polyester elastomer.

Lewis teaches a dental appliance with an outer soft polymer layer which includes thermoplastic elastomer (claim 1). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/deSimone soft polymer layers to be thermoplastic elastomer as taught by Lewis, as Liews states that the material is elastically deformable in order to be highly adaptable so that, when placed over a

person's teeth during use, the layer adapts and at least partially conforms to unique ridges, depressions and contours of the person's teeth (claim 1).

Response to Arguments

6. Applicant's arguments filed 20 December 2013 have been fully considered but they are not persuasive. In response to applicant's argument that the polycarbonate layer in Chen cannot correspond to the hard polymer layer in claims 1 and 13, the examiner respectfully disagrees. In [0036] lines 5-7, Chen states that inner layer 150 may be made from polycarbonate, and states in lines 8-16 that the inner layer 150 may have a higher glass transition temperature (and therefore be harder) than the outer layer 152. The soft outer layer 152 of Chen is then modified in view of de Simone to be made from a polyurethane elastomer. To support the examiner's position regarding the relationship of elastic moduli, the evidence of Boedeker and Lubrizol was provided to support the examiner's position with respect to the material properties of polycarbonate (Boedeker: modulus=375,000 psi) and polyurethane elastomer (Lubrizol: modulus=333586.8 psi). The combination of Chen/de Simone thus meets the claim 1 and 13 limitations of a hard polymer layer disposed between first and second soft polymer layers.

7. It is also noted that applicant is arguing against the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The rejection of claims 1 and 13 is not based solely on the referenced Chen embodiment, but rather on the combination of Chen and de Simone.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of Chen et al. (US 2009/0246724).

The differences between instant claims 1 and 13, and patented claims 1, 2, and 6 are twofold. First, patented claims 1, 2, and 6 contain the additional limitations of "wherein at least one of the appliances comprises a shell having a different geometry than that of at least one other appliance, and wherein at least two different appliances of

the system have different elastic moduluses and hardnesses; and a first appliance consisting entirely of the first material; and a second appliance consisting entirely of the second material," and is thus more specific, in effect making the invention of patented claim 6 a "species" of the "generic" invention of instant claims 1 and 13. It has been held that the generic invention is "anticipated" by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). The second difference between the claims is that patented claim 6 does not specify that the hard polymer layer (patented claims: the first polymeric material with an elastic modulus greater than the second polymeric material) is disposed between a first soft polymer layer and a second soft polymer layer.

Chen teaches an appliance which includes a hard polymer layer (150, Fig. 5) disposed between a first soft polymer layer (outer 152) and a second soft polymer layer (inner, tooth-facing 152). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify claim 6 of U.S. Patent No. 8,235,713 to include the Chen layers, as Chen states in [0012] and [0032] that the combination of layers with differing glass transition temperatures allows the appliance to transition from a deformed and/or relaxed shape to an original shape upon an application of an external stimulus, thereby extending the useful lifespan of the dental appliance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Justin O'Donnell whose telephone number is (571)270-5131. The examiner can normally be reached Monday-Friday, 10:30-8:30.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Cris Rodriguez, at* (571) 272-4964**. 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.

/Justin O'Donnell/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L230	3279	433/2,6,18,24.ccls. 264/16,17,18.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/12 20:39
L229	18	228 and "433".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 20:21
L228	5411	227 with (film layer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 20:21
L227	33677	226 with (soft low)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 20:21
L226	323647	(silicone near2 rubber) (elastomer$2 near2 alloy) tpv tpe (thermoplastic near2 (elastomer vulcanizate polyamide copolyester (co adj polyester))) (polyolefin near2 elastomer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 20:20
L5	20	4 same orthodonti$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 18:24
L4	191985	(copolyester (co adj polyester) polyester (thermoplastic near2 polyurethane) tpe) with layer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 18:23
L3	123	(copolyester (co adj polyester) polyester (thermoplastic near2 polyurethane) tpe) same orthodonti$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 18:23
L2	1678	(copolyester (co adj polyester) polyester (thermoplastic near2	US-PGPUB; USPAT;	OR	ON	2014/01/12 18:22

		polyurethane) tpe) and "433".clas.	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S71	8	S70 same (dental dentist$2 orthodonti$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 04:23
S70	2008	S68 same S69	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 04:23
S69	22764	(shore durometer) with (((6{d} 7{d} 8{d} 9{d} "100") near2 a) (1{d2} near2 d))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 04:23
S68	238218	(polyurethane near2 (resin elastomer thermoplastic polymer)) (isoplast near2 "2530")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 04:23
S65	22764	(shore durometer) with (((6{d} 7{d} 8{d} 9{d} "100") near2 a) (1{d2} near2 d))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 04:08
S64	238218	(polyurethane near2 (resin elastomer thermoplastic polymer)) (isoplast near2 "2530")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/01/12 03:56

EAST Search History (Interference)

<This search history is empty>

1/12/2014 8:47:12 PM
C:\Users\jodonnell\Documents\EAST\Workspaces\13470681.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO
Updated	All	9/10/2013	JO
Updated	All	1/11/2014	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO
Updated EAST search	9/10/2013	JO
Updated EAST search	1/11/2014	JO

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 03/25/2014

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

EXAMINER	
O'DONNELL, JUSTIN R	
ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
03/25/2014	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.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	Justin O'Donnell	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Justin O'Donnell*.

(3) *Mark McMaster*.

(2) *Sunil Singh*.

(4)_____.

Date of Interview: *19 March 2014*.

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: *1 and 13*.

Identification of prior art discussed: *Prior art of record*.

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's arguments concerning the material properties of ISOPLAST 2530 cited in DeSimone were discussed and found to be convincing, as its Rockwell R Hardness of 121 (see Lubrizol evidence) lies outside the claimed range of about 60 A to about 85 D. In order to further distinguish over the rejection of record, it was recommended that claim 13 be amended to include a limitation directed to a final appliance or several appliances in the plurality of appliances having a geometry configured to overcorrect a tooth arrangement, where individual teeth are moved beyond a final tooth arrangement to offset relapse after teeth have been positioned (as supported by page 7, lines 12-21 of the as-filed disclosure). Any amendments made in a formal reply will require further consideration and/or search.

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

/Justin O'Donnell/ Examiner, Art Unit 3732	/Sunil K Singh/ Primary Examiner, Art Unit 3732

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 examiner's 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 applicant's 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 applicant's 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 examiner's 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 examiner's initials.

Wilson Sonsini Goodrich & Rosati
PROFESSIONAL CORPORATION

Date: 2014-03-14 14:44:09 PDT

Fax: 15712706131

From: Helenius, Kimberly

Subject: For the attention of: Examiner Justin R. O'Donnell

Dear Examiner O'Donnell:

Please see the attached remarks for discussion on March 19, 2014 at 2pm EST.

Best regards,

On behalf of Mark McMaster

Kim Helenius
IP Practice Group Assistant
WILSON SONSINI GOODRICH & ROSATI
Suite 5100 | 701 Fifth Avenue | Seattle, WA 98104-7036
office 206.883.2626| fax 206.883.2699
khelenius@wsgr.com<mailto:khelenius@wsgr.com> | www.wsgr.com<http://www.wsgr.com/>

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1582522239.1 rtf (817)

PAGE 1/6 * RCVD AT 3/14/2014 5:44:23 PM [Eastern Daylight Time] * SVR:W-PTOFAX-002/18 * DNIS:2706131 * CSID:Wilson Sonsini Goodr * DURATION (mm-ss):03-22

Wilson Sonsini Goodrich & Rosati
PROFESSIONAL CORPORATION

Date: March 14, 2014

To: Examiner Justin R. O'Donnell	**Fax:** 571-270-6131	☒ Use this fax number only
Company: USPTO	**Phone:** 571-272-8300	☐ Notify recipient before sending

From: Mark McMaster **Phone:** 206-883-2584 **Return Fax:** 206-883-2699

Original: ☐ To follow via mail ☐ To follow via courier ☐ To follow via email ☒ Original will not follow

Fax Contains: 5 pages *(including this sheet)*. If incomplete, call 206-883-2626.

Message:

Dear Examiner O'Donnell:

Following is my proposal for points of discussion for our telephonic interview scheduled for Wednesday, March 19th at 2pm EST.

Ref: 22773-826.201 Return Original to: Kim Helenius Location: 52

650 Page Mill Road, Palo Alto, CA 94304-1050
650.493.9300 Tel • 650.493.6811 Fax • www.wsgr.com

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****PLEASE DO NOT ENTER****

Application No: 13/470,681
Title: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
Office Action Mail Date: January 14, 2014
Examiner: Justin R. O'Donnell
Attorney Docket No.: 22773-826.201

Patent Examiner Interview Agenda

January 15, 2014 Office Action

- Discuss claim rejections under 35 U.S.C. 103

Please consider the remarks submitted herewith

Claim Rejections – 35 USC § 103

Claims 1-5, 9-15, 18, and 19 stand rejected under pre-AIA 35 U.S.C. 103(a) as allegedly obvious over *Chen et al. (US 2009/0246724)*, in view of *DeSimone et al (US 7,641,828)*, as evidenced by *Boedeker, Lubrizol*, and *Hostettler (US 4,791,156)*. These rejections are respectfully traversed for the reasons set forth below.

First, the cited references fail to disclose or suggest all the elements recited in the claims. As acknowledged by the Examiner on page 4 of the Office Action, *Chen* fails to teach multiple elements recited in the claims, including "*... wherein 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 and a hardness of about 60A to about 85D*" as recited in claim 1. Instead, *DeSimone* is cited as disclosing the use of a soft layer of polyurethane elastomer (col. 10 ll. 14-16: ISOPLAST 2530). As evidence of the flexural modulus of ISOPLAST 2530, the Examiner cites to *Lubrizol*. *Lubrizol*, however, also indicates that the Rockwell Hardness of ISOPLAST 2530 is 121 on the Rockwell Hardness R Scale, which is significantly harder than 85D. The failure of ISOPLAST 2530 to meet the recited hardness range was discussed in Applicants' prior response (filed December 20, 2013), and has not been directly addressed by the Examiner. Instead, *Hostettler* is newly cited as evidence

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that soft polyurethane elastomers used in dental prostheses have a hardness of not greater of than about 65A (col. 2 ll. 38-44). Clearly, in light of the explicit hardness data for ISOPLAST 2530 disclosed in *Lubrizol* (Rockwell Hardness of 121 on R Scale), the statement in *Hostettler* is simply not applicable to ISOPLAST 2530, upon which the proposed combination of references relies. Given the significant greater hardness of ISOPLAST 2530 (as disclosed in *Lubrizol*) compared to the "soft non-hydrophilic polyurethane elastomers of U.S. Pat. Nos. 4,024,636 and 4,080,412 to Colpitts et al, supra, which have a hardness of not greater than about Shore A 65 ..." as disclosed at col. 2 lines 38-44 of *Hostettler*, it is clear that the cited portion of *Hostettler* in no way provides any credible evidence as to the hardness of ISOPLAST 2530.

Additionally, the proposed modification of *Chen*, specifically "to make the *Chen* soft polymer layers using polyurethane elastomer as taught by *DeSimone*" cannot be used to render the claims obvious because the proposed combination would change the principle of operation of *Chen*. (See MPEP 2143.01 VI). For example, as disclosed with respect to a relevant embodiment of *Chen*:

> [0032] An example embodiment is to have Polycarbonate outer layers 134 and PVC inner layers 132. Here, while under a glass transition temperature of both materials, the forces of all layers have a combined modulus that may be used as forces to grab hold of and reposition the teeth. If desired to restore the dental appliance to an original shape, heat may be applied to obtain the glass transition temperature of the inner layers. The forces of the inner layers will relax, transition, and may eventually return to a previous alignment, thereby allowing the dental appliance to return to an approximate original shape.

In contrast, the rationale provided "to make the *Chen* soft polymer layers using polyurethane elastomer as taught by *DeSimone*" is that doing so would "reinforce the appliance with a layer having excellent chemical resistance, high heat, low moisture sensitivity, toughness, and dimensional stability." Having excellent dimensional stability and excellent resistance to high heat, however, is contrary to the operational aspects in *Chen* related to the reshaping of the PVC inner layers via heating of the appliance. Moreover, there is simply no evidence cited that ISOPLAST 2530 would be a suitable substitute for the soft layers of *Chen* with respect to providing the above-noted operational characteristics of the soft layers of *Chen*.

Accordingly, for the reasons set forth above, claim 1 is not rendered obvious by the proposed combination of *Chen* in view of *DeSimone*. Claims 2-5 and 9-12 depend from claim 1 and

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are therefore allowable over the cited references for the same rationale as for claim 1, as well as on their own merits. Claim 13 recites elements similar to the above-noted claim 1 elements, and is therefore also allowable over the cited references for a similar rationale as for claim 1, as well as on its own merits. Claims 14, 15, 18, and 19 depend from claim 13 and are therefore also allowable over the cited references for the same rationale as for claim 13, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 1-5, 9-15, 18, and 19 under 35 U.S.C. 103(a) is respectfully requested.

Claims 6-8, 16, and 17 stand rejected under pre-AIA 35 U.S.C. 103(a) as allegedly obvious over *Chen et al. (US 2009/0246724)*, in view of *DeSimone et al (US 7,641,828)*, as evidenced by *Boedeker, Lubrizol*, and *Hostettler (US 4,791,156)* as applied to claims 1 and 13 above, and further in view of *Lewis et al. (US 2010/0055639)*.

As set forth above, claims 1 and 13 are allowable over the proposed combination of *Chen* in view of *DeSimone*. *Chen* in view of *DeSimone* at least fails to disclose "... *wherein 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 and a hardness of about 60A to about 85D*" as recited in claims 1 and 13.

Lewis fails to remedy the above-noted failings of the proposed combination of *Chen* in view of *DeSimone*. The newly cited *Lewis* discloses non-customized dental treatment trays that are formed from elastomeric silicone or silicone-like material. *Lewis* is additionally cited in support of the rejection of dependent claims 6, 7, 8, 16, and 17. It is asserted in the Office Action that:

> It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/deSimone soft polymer layers to be thermoplastic elastomer as taught by Lewis, as [Lewis] states that the material is elastically deformable in order to be highly adaptable so that, when placed over a person's teeth during use, the layer adapts and at least partially conforms to unique ridges, depressions and contours of the person's teeth (claim 1).

A layer that is elastically deformable in order to be highly adaptable, however, is contrary to the operational functionality of the soft layers in *Chen*, which are configured to contribute to a combined stiffness so as to "grab hold of and reposition the teeth" as disclosed in *Chen*. Thus, the

PAGE 5/6 * RCVD AT 3/14/2014 5:44:23 PM [Eastern Daylight Time] * SVR:W-PTOFAX-002/18 * DNIS:2706131 * CSID:Wilson Sonsini Goodr * DURATION (mm-ss):03-22

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proposed modification of *Chen* to use the elastomers as taught by *Lewis* cannot be used to render the claims obvious because the proposed modification would change the principle of operation of *Chen*. (See MPEP 2143.01 VI). Thus, claims 6-8, 16, and 17 are not rendered obvious by the proposed combination of references

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 6-8, 16, and 17 under pre-AIA 35 U.S.C. 103(a) is respectfully requested.

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REMARKS

Claims 1-29 are pending in the present application. Claims 20-29 stand withdrawn from consideration. No claim amendments are submitted herewith as none are deemed necessary in view of the present rejections. Reconsideration in view of the remarks set forth below is respectfully requested.

Telephone Interview

Applicants' undersigned representative thanks Examiner Justin O'Donnell for the telephone conference on March 19, 2014 discussing the subject Office Action. Agreement was reached that the obviousness rejections made in the subject Office Action, for the reasons set forth below, should be withdrawn. The Examiner indicated that the present claims, however, may require further search and consideration.

Double Patenting

Claims 1 and 13 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly obvious over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of *Chen et al. (US 2009/0246724).*

The rejection is acknowledged and will be addressed upon final resolution of the claims by, e.g., filing a terminal disclaimer, if necessary.

Claim Rejections – 35 USC § 103

Claims 1-5, 9-15, 18, and 19 stand rejected under pre-AIA 35 U.S.C. 103(a) as allegedly obvious over *Chen et al. (US 2009/0246724)*, in view of *DeSimone et al (US 7,641,828)*, as evidenced by *Boedeker, Lubrizol*, and *Hostettler (US 4,791,156)*. These rejections are respectfully traversed for the reasons set forth below.

First, the cited references fail to disclose or suggest all the elements recited in the claims. As acknowledged by the Examiner on page 4 of the Office Action, *Chen* fails to

ClearCorrect Exhibit 1010, Page 1098 of 1447

teach multiple elements recited in the claims, including *"... wherein 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 and a hardness of about 60A to about 85D"* as recited in claim 1. Instead, *DeSimone* is cited as disclosing the use of a soft layer of polyurethane elastomer (col. 10 ll. 14-16: ISOPLAST 2530). As evidence of the flexural modulus of ISOPLAST 2530, the Examiner cites to *Lubrizol*. *Lubrizol*, however, also indicates that the Rockwell Hardness of ISOPLAST 2530 is 121 on the Rockwell Hardness R Scale, which is significantly harder than 85D. The failure of ISOPLAST 2530 to meet the recited hardness range was discussed in Applicants' prior response (filed December 20, 2013), and has not been directly addressed by the Examiner. Instead, *Hostettler* is newly cited as evidence that soft polyurethane elastomers used in dental prostheses have a hardness of not greater of than about 65A (col. 2 ll. 38-44). Clearly, in light of the explicit hardness data for ISOPLAST 2530 disclosed in *Lubrizol* (Rockwell Hardness of 121 on R Scale), the statement in *Hostettler* is simply not applicable to ISOPLAST 2530, upon which the proposed combination of references relies. Given the significant greater hardness of ISOPLAST 2530 (as disclosed in *Lubrizol*) compared to the "soft non-hydrophilic polyurethane elastomers of U.S. Pat. Nos. 4,024,636 and 4,080,412 to Colpitts et al, supra, which have a hardness of not greater than about Shore A 65 ..." as disclosed at col. 2 lines 38-44 of *Hostettler*, it is clear that the cited portion of *Hostettler* in no way provides any credible evidence as to the hardness of ISOPLAST 2530.

Additionally, the proposed modification of *Chen*, specifically "to make the *Chen* soft polymer layers using polyurethane elastomer as taught by *DeSimone*" cannot be used to render the claims obvious because the proposed combination would change the principle of operation of *Chen*. (See MPEP 2143.01 VI). For example, as disclosed with respect to a relevant embodiment of *Chen*:

> [0032] An example embodiment is to have Polycarbonate outer layers 134 and PVC inner layers 132. Here, while under a glass transition temperature of both materials, the forces of all layers have a combined modulus that may be used as forces to grab hold of and reposition the teeth. If desired to restore the

> dental appliance to an original shape, heat may be applied to obtain the glass transition temperature of the inner layers. The forces of the inner layers will relax, transition, and may eventually return to a previous alignment, thereby allowing the dental appliance to return to an approximate original shape.

In contrast, the rationale provided "to make the *Chen* soft polymer layers using polyurethane elastomer as taught by *DeSimone*" is that doing so would "reinforce the appliance with a layer having excellent chemical resistance, high heat, low moisture sensitivity, toughness, and dimensional stability." Having excellent dimensional stability and excellent resistance to high heat, however, is contrary to the operational aspects in *Chen* related to the reshaping of the PVC inner layers via heating of the appliance. Moreover, there is simply no evidence cited that ISOPLAST 2530 would be a suitable substitute for the soft layers of *Chen* with respect to providing the above-noted operational characteristics of the soft layers of *Chen*.

Accordingly, for the reasons set forth above, claim 1 is not rendered obvious by the proposed combination of *Chen* in view of *DeSimone*. Claims 2-5 and 9-12 depend from claim 1 and are therefore allowable over the cited references for the same rationale as for claim 1, as well as on their own merits. Claim 13 recites elements similar to the above-noted claim 1 elements, and is therefore also allowable over the cited references for a similar rationale as for claim 1, as well as on its own merits. Claims 14, 15, 18, and 19 depend from claim 13 and are therefore also allowable over the cited references for the same rationale as for claim 13, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 1-5, 9-15, 18, and 19 under 35 U.S.C. 103(a) is respectfully requested.

Claims 6-8, 16, and 17 stand rejected under pre-AIA 35 U.S.C. 103(a) as allegedly obvious over *Chen et al. (US 2009/0246724)*, in view of *DeSimone et al (US*

7,641,828), as evidenced by *Boedeker, Lubrizol*, and *Hostettler (US 4,791,156)* as applied to claims 1 and 13 above, and further in view of *Lewis et al. (US 2010/0055639)*.

As set forth above, claims 1 and 13 are allowable over the proposed combination of *Chen* in view of *DeSimone*. *Chen* in view of *DeSimone* at least fails to disclose "... *wherein 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 and a hardness of about 60A to about 85D*" as recited in claims 1 and 13.

Lewis fails to remedy the above-noted failings of the proposed combination of *Chen* in view of *DeSimone*. The newly cited *Lewis* discloses non-customized dental treatment trays that are formed from elastomeric silicone or silicone-like material. *Lewis* is additionally cited in support of the rejection of dependent claims 6, 7, 8, 16, and 17. It is asserted in the Office Action that:

> It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/deSimone soft polymer layers to be thermoplastic elastomer as taught by Lewis, as [Lewis] states that the material is elastically deformable in order to be highly adaptable so that, when placed over a person's teeth during use, the layer adapts and at least partially conforms to unique ridges, depressions and contours of the person's teeth (claim 1).

A layer that is elastically deformable in order to be highly adaptable, however, is contrary to the operational functionality of the soft layers in *Chen*, which are configured to contribute to a combined stiffness so as to "grab hold of and reposition the teeth" as disclosed in *Chen*. Thus, the proposed modification of *Chen* to use the elastomers as taught by *Lewis* cannot be used to render the claims obvious because the proposed modification would change the principle of operation of *Chen*. (See MPEP 2143.01 VI). Thus, claims 6-8, 16, and 17 are not rendered obvious by the proposed combination of references

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 6-8, 16, and 17 under pre-AIA 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: April 3, 2014

/Yin Cheung/

Yin Cheung
Registration No. 70,386

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
Tel: 650-493-9300
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YC2/COCH:/kbh

Electronic Acknowledgement Receipt

EFS ID:	18661983
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Yin Cheung/Kim Helenius
Filer Authorized By:	Yin Cheung
Attorney Docket Number:	22773-826.201
Receipt Date:	03-APR-2014
Filing Date:	14-MAY-2012
Time Stamp:	12:41:42
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		2014_04_03_REQ_RECON_22773_826_201.pdf	193618 029e64863f650f38b4978a05d0ad6dfef8572357	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	8
	Applicant Arguments/Remarks Made in an Amendment	9	13
Warnings:			
Information:			
	Total Files Size (in bytes):	193618	

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.

Amendments to the Claims:

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

Listing of Claims:

1. (Previously Presented) 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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 and a hardness of about 60A to about 85D.

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

3. (Previously Presented) The dental appliance of claim 1, wherein the hard

polymer layer comprises a layer of a co-polyester, a polyester, or a thermoplastic polyurethane.

4. (Previously Presented) 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 thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

5. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

7. (Previously Presented) 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, or a polyester elastomer.

8. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

9. (Previously Presented) The dental appliance of claim 1, wherein at least one of the first soft polymer layer and the second soft polymer layer has a thickness in a range from 25 μm to 100 μm.

10. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer, the first soft polymer layer and the second soft polymer layer combined has a thickness of 500 μm to 1200 μm.

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

13. (Previously Presented) 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 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 being greater that each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer 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; and

wherein 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 and a hardness of about 60A to about 85D.

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

15. (Previously Presented) 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 thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

16. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic

vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

17. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

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

28. (Withdrawn) 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. (Withdrawn) 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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on April 3, 2014.

WILSON SONSINI GOODRICH & ROSATI

By: /Kim Helenius/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5655
Chunhua Li	
Application No.: 13/470,681	Examiner: Justin R. O'Donnell
Filed: May 14, 2012	Art Unit: 3732
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	REQUEST FOR RECONSIDERATION
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 January 15, 2014, 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 9 of this paper.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/470,681	Filing Date 05/14/2012	☐ 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 $ =	
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

		(Column 1)		(Column 2)	(Column 3)		
	04/03/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	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

		(Column 1)		(Column 2)	(Column 3)		
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ 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.
** 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
/MYRTLE LEIGH/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 08/01/2014

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

EXAMINER	
O'DONNELL, JUSTIN R	
ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
08/01/2014	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. 13/470,681	Applicant(s) LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	AIA (First Inventor to File) 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 *03 April 2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-29* is/are pending in the application.

5a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-19* 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 *08 January 2013* 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: *NPL document*.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see the Interview Summary of 25 March 2014 and pp. 9-10 of the Remarks filed 03 April 2014, with respect to the rejection(s) of claim(s) 1 and 13 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hostettler, as evidenced by Plastics (see attached document).

Claim Rejections - 35 USC § 103

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 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter

of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

3. Claims 1, 5, 9, 10, 11, 12, 13, 18, 19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2009/0246724 A1), in view of Hostettler (US 4,791,156), as evidenced by Boedeker (previously cited) and Plastics (see attached).

Chen teaches an orthodontic system including: a plurality of incremental tooth position adjustment appliances (100) having teeth receiving cavities (102) shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, where the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement ([0014]-[0015] line 5), and where at least one of the appliances includes a hard polymer layer (150, Fig. 5; [0036] ll. 5-7: polycarbonate) having a hard polymer layer elastic modulus disposed between a first soft polymer layer (outer 152) having a first soft polymer layer elastic modulus and a second soft polymer layer (inner, tooth-facing 152) having a second soft polymer layer elastic modulus, the hard polymer layer elastic modulus being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus ([0036] lines 8-10, 13-16: outer layer 152 may have…lower glass transition

temp than inner layers 150; layers with lower glass transition temp may be the softer segment… layers with higher glass transition temp may be harder segment); where at least one of the first and second soft polymer layers includes two layers ([0033] lines 1-3).

Chen does not teach that the at least two layers of at least one of the first and second soft polymer layer independently includes 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, a polyester elastomer, or a combination thereof; and that the first and second soft polymer layer each independently include 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 ℃ 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%.

Hostettler teaches a multilayer polymeric dental appliance (col. 2 ll. 33-38), which includes a hard layer (col. 2 ll. 22-26, 34-35: hardness of about 60D to about 100D), and a separate soft layer of polyurethane elastomer having a hardness of about 60A to about 85D (col. 2 ll. 36-44: not greater than about 65A). It would have been obvious to one of ordinary skill in the art at the time of invention to use soft polyurethane elastomer for the soft polymer layers of Chen as taught by Hostettler in order to provide a soft

layer which provides tissue relief, is inexpensive, trouble-free, and easy to keep clean (col. 1 ll. 40-41, 50-59).

To support the examiner's position with respect to the above rejection of claims 1 and 13, applicant is directed to the previously cited Boedeker document, and to the newly cited Plastics document. The Boedeker document contains a table with typical properties of polycarbonate, with the "Unfilled" column stating that the flexural modulus of polycarbonate is 375,000 psi. The Plastics document shows that polyurethane elastomers have a flexural modulus greater than about 35,000 psi (3600 to 648000 psi), an ultimate tensile strength of greater than about 5000 psi (235 to 5570 psi), and an elongation at break of greater than about 200% (8.5 to 800%). As combined, the materials of Chen (hard polycarbonate) and Hostettler (soft polyurethane elastomer) thus meet the material property limitations of claims 1, 12, 13, and 19 for a hard polymer layer disposed between first and second soft polymer layers.

With respect to claims 5, 10, 11, and 18, Chen teaches that the hard polymer layer has a thickness in a range from 400 µm to 1100 µm ([0031] lines 5-6: at 10 mil per layer, the two inner layers in Fig. 5 have combined thickness of 20 mil = 508 µm), a tensile and flexural modulus greater than 150,000 psi (respectively 320,000 and 375,000 psi; see 'Unfilled' column in the previously cited Boedeker evidence), that the combined hard and soft polymer layers (Fig. 5) have a thickness of 500 µm to 1200 µm (4 x 10 mil = 40 mil = 1016 µm).

With respect to claim 9, Chen/Hostettler do not teach at least one of the first and second soft polymer layer as having a thickness in a range from 25 µm to 100 µm. At

the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to select a soft polymer layer having a thickness from 25 to 100 µm because Applicant has not disclosed this parameter as contributing any unexpected result to the appliance. One of ordinary skill in the art, furthermore, would have expected Chen's appliance and applicant's invention to perform equally well with either the layer taught by Chen or the claimed layer having a thickness from 25 to 100 µm because both layers would perform the same function of providing an aligner appliance with a combined modulus sufficient to grab hold of and reposition teeth.

4. Claims 2, 3, 4, 14, 15 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen in view of Hostettler as evidenced by Boedeker and Plastics as applied to claims 1 and 13 above, and further in view of DeSimone et al. (US 7641828 B2).

Chen/Hostettler teach the invention substantially as claimed and discussed above, including that the hard polymer layer includes at least two layers (Chen: Fig. 5: two inner layers 150), but do not specifically teach that the hard layers are independently selected from a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

DeSimone teaches that polyester, thermoplastic polyurethane, acrylic, polyamide, or polyetherimide (col. 6 ll. 47-59), polyethylene terephthalate, or

polybutylene terephthalate (col. 7 ll. 24-31) may be used for hard layers (col. 6 ll. 47-59: polymeric materials with high glass transition temperatures). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/Hostettler hard polymer layer to include the materials taught by DeSimone, as DeSimone states that polyester blends improve the strength, chemical resistance, and tendency of the appliance to creep.

5. Claims 6, 7, 8, 16, 17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen in view of Hostettler as evidenced by Boedeker and Plastics as applied to claims 1 and 13 above, and further in view of Lewis et al. (US 2010/0055639 A1).

Chen/Hostettler teach the invention substantially as claimed and discussed above, including that at least one of the first and second soft polymer layers includes two layers (Chen: [0033] lines 1-3), but do not specifically teach that the at least two layers are independently selected from the group consisting of a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a polyester elastomer.

Lewis teaches a dental appliance with an outer soft polymer layer which includes thermoplastic elastomer (claim 1). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/Hostettler soft polymer layers to be thermoplastic elastomer as taught by Lewis, as Lewis states that the material is

elastically deformable in order to be highly adaptable so that, when placed over a person's teeth during use, the layer adapts and at least partially conforms to unique ridges, depressions and contours of the person's teeth (claim 1).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of Chen et al. (US 2009/0246724).

The differences between instant claims 1 and 13, and patented claims 1, 2, and 6 are twofold. First, patented claims 1, 2, and 6 contain the additional limitations of "wherein at least one of the appliances comprises a shell having a different geometry

than that of at least one other appliance, and wherein at least two different appliances of the system have different elastic moduluses and hardnesses; and a first appliance consisting entirely of the first material; and a second appliance consisting entirely of the second material," and is thus more specific, in effect making the invention of patented claim 6 a "species" of the "generic" invention of instant claims 1 and 13. It has been held that the generic invention is "anticipated" by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). The second difference between the claims is that patented claim 6 does not specify that the hard polymer layer (patented claims: the first polymeric material with an elastic modulus greater than the second polymeric material) is disposed between a first soft polymer layer and a second soft polymer layer.

Chen teaches an appliance which includes a hard polymer layer (150, Fig. 5) disposed between a first soft polymer layer (outer 152) and a second soft polymer layer (inner, tooth-facing 152). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify claim 6 of U.S. Patent No. 8,235,713 to include the Chen layers, as Chen states in [0012] and [0032] that the combination of layers with differing glass transition temperatures allows the appliance to transition from a deformed and/or relaxed shape to an original shape upon an application of an external stimulus, thereby extending the useful lifespan of the dental appliance.

Response to Arguments

7. Applicant's arguments filed 03 April 2014 have been fully considered but they are not persuasive. With respect to the rejection of claims 6-8, 16, and 17 as being obvious over Chen, DeSimone, and Lewis, Applicant argues that the .

> A layer that is elastically deformable in order to be highly adaptable, however, is contrary to the operational functionality of the soft layers in *Chen,* which are configured to contribute to a combined stiffness so as to "grab hold of and reposition the teeth" as disclosed in *Chen.* Thus, the proposed modification of *Chen* to use the elastomers as taught by *Lewis* cannot be used to render the claims obvious because the proposed modification would change the principle of operation of *Chen.* (See MPEP 2143.01 VI). Thus, claims 6-8, 16, and 17 are not rendered obvious by the proposed combination of references

8. The examiner respectfully disagrees that the proposed modification to include an elastically deformable thermoplastic elastomer in the soft outer layer would change the principle of operation of Chen, since Chen already discloses that the soft outer layer may be adapted to different shapes ([0037] ll. 1-3, 7-10: “the [softer] material… repositions, and remolds to the shape of the harder segment”). As the Chen soft layer is disclosed as being able adapt to different shapes, modifying the layer to be of a particular deformable material is seen to be consistent with this principle of operation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Justin O’Donnell whose telephone number is (571)270-5131. The examiner can normally be reached Monday-Friday, 10:30-8:30.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Cris Rodriguez, at* (571) 272-4964**. 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.

/Justin O'Donnell/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	JUSTIN O'DONNELL	3732

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO
Updated	All	9/10/2013	JO
Updated	All	1/11/2014	JO
Updated	All	7/28/2014	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO
Updated EAST search	9/10/2013	JO
Updated EAST search	1/11/2014	JO
Updated EAST search	7/28/2014	JO

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S94	10	"4024636".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 05:05
S93	0	S92 and (denture aligner orthodonti$2 dental "433".clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 05:04
S92	50	S90 with (mpa megapascal gpa gigapascal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 05:04
S91	0	S90 and (denture aligner orthodonti$2 dental "433".clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 05:00
S90	159	S84 with S89	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 05:00
S89	46818	polyurethane near2 elastomer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 05:00
S88	0	S87 and (denture aligner orthodonti$2 dental "433".clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 04:58
S87	199	S86 with (psi ksi)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 04:58
S86	459	S83 with S84	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 04:56
S85	1485	S83 same S84	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 04:56
S84	46986	(flexural flex$3 bend$3) near2 modulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 04:55
S83	249022	(polyurethane near2 (resin elastomer thermoplastic polymer))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/07/28 04:54

S82	898	264/16,17,18.ccls. not (@pd<="19710105" and USPT.DBNM.) not (usocr adj1 database).ti.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/07/28 03:27
S81	2424	433/2,6,18,24.ccls. not (@pd<="19710105" and USPT.DBNM.) not (usocr adj1 database).ti.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/07/28 03:14

EAST Search History (Interference)

<This search history is empty>

7/28/2014 6:10:36 AM
C:\Users\jodonnell\Documents\EAST\Workspaces\13470681.wsp

Notice of References Cited	Application/Control No. 13/470,681	Applicant(s)/Patent Under Reexamination LI ET AL.	
	Examiner Justin O'Donnell	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	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
	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
	13470681	LI ET AL.
	Examiner	**Art Unit**
	JUSTIN O'DONNELL	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014	07/28/2014				
	1	÷	✓	✓	✓	✓				
	2	÷	✓	✓	✓	✓				
	3	÷	✓	✓	✓	✓				
	4	÷	✓	✓	✓	✓				
	5	÷	✓	✓	✓	✓				
	6	÷	✓	✓	✓	✓				
	7	÷	✓	✓	✓	✓				
	8	÷	✓	✓	✓	✓				
	9	÷	✓	✓	✓	✓				
	10	÷	✓	✓	✓	✓				
	11	÷	✓	✓	✓	✓				
	12	÷	✓	✓	✓	✓				
	13	÷	✓	✓	✓	✓				
	14	÷	✓	✓	✓	✓				
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	26	÷	N	N	N	N				
	27	÷	N	N	N	N				
	28	÷	N	N	N	N				
	29	÷	N	N	N	N				

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 10/01/2014

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

EXAMINER	
O'DONNELL, JUSTIN R	
ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
10/01/2014	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.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	Justin O'Donnell	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Justin O'Donnell*.

(2) *Heidi Eide*.

(3) *Connie Cheng*.

(4) *Yin Cheung*.

Date of Interview: *25 September 2014*.

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: *1*.

Identification of prior art discussed: *Prior art of record*.

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...)

The prior art and proposed amendments were discussed, and Applicant argued that the claim 1 amendment to include "thermoplastic polymer" distinguishes over the Hostettler reference, which Applicant argues teaches a thermoset polymer (see also the "Plastics" evidence provided in the 08/01/2014 office action). The examiner noted that the claims are directed to an apparatus and not a method of making, and recommended including arguments in a response as to how the claimed thermoplastic polyurethane elastomer is structurally, unobviously different from a thermoset polyurethane elastomer (as in the cited prior art). Such arguments, if found convincing, would be sufficient to overcome the rejection of record. The examiner also recommended taking into account that the Chen base reference discusses the use of thermoplastic polymers for soft outer layers (but not any of the specific materials currently claimed), and that the inclusion of any additional structure supported by the specification would aid in distinguishing ove the rejection of record. Any amendments filed in a formal reply will require further search and/or consideration.

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

/HEIDI M EIDE/	/Justin O'Donnell/
Primary Examiner, Art Unit 3732	Examiner, Art Unit 3732

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 examiner's 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 applicant's 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 applicant's 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 examiner's 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 examiner's initials.

FAX COVER SHEET

TO	
COMPANY	
FAX NUMBER	15712706131
FROM	Tronvig, William
DATE	2014-09-24 12:16:34 PDT
RE	Deliver to: Examiner Justin O'Donnell - Application No.: 13/470,681

COVER MESSAGE

Please see the attached Interview Agenda Confirmation.

Thank you,

William Tronvig
Patent Practice Group Assistant
Wilson Sonsini Goodrich & Rosati
701 Fifth Ave., Suite 5100
Seattle, WA 98104-7036
phone: (206) 883-2639
fax: (206) 883-2699
wtronvig@wsgr.com<mailto:wtronvig@wsgr.com>

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Wilson Sonsini Goodrich & Rosati
PROFESSIONAL CORPORATION

Date: September 24, 2014

To: Examiner Justin O'Donnell **Fax:** 571-270-6131 ☒ Use this fax number only

Company: USPTO **Phone:** ☐ Notify recipient before sending

From: Yin Cheung **Phone:** 206-883- 2554 **Return Fax:** 206-883-2699

Original: ☐ To follow via mail ☐ To follow via courier ☐ To follow via email ☒ Original will not follow

Fax Contains: 3 pages *(including this sheet)*. If incomplete, call 206-883-2639.

Message:

Dear Examiner O'Donnell:

Following is my proposal for points of discussion for our telephonic interview.

Ref: 22773-826.201 Return Original to: William Tronvig Location: 52-E

650 Page Mill Road, Palo Alto, CA 94304-1050
650.493.9300 Tel • 650.493.6811 Fax • www.wsgr.com

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22773-826.201 Interview Agenda.docx (884)

PAGE 2/4 * RCVD AT 9/24/2014 3:16:53 PM [Eastern Daylight Time] * SVR:W-PTOFAX-002/46 * DNIS:2706131 * CSID:Wilson Sonsini Goodr * DURATION (mm-ss):01-42

FOR DISCUSSION PURPOSES ONLY
PLEASE DO NOT ENTER

Application No: 13/470,681
Title: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
Office Action Mail Date: August 1, 2014
Examiner: Justin O'Donnell
Attorney Docket No.: 22773-826.201

Patent Examiner Interview Agenda – Thursday, September 25, 2014, at 1:30 PM EST

August 1, 2014 – Non-Final Office Action

- Discuss proposed claim amendments relating to 103 rejections, particularly with respect to Hostettler (US 4,791,156) and Plastics.

PAGE 3/4 * RCVD AT 9/24/2014 3:16:53 PM [Eastern Daylight Time] * SVR:W-PTOFAX-002/46 * DNIS:2706131 * CSID:Wilson Sonsini Goodr * DURATION (mm-ss):01-42

FOR DISCUSSION PURPOSES ONLY – DO NOT ENTER

WSGR Ref. No. 22773-826.201

September 19, 2014

1. (Currently Amended) 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer that comprises ~~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; and

wherein 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 and a hardness of about 60A to about 85D.

C:\Users\wdt\Desktop\22773-826.201 proposed claim amendments_(palib1_6649371_1).DOCX

REMARKS

Upon entry of this amendment, claims 1-29 will be pending in the present application. Claims 20-29 stand withdrawn. Claims 1 and 13 have been amended. Support for the amendments can be found in the specification as originally filed. Accordingly, no new matter has been added. Reconsideration is respectfully requested.

Telephone Interview

Applicants thank Examiner O'Donnell and Examiner Eide for participating in a telephonic interview on September 25, 2014 with Applicants' undersigned representative Yin Cheung and her colleague Connie Cheng. During the interview, proposed claimed amendments consistent with those presented herein were discussed. Applicants' representatives pointed out that the Hostettler (U.S. Patent No. 4,791,156) and Plastics references cited in the Office Action appear to teach thermosets rather than thermoplastics, contrary to the amended claims. The Examiner indicated that the proposed amendments appeared to overcome the cited references, although additional search and consideration may be required.

Claim Rejections – 35 USC § 103

Claims 1, 5, 9-13, 18 and 19 are rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being obvious over Chen et al. (U.S. Pub. No. 2009/0246724), in view of Hostettler (U.S. Patent No. 4,791,156), as evidenced by Boedeker and Plastics. Claims 2-4, 14 and 15 are rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being obvious over Chen in view of Hostettler, as evidenced by Boedeker and Plastics, and further in view of DeSimone et al. (U.S. Patent No. 7,641,828). Claims 6-8, 16 and 17 are rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being obvious over Chen, in view of Hostettler, as evidenced by Boedeker and Plastics, and further in view of Lewis et al. (U.S. Pub. No. 2010/0055639).

Without conceding the merit of the rejections, the claims have been amended solely to expedite prosecution. Support for the claim amendments can be found throughout the application as originally filed, e.g., at paragraphs [0027] and [0029]-[0031], and in Fig. 3. It is

respectfully submitted that the cited references fail to disclose or suggest every element recited in the claims, thereby precluding the establishment of a *prima facie* case of obviousness. For instance, amended claim 1 recites in part "wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer . . . and wherein the 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 and a hardness of about 60A to about 85D." At least such subject matter is not taught or suggested by the cited references.

Chen, while representing a significant advancement in the art, has not been shown to describe or suggest every element recited in claim 1. Chen is directed to "[a] concave trough [comprising] a shape memory material" (Abstract). However, Chen has not been shown to describe or suggest a dental appliance "wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer . . . and wherein the 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 and a hardness of about 60A to about 85D***" (***emphasis*** added), as recited in claim 1.

Hostettler fails to cure the deficiencies of Chen. Hostettler is directed to non-toxic, substantially non-hydrophilic dentures (Abstract). Hostettler, however, also fails to describe or suggest a dental appliance "wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a ***thermoplastic*** polymer layer . . . and wherein the 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 and a hardness of about 60A to about 85D***" (***emphasis*** added), as recited in claim 1. Hostettler is entirely silent regarding the use of thermoplastic polymers for layered dental appliances. In fact, the polymers described in Hostettler appear to be ***thermoset*** polymers, contrary to the claimed invention. The Hostettler polymers are described as having "resistance to distortion under high thermal conditions" (Abstract). Additionally, the Hostettler dentures are formed by curing (col. 7, ll. 56-58; col. 8, ll. 36-38), which is a process associated with thermoset polymers. For instance, Hostettler describes cross-linking reactions between branched polyols and polyisocyanates (col. 3, ll. 12-30, 40-48; col. 4, ll. 48-61), which are

ClearCorrect Exhibit 1010, Page 1139 of 1447

indicative of thermoset polymers. Furthermore, Applicants note that the portions of Hostettler cited in the Office Action (col. 2, ll.22-26, 34-35) are actually quoted from the "Summary of the Invention section" of U.S. Patent No. 4,225,696 to Colpitts et al. ("Colpitts"). Colpitts explicitly describes formation of polymers by a curing or cross-linking process (col. 3, ll.2-9, 34-40, 46-50, 64-65 and col. 4, ll. 6-24), thus indicating that the Colpitts polymers referenced by Hostettler and cited in the Office Action are actually thermoset polymers. Therefore, Hostettler fails to disclose a soft polymer layer comprising a thermoplastic polymer layer and having the claimed flexural modulus and hardness.

Plastics fails to cure the deficiencies of Chen and Hostettler. Plastics describes typical properties for polyurethane ***thermoset*** elastomers (p.1), and therefore also fails to describe or suggest a dental appliance "wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a ***thermoplastic*** polymer layer . . . and wherein the 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 and a hardness of about 60A to about 85D***" (***emphasis*** added), as recited in claim 1.

Boedeker and Lewis fail to provide the elements missing from Chen, Hostettler, and Plastics. Boedeker is directed to typical properties of polycarbonate (p. 1). Lewis is directed to dental treatment trays formed from elastomeric silicone or a silicone-like material (Abstract). Boedeker and Lewis, however, also fail to disclose or suggest a dental appliance "wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a ***thermoplastic*** polymer layer . . . and wherein the 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 and a hardness of about 60A to about 85D***" (***emphasis*** added), as recited in claim 1.

DeSimone, while representing a significant advancement in the art, has not been shown to cure the deficiencies of the aforementioned cited references. DeSimone is directed to "[m]ethods of making a removable dental positioning appliance" (Abstract). DeSimone, however, has not been shown to disclose or suggest a dental appliance "wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a ***thermoplastic*** polymer

layer . . . and wherein the 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 and a hardness of about 60A to about 85D***" (***emphasis*** added), as recited in claim 1. Therefore, claim 1 is allowable over the cited references.

Claim 13 recites elements similar to claim 1 and is therefore allowable for similar reasons. Claims 2-12 and 14-19 are allowable for depending from claims 1 and 13, respectively, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 1-19 under pre-AIA 35 U.S.C. § 103(a) is respectfully requested.

Double Patenting

Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being obvious over claims 1, 2, and 6 of U.S. Patent No. 8,235,713 in view of Chen et al. (U.S. Pub. No. 2009/0246724).

The rejection is acknowledged and will be addressed upon final resolution of the claims by, e.g., filing a terminal disclaimer, if necessary.

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 3, 2014

/Connie Cheng/

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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. (Currently Amended) 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 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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer that comprises [[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; and

wherein the 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 and a hardness of about 60A to about 85D.

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

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

4. (Previously Presented) 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 thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

5. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

7. (Previously Presented) 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, or a polyester elastomer.

8. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

9. (Previously Presented) The dental appliance of claim 1, wherein at least one of the first soft polymer layer and the second soft polymer layer has a thickness in a range from 25 μm to 100 μm.

10. (Previously Presented) The dental appliance of claim 1, wherein the hard polymer layer, the first soft polymer layer and the second soft polymer layer combined has a thickness of 500 μm to 1200 μm.

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

13. (Currently Amended) 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 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 being greater that each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,

wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer that comprises [[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; and

wherein the 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 and a hardness of about 60A to about 85D.

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

15. (Previously Presented) 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 thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

16. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

17. (Previously Presented) 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 silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, or a thermoplastic polyamide elastomer.

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

28. (Withdrawn) 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. (Withdrawn) 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.

Electronic Acknowledgement Receipt

EFS ID:	20595453
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Connie Cheng
Filer Authorized By:	
Attorney Docket Number:	22773-826.201
Receipt Date:	03-NOV-2014
Filing Date:	14-MAY-2012
Time Stamp:	20:08:15
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		2014_11_03_AMD_22773_826_201.pdf	89392 9e7753352076b9e6a076702edb9cba2940a6f9ba	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	9
	Applicant Arguments/Remarks Made in an Amendment	10	14
Warnings:			
Information:			
	Total Files Size (in bytes):	89392	

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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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on November 3, 2014

WILSON SONSINI GOODRICH & ROSATI

By: /William D. Tronvig/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5655
Chunhua Li et al.	
Application No.: 13/470,681	Examiner: Justin R. O'Donnell
Filed: May 14, 2012	Art Unit: 3732
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 August 1, 2014, 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 10 of this paper.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	Hao Mai	3732

CPC- SEARCHED		
Symbol	Date	Examiner
A61C 7/00, 08, 14, 146; 9/00; 19/063	2/23/2015	JO
A61K 6/0023, 083, 09, 10	2/23/2015	JO
Updated Search	08/10/2015	HDM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO
Updated	All	9/10/2013	JO
Updated	All	1/11/2014	JO
Updated	All	7/28/2014	JO
Updated	All	2/23/2015	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO
Updated EAST search	9/10/2013	JO
Updated EAST search	1/11/2014	JO
Updated EAST search	7/28/2014	JO
Updated EAST search	2/23/2015	JO
Update Search	08/10/2015	HDM

INTERFERENCE SEARCH

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

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

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	Hao Mai	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014	07/28/2014	02/23/2015	08/10/2015		
	1	÷	✓	✓	✓	✓	✓	✓		
	2	÷	✓	✓	✓	✓	✓	✓		
	3	÷	✓	✓	✓	✓	✓	✓		
	4	÷	✓	✓	✓	✓	✓	✓		
	5	÷	✓	✓	✓	✓	✓	✓		
	6	÷	✓	✓	✓	✓	✓	✓		
	7	÷	✓	✓	✓	✓	✓	✓		
	8	÷	✓	✓	✓	✓	✓	✓		
	9	÷	✓	✓	✓	✓	✓	✓		
	10	÷	✓	✓	✓	✓	✓	✓		
	11	÷	✓	✓	✓	✓	✓	✓		
	12	÷	✓	✓	✓	✓	✓	✓		
	13	÷	✓	✓	✓	✓	✓	✓		
	14	÷	✓	✓	✓	✓	✓	✓		
	15	÷	✓	✓	✓	✓	✓	✓		
	16	÷	✓	✓	✓	✓	✓	✓		
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	19	÷	✓	✓	✓	✓	✓	✓		
	20	÷	N	N	N	N	N	N		
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	22	÷	N	N	N	N	N	N		
	23	÷	N	N	N	N	N	N		
	24	÷	N	N	N	N	N	N		
	25	÷	N	N	N	N	N	N		
	26	÷	N	N	N	N	N	N		
	27	÷	N	N	N	N	N	N		
	28	÷	N	N	N	N	N	N		
	29	÷	N	N	N	N	N	N		

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 08/17/2015

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

EXAMINER
MAI, HAO D

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
08/17/2015	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. 13/470,681	Applicant(s) LI ET AL.	
	Examiner HAO D. MAI	Art Unit 3732	AIA (First Inventor to File) 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 *11/03/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-29* is/are pending in the application.

5a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-19* 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 present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 103

2. 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 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1, 5, 9, 10, 11, 12, 13, 18, 19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2009/0246724 A1), in view of Hostettler (US 4,791,156),** *as evidenced by Boedeker (non-patent literature, previously cited) and Plastics (non-patent literature, previously cited).*

Chen teaches an orthodontic system including: a plurality of incremental tooth position adjustment appliances (100) having teeth receiving cavities (102) shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, where the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement ([0014]-[0015] line 5), and where at least one of the appliances includes a hard polymer layer (150, Fig. 5; [0036] ll. 5-7: polycarbonate) having a hard polymer layer elastic modulus disposed between a first soft polymer layer (outer 152) having a first soft polymer layer elastic modulus and a second soft polymer layer (inner, tooth-facing 152) having a second soft polymer layer elastic modulus, the hard polymer layer elastic modulus being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus (paragraph 36 lines 8-10, 13-16: outer layer 152 may have…lower glass transition temp than inner layers 150; layers with lower glass transition temp may be the softer

segment… layers with higher glass transition temp may be harder segment); where at least one of the first and second soft polymer layers includes two layers ([0033] lines 1-3).

Chen discloses that it is well known to use thermoplastic polyurethane (paragraph 3); Chen further explicitly discloses the dental appliance comprising thermoplastic polymer (paragraph 25) but is silent to the claimed ranges of flexural modulus and hardness.

Hostettler teaches that it is well known that multilayer polymeric dental appliance (column 2 lines 33-38), includes a hard layer (column 2 lines 22-26, 34-35: hardness of about 60D to about 100D), and a separate soft layer of polyurethane elastomer having a hardness of about 60A to about 85D (column 2 lines 36-44: not greater than about 65A). It would have been obvious to one of ordinary skill in the art at the time of invention to use soft polyurethane elastomer for the soft polymer layers of Chen as taught by Hostettler in order to provide a soft layer which provides tissue relief, is inexpensive, trouble-free, and easy to keep clean (column1 lines 40-41, 50-59).

To support the examiner's position with respect to the above rejection of claims 1 and 13, applicant is directed to the previously cited Boedeker and Plastics documents. The Boedeker document contains a table with typical properties of polycarbonate, with the "Unfilled" column stating that the flexural modulus of polycarbonate is 375,000 psi. The Plastics document shows that polyurethane elastomers have a flexural modulus greater than about 35,000 psi (3600 to 648000 psi), an ultimate tensile strength of greater than about 5000 psi (235 to 5570 psi), and an elongation at break of greater than about 200% (8.5 to 800%). As combined, the materials of Chen and Hostettler thus meet the material property limitations of claims 1, 12, 13, and 19 for a hard polymer layer disposed between first and second soft polymer layers.

With respect to claims 5, 10, 11, and 18, Chen teaches that the hard polymer layer has a thickness in a range from 400 µm to 1100 µm ([0031] lines 5-6: at 10 mil per layer, the two inner

layers in Fig. 5 have combined thickness of 20 mil = 508 µm), a tensile and flexural modulus greater than 150,000 psi (respectively 320,000 and 375,000 psi; see 'Unfilled' column in the previously cited Boedeker evidence), that the combined hard and soft polymer layers (Fig. 5) have a thickness of 500 µm to 1200 µm (4 x 10 mil = 40 mil = 1016 µm).

With respect to claim 9, Chen/Hostettler do not teach at least one of the first and second soft polymer layer as having a thickness in a range from 25 µm to 100 µm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to select a soft polymer layer having a thickness from 25 to 100 µm because Applicant has not disclosed this parameter as contributing any unexpected result to the appliance. One of ordinary skill in the art, furthermore, would have expected Chen's appliance and applicant's invention to perform equally well with either the layer taught by Chen or the claimed layer having a thickness from 25 to 100 µm because both layers would perform the same function of providing an aligner appliance with a combined modulus sufficient to grab hold of and reposition teeth.

4. **Claims 2, 3, 4, 14, 15 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen in view of Hostettler, as applied to claims 1 and 13 above, and further in view of DeSimone et al. (US 7641828).**

Chen/Hostettler teach the invention substantially as claimed and discussed above, including that the hard polymer layer includes at least two layers (Chen: Fig. 5: two inner layers 150), but do not specifically teach that the hard layers are independently selected from a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

DeSimone teaches that polyester, thermoplastic polyurethane, acrylic, polyamide, or polyetherimide (col. 6 ll. 47-59), polyethylene terephthalate, or polybutylene terephthalate (col. 7 ll. 24-31) may be used for hard layers (col. 6 ll. 47-59: polymeric materials with high glass transition temperatures). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/Hostettler hard polymer layer to include the materials taught by DeSimone, as DeSimone states that polyester blends improve the strength, chemical resistance, and tendency of the appliance to creep.

5. **Claims 6, 7, 8, 16, 17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen in view of Hostettler, as applied to claims 1 and 13 above, and further in view of Lewis et al. (US 2010/0055639).**

Chen/Hostettler teach the invention substantially as claimed and discussed above, including that at least one of the first and second soft polymer layers includes two layers (Chen: [0033] lines 1-3), but do not specifically teach that the at least two layers are independently selected from the group consisting of a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a polyester elastomer.

Lewis teaches a dental appliance with an outer soft polymer layer which includes thermoplastic elastomer (claim 1). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/Hostettler soft polymer layers to be thermoplastic elastomer as taught by Lewis, as Lewis states that the material is elastically deformable in order to be highly adaptable so that, when placed over a person's teeth during use, the layer adapts

and at least partially conforms to unique ridges, depressions and contours of the person's teeth (claim 1).

Response to Arguments

6. The previous double patenting ground(s) of rejection have been withdrawn. Applicant's arguments filed 11/03/2014 have been fully considered but they are not persuasive. Applicant argued that the cited references disclose thermoset elastomers while the invention is directed to thermoplastic polymer. It is maintained that the primary reference Chen discloses that it is well known to use thermoplastic polyurethane (paragraph 3); Chen further explicitly discloses the dental appliance comprising thermoplastic polymer. The secondary reference Hostettler and evidence references Boedeker and Plastics are cited to show that the claimed ranges of flexural modulus and hardness are inherent of the claimed member polyurethane elastomer of the Markush group. That is, with Chen disclosing that it is well known to use thermoplastic polyurethane elastomer, which is a member within the claimed Markush Group, the claimed ranges of flexural modulus and hardness are shown to be inherent properties polyurethane elastomer as shown by Hostettler, Boedeker and Plastics. At the very least, such claimed ranges of flexural modulus and hardness are result-effective variables that can be optimized via routine experimentation in order to improve upon what is already generally known. *See MPEP §§ 2144.05.*

In conclusion, the claims currently fail to distinguish the claimed invention comprising thermoplastic being structurally different than the prior art's allegedly distinguishable thermoset polymer.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday 8:00AM - 4:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. 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.

/HAO D MAI/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	160	("20050055118" | "3660900" | "3922786" | "4253828" | "4505673" | "4663720" | "4664626" | "4676747" | "4850865" | "4935635" | "4936862" | "5017133" | "5128870" | "5278756" | "5382164" | "5452219" | "5456600" | "5474448" | "6044309" | "6190165" | "6382975" | "6554611" | "6629840" | "6722880" | "4791156" | "2467432" | "20030009252" | "4591341" | "4763791" | "4850864" | "4964770" | "4983334" | "5055039" | "5059118" | "5176517" | "5257203" | "5440326" | "5447432" | "5518397" | "5587912" | "5621648" | "5934288" | "6015289" | "6183248" | "20090246724" | "7641828" | "3683502" | "3860803" | "4575330" | "4611288" | "4836778" | "5027281" | "5340309" | "5533895" | "5562448" | "5614075" | "5800175" | "5964587" | "6322359" | "6398548" | "6572372" | "3600808" | "3950851" | "4656860" | "4755139" | "4793803" | "4975052" | "5100316" | "5121333" | "5368478" | "5395238" | "5605459" | "6099314" | "6315553" | "6705863" | "8235713" | "4014096" | "4195046" | "4575805" | "4880380" | "4890608" | "5342202" | "5528735" | "5607305" | "5683243" | "5740267" | "5742700" | "5795893" | "5823778" | "6049743" | "6217325" | "20020006597" | "3407500" | "3916526" | "3983628" | "4478580" | "4500294" | "4937928" | "5011405" | "5131843" | "5145364" | "5186623" | "5328362" | "5338198" | "5440496" | "5542842" | "5549476" | "5655653" | "5866058" | "5957686" | "5971754" | "6062861" | "6123544" | "6524101" | "20030139834" | "20040128010" | "4324546" | "4324547" | "4348178" | "4504225" | "4798534" | "4837732" | "5131844" | "5139419" | "5184306" | "5431562" | "5454717" | "5692894" | "5733126" | "6068482" | "6217334" | "6244861" | "6309215" | "6350120" | "6402707" | "5024790" | "20100055639" | "20030224311" | "3738005" | "4526540" | "4609349" | "4742464" | "4856991" | "4877398" | "4889238" | "4941826" | "5035613" | "5130064" | "5273429" | "5645421" | "5725376" | "5725378" | "5799100" | "5848115" | "5857853" | "5879158" | "5880961" | "5880962" |	US-PGPUB; USPAT	ADJ	ON	2015/08/10 08:49

		"6152731" | "6482298").PN.				
L2	10	l1 and psi	US-PGPUB; USPAT	ADJ	ON	2015/08/10 08:58
L3	0	l1 and boedeker.in.	US-PGPUB; USPAT	ADJ	ON	2015/08/10 10:17
L4	3	"8235713"	US-PGPUB; USPAT	ADJ	ON	2015/08/10 10:32
L5	1	(12/055010).APP.	USPAT; USOCR	ADJ	ON	2015/08/10 10:34
L6	113	((Chunhua) near2 (Li)).INV.	US-PGPUB; USPAT	ADJ	ON	2015/08/10 10:38
L7	806	((Yan) near2 (Chen)).INV.	US-PGPUB; USPAT	ADJ	ON	2015/08/10 10:38
L8	33	(l6 or l7) and (dental appliance)	US-PGPUB; USPAT	ADJ	ON	2015/08/10 10:39
L9	1	(l6 or l7) and (dental appliance) and (first second soft).clm.	US-PGPUB; USPAT	WITH	ON	2015/08/10 10:39
L10	1278	A61C7/00.cpc.	US-PGPUB; USPAT	ADJ	ON	2015/08/10 11:12
L11	810	A61C7/08.cpc.	US-PGPUB; USPAT	ADJ	ON	2015/08/10 11:12
L12	313	A61C7/08.cpc. and (layer)	US-PGPUB; USPAT	ADJ	ON	2015/08/10 11:12
L13	1	A61C7/00.cpc. and (layer and psi and harness)	US-PGPUB; USPAT	ADJ	ON	2015/08/10 11:13
L14	1	A61C7/08.cpc. and (layer) and psi and hardness	US-PGPUB; USPAT	ADJ	ON	2015/08/10 11:13
L15	1	A61C7/08.cpc. and (layer) and psi and hardness	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/10 11:13
L16	10	A61C7/08.cpc. and psi and hardness	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/10 11:13

EAST Search History (Interference)

< This search history is empty>

8/10/2015 11:13:58 AM
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 09/24/2015

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

EXAMINER
MAI, HAO D

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
09/24/2015	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.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	HAO D. MAI	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Hao D. Mai*.

(3) *John Schmmick*.

(2) *Connie Cheng*.

(4)_____.

Date of Interview: *18 September 2015*.

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: *1*.

Identification of prior art discussed: *Chen et al., Hostettler*.

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...)

The prior art and proposed amendments were discussed. Applicant discussed the proposed amendment includes the hard polymer layer comprising a co-polyester, and the first and second soft polymer layers each having a thickness within a range from 25 um to 100 um which are not disclosed by the cited prior art. Further search and/or consideration will be conducted upon receipt of filing of the amendment.

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

/HAO D MAI/ Examiner, Art Unit 3732	

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 examiner's 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 applicant's 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 applicant's 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 examiner's 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 examiner's initials.

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/470,681	Filing Date 05/14/2012	☐ 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 **10/13/2015**

	(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))	* 27	Minus	** 29	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 2	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

	(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))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ 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.

** 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
/DORRETTA BROOKS/

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.

REMARKS

Upon entry of this amendment, claims 1-19 and 30-37 will be pending in the present application. Claims 20-29 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue any canceled subject matter in a related, future application. Claims 1-19 have been amended. Claims 30-37 have 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 Mai for the courtesy extended during a telephonic interview conducted on September 18, 2015 with Applicants' undersigned representative Connie Cheng and her colleague, John Shimmick. During the interview, a proposed claim amendment was discussed and no specific agreement was reached.

Claim Rejections – 35 USC § 103

Claims 1, 5, 9-13, 18, and 19 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen et al. (U.S. Pub. No. 2009/0246724 A1), in view of Hostettler (U.S. Pat. No. 4,791,156), as evidenced by Boedeker and Plastics.

Without conceding the merit of the rejections, Applicants have amended the claims solely to expedite prosecution. Support for the amendments can be found throughout the application as originally filed, e.g., at paragraphs [0024]-[0029] and [0034]-[0035], therefore no new matter has been added. It is respectfully submitted that the cited references fail to teach or suggest every element recited in the claims, thereby precluding the establishment of a *prima facie* case of obviousness. For example, independent claim 1 recites:

> A removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of a patient's teeth and apply a resilient positioning force to the patient's teeth, the

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appliance comprising:

a hard inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn.

Chen, while representing a considerable advancement in the art, has not been shown to teach or suggest every element recited in claim 1. Chen is directed to a "dental appliance compris[ing] a concave trough conforming to a plurality of teeth." (Abstract). Chen, however, has not been shown to teach or suggest at least "a hard inner polymer layer comprising a co-polyester," "a first soft outer polymer layer and a second soft outer polymer layer each comprising . . . a thickness in a range from 25 μm to 100 μm," and "wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn," as recited in claim 1.

Hostettler fails to cure the deficiencies of Chen. Hostettler is directed to non-toxic, substantially non-hydrophilic dentures (Abstract). Hostettler, however, also fails to teach or suggest at least "a hard inner polymer layer comprising a co-polyester," "a first soft outer polymer layer and a second soft outer polymer layer each comprising . . . a thickness in a range from 25 μm to 100 μm," and "wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn," as recited in claim 1.

Boedeker and Plastics fail to provide the elements missing from Chen and Hostettler. Boedeker describes typical properties of polycarbonate. Plastics describes typical properties of polyurethane thermoset elastomer. Boedeker and Plastics, however, both fail to teach or suggest at least "a hard inner polymer layer comprising a co-polyester," "a first soft outer polymer layer and a second soft outer polymer layer each comprising . . . a thickness in a range from 25 μm to 100 μm," and "wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn," as recited in claim 1. Therefore, claim 1 is allowable over the proposed combination of Chen, Hostettler, Boedeker, and Plastics.

Claim 13 recites elements similar to claim 1 and is therefore allowable for similar reasons. Claims 2-12 and 14-19 are allowable for depending from claims 1 and 13, respectively, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 1, 5, 9-13, 18, and 19 under 35 U.S.C. § 103(a) is respectfully requested.

Claims 2-4, 14, and 15 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen in view of Hostettler, as applied to claims 1 and 13 above, and further in view of DeSimone et al. (U.S. Pat. No. 7,641,828).

Claims 2-4 and 14-15 depend from claims 1 and 13, respectively, which have been distinguished from Chen and Hostettler as discussed above. DeSimone, while representing a significant advancement in the art, has not been shown to cure the deficiencies of the aforementioned cited references. DeSimone is directed to "[m]ethods of making a removable dental positioning appliance" (Abstract). DeSimone, however, has not been shown to teach or suggest at least "a hard inner polymer layer comprising a co-polyester," "a first soft outer polymer layer and a second soft outer polymer layer each comprising . . . a thickness in a range from 25 μm to 100 μm," and "wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of

the resilient positioning force applied to the teeth when the appliance is worn," as recited in claim 1.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 2-4, 14, and 15 under 35 U.S.C. § 103(a) is respectfully requested.

Claims 6-8, 16, and 17 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen in view of Hostettler, as applied to claims 1 and 13 above, and further in view of Lewis et al. (U.S. Pub. No. 2010/0055639).

Claims 6-8 and 16-17 depend from claims 1 and 13, respectively, which have been distinguished from Chen and Hostettler as discussed above. Lewis fails to cure the deficiencies of Chen and Hostettler. Lewis is directed to dental treatment trays formed from elastomeric silicone or a silicone-like material (Abstract). Lewis, however, has not been shown to teach or suggest at least "a hard inner polymer layer comprising a co-polyester," "a first soft outer polymer layer and a second soft outer polymer layer each comprising . . . a thickness in a range from 25 μm to 100 μm," and "wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn," as recited in claim 1.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 6- 8, 16, and 17 under 35 U.S.C. § 103(a) is respectfully requested.

New Claims

Claims 30-37 have been newly added. Support for claims 30-37 can be found throughout the application as originally filed, e.g., at paragraphs [0026]-[0029], therefore no new matter has been added. Claims 30-33 and 34-37 depend from claims 1 and 13, respectively, and are therefore allowable for similar reasons, as well as on their own merits.

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: October 13, 2015

/Connie Cheng/

Connie Cheng
Registration No. 72,940

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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 October 13, 2015

WILSON SONSINI GOODRICH & ROSATI

By: /William D. Tronvig/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5655
Chunhua Li et al.	
Application No.: 13/470,681	Examiner: Hao D. Mai
Filed: May 14, 2012	Art Unit: 3732
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 August 17, 2015, 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 10 of this paper.

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Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
22773-826.201	13/470,681	May 14, 2012
First Named Inventor:	**Title:**	
Chunhua Li et al.	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
    - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
    - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
        - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
        - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
            - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
            - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Connie Cheng/	October 13, 2015
Name (Print/Typed) Connie Cheng	**Practitioner Registration No.** 72,940

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

Amendments to the Claims:

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

Listing of Claims:

1. (Currently Amended) 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]] a patient's teeth and apply a resilient positioning force to the patient's teeth, the appliance comprising:

a hard inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn. ~~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 being greater than each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,~~

~~wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer that comprises 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; and~~

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~~wherein the 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 and a hardness of about 60A to about 85D.~~

2. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the hard inner polymer layer comprises a blend of polymeric materials including the co-polyester and one or more of: ~~a layer of~~ a polyester, ~~a co-polyester,~~ a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

3. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the hard inner polymer layer comprises a plurality of co-extruded or laminated polymer layers . ~~a layer of a co-polyester, a polyester, or a thermoplastic polyurethane~~.

4. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the hard inner polymer layer comprises at least two layers including a first layer comprising the co-polyester and a second layer comprising one or more of: ~~and the at least two layers are independently selected from~~ a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, [[and]] or a polytrimethylene terephthalate.

5. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the hard inner polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of:

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~~independently comprises a layer of~~ a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

7. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: ~~independently comprises a layer of~~ an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a thermoplastic co-polyester elastomer, or a polyester elastomer.

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

9. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein ~~at least one of~~ the first soft outer polymer layer and the second soft outer polymer layer each have ~~has~~ a thickness in a range from [[25]] 35 μm to [[100]] 80 μm.

10. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the hard inner polymer layer, the first soft outer polymer layer, and the second soft outer polymer layer combined [[has]] have a thickness of 500 μm to 1200 μm.

11. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the hard inner 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]] or a light transmission between 400 nm and 800 nm of greater than about 75%.

12. (Currently Amended) The ~~dental~~ appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer 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]] or a light transmission between 400 nm and 800 nm of greater than about 75%.

13. (Currently Amended) 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 inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

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wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn. ~~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 being greater that each of the first soft polymer layer elastic modulus and the second soft polymer layer elastic modulus,~~

~~wherein at least one of the first soft polymer layer and the second soft polymer layer comprises a thermoplastic polymer layer that comprises 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; and~~

~~wherein the 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 and a hardness of about 60A to about 85D.~~

14. (Currently Amended) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises a blend of polymeric materials including the co-polyester and one or more of: ~~a layer of~~ a polyester, ~~a co-polyester,~~ a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

15. (Currently Amended) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises at least two layers including a first layer comprising the co-polyester and a second layer ~~and the at least two layers are independently~~ selected from [[a]] the group consisting of: a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a

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polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

16. (Currently Amended) The orthodontic system of claim 13, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: ~~independently comprises a layer of~~ a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

17. (Currently Amended) The orthodontic system of claim 13, wherein at least one of the first soft outer polymer layer and the second soft outer polymer layer comprises at least two layers including a first layer comprising the thermoplastic polyurethane elastomer and a second layer~~, and wherein the at least two layers are independently~~ selected from the group consisting of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, [[or]] and a thermoplastic polyamide elastomer.

18. (Currently Amended) The orthodontic system of claim 13, wherein the hard inner 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]] or a light transmission between 400 nm and 800 nm of greater than about 75%.

19. (Currently Amended) The orthodontic system of claim 13, wherein the first soft outer polymer layer and the second soft outer polymer layer each independently

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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]] or a light transmission between 400 nm and 800 nm of greater than about 75%.

20.-29. (Canceled)

30. (New) The appliance of claim 1, wherein the hard inner polymer layer comprises 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%.

31. (New) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each comprise 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, and a light transmission between 400 nm and 800 nm of greater than about 75%.

32. (New) The appliance of claim 1, wherein one or more of the first soft outer polymer layer or the second soft outer polymer layer comprise a plurality of polymer layers.

33. (New) The appliance of claim 1, wherein the first soft outer polymer layer comprises a different material than the second soft outer polymer layer.

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34. (New) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises 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%.

35. (New) The orthodontic system of claim 13, wherein the first soft outer polymer layer and the second soft outer polymer layer each comprise 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, and a light transmission between 400 nm and 800 nm of greater than about 75%.

36. (New) The orthodontic system of claim 13, wherein one or more of the first soft outer polymer layer or the second soft outer polymer layer comprise a plurality of polymer layers.

37. (New) The orthodontic system of claim 13, wherein the first soft outer polymer layer comprises a different material than the second soft outer polymer layer.

Electronic Acknowledgement Receipt

EFS ID:	23765909
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Connie Cheng/William Tronvig
Filer Authorized By:	Connie Cheng
Attorney Docket Number:	22773-826.201
Receipt Date:	13-OCT-2015
Filing Date:	14-MAY-2012
Time Stamp:	13:53:54
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		2015_10_13_AMD_AFCP_REQ_22773_826_201.pdf	239267 b51fe707077a300b1646946450f8dd56efff4024	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	9
	Applicant Arguments/Remarks Made in an Amendment	10	14
	After Final Consideration Program Request	15	15
Warnings:			
Information:			
	Total Files Size (in bytes):	239267	

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.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	HAO D. MAI	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Hao Mai*. (3)_____.

(2) *Connie Cheng*. (4)_____.

Date of Interview: *10/15/2015*.

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: *1,13 and 30-37*.

Identification of prior art discussed: *N/A*.

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's cousel discussed the proposed amendment in independent claims 1 and 13 and the new claims 30-37 filed in the Response After Final Action on 10/13/2015. The proposed amendment and the new claims raise new issues that require further search and consideration that cannot be fully completed within the guidelines of the AFCP 2.0 .

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of 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

/HAO D MAI/ Examiner, Art Unit 3732	

Receipt date: 10/13/2015

DO NOT ENTER: /H.D.M./ 10/15/2015

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on October 13, 2015

WILSON SONSINI GOODRICH & ROSATI

By: /William D. Tronvig/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No. 5655
Chunhua Li et al.	
Application No.: 13/470,681	Examiner: Hao D. Mai
Filed: May 14, 2012	Art Unit: 3732
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 August 17, 2015, 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 10 of this paper.

AFCP 2.0 Decision	Application No.	Applicant(s)
	13/470,681	LI ET AL.
	Examiner	Art Unit
	HAO D. MAI	3732

This is in response to the After Final Consideration Pilot request filed 13 October 2015.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ A proper AFCP 2.0 request was submitted in response to the most recent final rejection.

   ☐ Other:

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☐ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action. See attached interview summary for further details.

   ☒ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other:

   Examiner Note: Please attach an interview summary when necessary as described above.

ClearCorrect Exhibit 1010, Page 1191 of 1447

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.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 10/20/2015

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

EXAMINER
MAI, HAO D

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
10/20/2015	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

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	HAO D. MAI	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Hao Mai*. (3)_____.

(2) *Connie Cheng*. (4)_____.

Date of Interview: *10/15/2015*.

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: *1,13 and 30-37*.

Identification of prior art discussed: *N/A*.

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(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...)

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☐ Attachment

/HAO D MAI/ Examiner, Art Unit 3732	

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 13/470,681	**Applicant(s)** LI ET AL.	
	Examiner HAO D. MAI	**Art Unit** 3732	**AIA (First Inventor to File) Status** No

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

THE REPLY FILED 13 October 2015 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☒ Other: forms PTOL413B and PTOL2323.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed: .
    Claim(s) objected to: .
    Claim(s) rejected: 1-19.
    Claim(s) withdrawn from consideration: .

/Cris L. Rodriguez/ Supervisory Patent Examiner, Art Unit 3732	/HAO D MAI/ Examiner, Art Unit 3732

Continuation of 3. NOTE: The proposed amendments in the independent claims 1 and 13, and the new claims 30-37, raise new issues that would require further search and consideration and do not materially reduce or simplify issues for appeal.

Continuation of 12. does NOT place the application in condition for allowance because: The extensive amendment to narrow and change the scope of the independent claims 1 and 13, and the new claims 30-37, raise new issues that would require further search and consideration.

Electronic Patent Application Fee Transmittal

Application Number:	13470681
Filing Date:	14-May-2012
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Filer:	Connie Cheng/William Tronvig
Attorney Docket Number:	22773-826.201

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($)
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1700**

Electronic Acknowledgement Receipt

EFS ID:	24093751
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Connie Cheng/William Tronvig
Filer Authorized By:	Connie Cheng
Attorney Docket Number:	22773-826.201
Receipt Date:	16-NOV-2015
Filing Date:	14-MAY-2012
Time Stamp:	15:31:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1700
RAM confirmation Number	1440
Deposit Account	232415
Authorized User	CHENG, CONNIE

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 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	Request for Continued Examination (RCE)	2015_11_16_RCE_22773_826_201.pdf	119643 d12c678b630db0fc0a04e0fbe515f086b4812f8d	no	1
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30314 bf495d1ed1462f20807ed6d60bec594dd192f2ea	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	149957		

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

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New International Application Filed with the USPTO as a Receiving Office

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PTO/SB/30 (07-14)
Approved for use through 07/31/2016 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.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	13/470,681
Filing Date	May 14, 2012
First Named Inventor	Chunhua Li
Art Unit	3732
Examiner Name	Hao D. Mai
Attorney Docket Number	22773-826.201

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, to any international application that does not compy with the requirements of 35 U.S.C 371, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO on page 2.)

1. 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).

a. [✔] 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.

i. [ ] Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. [✔] Other Amendment After Final Filed on October 13, 2015

b. [ ] Enclosed

i. [ ] Amendment/Reply

ii. [ ] Affidavit(s)/ Declaration(s)

iii. [ ] Information Disclosure Statement (IDS)

iv. [ ] Other _____

2. Miscellaneous

a. [ ] 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)

b. [ ] Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

a. [✔] The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 23-2415.

i. [✔] RCE fee required under 37 CFR 1.17(e)

ii. [ ] Extension of time fee (37 CFR 1.136 and 1.17)

iii. [ ] Other _____

b. [ ] Check in the amount of $ _____ enclosed

c. [ ] Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Connie Cheng/	Date	November 16, 2015
Name (Print/Type)	Connie Cheng	Registration No.	72,940

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	/William Tronvig/		
Name (Print/Type)	William Tronvig	Date	November 16, 2015

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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, 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.

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/470,681	Filing Date 05/14/2012	☐ 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 **11/16/2015**

	(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))	* 27	Minus	** 29	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 2	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

	(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))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ 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.
** 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
/LINDA A. WASHINGTON/

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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	Hao Mai	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE							
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014	07/28/2014	02/23/2015	08/10/2015	06/16/2016
	1	÷	✓	✓	✓	✓	✓	✓	✓
	2	÷	✓	✓	✓	✓	✓	✓	✓
	3	÷	✓	✓	✓	✓	✓	✓	✓
	4	÷	✓	✓	✓	✓	✓	✓	✓
	5	÷	✓	✓	✓	✓	✓	✓	✓
	6	÷	✓	✓	✓	✓	✓	✓	✓
	7	÷	✓	✓	✓	✓	✓	✓	✓
	8	÷	✓	✓	✓	✓	✓	✓	✓
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	10	÷	✓	✓	✓	✓	✓	✓	✓
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	19	÷	✓	✓	✓	✓	✓	✓	✓
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	22	÷	N	N	N	N	N	N	-
	23	÷	N	N	N	N	N	N	-
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	28	÷	N	N	N	N	N	N	-
	29	÷	N	N	N	N	N	N	-
	30								✓
	31								✓
	32								✓
	33								✓
	34								✓
	35								✓
	36								✓

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	13470681	LI ET AL.
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CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014	07/28/2014	02/23/2015	08/10/2015	06/16/2016	
	37								✓	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 06/22/2016

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

EXAMINER
MAI, HAO D

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
06/22/2016	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. 13/470,681	Applicant(s) LI ET AL.	
	Examiner HAO D. MAI	Art Unit 3732	AIA (First Inventor to File) 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 *11/16/2015*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-19 and 30-37* 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) *1-19 and 30-37* 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 present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. 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 11/16/2015 has been entered.

Claim Rejections - 35 USC § 103

3. 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 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-5, 9-15, 18-19, 30-32, and 34-36, are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2009/0246724 A1), in view of DeSimone et al. (US 7641828), and further in view of Hostettler (US 4,791,156),** *as evidenced by Boedeker (non-patent literature, previously cited) and Plastics (non-patent literature, previously cited).*

Regarding claim 1, Chen discloses a removable orthodontic tooth positioning appliance 100 having teeth receiving cavities 102 shaped to directly receive at least some of a patient's teeth 114 and apply a resilient positioning force to the patient's teeth (Fig. 1, paragraph 4). The appliance 100 comprises: a hard inner polymer layer 132 having a hard polymer layer elastic

modulus, i.e. higher glass transition temperature (Fig. 4C, paragraphs 32, 36). There is further a first soft outer polymer layer 134 and a second soft outer polymer layer 134, each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, i.e. the soft outer layers 134 may have a glass transition temperature lower than that of the hard inner layer 132 (Fig. 4C; paragraphs 3, 32, 36). The hard inner polymer layer 132 is disposed between the first soft outer polymer layer 134 and the second soft outer polymer layer 134 (Fig. 4C) capable of reducing degradation of the resilient positioning force applied to the teeth when the appliance is worn.

Regarding claim 13, Chen discloses a plurality of such incremental tooth position adjustment appliances 100, where the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement (paragraphs 14-15).

As to claim 1-4 and 13-15, **regarding the hard inner polymer layer**, Chen fails to disclose the hard inner polymer layer comprising a co-polyester (as claimed in claim1). Chen also does not specifically teach that the hard layer is selected from a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate (as claimed in claims 2-4). DeSimone et al. discloses a polymer orthodontic appliance 10 made of co-polyesters and blends (column 5 lines 66-67). DeSimone also teaches that polyester, thermoplastic polyurethane, acrylic, polyamide, or polyetherimide (col. 6 ll. 47-59), polyethylene terephthalate, or polybutylene terephthalate (col. 7 ll. 24-31) may be used for hard layers (col. 6 ll. 47-59: polymeric materials with high glass transition temperatures). It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the materials taught by DeSimone to form Chen's hard layer since DeSimone teaches that such materials are suitable for the

intended use of such hard layer with predictable results and/or reasonable expectation of success.

Regarding the first and second soft outer layers, Chen discloses the first and second soft outer layers 134 being softer (i.e. less stiff) than the hard inner layer 132 (paragraphs 3, 32, 36); therefore, the soft outer layers 134 each has a soft polymer elastic modulus less than the inner layer 132's hard polymer layer elastic modulus, as claimed. Chen also discloses that it is well known to use thermoplastic polyurethane for such appliance (paragraph 3).

However, Chen is silent to the claimed flexural modulus and hardness of the first and second soft outer layers 134. Hostettler teaches that it is well known that multilayer polymeric dental appliance (column 2 lines 33-38), includes a hard layer of hardness about "60D-100D" (column 2 lines 22-26, 34-35), and a separate soft layer of polyurethane elastomer having a hardness of "not greater than about 65A" (column 2 lines 36-44) which at least 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 invention to use soft polyurethane elastomer for the soft polymer layers of Chen as taught by Hostettler in order to provide a soft layer which provides tissue relief, is inexpensive, trouble-free, and easy to keep clean (column1 lines 40-41, 50-59).

As to claims 1, 5, 9-10, 12-13, 19, 30-31, and 34-35 Chen/Hostettler teaches the soft outer layers are made of polyurethane elastomer as claimed, but is silent to the flexural modulus of such polyurethane elastomer being greater than about 35,000 psi as claimed. Chen also discloses the hard layer being made of polycarbonate (paragraph 36). The Boedeker document contains a table with typical properties of polycarbonate, with the "Unfilled" column stating that the flexural modulus of polycarbonate is 375,000 psi. The Plastics document shows that polyurethane elastomers have a flexural modulus of 3600 to 648000psi, which overlaps with the claimed range of greater than about 35,000 psi. As combined, the materials of Chen and

Hostettler thus meet the material property limitations of **claims 1, 12, 13, and 19** for a hard polymer layer disposed between first and second soft polymer layers.

Chen fails to disclose the claimed range of 25um to 100um for the thickness for each of the first and second soft outer layers (as claimed in **claim 1**), and 400um to 1100 um for the thickness of the hard inner layer (as claimed in **claim 5**). However, note that Chen discloses that the single material inner layer 132 in Fig. 4D having a thickness of about 1 mil to 60 mils (paragraph 30), which is converted to be about 25.4um to 1524um, which overlaps with the claimed thickness range of 25um to 100um for the soft outer layer (as claimed in claim 1), 400um to 1100um for the hard inner layer (as claimed in claim 5), and 35 um to 80 um for each of the soft outer layers (as claimed in **claim 9**), and 500um to 1200um for the combined thickness for the inner and soft layers (as claimed in **claim 10**). Considering Chen/Hostettler discloses the soft outer layers as claimed, and considering the disclosed ranges for the soft outer layers' flexural modulus, hardness, and thickness, overlapping with the claimed range or at least indicating that such ranges are result-effective variables, such claimed ranges would have been obvious to one having ordinary skill in art at the time the invention was made since it has been held that discovering an optimum or workable ranges is well within the skill of an artisan via routine experimentation in order to improve upon what is already generally known. *See MPEP §§ 2144.05.*

As to claims 11 and 18, Chen teaches that the hard polymer layer has a thickness in a tensile and flexural modulus greater than 150,000 psi (respectively 320,000 and 375,000 psi; see 'Unfilled' column in the previously cited Boedeker evidence).

As to claims 32 and 36, Chen discloses at least one of the first and second soft polymer layers includes two layers (paragraphs 33).

5. **Claims 6-8 and 16-17, 33, and 37,are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chen in view of DeSimone and Hostettler, as applied to claims 1 and 13 above, and further in view of Lewis et al. (US 2010/0055639).**

Chen/DeSimone/Hostettler teach the invention substantially as claimed and discussed above, including that at least one of the first and second soft polymer layers includes two layers (Chen: [0033] lines 1-3), but do not specifically teach that the at least two layers are independently selected from the group consisting of a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a polyester elastomer.

Lewis teaches a dental appliance with an outer soft polymer layer which includes thermoplastic elastomer (claim 1). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Chen/DeSimone/Hostettler soft polymer layers to be thermoplastic elastomer as taught by Lewis, as Lewis states that the material is elastically deformable in order to be highly adaptable so that, when placed over a person's teeth during use, the layer adapts and at least partially conforms to unique ridges, depressions and contours of the person's teeth (claim 1).

Response to Arguments

6. Applicant's arguments filed 11/16/2015 regarding the amendments newly made to the claims have been fully considered but are not persuasive.

Regarding the newly recited limitations “hard inner polyester layer comprising a co-polyester”, although Chen fails to disclose the hard inner polymer layer comprising a co-polyester as claimed, DeSimone et al. discloses a polymer orthodontic appliance 10 made of co-polyesters and blends (column 5 lines 66-67). It would have been obvious to one of ordinary

skill in the art at the time of invention to utilize the co-polyesters and blends as taught by DeSimone to form Chen's hard layer since DeSimone teaches that such co-polyesters and blends are suitable for the intended use of such hard layer while yielding predictable results and/or reasonable expectation of success.

Regarding the newly recited limitations "a first and second soft outer layers each comprising…a thickness in a range from 25um to 100um", note that Chen discloses that the single material inner layer 132 in Fig. 4D having a thickness of about 1 mil to 60 mils (paragraph 30), which is converted to be about 25.4um to 1524um. Since Chen's single material inner layer 132 is shown to be thicker than each of the outer layers 134 (Figs. 3-4D), one would expect the outer layers 134 each has a thickness ***less than*** the range of 25.4um to 1524um, overlapping with the claimed range of 25um to 100um. Furthermore, considering Chen disclosing the range thickness for the layers, the disclosed range overlapping with the claimed range, and it is well known in the art to provide such orthodontic polymeric as thin (invisible) as possible for cosmetic purpose, the thickness for inner and outer layers are clearly result-effective variables, therefore such claimed ranges for the thickness of the inner and outer layers would have been obvious to one having ordinary skill in art at the time the invention was made since it has been held that discovering an optimum or workable ranges is well within the skill of an artisan via routine experimentation in order to improve upon what is already generally known. *See MPEP §§ 2144.05.*

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday 8:00AM - 4:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be

reached on (571) 272-4964. 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.

/HAO D MAI/
Examiner, Art Unit 3732

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S14	11	433/24.ccls. and (copolyester or (co-polyester))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 14:05
S15	1	(11/757299).APP.	USPAT; USOCR	ADJ	ON	2016/06/15 14:12
S16	2	(11/757299).APP.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2016/06/15 14:14
S17	2	("4791156").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2016/06/15 15:10
S18	564	433/24.ccls. and (thickness)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:10
S19	0	433/24.ccls. and (soft layer) and (hard layer) and (thickness)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:11
S20	10	433/24.ccls. and (soft$2 with layer) and (hard$2 with layer) and (thickness)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:12
S21	29	433/24.ccls. and (elastic modulus) and (thickness)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	ADJ	ON	2016/06/15 16:18

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S23	5	433/6.ccls. and (elastic modulus) and (thickness same (millimeter or mils or micronmeter))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:24
S24	6	433/6.ccls. and (elastic modulus) and (thickness same (millimeter or mils or ".mu.m"))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:26
S25	2	433/24.ccls. and (elastic modulus) and (thickness same (millimeter or mils or ".mu.m"))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:27
S26	4	433/24.ccls. and (polyester) and (thickness same (millimeter or mils or ".mu.m"))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/15 16:28
S27	47	align.as. and ((thick or thickness) with layer)	US-PGPUB; USPAT	ADJ	ON	2016/06/16 00:01
S28	11	align.as. and ((thick or thickness) with segment)	US-PGPUB; USPAT	ADJ	ON	2016/06/16 00:01
S29	4	"433".clas. and orthodontic and polyester and (layer with (thick or thickness) with (mils or "mu.m."))	US-PGPUB; USPAT	ADJ	ON	2016/06/16 00:09
S30	97	("20030224311" | "2467432" | "3407500" | "3660900" | "3860803" | "3916526" | "3950851" | "4014096" | "4055895" | "4195046" | "4324546" | "4330272" | "4348178" | "4478580" | "4504225" | "4505673" | "4526540" | "4575805" | "4591341" | "4611288" | "4656860" | "4663720" | "4742464" | "4755139" | "4763791" | "4793803" | "4798534" | "4799884" | "4837732" | "4850864" | "4856991" | "4936862" | "4937928" | "4964770" | "4975052" | "4983334" | "5011405" | "5017133" | "5027281" | "5035613" | "5037295" | "5055039" | "5059118" | "5100316" | "5121333" | "5128870" | "5131843" | "5131844" |	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/16 00:20

		"5139419" | "5184306" | "5186623" | "5203695" | "5257203" | "5273429" | "5278756" | "5312247" | "5328362" | "5338198" | "5340309" | "5342202" | "5368478" | "5382164" | "5395238" | "5431562" | "5440496" | "5447432" | "5452219" | "5454717" | "5456600" | "5474448" | "5518397" | "5533895" | "5542842" | "5549476" | "5587912" | "5605459" | "5607305" | "5645420" | "5645421" | "5655653" | "5683243" | "5733126" | "5740267" | "5836761" | "5975893" | "6183248" | "6482298" | "6572372").PN. OR ("7121825").URPN.				
S31	2	(layer with inner) and (layer with outer) and S30	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/16 00:21
S32	5	("5372796" | "5405921" | "5670583" | "5975893").PN. OR ("7641828").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/16 00:30
S33	2	("20100055639").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2016/06/16 00:30
S34	1	("20130302742").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2016/06/16 00:31
S35	2537	A61C7/08.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/16 02:41
S36	33	A61C7/08.cpc. and (orthodontic) and (copolyester or (co-polyester))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2016/06/16 11:05

EAST Search History (Interference)

<This search history is empty>

6/16/2016 11:07:15 AM
C:\Users\hmai1\Documents\EAST\Workspaces\13470681.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	Hao Mai	3732

CPC- SEARCHED		
Symbol	Date	Examiner
A61C 7/00, 08, 14, 146; 9/00; 19/063	2/23/2015	JO
A61K 6/0023, 083, 09, 10	2/23/2015	JO
Updated Search	08/10/2015	HDM
Update Search	06/16/2016	HDM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO
Updated	All	9/10/2013	JO
Updated	All	1/11/2014	JO
Updated	All	7/28/2014	JO
Updated	All	2/23/2015	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO
Updated EAST search	9/10/2013	JO
Updated EAST search	1/11/2014	JO
Updated EAST search	7/28/2014	JO
Updated EAST search	2/23/2015	JO
Update Search	08/10/2015	HDM
Update Search	06/16/2016	HDM

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 10/31/2016

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

EXAMINER
MAI, HAO D

ART UNIT	PAPER NUMBER
3732	

NOTIFICATION DATE	DELIVERY MODE
10/31/2016	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.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	HAO D. MAI	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Hao Mai*.

(2) *Cris Rodriquez*.

(3) *Melissa Harwood*.

(4) *Esther Kepplinger*.

Date of Interview: *26 October 2016*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☒ Yes ☒ No.
If Yes, brief description: *Applicant showed examples of Invisalign appliances and demonstrated "before and after" models of teeth resulted from treatments using the invention*.

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: *1*.

Identification of prior art discussed: *Chen, DeSimone, Hostettler*.

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...)

Other participants: Arther Hsieh, Chunhua Li.
Current grounds of rejection and cited prior arts were disscussed. Applicant also discussed unexpected results and possible filing of declaration for such unexpected results.

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

/HAO D MAI/ Examiner, Art Unit 3732	

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 examiner's 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 applicant's 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 applicant's 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 examiner's 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 examiner's initials.

REMARKS

Upon entry of this Amendment, claims 1-19 and 30-41 will be pending in the present application. No claims have been amended. New claims 38-41 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.

Examiner Interview

Applicants thank Examiners Mai and Rodriguez for participating in an in-person interview on October 26, 2016. Additional participants in the interview included Applicants' representatives, Melissa Harwood and Esther Kepplinger, as well as Arthur Hsieh and Chunhua Li. The Examiner's rejections of the claims made in a Non-Final Office Action mailed on June 22, 2016, and the submission of a declaration demonstrating the unexpected results of the present invention were discussed.

Claim Rejections – 35 U.S.C. § 103

Claims 1-5, 9-15, 18-19, 30-32, and 34-36 stand rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being obvious over US 2009/0246724 (hereinafter "Chen") in view of US 7,641,828 (hereinafter "DeSimone"), and further in view of US 4,791,156 (hereinafter "Hostettler") as evidenced by Boedeker.com, "Polycarbonate specifications" (hereinafter "Boedeker") and plastics.ides.com/generics/57/c/t/polyurethane-thermoset-elastomer-tsu-properties-processing (hereinafter "Plastics").

In particular, with regard to the hard inner layer, the Examiner asserts that although "Chen fails to disclose the hard inner polymer layer comprising a co-polyester," that it "would have been obvious to one of ordinary skill in the art at the time of invention to utilize the materials taught by DeSimone to form Chen's hard layer since DeSimone teaches that such materials are suitable for the intended use of such hard layer with predictable results and/or reasonable expectation of success." Office Action at 3-4. With regard to the soft outer layer, the

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Examiner asserts that "Chen also discloses that it is well known to use thermoplastic polyurethane for such appliance." *Id.* at 4.

Applicants respectfully disagree with the Examiner's assertions at least because (1) the cited references provide no reason to select a polymer of DeSimone for use in Chen; (2) 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 the presently claimed orthodontic appliances; (3) the presently claimed orthodontic appliances were found to exhibit unexpectedly good results when compared with the most relevant art; and (4) the presently claimed orthodontic appliances gave rise to considerable commercial success. These positions are supported by the present specification and further supported by the attached November 21, 2016 Declaration under 37 C.F.R. § 1.132 of Dr. Chunhua Li ("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 of appliances comprising material according to the present claims, which is referred to herein as ST30—a material that has soft outer layers comprising a thermoplastic polyurethane elastomer and a hard inner layer comprising a co-polyester—to the prior art, including a thermoplastic polyurethane referred to as EX30, which was the standard of care prior to the release of ST30.

1. Obvious to Try Rejection—The Examiner Provides No Reason Why the Skilled Artisan Would Select a Polymer of DeSimone for use in Chen

Independent claims 1 and 13 stand rejected over Chen, DeSimone, and Hostettler, as evidenced by Boedeker and Plastics. Office Action at 2. Of these, Hostettler, Boedeker, and Plastics are unrelated to orthodontic, tooth-moving appliances (e.g., Hostettler relates to dentures), and are used only in relation to flexural modulus and hardness. With regard to Chen and DeSimone, the Examiner proposes a combination of three different embodiments: the EX30 thermoplastic polyurethane appliance of Chen paragraph [0003], the multilayer polycarbonate/PVC material of Chen paragraph [0032], and the co-polyester mentioned in column 5, line 66 of DeSimone. Each embodiment provides only one element of the proposed combination. Moreover, the Examiner fails to identify any reason why one of ordinary skill

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would have selected these elements in combination with one another and the cited references themselves fail to provide such guidance.

The Examiner improperly relies on Chen for teaching the use of a thermoplastic polyurethane elastomer as a soft outer layer, however, Chen does not teach the use of a thermoplastic polyurethane elastomer as a soft outer layer. Chen refers to thermoplastic polyurethane only in paragraph [0003], discussing the existence of dental appliances consisting of polymers such as thermoplastic polyurethane. No mention of layered materials is made in reference to thermoplastic polyurethane elastomer. Neither of the other two paragraphs cited to in Chen (i.e., paragraphs [0032] and [0036]) discusses the use of a thermoplastic polyurethane elastomer in a soft (or other) layer. Nor does Chen describe this elsewhere. Thus, contrary to the Examiner's assertions, Chen fails to disclose the use of a thermoplastic polyurethane elastomer as a soft outer layer.

The Examiner improperly uses an "obvious to try" approach and fails to provide any reason why one of ordinary skill in the art would select a co-polyester material from DeSimone for use in the multi-layer material of Chen. In fact, DeSimone lists hundreds of materials, from which the Examiner points to a single reference of "co-polyester." (DeSimone, col. 5). Notably, neither Chen nor DeSimone provide any sort of guidance suggesting why one might select any one of these numerous materials of DeSimone over any other disclosed material. The references do not provide a finite number of identified, predictable solutions to the problem and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success. The obvious to try rationale is improper when what would have been obvious to try would have been to vary all parameters and try each of numerous possible choices until one possibly arrived at a successful result and where the prior art gave no indication of which parameters were critical or no direction as to of which of many possible choices is likely to be successful. *In re Kubin* (Fed. Cir. 2009). There is no guidance in the references about which of many choices might be successful. There is no indication that the hard layers described in DeSimone would have the properties recited in Chen nor any other basis for selecting them from the list of hundreds of materials. In the absence of any such guidance, the

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selection of the co-polyester material from DeSimone for use in Chen represents nothing more than an "obvious to try" rationale or impermissible hindsight bias.

2. No 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 presently claimed orthodontic appliances 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 multi-layer 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"), which is a product according to the instant claims comprising a layered material with a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer. 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 of the present claims met Align's criteria for a multi-layer orthodontic appliance. *Id.* at ¶¶4-5. The tested materials included many multi-layer (e.g., three-layer) materials, yet of those tested only the materials of 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 ¶6.

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 presently claimed orthodontic appliances. Li Declaration at ¶7. As mentioned above, the

presently claimed multi-layer, 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 of the instant claims met Align's development criteria. *Id.* at 5. It was not a simple or predictable process to identify those materials that would work together to create the multi-layer 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 sufficient modulus of elasticity, 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 a suitable material. 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 presently claimed orthodontic appliances. 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 presently claimed orthodontic appliances. 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 polymers for use in the claimed multi-layer orthodontic appliances. *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 presently claimed orthodontic appliances based on the teachings of Chen, DeSimone and Hostettler. *Id.* at ¶10.

During the course of their evaluations, Applicants determined that merely combining the materials into multiple layers was insufficient to improve performance relative to the EX30 material. *Id.* at ¶6-7. In fact, many three-layer materials tested proved inferior to the EX30 material. These three-layer materials included combinations of materials disclosed in Chen and/or DeSimone. *Id.* In particular, the sole exemplified multi-layer 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 multi-layer configuration, would be inferior to EX30. *Id.* 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.

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 described in the present claims. *Id.* at ¶¶7-10.

3. Unexpected Results

Applicants have also established that the presently claimed appliances 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, called ST30, that has soft outer layers comprising a thermoplastic polyurethane elastomer and a hard inner layer comprising a co-polyester. Li Declaration at ¶¶11-16.

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As described in the Li Declaration, each study found that ST30 appliances provided strongly superior performance. 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 ¶¶13-14. 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 ¶15, Appendix B. Overall, patients treated with ST30 appliances showed a 75% improvement in tooth movement predictability over patients treated with EX30 appliances. *Id.* at ¶16. This surprising improvement would not have been predicted by a person of ordinary skill in the art. *Id.*

The unexpected results described above are commensurate in scope with independent claims 1, 13, and 38. Each claim describes orthodontic appliances with a hard co-polyester layer between soft layers of thermoplastic polyurethane elastomer. This corresponds to the material tested in the studies, ST30. Li Declaration at ¶¶4, 11. Accordingly, the unexpected results demonstrated by the studies, as described in the Li Declaration, correspond to the present claims.

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 as of the present filing date, and a person of ordinary skill would have considered it the closest relevant art. Thus, the skilled artisan would consider the superiority of the presently claimed orthodontic appliances relative to EX30 to be predictive of similar superiority of ST30 relative to other prior art appliances. Li Declaration at ¶16. During the course of Applicants' evaluations, they determined that merely combining the materials into multiple layers was insufficient to improve performance relative to the EX30 material. *Id.* at ¶6 In fact, many three-layer materials tested proved inferior to the EX30 material. *Id.* Based on these evaluations, none of these inferior multi-layer 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 was superior to many three-layer 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**.

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 presently claimed appliances produce unexpectedly positive results relative to the closest relevant art.

4. 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 ¶18. 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, Baird Q3 2013 Report at 9 (submitted herewith in an accompanying IDS). This striking commercial success was due to the superior performance of ST30 appliances to EX30 and other appliances on the market. Li Declaration at ¶¶18-19.

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

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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 as disclosed and claimed, 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 herewith in an accompanying IDS). 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.

Independent claims 1, 13, and 38 are not obvious over the combination of Chen, DeSimone, and Hostettler, as evidenced by Boedeker, and Plastics for at least the reasons described above. Claims 2-5, 9-15, 19, 30-32, 34-36, and 39-41 depend from claims 1, 13, and 38 respectively, 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 1-5, 9-15, 18-19, 30-32, and 34-36 under pre-AIA 35 U.S.C. § 103(a) is respectfully requested.

Claims 6-8, 16-17, 33, and 37 stand rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chen in view of DeSimone and Hostettler, as applied to claims 1 and 13 above, and further in view of U.S. Pub. No. 2010/0055639 (hereinafter "Lewis").

Lewis fails to remedy the deficiencies of Chen, DeSimone, and Hostettler as described above. Accordingly, as claims 6-8, 16-17, 33, and 37 depend respectively from allowable claims 1 and 13, they are allowable for similar reasons, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 6-8, 16-17, 33, and 37 under pre-AIA 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: November 22, 2016

/Melissa M. Harwood/

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Electronic Patent Application Fee Transmittal

Application Number:	13470681
Filing Date:	14-May-2012
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Filer:	Melissa Mitchell Harwood/William Tronvig
Attorney Docket Number:	22773-826.201

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 $0 paid	1252	1	600	600
Miscellaneous:				
			Total in USD ($)	**600**

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on November 22, 2016

WILSON SONSINI GOODRICH & ROSATI

By: /William D. Tronvig/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5655
Chunhua Li et al.	
Application No.: 13/470,681	Examiner: Hao D. Mai
Filed: May 14, 2012	Art Unit: 3732
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 June 22, 2016, please enter the following amendments and remarks. The fee for a Petition for Extension of Time of 2 months accompanies this response.

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

Remarks begin on page 10 of this paper.

PATENT

Attorney Docket No. 22773-826.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:	Confirmation No.: 5655
Inventor: Chunhua Li et al.	Examiner: Hao D. Mai
Application No.: 13/470,681	Group Art Unit: 3732
Filing or 371 (c) date: May 14, 2012	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 13 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 14 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 13/470,681 patent application (the "'681 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 June 22, 2016, and understand the rejections made in it. In particular, the Office Action states that claims 1-5, 9-15, 18-19, 30-32, and 34-36 of the US 13/470,681 patent application are rejected under 35 U.S.C. § 103(a) as being unpatentable 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 further in view of Hostettler, US 4,791,156, as evidenced by Boedeker and Plastics. Claims 6-8, 16-17, 33, and 37 are rejected under the same combination, and further in view of Lewis et al., US 2010/0055639. The Office Action at pages 3-4 states that, "It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the materials taught by DeSimone to form Chen's hard layer since DeSimone teaches that such materials are suitable for the intended use of such hard layer 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 '681 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 '681 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 device. After years of development, Align produced the SmartTrack™ material (also referred to herein as "ST30"), which is a product according to the instant claims comprising a layered material with a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer. We found that the resulting orthodontic appliances incorporating the SmartTrack material had surprisingly superior properties of modulus of elasticity, 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.

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 of the instant 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 modulus of elasticity, elongation, time stress-relaxation, durability, and thermoform ability.

6. In the course of developing the ST30 material, we evaluated numerous multi-layer 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 three-layer materials tested proved inferior to the EX30 material. Some of the three-layer materials that proved inferior to the EX30 material included combinations of materials disclosed in Chen and/or DeSimone. In particular, the sole exemplified multi-layer 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 multi-layer 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 multi-layer material combination according to the instant 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 present 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 presently 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 presently claimed orthodontic appliances. 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 multi-layer 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 of the instant claims was found to meet Align's criteria for a multi-layer 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 orthodontic appliances as described in the present claims. The study compared the performance of clear plastic appliances made with Align Technology's SmartTrack material (ST30), which is a product according to the instant claims comprising a layered material with a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer, 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. Patients in the study were assigned to one of two groups—an Experimental Group or a Control Group. The Experimental Group received 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 three-layer 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. A retrospective analysis was performed providing further evidence of the superior performance of SmartTrack materials as recited in the present 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.

16. 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 multi-layered appliances. Accordingly, the use of a layered material comprising materials as described in the present application (e.g., thermoplastic polyurethane elastomer layers surrounding a co-polyester layer, as recited in the present 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.

VI. UNEXPECTED EFFICACY OF SMARTTRACK MATERIALS

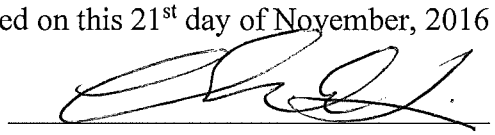
17. The above-described clinical studies demonstrate the significantly improved performance of SmartTrack materials relative to the previous standard of care in orthodontic treatment with clear plastic appliances (EX30)—a surprising result that would not have been expected by a person of ordinary skill 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.

18. The effectiveness of appliances made with SmartTrack materials 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 SmartTrack materials compared to the prior art.

19. 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 21st day of November, 2016



Chunhua Li, Ph.D.

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:

14 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; and 9,241,774

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

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[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 Acknowledgement Receipt

EFS ID:	27595146
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Melissa Mitchell Harwood/William Tronvig
Filer Authorized By:	Melissa Mitchell Harwood
Attorney Docket Number:	22773-826.201
Receipt Date:	22-NOV-2016
Filing Date:	14-MAY-2012
Time Stamp:	19:32:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$600
RAM confirmation Number	112316INTEFSW00007121232415
Deposit Account	232415
Authorized User	Melissa Harwood

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		2016_11_22_AMD_DEC_22773_826_201.pdf	1181392 ded372202e74a4b479ae09c5fc6d580a11291f99	yes	31

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Affidavit-traversing rejectns or objectns rule 132	21	31
	Applicant Arguments/Remarks Made in an Amendment	10	20
	Claims	2	9
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30818 20067b96e144cf4916437036071dcb3a96c752f2	no	2

Warnings:

Information:

Total Files Size (in bytes):	1212210

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.

Amendments to the Claims:

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

Listing of Claims:

1. (Previously Presented) A removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of a patient's teeth and apply a resilient positioning force to the patient's teeth, the appliance comprising:

a hard inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn.

2. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises a blend of polymeric materials including the co-polyester and one or more of: a polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

3. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises a plurality of co-extruded or laminated polymer layers.

4. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises at least two layers including a first layer comprising the co-polyester and a second layer comprising one or more of: a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

5. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Previously Presented) The appliance of claim 1, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

7. (Previously Presented) The appliance of claim 1, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a thermoplastic co-polyester elastomer, or a polyester elastomer.

8. (Previously Presented) The appliance of claim 1, wherein at least one of the first soft outer polymer layer and the second soft outer polymer layer comprises at least two layers including a first layer comprising the thermoplastic polyurethane elastomer and a second layer selected from the group consisting of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

9. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each have a thickness in a range from 35 μm to 80 μm.

10. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer, the first soft outer polymer layer, and the second soft outer polymer layer combined have a thickness of 500 μm to 1200 μm.

11. (Previously Presented) The appliance of claim 1, wherein the hard inner 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%, or a light transmission between 400 nm and 800 nm of greater than about 75%.

12. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each independently comprise at least one of: 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, or a light transmission between 400 nm and 800 nm of greater than about 75%.

13. (Previously Presented) 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:

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a hard inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn.

14. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises a blend of polymeric materials including the co-polyester and one or more of: a polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

15. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises at least two layers including a first layer comprising the co-polyester and a second layer selected from the group consisting of: a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

16. (Previously Presented) The orthodontic system of claim 13, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic

vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

17. (Previously Presented) The orthodontic system of claim 13, wherein at least one of the first soft outer polymer layer and the second soft outer polymer layer comprises at least two layers including a first layer comprising the thermoplastic polyurethane elastomer and a second layer selected from the group consisting of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

18. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner 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%, or a light transmission between 400 nm and 800 nm of greater than about 75%.

19. (Previously Presented) The orthodontic system of claim 13, wherein the first soft outer polymer layer and the second soft outer polymer layer each independently comprise at least one of: 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, or a light transmission between 400 nm and 800 nm of greater than about 75%.

20.-29. (Canceled)

30. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises a tensile strength at yield of between about 4000 pounds per square

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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%.

31. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each comprise 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, and a light transmission between 400 nm and 800 nm of greater than about 75%.

32. (Previously Presented) The appliance of claim 1, wherein one or more of the first soft outer polymer layer or the second soft outer polymer layer comprise a plurality of polymer layers.

33. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer comprises a different material than the second soft outer polymer layer.

34. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises 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%.

35. (Previously Presented) The orthodontic system of claim 13, wherein the first soft outer polymer layer and the second soft outer polymer layer each comprise an ultimate

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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, and a light transmission between 400 nm and 800 nm of greater than about 75%.

36. (Previously Presented) The orthodontic system of claim 13, wherein one or more of the first soft outer polymer layer or the second soft outer polymer layer comprise a plurality of polymer layers.

37. (Previously Presented) The orthodontic system of claim 13, wherein the first soft outer polymer layer comprises a different material than the second soft outer polymer layer.

38. (New) An orthodontic appliance for repositioning a patient's teeth, the appliance comprising:

a shell having a plurality of teeth receiving cavities shaped to apply a repositioning force to the patient's teeth, wherein the shell is formed from a multilayer material configured to reduce degradation of the repositioning force over time when the shell is worn on the patient's teeth, the multilayer material comprising:

a first soft polymer layer and a second soft polymer layer each having a compression set greater than 40% after 2 hours at 70 ºC, wherein the first and second soft polymer layers each comprise a thermoplastic polyurethane elastomer; and

a single hard polymer layer disposed between the first and second soft polymer layers and having a stress relaxation greater than 10% at 24 hour testing between 90% to 100% humidity, wherein the single hard polymer layer comprises a co-polyester.

39. (New) A plurality of orthodontic appliances as in claim 38, wherein the teeth receiving cavities of each of the plurality of orthodontic appliances are configured to move the patient's teeth along a path from a starting position to a final position when the plurality of

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orthodontic appliances is worn in succession, each appliance of the plurality of orthodontic appliances providing an incremental movement along said path.

40. (New) The orthodontic appliance of claim 38, wherein the shell consists essentially of the multilayer material.

41. (New) The orthodontic appliance of claim 40, wherein the first and second soft polymer layers each consists essentially of the thermoplastic polyurethane elastomer, and the single hard polymer layer consists essentially of the co-polyester.

Espacenet

Bibliographic data: DE102004014023 (A1) — 2005-10-20

Laminated plastic glazing for vehicles

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Classification: - international: ***B29C45/16; B32B27/08; B32B27/30; B32B27/36; B60J1/00; B64C1/14; C08L33/24; H05B3/84; H05B3/86;*** (IPC1-7): B29C45/14; B29C47/06; B32B27/08; B32B27/30; B32B27/36; B32B27/40; B60J1/18

- cooperative: **B32B27/08**; **B32B27/30**; **B32B27/36**; **B32B27/40**; H05B2203/002; H05B2203/013; H05B2203/017

Application number: DE20041014023 20040319

Priority number(s): DE20041014023 20040319

Also published as: EP1577084 (A1) EP1577084 (B1) AT439234 (T)

Abstract not available for DE102004014023 (A1)
Abstract of corresponding document: EP1577084 (A1)

Plastic laminated plates (I), for vehicle movement, comprises an inner layer of plastic polycarbonate (polycarbonate-plate), an outer layer of plastic acrylate (acrylate-plate) and a thermoplastic polyurethane layer arranged in between the two layers. Independent claims are also included for the preparations of (I).

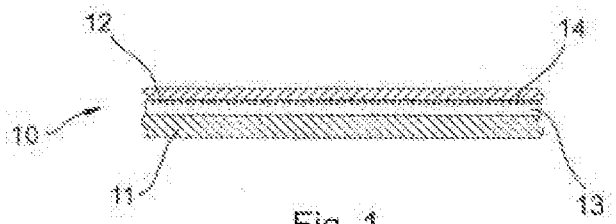


Fig. 1

(19) Bundesrepublik Deutschland
Deutsches Patent- und Markenamt

(10) **DE 10 2004 014 023 A1** 2005.10.20

(12) # Offenlegungsschrift

(21) Aktenzeichen: **10 2004 014 023.5**
(22) Anmeldetag: **19.03.2004**
(43) Offenlegungstag: **20.10.2005**

(51) Int Cl.[7]: **B32B 27/08**
B32B 27/30, B32B 27/36, B32B 27/40, B29C 47/06, B29C 45/14, B60J 1/18

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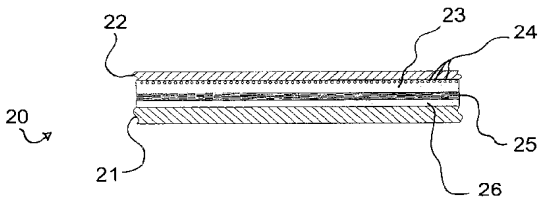
(56) Für die Beurteilung der Patentfähigkeit in Betracht gezogene Druckschriften:
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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gemäß § 44 PatG ist gestellt.

(54) Bezeichnung: **Kunststoff-Verbundscheibe für die Fahrzeugverscheibung**

(57) Zusammenfassung: Eine Kunststoff-Verbundscheibe mit einer Innen- und einer Außenseite für die Fahrzeugverscheibung ist dadurch gekennzeichnet, dass die Verbundscheibe eine Innenscheibe aus einem Polycarbonat-Kunststoff (Polycarbonat-Scheibe), eine Außenscheibe aus einem Acrylat-Kunststoff (Acrylat-Scheibe) und eine zwischen diesen Scheiben angeordnete Schicht aus thermoplastischem Polyurethan aufweist.



Beschreibung

[0001] Die vorliegende Erfindung betrifft eine Kunststoff-Verbundscheibe für die Fahrzeugverscheibung gemäß dem Oberbegriff des Anspruchs 1.

[0002] Kunststoffscheiben weisen im Vergleich zu Silikatglasscheiben eine Reihe von Vorteilen für die Fahrzeugverscheibung auf. Sie bilden bei mechanischer Zerstörung keine verletzungsträchtigen Splitter, haben ein geringeres Gewicht, eine geringere thermische Leitfähigkeit und eine bessere Formbarkeit als Silikatglas, und lassen sich überdies durch gezielte Modifikation oder Dotierung mit speziellen Eigenschaften versehen.

[0003] Um die Vorteile verschiedener Kunststoffe in einer Scheibe zu vereinigen, können Kunststoffscheiben auch aus mehreren aufeinandergelegten Einzelscheiben aufgebaut sein. Solche Scheiben sind als Kunststoff-Verbundglasscheiben bekannt. Überdies bietet diese Bauweise die Möglichkeit, zwischen den Einzelscheiben weitere Schichten mit weiteren Funktionalitäten einzubringen.

Stand der Technik

[0004] Aus der EP 0007857 ist eine Kunststoff-Verbundglasscheibe bekannt, die z.B. aus einer Acrylatscheibe und einer dünnen Beschichtung aus wärmestabilisiertem Polyurethan besteht. Letzteres weist selbstheilende Eigenschaften auf und eignet sich damit zur Veredelung der Oberfläche der Kunststoff-Verbundglasscheibe. Zwischen beiden Schichten befindet sich eine Schicht aus thermoplastischem Polyurethan, in die elektrisch leitende Drähte eingebettet sind, die z.B. als Scheibenbeheizung fungieren können.

[0005] Ein Kunststoff, der sich aufgrund seiner Eigenschaften für die Fahrzeugverscheibung anbietet, ist Polycarbonat (PC). Polycarbonat ist ein klarsichtiger Werkstoff mit extrem hoher Schlagfestigkeit, rückstellenden Eigenschaften nach mechanischen Einwirkungen, hoher Temperaturbeständigkeit und hoher Transparenz. Er eignet sich daher sehr gut für die Verscheibung von Kraftfahrzeugen insbesondere im sicherheitsrelevanten Bereich, z.B. in Polizeifahrzeugen. Allerdings weist PC eine schlechte Witterungsbeständigkeit auf und wird gerade bei dauerhafter UV-Einstrahlung farbstichig und spröde.

[0006] PC läßt sich durch Aufbringung eines UV-Schutzlacks vor der lichtbedingten Alterung schützen. Solche UV-Schutzlacke weisen jedoch hohe Konzentrationen von UV-Schutzadditiven auf und sind daher farbstichig. Überdies ist die UV-Schutzwirkung aufgrund der geringen Schichtdicke des aufgetragenen Lacks nicht befriedigend. Zudem altert der Lack unter UV-Einwirkung und bildet dabei Mikrorisse.

[0007] Ein weiterer Kunststoff mit für die Fahrzeugverscheibung geeigneten Eigenschaften ist das Acrylat Polymethylmethacrylat (PMMA), ein kratzfester und klarsichtiger Werkstoff. Er besitzt eine geringere Zähigkeit als PC und ist deshalb schlag- und spannungsrissempfindlich. Er weist jedoch eine weitaus höhere Witterungsbeständigkeit auf, und ist insbesondere unempfindlich gegen UV-Bestrahlung. Ähnliche Vorteile wie für PMMA gelten für andere Acrylate.

[0008] PMMA ist zwar transparent für UV-Licht, läßt sich jedoch gut mit farblosen UV-Schutzadditiven wie z.B. Benzophenon oder Benzotriazol dotieren. Aufgrund der im Vergleich zu einem UV-Schutzlack weitaus höheren Schichtdicke ist dabei die UV-Schutzwirkung weitaus besser.

[0009] Es hat in der Vergangenheit Versuche gegeben, Co-Extrudate oder Co-Laminate aus Acrylat und Polycarbonat herzustellen, um die Vorteile beider Werkstoffe zu vereinigen. Die dabei hergestellten Bauteile besaßen jedoch nur eine geringe Lebensdauer auf, da PMMA und PC unterschiedliche thermische Dehnungskoeffizienten aufweisen (PMMA: $8 \times 10^{-5}\ K^{-1}$; PC: $7 \times 10^{-5}\ K^{-1}$), und aufgrund der unterschiedlichen Dehnungseigenschaften der beiden Werkstoffe Spannungen in den Bauteilen auftraten, die z.B. zu einer Delaminierung oder zur Bildung von Rissen in den Bauteilen führten.

Aufgabenstellung

[0010] Aufgabe der vorliegenden Erfindung ist es, eine Kunststoffscheibe z.B. für die Fahrzeugverscheibung zur Verfügung zu stellen, die eine hohe Witterungsbeständigkeit, eine hohe Schlagfestigkeit und eine hohe Lebensdauer aufweist.

[0011] Dies Aufgabe wird mit den Merkmalen des vorliegenden Anspruchs 1 gelöst. Demnach ist eine Kunststoff-Verbundscheibe für die Fahrzeugverscheibung vorgesehen, die eine Innen- und eine Außenseite aufweist. Die Verbundscheibe ist dadurch gekennzeichnet, dass sie eine Innenscheibe aus einem Polycarbonat-Kunststoff (Polycarbonat-Scheibe), eine Außenscheibe aus einem Acrylat-Kunststoff (Acrylat-Scheibe) und eine zwischen diesen Scheiben angeordnete Schicht aus thermoplastischem Polyurethan (tPU) aufweist.

[0012] Dabei ist es der Anmelderin erstmals gelungen, eine Verbundscheibe aus Acrylat und Polycarbonat mit hoher Lebensdauer herzustellen. Die hergestellte Verbundscheibe vereinigt die Vorteile beider Werkstoffe, nämlich einerseits eine hohe Witterungs- und UV-Beständigkeit durch das außen liegende Acrylat, und andererseits eine hohe Schlagfestigkeit

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und hohe Temperaturbeständigkeit durch das innen liegende Polycarbonat.

[0013] Überdies hat dieser Aufbau den Vorteil, dass das außen liegende Acrylat mit UV-Schutzadditiven dotiert werden kann und so in der Verbundscheibe dazu verwendet werden, die darunter liegende Polycarbonat-Scheibe vor UV-Bestrahlung zu schützen.

[0014] Hinzu kommen die bereits in der Einleitung beschriebenen Vorteile von Kunststoffscheiben gegenüber Silikatglasscheiben für die Fahrzeugverscheibung. Überdies bietet die Schichtbauweise die Möglichkeit, zwischen den beiden Einzelscheiben weitere Schichten mit weiteren Funktionalitäten einzubringen.

[0015] Die Anmelderin hat das Problem, das sich durch die unterschiedlichen thermische Dehnungskoeffizienten der beiden Werkstoffe ergibt, dadurch gelöst, dass sie beide Werkstoffe mit einer Schicht aus thermoplastischem Polyurethan (tPU) verbindet. Bei tPU handelt es sich um einen elastischen Werkstoff mit einem hohen Rückstellvermögen und einer hohen Transparenz, die den Werkstoff überhaupt erst für die Verwendung in Kunststoffscheiben geeignet macht. Die tPU-Schicht klebt dabei einerseits die beiden Scheiben zusammen, andererseits wirkt die Schicht aber auch als Puffer zwischen den beiden Scheiben, nimmt mechanische Verspannungen auf und verhindert so eine Delaminierung der beiden Scheiben.

[0016] Die tPU-Schicht kann als Folie oder als flüssiger oder pastöser Kleber auf eine der beiden Scheiben aufgebracht werden. Ebenso kann die tPU-Schicht zusammen mit Polycarbonat in Form eines Co-Extrudats hergestellt werden.

[0017] Dabei ist besonders bevorzugt vorgesehen, dass die zwischen der Polycarbonat-Scheibe und der Acrylat-Scheibe angeordnete Schicht aus einer tPU-Folie besteht.

[0018] In einer weiteren bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass die Polycarbonat-Scheibe auf der Innenseite mit einem Kratzschutzlack versehen ist. Ebenso bevorzugt ist vorgesehen, dass die Acrylat-Scheibe auf der Außenseite mit einem Kratzschutzlack versehen ist. Hierbei kann es sich z.B. um übliche Silikatlacke handeln.

[0019] In einer bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass die Scheibe im Bereich der Schicht aus thermoplastischem Polyurethan eine Schicht elektrisch leitender Drähte aufweist. Die Drähte werden dabei in die tPU-Schicht eingebettet, ohne dass sich Luftblasen bilden.

[0020] Bei diesen Drähten kann es sich z.B. um Wolfram- oder Silberdrähte oder aus einer Legierung wie Cronifer hergestellte Drähte handeln.

[0021] In einer besonders bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass es sich bei der Schicht elektrisch leitender Drähte um eine Scheibenbeheizung und/oder eine Funkantenne handelt. Handelt es sich z.B. um eine Scheibenbeheizung, verlaufen die Drähte bevorzugt in senkrechter Richtung. Diese Ausrichtung hat für Scheibenbeheizungen eine Reihe von Vorteilen. Bei einer vereisten Scheibe bilden sich bei senkrechter Ausrichtung der Drähte senkrechte Schmelzkanäle, durch die das entstehende Schmelzwasser nach unten ablaufen kann. Bei waagerechter Ausrichtung der Drähte würden hingegen waagerechte Kanäle entstehen, die das Ablaufen des Schmelzwassers verhindern würden.

[0022] Der Durchmesser der verwendeten Drähte richtet sich u.a. nach dem spezifischen Widerstand des verwendeten Materials sowie der Größe der betreffenden Scheibe, andererseits aber auch nach optischen Erfordernissen. In jedem Fall liegt der Durchmesser der Drähte weit unterhalb der Dicke der tPU-Schicht.

[0023] Vorzugsweise verlaufen die Drähte nicht geradlinig, sondern wellenförmig, so dass die Wellen eine parallel zur Scheibenebene angeordnete Fläche ausbilden. Auf diese Weise wird einerseits eine bessere flächige Verteilung der Heizwärme in der Scheibe erreicht, andererseits wird dem Dehnungsverhalten der Drähte Rechnung getragen, die sich so unter der bei der Erwärmung auftretenden Elongation besser ausdehnen können als geradlinige Drähte, die gestaucht würden. Überdies verbessert der wellenförmige Verlauf die optischen Eigenschaften der Scheibe, da geradlinig und parallel zu einander in einer Scheibe verlaufende Drähte geringen Durchmessers bekanntermaßen zu Blendeffekten führen, wenn z.B. von jenseits der Scheibe eine punktförmige Lichtquelle (wie z.B. ein Autoscheinwerfer) in Richtung der Scheibe strahlt. Es wird vermutet, daß diese Blendeffekte auf Reflektionsphänomene an den Drähten zurückgehen.

[0024] Drähte können aber ebenso auch als Funkantenne verwendet werden, so z.B. für mobile Telefonie nach dem GSM-, GPRS- oder dem UMTS-Standard, für den Radioempfang, oder für die Ansteuerung von externen funkgesteuerten Schaltkreisen, wie z.B. Garagenantrieben.

[0025] Es ist denkbar, dass Drähte als Scheibenbeheizung und als Funkantenne in einer Fläche angeordnet werden.

[0026] In einer besonders bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass die Scheibe

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zwei zwischen der Polycarbonat-Scheibe und der Acrylat-Scheibe angeordnete Schichten aus thermoplastischem Polyurethan und eine zwischen diesen Schichten angeordnete nicht-metallische IR-Schutzfolie aufweist.

[0027] Bei letzterer handelt es sich z.B. um eine mehrschichtige transparente Polyesterfolie mit besonderen Reflexionseigenschaften. Das Einbringen einer solchen Schutzfolie verringert die im Vergleich zu Silikatglas bereits geringe thermische Leitfähigkeit der Verbundglasscheibe zusätzlich. Insbesondere reduziert sie die Aufheizung des Fahrzeuginnenraums durch den langwelligen Anteil der Sonneneinstrahlung.

[0028] Überdies beeinträchtigt eine Nicht-metallische IR-Schutzfolie im Unterschied zu einer metallischen IR-Schutzfolie die Transmission von Funksignalen (mobile Telefonie, Satellitennavigation, Radioempfang etc.) nicht.

[0029] Nicht-metallische IR-Schutzfolien werden bereits in Silikatglasscheiben verwendet. Dazu ist es erforderlich, die Oberfläche der Polyesterfolie durch eine Beschichtung zu modifizieren, damit sie mit der Silikatglasscheibe verbunden werden kann. Nicht-metallische IR-Schutzfolien werden daher in der Regel bereits ab Hersteller fertig konfektioniert mit einer solchen Beschichtung geliefert.

[0030] Der Anmelderin ist es erstmals gelungen, eine nicht-metallische IR-Schutzfolie in einer Kunststoffscheibe zu verwenden. Da die Folie nicht unmittelbar auf eine Polycarbonat- oder Acrylat-Scheibe aufgebracht werden kann, kam die Anmelderin auf die Idee, die Folie in eine tPU-Schicht einzubetten, wie sie in einer erfindungsgemäßen Kunststoff-Verbiundscheibe verwendet wird. Dabei ist die erwähnte Beschichtung der IR-Schutzfolie sehr hinderlich. Die Anmelderin kam daher erstmals auf die Idee, für diesen Zweck nicht beschichtete IR-Schutzfolien, die in dieser Form nur schwer erhältlich sind, zu verwenden.

[0031] Dabei ist bevorzugt vorgesehen, dass die Scheibe zusätzlich im Bereich einer der Schichten aus thermoplastischem Polyurethan eine Schicht elektrisch leitender Drähte aufweist, die wie bereits beschrieben als Scheibenbeheizung und/oder als Funkantenne fungieren kann.

[0032] In einer weiteren, besonders bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass die Acrylat-Scheibe mit UV-Schutzadditiven dotiert ist. Acrylat ist zwar unempfindlich gegenüber UV-Licht, läßt dieses jedoch ungehindert passieren. Eine Dotierung mit farblosen UV-Schutzadditiven wie z.B. Benzophenon oder Benzotriazol macht das Material UV-undurchlässig, und kann so z.B bewirken, dass darunter liegende UV-empfindliche Schichten geschützt werden. Aufgrund der im Vergleich zu einem UV-Schutzlack weitaus höheren Schichtdicke ist dabei die UV-Schutzwirkung sehr viel besser.

[0033] In einer ebenfalls bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass die Acrylat-Scheibe mindestens das Acrylat Polymethylmethacrylimid (PMMI) enthält.

[0034] PMMI ist ebenso wie PMMA und andere Acrylate witterungsbeständig und mit UV-Schutzadditiven dotierbar. Es weist jedoch gegenüber PMMA eine höhere thermische Formbestädigkeit auf. Während PMMA nur bis zu Temperaturen von 95°C verarbeitet werden kann, weist PMMI eine Temperaturbeständigkeit bis 150°C auf und übertrifft damit sogar PC, das bis zu einer Temperatur von 130°C verarbeitet werden kann. Die Temperaturbeständigkeit ist deswegen wichtig, weil bei einigen Herstellungverfahren die beiden Einzelscheiben mit dem tPU in einem Autoklaven verbunden werden. Die Verarbeitungstemperatur beträgt dabei mindestens 120°C. PMMA kann aufgrund seiner schlechteren Wärmebeständigkeit bei diesen Verfahren nicht verarbeitet werden, wohl aber PMMI. Überdies weist PMMI eine noch härtere Oberfläche auf als PMMA.

[0035] In einer weiteren bevorzugten Ausgestaltung der Erfindung ist vorgesehen, dass die Scheibe auf der Innenseite und/oder auf der Außenseite eine lichtundurchlässige Scheibenrandbedruckung aufweist. Diese Bedruckung schützt einerseits Verklebungen im Randbereich der Verbundscheibe, die oftmals lichtempfindlich sind. Andereseits schützt die Bedruckung im Randbereich der Verbundscheibe angeordnete Bauteile, wie z.B. Sicherungselektronik, vor dem Einblick durch Dritte. Der zum Innenbereich der Scheibe gerichtete Rand der Bedruckung weist bevorzugt eine aufgelöste Struktur auf, z.B. ein Punkt-Muster. Hierdurch wird der Wärmegradient zwischen dem Bereich der Scheibenrandbedruckung, wo aufgrund der schwarzen Farbe eine starke Aufhezung stattfindet, und dem Innenbereich der Scheibe, geglättet, und so thermische Spannungen in der Scheibe vermindert.

[0036] Die vorliegende Erfindung betrifft überdies verschiedene Verfahren zur Herstellung einer erfindungsgemäßen Kunststoff-Verbundscheibe.

[0037] Eines dieser Verfahren ist dadurch gekennzeichnet, dass eine geformte Acrylat-Scheibe, eine Schicht aus thermoplastischem Polyurethan (tPU) und eine geformte Polycarbonat-Scheibe in einem Autoklaven miteinander verbunden werden. Die beiden Einzelscheiben werden also separat geformt und ausgehärtet und erst danach zusammengefügt. Die tPU-Schicht kann als Folie oder als flüssiger oder pastöser Kleber auf eine der beiden Scheiben aufge-

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bracht werden, und wirkt als Puffer zwischen den beiden Scheiben, nimmt mechanische Verspannungen auf und verhindert so eine Delaminierung der beiden Scheiben.

[0038] Ein anderes geeignetes Herstellungsverfahren ist dadurch gekennzeichnet, dass Polycarbonat und thermoplastisches Polyurethan zu einem Colaminat coextrudiert und anschließend mit einer geformten Polycarbonat-Scheibe in einem Autoklaven miteinander verbunden werden.

[0039] Ein ebenso geeignetes Herstellungsverfahren ist dadurch gekennzeichnet, dass zunächst eine Acrylat-Folie mit einer thermoplastischen Polyurethan-Folie laminiert und anschließend mit Polycarbonat hinterspritzt wird.

[0040] Ein weiteres ebenso geeignetes Herstellungsverfahren ist dadurch gekennzeichnet, dass die Verbundscheibe in einem Zwei-Komponenten-Spritzverfahren hergestellt wird. Dabei wird eine Folie aus einem modifizierten thermoplastischen Polyurethan von der einen Seite mit einem Acrylat-Kunststoff und von der anderen Seite mit einem Polycarbonat-Kunststoff hinterspritzt wird.

[0041] Die genannten Herstellungsverfahren lassen sich ebenso für die Herstellung von erfindungsgemäßen Kunststoff-Verbundscheiben verwenden, die im Bereich der tPU-Schicht bzw. der tPU-Schichten eine Schicht elektrisch leitender Drähte IR- und/oder eine nicht-metallische IR-Schutzfolie aufweisen.

[0042] Weitere Einzelheiten und Vorteile des Gegenstands der Erfindung gehen aus der Zeichnung eines Ausführungsbeispiels sowie der dazugehörigen Beschreibung hervor.

Ausführungsbeispiel

[0043] Es zeigen in nicht maßstabsgetreuer Darstellung:

[0044] Fig. 1 eine erfindungsgemäße Kunststoff-Verbundscheibe mit einer Schicht elektrisch leitender Drähte, und

[0045] Fig. 2 eine erfindungsgemäße Kunststoff-Verbundscheibe mit einer Schicht elektrisch leitender Drähte sowie einer nicht-metallischen IR-Schutzfolie

[0046] Fig. 1 zeigt eine erfindungsgemäße Kunststoff-Verbundscheibe **10** mit einer Innenscheibe **11** aus einem Polycarbonat-Kunststoff und einer Außenscheibe **12** aus einem Acrylat-Kunststoff. Die Verbundscheibe vereinigt die Vorteile beider Werkstoffe, nämlich einerseits eine hohe Witterungs- und UV-Beständigkeit durch das außen liegende Acrylat, und andererseits eine hohe Schlagfestigkeit, hohe Temperaturbeständigkeit und selbstverlöschende Eigenschaften durch das innen liegende Polycarbonat.

[0047] Überdies hat dieser Aufbau den Vorteil, dass das außen liegende Acrylat mit UV-Schutzadditiven dotiert werden kann und so in der Verbundscheibe dazu verwendet werden, die darunter liegende Polycarbonat-Scheibe vor UV-Bestrahlung zu schützen.

[0048] Zwischen den Einzelscheiben ist eine nicht maßstabsgetreu dargestellte Schicht **13** aus thermoplastischem Polyurethan (tPU) angeordnet, die als Puffer zwischen den beiden Scheiben wirkt, indem sie mechanische Verspannungen aufnimmt, die durch die unterschiedlichen thermische Dehnungskoeffizienten der beiden Werkstoffe entstehen, und so eine Delaminierung verhindert.

[0049] Im Bereich der Schicht **13** aus tPU ist überdies eine Schicht **14** elektrisch leitender Drähte angeordnet. Die Drähte sind in die tPU-Schicht eingebettet und fungieren im gezeigten Beispiel als Scheibenbeheizung.

[0050] Fig. 2 zeigt eine erfindungsgemäße Kunststoff-Verbundscheibe **20** mit einer Innenscheibe **21** aus einem Polycarbonat-Kunststoff und einer Außenscheibe **22** aus einem Acrylat-Kunststoff.

[0051] Zwischen den Einzelscheiben ist eine ist eine nicht maßstabsgetreu dargestellte Schicht **23** aus thermoplastischem Polyurethan (tPU) angeordnet, in die eine Schicht **24** elektrisch leitender Drähte eingebettet ist, sowie eine weitere Schicht **26** aus tPU. Zwischen den tPU-Schichten **23** und **26** ist eine nicht-metallische IR-Schutzfolie **25** angeordnet. Hierbei handelt es sich z.B. um eine mehrschichtige transparente Polyesterfolie mit besonderen Reflexionseigenschaften. Das Einbringen einer solchen Schutzfolie verringert die im Vergleich zu Silikatglas bereits geringe thermische Leitfähigkeit der Verbundglasscheibe zusätzlich. Insbesondere reduziert sie die Aufheizung des Fahrzeuginnenraums durch den langwelligen Anteil der Sonneneinstrahlung. Überdies beeinträchtigt diese Folie im Gegensatz zu metallischen IR-Schutzfolien den Empfang und/oder das Versenden von Funksignalen (mobile Telefonie, Satellitennavigation, Radioempfang etc.) nicht.

[0052] Das folgende nicht-ausschließliche Beispiel beschreibt ein Verfahren zur Herstellung einer erfindungsgemäßen Kunststoff-Verbundscheibe zur Verwendung in einem Kraftfahrzeug.

1. Eine im Extrusionsverfahren hergestellte Polycarbonat-Scheibe (Dicke: 3 mm) wird nach dem Aushärten durch Thermoformen in eine gewünschte Form gebracht und anschließend auf der Seite, die später zum Fahrzeuginnenraum weist, mit einem Siloxan-Abriebschutzlack (KASI

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abreibfester Lack, Hersteller: KRD Coatings, Geesthacht) beschichtet.

2. Auf die Seite der Polycarbonat-Scheibe, die später nach außen weist, wird eine Folie aus thermoplastischem Polyurethan (Dureflex A4700, Stärke: 381 µm bzw. 635 µm, Hersteller: Epurex Films) aufgebracht.

3. Auf diese Folie wird zunächst eine nicht-metallische IR-Schutzfolie aus Polyester (Dicke: ca 50 µm) und danach eine weitere Folie aus thermoplastischem Polyurethan aufgebracht.

[0053] Die Schutzfolie besteht aus mehreren hundert alternierenden Lagen von 2 optisch transparenten Kunststoffen, die über eine hohe Doppelbrechung in ihren Brechungsindizes verfügen und zusammen eine Reflektionsbande ausbilden.

4. Mit Hilfe einer Plottingmaschine wird ein Wolfram-Draht (Durchmesser: 18–35 µm) erwärmt und in cosinus-ähnlichen Kurven auf die Folie aus thermoplastischem Polyurethan aufgetragen und eingedrückt.

5. Auf die Folie aus thermoplastischem Polyurethan wird eine Polymethylmethacrylimid-Scheibe (Dicke: 1 mm) aufgebracht, die im Extrusionsverfahren hergestellt, nach dem Aushärten durch Thermoformen in eine der Polycarbonat-Scheibe entsprechende Form gebracht und auf der zukünftigen Außenseite mit einem Siloxan-Abriebschutzlack beschichtet wurde. Auf der Innenseite dieser Scheibe kann auch vor der Verformung gegebenenfalls ein Schwarzrand mittels Siebdruck aufgebracht werden.

6. Die zusammengesetzte Scheibe wird in eine Vakuumhülle gegeben, an der ein Vakuum von ca. 0,2 bar angelegt wird. Diese wird anschließend in einem Autoklaven bei ca. 4 bar und 120°C für 4h zusammengepresst.

Patentansprüche

1. Kunststoff-Verbundscheibe mit einer Innen- und einer Außenseite für die Fahrzeugverscheibung, **dadurch gekennzeichnet**, dass die Verbundscheibe eine Innenscheibe aus einem Polycarbonat-Kunststoff (Polycarbonat-Scheibe), eine Außenscheibe aus einem Acrylat-Kunststoff (Acrylat-Scheibe) und eine zwischen diesen Scheiben angeordnete Schicht aus thermoplastischem Polyurethan aufweist.

2. Kunststoff-Verbundscheibe gemäß Anspruch 1, dadurch gekennzeichnet, dass die zwischen der Polycarbonat-Scheibe und der Acrylat-Scheibe angeordnete Schicht aus einer Folie aus thermoplastischem Polyurethan besteht.

3. Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass die Polycarbonat-Scheibe auf der Innenseite und/oder die Acrylat-Scheibe auf der Außenseite mit einem Kratzschutzlack versehen ist.

4. Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass die Scheibe im Bereich der Schicht aus thermoplastischem Polyurethan eine Schicht elektrisch leitender Drähte aufweist.

5. Kunststoff-Verbundscheibe gemäß Anspruch 4, dadurch gekennzeichnet, dass es sich bei der Schicht elektrisch leitender Drähte um eine Scheibenbeheizung und/oder eine Funkantenne handelt.

6. Kunststoff-Verbundscheibe gemäß einem der Ansprüche 1–3, dadurch gekennzeichnet, dass die Scheibe zwei zwischen der Polycarbonat-Scheibe und der Acrylat-Scheibe angeordnete Schichten aus thermoplastischem Polyurethan und eine zwischen diesen Schichten angeordnete nicht-metallische IR-Schutzfolie aufweist.

7. Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass die Acrylat-Scheibe mit UV-Schutzadditiven versehen ist.

8. Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass die Acrylat-Scheibe das Acrylat Polymethylmethacrylimid enthält.

9. Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass die Scheibe auf der Innenseite und/oder auf der Außenseite eine lichtundurchlässige Scheibenrandbedruckung aufweist.

10. Verfahren zur Herstellung einer Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass eine geformte Acrylat-Scheibe, einer Schicht aus thermoplastischem Polyurethan und eine geformte Polycarbonat-Scheibe in einem Autoklaven miteinander verbunden werden.

11. Verfahren zur Herstellung einer Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass Polycarbonat und thermoplastisches Polyurethan zu einem Laminat coextrudiert und anschließend mit einer geformten Polycarbonat-Scheibe in einem Autoklaven miteinander verbunden werden.

12. Verfahren zur Herstellung einer Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass eine Acrylat-Folie mit einer thermoplastischen Polyurethan-Folie laminiert und anschließend mit Polycarbonat hinterspritzt wird.

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13. Verfahren zur Herstellung einer Kunststoff-Verbundscheibe gemäß einem der vorherigen Ansprüche, dadurch gekennzeichnet, dass die Verbundscheibe in einem Zwei-Komponenten-Spritzverfahren hergestellt wird, bei dem eine Folie aus einem modifizierten thermoplastischen Polyurethan von der einen Seite mit einem Acrylat-Kunststoff und von der anderen Seite mit einem Polycarbonat-Kunststoff hinterspritzt wird.

Es folgt ein Blatt Zeichnungen

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Anhängende Zeichnungen

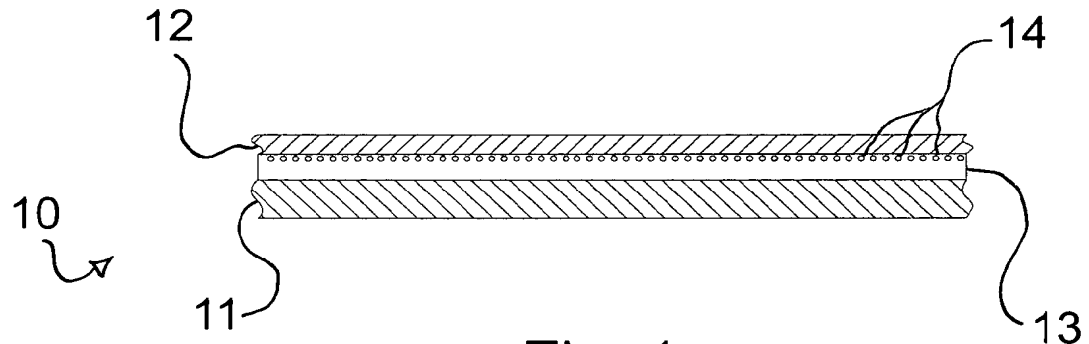


Fig. 1

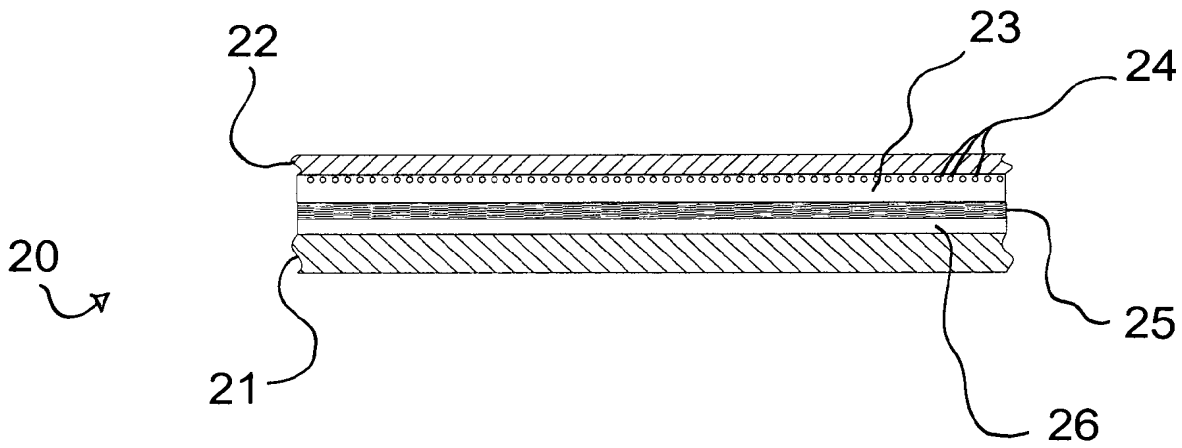


Fig. 2

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 November 2013 (21.11.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/172812 A1

(51) **International Patent Classification**:
C08J 5/18 (2006.01) ***C08L 75/08*** (2006.01)
C08L 67/02 (2006.01) ***B32B 27/36*** (2006.01)
C08L 69/00 (2006.01)

(21) **International Application Number**:
PCT/US2012/037745

(22) **International Filing Date**:
14 May 2012 (14.05.2012)

(25) **Filing Language**: English

(26) **Publication Language**: English

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

WO 2013/172812 A1

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

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

MULTI-LAYER FILM WITH IMPROVED MODULUS PROPERTIES

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

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

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

SUMMARY OF THE INVENTION

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

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

DETAILED DESCRIPTION OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HO-Z-OH (III)

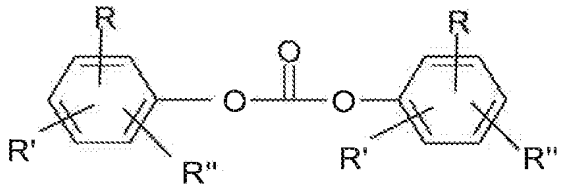
wherein Z is an aromatic radical having 6 to 34 C atoms, which can contain one or more optionally substituted aromatic nuclei and aliphatic or cycloaliphatic radicals or alkylaryls or hetero atoms as bridge members.

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

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

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

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



(IV)

wherein

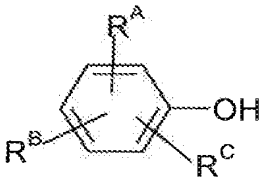
R, R' and R" independently of each another are identical or different and represent hydrogen, linear or branched C_1-C_{34}-alkyl, C_7-C_{34}-alkylaryl or C_6-C_{34}-aryl, and R can furthermore also denote -COO-R'", wherein R'" represents hydrogen, linear or branched C_1-C_{34}-alkyl, C_7-C_{34}-alkylaryl or C_6-C_{34}-aryl.

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

Diphenyl carbonate is very particularly preferred.

Either one diaryl carbonate or different diaryl carbonates can be used

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



(V)

wherein

R^A represents linear or branched C_1-C_{34}-alkyl, C_7-C_{34}-alkylaryl, C_6-C_{34}-aryl or -COO-R^D, wherein R^D represents hydrogen, linear or branched C_1-C_{34}-alkyl, C_7-C_{34}-alkylaryl or C_6-C_{34}-aryl, and

R^B, R^C independently of each other are identical or different and represent hydrogen, linear or branched C_1-C_{34}-alkyl, C_7-C_{34}-alkylaryl or C_6-C_{34}-aryl.

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

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

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

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

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

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

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

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

carbon atoms, preferably having 8 to 14 carbon atoms, and which can be linear, para-oriented, or symmetrical. Examples of modifying aromatic dicarboxylic acids which may be used in this invention include, but are not limited to, phthalic acid, isophthalic acid, 4,4'-biphenyldicarboxylic acid, 1,4-, 1,5-, 2,6-, 2,7-naphthalenedicarboxylic acid (in case of poly- or copolyalkylene terephthalates), terephthalic acid (in case of poly- or copolyalkylene naphthalates) and trans-4,4'-stilbenedicarboxylic acid, and esters thereof.

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

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

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

and 2-ethylhexanediol-1,6, 2,2-diethylpropanediol-1,3, hexanediol-2,5, 1,4-di-([beta]-hydroxyethoxy)-benzene, 2,2-bis-(4-hydroxycyclohexyl)propane, 2,4-dihydroxy-1,1,3,3-tetramethylcyclobutane, 2,2-bis-(3-[beta]-hydroxyethoxyphenyl)propane and 2,2-bis-(4-hydroxypropoxyphenyl)propane (cf. DE-OS 24 07 674, 24 07 776, 27 15 932).

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

Examples of branching monomers, if present, include, but are not limited to, multifunctional acids or multifunctional alcohols such as trimellitic acid, trimellitic anhydride, pyromellitic dianhydride, trimethylolpropane, glycerol, pentaerythritol, citric acid, tartaric acid, 3-hydroxyglutaric acid and the like. In one embodiment, the branching monomer residues can comprise 0.1 to 0.7 mole percent of one or more residues chosen from at least one of the following: trimellitic anhydride, pyromellitic dianhydride, glycerol, sorbitol, 1,2,6-hexanetriol, pentaerythritol, trimethylolethane, and/or trimesic acid. The branching monomer may be added to the copolyester reaction mixture or blended with the copolyester in the form of a concentrate as described, for example, in U.S. Patent Nos. 5,654,347 and 5,696,176.

Preferred poly- or copolyalkylene terephthalates or poly- or copolyalkylene naphthalates contain at least 70 mole %, preferably 80 mole % terephthalic acid or naphthalene dicarboxylic acid residues, relative to the

dicarboxylic acid component, and at least 70 mole %, preferably at least 80 mole % ethylene glycol, butanediol-1,4, 2,2,4,4-tetramethyl-1,3-cyclobutanediol and/or 1,4-cyclohexanedimethanol residues, relative to the diol component.

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

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

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

(a) a dicarboxylic acid component comprising

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

ii) 0 mole % to 30 mole % aromatic dicarboxylic acid residues with up to 20 carbon atoms, and

iii) 0 mole % to 10 mole % aliphatic dicarboxylic acid residues with up to 16 carbon atoms, and

(b) a diol component comprising

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

ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,

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

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

Particularly preferably such at least one thermoplastic polyurethane is obtainable from

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

b) one or more organic diisocyanates,

c) one or more diol chain-extenders with molecular weights from 60 g/mol to 500 g/mol and with, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms

in the presence of

d) optionally, one or more catalysts

with addition of

e) optionally, auxiliary substances and additives,

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

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

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

(a) a dicarboxylic acid component comprising

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

ii) 0 mole % to 30 mole % aromatic dicarboxylic acid residues with up to 20 carbon atoms, and

iii) 0 mole % to 10 mole % aliphatic dicarboxylic acid residues with up to 16 carbon atoms, and

(b) a diol component comprising

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

ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,

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

and wherein the inherent viscosity of the copolyester amounts to 0.50 dL/g to 1.20 dL/g and the copolyester exhibits a glass transition temperature T_g from 80 °C to 150 °C,

- and this core layer is located between two outer layers B containing at least one thermoplastic polyurethane, the thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D and being obtainable from

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

b) one or more organic diisocyanates,

c) one or more diol chain-extenders with molecular weights from 60 g/mol to 500 g/mol and with, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms

in the presence of

d) optionally, one or more catalysts

with addition of

e) optionally, auxiliary substances and additives,

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

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

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

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

a) polyether diols

b) organic diisocyanates

c) chain-extenders.

By way of diisocyanates b), use may be made of aromatic, aliphatic, araliphatic, heterocyclic and cycloaliphatic diisocyanates or mixtures of these diisocyanates (cf. HOUBEN-WEYL "Methoden der organischen Chemie", Volume E20 "Makromolekulare Stoffe", Georg Thieme Verlag, Stuttgart, New York 1987, pp 1587-1593 or "Justus Liebigs Annalen der Chemie", 562, pages 75 to 136).

In detail, let the following be mentioned in exemplary manner: aliphatic diisocyanates, such as hexamethylene diisocyanate, cycloaliphatic diisocyanates, such as isophorone diisocyanate, 1,4-cyclohexane diisocyanate, 1-methyl-2,4-cyclohexane diisocyanate and 1-methyl-2,6-cyclohexane diisocyanate and also the corresponding isomer mixtures, 4,4'-dicyclohexylmethane diisocyanate, 2,4'-dicyclohexylmethane diisocyanate and 2,2'-dicyclohexylmethane diisocyanate and also the corresponding isomer mixtures, aromatic diisocyanates, such as 2,4-toluylene diisocyanate, mixtures consisting of 2,4-toluylene diisocyanate and 2,6-toluylene diisocyanate, 4,4'-diphenylmethane diisocyanate, 2,4'-diphenylmethane - diisocyanate and 2,2'-diphenylmethane diisocyanate, mixtures consisting of 2,4'-diphenylmethane diisocyanate and 4,4'-diphenylmethane diisocyanate, urethane-modified liquid 4,4'-diphenylmethane diisocyanates and 2,4'-diphenylmethane - diisocyanates, 4,4'-diisocyanatodiphenylethane-(1,2) and 1,5-naphthylene diisocyanate. Use is preferentially made of 1,6-hexamethylene diisocyanate, isophorone diisocyanate, dicyclohexylmethane-4,4'-diisocyanate, diphenylmethane-diisocyanate isomer mixtures with a content of 4,4'-diphenylmethane diisocyanate of more than 96 wt.% and, in particular, 4,4'-

diphenylmethane diisocyanate and 1,5-naphthylene diisocyanate. The stated diisocyanates may find application individually or in the form of mixtures with one another. They may also be used together with up to 15 wt.% (calculated with respect to the total quantity of diisocyanate) of a polyisocyanate, for example triphenylmethane-4,4',4''-triisocyanate or polyphenyl-polymethylene polyisocyanates.

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

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

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

Suitable such polyether diols can be produced by one or more alkylene oxides with 2 to 4 carbon atoms in the alkylene residue being converted with a starter molecule that contains two active hydrogen atoms in bonded form. By way of alkylene oxides, let the following be mentioned, for example: ethylene oxide, 1,2-propylene oxide, epichlorohydrin, 1,2-butylene oxide and 2,3-butylene oxide. The alkylene oxides may be used individually, alternately in succession or as mixtures. By way of starter molecules there enter into consideration, for example: water, amino alcohols, such as N-alkyldiethanolamines, for example N-methyldiethanolamine, and diols such as ethylene glycol, 1,3-propylene glycol, 1,4-butanediol and 1,6-hexanediol. Optionally, mixtures of starter molecules may

also be employed. Suitable polyether diols are furthermore the hydroxyl-group-containing polymerisation products of tetrahydrofuran and/or of 1,3-propylene glycol. Trifunctional polyethers in proportions from 0 wt.% to 30 wt.%, relative to the bifunctional polyethers, may also be employed, but at most in such quantity that a product arises that is still thermoplastically workable.

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

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

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

Employed by way of chain-extension agents are, for example and preferably, diols or diamines with a molecular weight from 60 g/mol to 500 g/mol, preferentially aliphatic diols with 2 to 14 carbon atoms, such as, for example, ethanediol, 1,2-propanediol, 1,3-propanediol, 1,4-butanediol, 2,3-butanediol, 1,5-pentanediol, 1,6-hexanediol, diethylene glycol and dipropylene glycol. Also suitable, however, are diesters of terephthalic acid with glycols with 2 to 4 carbon atoms, for example terephthalic acid-bis-ethylene glycol or terephthalic acid-bis-1,4-butanediol, hydroxyalkylene ethers of hydroquinone, for example 1,4-di(β-hydroxyethyl)hydroquinone, ethoxylated bisphenols, for example 1,4-di(β-hydroxyethyl)bisphenol A, (cyclo)aliphatic diamines, such as isophoronediamine,

ethylenediamine, 1,2-propylenediamine, 1,3-propylenediamine, N-methylpropylene-1,3-diamine,, N,N'-dimethylethylenediamine, and aromatic diamines, such as 2,4-toluylenediamine, 2,6-toluylenediamine, 3,5-diethyl-2,4-toluylenediamine or 3,5-diethyl-2,6-toluylenediamine or primary mono-, di-, tri- or tetraalkyl-substituted 4,4'-diaminodiphenylmethanes. Particularly preferably, use is made of 1,2-ethylene glycol, 1,2-propanediol, 1,3-propanediol, 1,4-butanediol, 1,6-hexanediol, 1,4-di(β-hydroxyethyl)hydroquinone or 1,4-di(β-hydroxyethyl)bisphenol A by way of chain-extenders. Mixtures of the aforementioned chain-extenders may also be employed. In addition, relatively small quantities of triols may also be added.

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

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

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

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

The thermoplastic polyurethanes employed in accordance with the invention may optionally contain catalysts d). Suitable catalysts are the tertiary amines that are known and conventional in accordance with the state of the art, such as, for example, triethylamine, dimethylcyclohexylamine, N-methylmorpholine, N,N'-dimethylpiperazine, 2-(dimethylaminoethoxy)ethanol,

diazabicyclo[2,2,2]octane and similar and also, in particular, organic metallic compounds such as titanic acid esters, iron compounds or tin compounds, such as tin diacetate, tin dioctoate, tin dilaurate, or the dialkyltin salts of aliphatic carboxylic acids, such as dibutyltin diacetate or dibutyltin dilaurate or similar. Preferred catalysts are organic metallic compounds, in particular titanic acid esters, iron compounds and tin compounds. The total quantity of catalysts in the thermoplastic polyurethanes amounts, as a rule, to about 0 wt.% to 5 wt.%, preferably 0 wt.% to 2 wt.%, relative to the total weight of the TPU.

The thermoplastic polyurethanes (TPU) employed in accordance with the invention may optionally contain, by way of auxiliary substances and additives e), 0 wt.% up to at most 20 wt.%, preferably 0 wt.% to 10 wt.%, relative to the total weight of the TPU, of the conventional auxiliary substances and additives. Typical auxiliary substances and additives are pigments, dyestuffs, flame retardants, stabilisers against the influences of ageing and weathering, plasticisers, slip additives, mould-release agents, chain terminators, substances acting fungistatically and bacteriostatically and also fillers and mixtures thereof.

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

Examples of further additives are slip additives, such as fatty-acid esters, the metallic soaps thereof, fatty-acid amides, fatty-acid ester amides and silicone compounds, anti-blocking agents, inhibitors, stabilisers against hydrolysis, light, heat and discoloration, flame retardants, dyestuffs, pigments, inorganic and/or organic fillers, for example polycarbonates, and also plasticisers and reinforcing

agents. Reinforcing agents are, in particular, fibrous reinforcing substances such as, for example, inorganic fibres, which are produced in accordance with the state of the art and which may also have been subjected to a sizing material. Further particulars concerning the stated auxiliary substances and additives can be gathered from the specialist literature, for example from the monograph by J.H. Saunders and K.C. Frisch entitled "High Polymers", Volume XVI, Polyurethanes: Chemistry and Technology, Parts 1 and 2, Interscience Publishers 1962 and 1964, from the *Taschenbuch der Kunststoff-Additive* by R.Gächter u. H.Müller (Hanser Verlag Munich 1990) or from DE-A 29 01 774.

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

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

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

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

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

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

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

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

comprises 98 to 100 mole % of terephthalic acid residues. In another particularly preferred embodiment the dicarboxylic acid component comprises 100 mole % of terephthalic acid residues.

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

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

The ratio of 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues and 1,4-cyclohexanedimethanol residues from the diol component of the copolyester preferably amounts to 10 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues to 65 mole % to 90 mole % 1,4-cyclohexanedimethanol residues, particularly preferably 15 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues to 65 mole % to 85 mole % 1,4-cyclohexanedimethanol residues, quite particularly preferably 15 mole % to 30 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues to 70 mole % to 85 mole % 1,4-cyclohexanedimethanol residues, whereby the sum of the mole % of these two components of the diol component amounts to 100 mole %.

The diol component of the copolyester(s) in the particularly preferred embodiment can contain 25 mole % or less of one or more modifying diols which are not 2,2,4,4-tetramethyl-1,3-cyclobutanediol or 1,4-cyclohexanedimethanol. In one embodiment, the copolyesters useful in the invention may contain 15 mole % or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention can contain 10 mole % or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention can contain 5 mole % or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention can contain 3 mole % or less of one or more modifying diols. In another embodiment, the copolyesters useful in the invention

can contain 0 mole % modifying diols. Certain embodiments can also contain 0.01 or more mole %, such as 0.1 or more mole %, 1 or more mole %, 5 or more mole %, or 10 or more mole % of one or more modifying diols. Thus, if present, it is contemplated that the amount of one or more modifying diols can range from any of these preceding endpoint values including, for example, from 0.01 to 15 mole % and preferably from 0.1 to 10 mole %.

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

Each of the diols 2,2,4,4-tetramethyl-1,3-cyclobutanediol or1,4-cyclohexanedimethanol may be cis, trans, or a mixture thereof.

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

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

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

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

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

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

This preferred embodiment of the plastic film according to the invention displays an excellent adhesion between the core layer B, particularly preferred the copolyester core layer B, and the outer layers A, particularly preferred the TPU outer layers A. Good adhesion between these layers is particularly advantageous and necessary, since a delamination of the plastic film during its use in a wet or humidity environment is undesirable. Moreover, after the production of three-dimensional shaped articles e.g. by means of thermoforming of the film according

to the invention and trimming on the cut edges, the articles have to be ground. Also in the course of this grinding process a delamination of the individual layers is undesirable.

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

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

For some application e.g. for medical applications it is, inter alia, also desirable that the film for the production of the shaped articles is as inconspicuous as possible during the course of usage. Therefore it is furthermore advantageous if the plastic film is as transparent as possible. This requirement is likewise satisfied by the film according to the invention.

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

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

The production of multi-layer plastic films by means of co-extrusion is known to a person skilled in the art. In this connection, for the respective plastic layers the respective plastics, for example and preferably in the form of granular

materials, are fused in a compounding extruder and are extruded into a film via a nozzle.

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

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

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

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

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

EXAMPLES

Feed materials

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

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

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

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

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

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

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

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

Production of the layered structures according to the invention:

Production of extruded films

The film extrusion line that is used for producing the co-extruded film(s) comprises:

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

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

Example 1 (not according to the invention)

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

Example 2 (not according to the invention)

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

Example 3 (according to the invention)

Co-extrusion of film

The film extrusion line that is used consists of

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

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

The granular material of the base material was supplied to the feed hopper of the main extruder. In the respective plasticising system constituted by cylinder/screw the melting and conveying of the respective material took place. Both material melts were brought together in the co-extrusion nozzle. From the nozzle the melt arrived at the calender. On the roll calender the definitive shaping and cooling of the material take place. For the purpose of structuring the surfaces of the film, in this connection two polished chromium rollers (for gloss/gloss surfaces) were employed. Subsequently the film was transported through a take-off, the protective film is applied on both sides, then the winding-up of the film took place.

With this film extrusion line , with a temperature of the main extruder from 220 °C to 240 °C and with a temperature of the co-extruder from 228 °C to 260 °C three-layer films according to the invention with two smooth, glossy sides with a layer thickness of 800 µm were extruded, the copolyester core layer being 650 µm thick and the thermoplastic polyurethane layer on each side being in each instance 75 µm thick.

Example 4 (according to the invention):

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

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

Example 5 (according to the invention):

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

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

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

Example 6 (according to the invention):

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

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

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

Example 7 (according to the invention):

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

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

Example 8 (according to the invention):

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

From this, with a temperature of the main extruder from 260 °C to 270 °C and with a temperature of the co-extruder from 210 °C to 240 °C three-layer films according to the invention with two smooth, shiny sides with a layer thickness of 750 µm were extruded, the copolyester core layer being 550 µm thick and the thermoplastic polyurethane layer on each side being in each instance 100 µm thick.

Example 9:

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

Preparation of the specimens:

1. Die-cut specimens to 4 inch L x 0.76 inch W (10 mm L x 19.3mm W): Die dimension can vary depending on availability (W: 0.75 ~ 1 inch, L: minimum 4 inch).

2. Mark on the side of the TPU layer being tested. Flip the sample to the other side. Scratch a line by a sharp cutter at 7mm from one edge of the specimen.

3. Gently bend the specimen along the cut line while having the tested TPU layer intact.

4. Gently start peeling the TPU layer by pulling the small cut portion away from the cut line.

5. Continue peeling until the peel TPU layer is 13 mm in length. Make sure the TPU layer is peeled uniformly across the whole specimen width.

6. Cut the other end of the specimen to make the total adhered area be 62 mm in length.

Example 10:

Determination of the peel strength

Method:

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

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

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

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

Example 11

Method for determination of tensile strenght

The measure of tensile strength was carried out following the model of ASTM D 638. The tensile tests were carried out on a tensile testing machine of

the type ZwickZ020/148385. Use was made of tensile test specimens of type 4. For the purpose of evaluation, the mean value of 5 measurements was drawn upon. The specimens were stored at > 48 hours at 50 % relative humidity and 23 °C and subsequently tested under these conditions. The speed of testing amounted to 12.7 mm/min, in the course of the determination of Young's modulus (elastic modulus or modulus of elasticity), 1 mm/min.

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

Results:

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

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

Example 12:

Method for determining the stress relaxation

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

- sample dimensions: 51 mm (length) X 21.5 mm (width) X ~0.8mm (thickness)
- water soaking of the samples at defined temperature (25 °C or 50°C) before measurement of stress relaxation

- three-point bending with 5% strain
- support span: 16 mm

Results:

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

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

The results show that at both storage temperatures the three-layer films according to the invention exhibited a higher remaining load after 24 h storage than the TPU single-layer film from Example 2. In particular for examples 3 and 7 it is the more surprising that - although at both storage temperatures the three-layer film according to the invention exhibited a distinctly lower initial load at the time prior to storage - the force that it was still able to exert after storage after 24 h fell to a considerably slighter extent.

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

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

WHAT IS CLAIMED IS:

1. Multi-layer plastic film, characterised in that

- it has a core layer A containing at least one polycarbonate or copolycarbonate and/or a polyester or copolyester having a glass transition temperature T_g from 80 °C to 200°C,

- and this core layer A is located between two outer layers B containing at least one thermoplastic polyurethane and/or polyester or copolyester exhibiting a hardness from 45 Shore D to 85 Shore D.

2. Multi-layer plastic film according to claim 1, characterised in that it has a core layer A containing at least one polyester or copolyester having an inherent viscosity from 0.50 dL/g to 1.20 dL/g and a glass transition temperature T_g from 80 °C to 200°C.

3. Multi-layer plastic film according to claim 1 or 2, characterised in that the two outer layers B containing at least one thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D.

4. Multi-layer plastic film according to at least one of Claims 1 to 3, characterised in that

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

(a) a dicarboxylic acid component comprising

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

ii) 0 mole % to 30 mole % aromatic dicarboxylic acid residues with up to 20 carbon atoms, and

iii) 0 mole % to 10 mole % aliphatic dicarboxylic acid residues with up to 16 carbon atoms, and

(b) a diol component comprising

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

ii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,

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

and wherein the inherent viscosity of the copolyester amounts to 0.50 dL/g to 1.20 dL/g and the copolyester exhibits a glass transition temperature T_g from 80 °C to 150 °C,

and this core layer is located between two outer layers B containing at least one thermoplastic polyurethane, the thermoplastic polyurethane exhibiting a hardness from 45 Shore D to 85 Shore D and being obtainable from

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

b) one or more organic diisocyanates,

c) one or more diol chain-extenders with molecular weights from 60 g/mol to 500 g/mol and with, on average, 1.8 to 3.0 Tserevitinov-active hydrogen atoms

in the presence of

d) optionally, one or more catalysts

with addition of

e) optionally, auxiliary substances and additives,

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

5. Multi-layer plastic film according to at least one of Claims 1 to 4, characterised in that the thermoplastic polyurethane exhibits a hardness from 50 Shore D to 80 Shore D.

6. Multi-layer plastic film according to Claim 4 or 5, characterised in that the polyether diols a) used for producing the thermoplastic polyurethane are selected from one or more polyether diols of the group based on 1,4-butanediol units and/or 1,3-propylene glycol units.

7. Multi-layer plastic film according to at least one of Claims 4 to 6, characterised in that the organic diisocyanate b) used for producing the thermoplastic polyurethane is selected from one or more isocyanates of the group containing 4,4'-diphenylmethane diisocyanate, isophorone diisocyanate, dicyclohexylmethane-4,4'-diisocyanate or 1,6-hexamethylene diisocyanate.

8. Multi-layer plastic film according to at least one of Claims 4 to 7, characterised in that the diol chain-extender c) used for producing of the thermoplastic polyurethane is selected from one or more chain-extenders of the group containing 1,4-butanediol, 1,3-propanediol, 1,2-propanediol, 1,2-ethylene glycol, 1,6-hexanediol, 1,4-di(β-hydroxyethyl)hydroquinone or 1,4-di(β-hydroxyethyl)bisphenol A.

9. Multi-layer plastic film according to at least one of Claims 4 to 8, characterised in that the thermoplastic polyurethane was produced in the prepolymer process.

10. Multi-layer plastic film according to at least one of Claims 4 to 9, characterised in that the diol component of the copolyester comprises 10 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues and 65 mole % to 90 mole % 1,4-cyclohexanedimethanol residues, preferably 15 mole % to 35 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues and 65 mole % to 85 mole % 1,4-cyclohexanedimethanol residues, particularly preferably 15 mole % to 30 mole % 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues and 70 mole % to 85 mole % 1,4-cyclohexanedimethanol residues, the sum of the mole % of these two components of the diol component amounting to 100 mole %.

11. Multi-layer plastic film according to at least one of Claims 4 to 10, characterised in that the residues from the dicarboxylic acid component of the polyester include 95 mole % to 100 mole % terephthalic acid residues.

12. Multi-layer plastic film according to at least one of Claims 1 to 11, characterised in that the film has been co-extruded.

13. Multi-layer plastic film according to at least one of Claims 1 to 12, characterised in that it has a total thickness from 300 µm to 2000 µm, preferably from 400 µm to 1500 µm, particularly preferably from 500 µm to 1200 µm.

14. Multi-layer plastic film according to at least one of Claims 1 to 13, characterised in that the core layer A has a layer thickness from 250 µm to 1600 µm, preferably from 350 µm to 1400 µm, particularly preferably from 400 µm to 1000 µm.

15. Multi-layer plastic film according to at least one of Claims 1 to 14, characterised in that the outer layers B each have a layer thickness from 25 µm to 500 µm, preferably from 30 µm to 300 µm, particularly preferably from 50 µm to 200 µm.

16. Multi-layer plastic film according to at least one of Claims 2 to 15, characterised in that the poly- or copolyester exhibits an inherent viscosity from 0.50 dL/g to 0.80 dL/g.

17. Multi-layer plastic film according to at least one of Claims 1 to 16, characterised in that the poly- or copolyester exhibits a glass transition temperature T_g from 85 °C to 130 °C, preferably from 90 °C to 120 °C.

18. Three-dimensionally shaped article obtained by three-dimensionally forming the multi-layer plastic film according to at least one of Claims 1 to 17.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/037745

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

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 January 2013	30/01/2013

Name and mailing address of the ISA/	Authorized officer
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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/037745

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		WO 2004069320 A1	19-08-2004
DE 102010009230 A1	25-08-2011	CN 102770271 A	07-11-2012
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		EP 2539147 A1	02-01-2013
		US 2012315484 A1	13-12-2012
		WO 2011104014 A1	01-09-2011
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		DE 102004014023 A1	20-10-2005
		EP 1577084 A1	21-09-2005

Electronic Acknowledgement Receipt

EFS ID:	27594854
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
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/Justin Hughes (PM0)
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.201
Receipt Date:	22-NOV-2016
Filing Date:	14-MAY-2012
Time Stamp:	18:19:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$180
RAM confirmation Number	112316INTEFSW00006250232415
Deposit Account	232415
Authorized User	Patrick Medley

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)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS22773-826-201-11-22-2016.pdf	259938 d436b6a3c01a336e8426f6a0a1dd165b34cd9275	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	DE102004014023A1-w-English-Abstract.pdf	685186 0296881a1863a4c95a10239d8662450b1a5a5655	no	9
Warnings:					
Information:					
3	Foreign Reference	DE102010009230A1-w-English-Abstract.pdf	1312768 74c2109467853e3d621bad0876e2a8626e1b89fc	no	19
Warnings:					
Information:					
4	Foreign Reference	WO2013172812.pdf	2828009 a12221e7085c6972fe6216b94e743f1d54f0a523	no	45
Warnings:					
Information:					
5	Non Patent Literature	Z-BAIRD-Analyst-Day-Recap-2014.pdf	485027 7ad073c4d43312746c0debd188465e9165dcf450	no	12
Warnings:					
Information:					

6	Non Patent Literature	Z-BAIRD-Impressive-Quarter-2013.pdf	673631 d4737102cf5c5c8b8293f6fd0cccd6e2e25dc6b0	no	15
Warnings:					
Information:					
7	Other Reference-Patent/App/Search documents	Z-IPRP-11-18-2014-PCT-US2012-037745.PDF	129751 6061291712c633351258b837096c1a781345a652	no	4
Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	Z-ISRWO-01-30-2013-PCT-US2012-037745.PDF	192946 c859eac1449f99d160e526529d2a821a8418a38e	no	6
Warnings:					
Information:					
9	Non Patent Literature	Z-Stifel-TAM-survey-2013.pdf	429832 018613ed491c72de417a0ecb33ab401208d9424a	no	12
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	30514 2a385a3aaea6b187f91a336be018919283ffa490	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	7027602		

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.

Approved for use through 07/31/2016. 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 1 of 3

Complete if Known	
Application Number	13470681
Filing Date	05-14-2012
First Named Inventor	LI; Chunhua
Art Unit	3732
Examiner Name	MAI; Hao D.
Attorney Docket Number	22773-826.201

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-8496473	07-30-2013	PHAN; Loc X. et al.	
	002	US-20010041320	11-15-2001	PHAN; Loc et al.	
	003	US-20040146670	07-29-2004	CHIN; Albert et al.	
	004	US-20070148608	06-28-2007	TADROS; Safwat et al.	
	005	US-20080299507	12-04-2008	LI; Chunhua et al.	
	006	US-20090087808	04-02-2009	SOO; Chia et al.	
	007	US-20090239188	09-24-2009	TING; Kang et al.	
	008	US-20160228215	08-11-2016	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	DE-102004014023-A1	10-20-2005	KRD COATINGS GMBH [DE]		☒
	002	DE-102010009230-A1	08-25-2011	GIESECKE & DEVRIENT GMBH [DE]		☒
	003	WO-2013172812-A1	11-21-2013	BAYER MATERIALSCIENCE AG [DE], et al.		☐

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 07/31/2016. 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 2 of 3

Complete if Known	
Application Number	13470681
Filing Date	05-14-2012
First Named Inventor	LI; Chunhua
Art Unit	3732
Examiner Name	MAI; Hao D.
Attorney Docket Number	22773-826.201

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	Baird Equity Research. Align Technology, Inc. (ALGN): Analyst Day Recap. May 30, 2014. 12 pages.	☐
	002	Baird Equity Research. Align Technology, Inc. (ALGN): Impressive Quarter/Guide, Momentum Stronger than We Realized. October 18, 2013. 15 pages.	☐
	003	International Preliminary Report on Patentability dated 11/18/2014 for International PCT Patent Application No. PCT/US2012/037745.	☐
	004	International Search Report and Written Opinion dated 01/30/2013 for International PCT Patent Application No. PCT/US2012/037745.	☐
	005	STIFEL. TAM Survey. Properly Aligning Expectations Ahead of 4Q13 Guidance. Align Technology, Inc. October 10, 2013. 12 pages.	☐

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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Approved for use through 07/31/2016. 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	3	of	3

Complete if Known	
Application Number	13470681
Filing Date	05-14-2012
First Named Inventor	LI; Chunhua
Art Unit	3732
Examiner Name	MAI; Hao D.
Attorney Docket Number	22773-826.201

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)	2016-11-22
Name/Print	Patrick Medley	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.

Electronic Patent Application Fee Transmittal

Application Number:	13470681
Filing Date:	14-May-2012
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Filer:	Patrick Michael Medley/Justin Hughes (PM0)
Attorney Docket Number:	22773-826.201

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($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	LI; Chunhua et al.	Group Art Unit:	3732
Serial Number:	13/470,681	Examiner:	MAI; Hao D.
Filing or 371 (c) Date:	2012-05-14	**CONFIRMATION NO:**	**5655**
Title:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS		

FILED ELECTRONICALLY ON: November 22, 2016

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

SUPPLEMENTAL 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 is 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 $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 22773-826.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: November 22, 2016

By: /Patrick Medley/
Patrick Medley
Reg. No. 74,735

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

Electronic Acknowledgement Receipt

EFS ID:	27594854
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
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/Justin Hughes (PM0)
Filer Authorized By:	Patrick Michael Medley
Attorney Docket Number:	22773-826.201
Receipt Date:	22-NOV-2016
Filing Date:	14-MAY-2012
Time Stamp:	18:19:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$180
RAM confirmation Number	112316INTEFSW00006250232415
Deposit Account	232415
Authorized User	Patrick Medley

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)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS22773-826-201-11-22-2016.pdf	259938 d436b6a3c01a336e8426f6a0a1dd165b34cd9275	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	DE102004014023A1-w-English-Abstract.pdf	685186 0296881a1863a4c95a10239d8662450b1a5a5655	no	9
Warnings:					
Information:					
3	Foreign Reference	DE102010009230A1-w-English-Abstract.pdf	1312768 74c2109467853e3d621bad0876e2a8626e1b89fc	no	19
Warnings:					
Information:					
4	Foreign Reference	WO2013172812.pdf	2828009 a12221e7085c6972fe6216b94e743f1d54f0a523	no	45
Warnings:					
Information:					
5	Non Patent Literature	Z-BAIRD-Analyst-Day-Recap-2014.pdf	485027 7ad073c4d43312746c0debd188465e9165dcf450	no	12
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Information:					

6	Non Patent Literature	Z-BAIRD-Impressive-Quarter-2013.pdf	673631 d4737102cf5c5c8b8293f6fd0cccd6e2e25dc6b0	no	15
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Information:					
7	Other Reference-Patent/App/Search documents	Z-IPRP-11-18-2014-PCT-US2012-037745.PDF	129751 6061291712c633351258b837096c1a781345a652	no	4
Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	Z-ISRWO-01-30-2013-PCT-US2012-037745.PDF	192946 c859eac1449f99d160e526529d2a821a8418a38e	no	6
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9	Non Patent Literature	Z-Stifel-TAM-survey-2013.pdf	429832 018613ed491c72de417a0ecb33ab401208d9424a	no	12
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	30514 2a385a3aaea6b187f91a336be018919283ffa490	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	7027602		

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.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference BMS121016PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2012/037745	International filing date *(day/month/year)* 14 May 2012 (14.05.2012)	Priority date *(day/month/year)*
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant BAYER MATERIALSCIENCE AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	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 Article 35(2) with regard to novelty, inventive step or 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

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 18 November 2014 (18.11.2014)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Athina Nickitas-Etienne e-mail: pt04.pct@wipo.int

Form PCT/IB/373 (January 2004)

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/US2012/037745	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.

Espacenet

Bibliographic data: DE102010009230 (A1) — 2011-08-25

Hochflexibles Folienverbundmaterial und seine Verwendung in Kartenkörpern

Inventor(s): RIEDL JOSEF [DE]; BRAUN ANDREAS [DE] ± (RIEDL, JOSEF, ; BRAUN, ANDREAS)

Applicant(s): GIESECKE & DEVRIENT GMBH [DE] ± (GIESECKE & DEVRIENT GMBH)

Classification: - international: ***B32B27/00; B32B27/08; B32B27/20; B32B27/36; B32B27/40; B32B37/15; G06K19/02***

- cooperative: **B29C47/0021**; **B29C47/065**; **B29C47/145**; **B29D7/01**; **B32B27/08**; **B32B27/36**; **B32B27/40**; **B32B7/02**; **B42D25/00**; B29C47/02; B29C47/56; B29K2021/003; B29K2067/00; B29K2067/003; B29K2069/00; B29K2105/0026; B29K2105/0032; B29K2105/0044; B29K2995/0025; B29K2995/0026; B29L2017/00; B42D2033/30; B42D2033/46; Y10T428/31507; Y10T428/31551; Y10T428/31565

Application number: DE20101009230 20100225

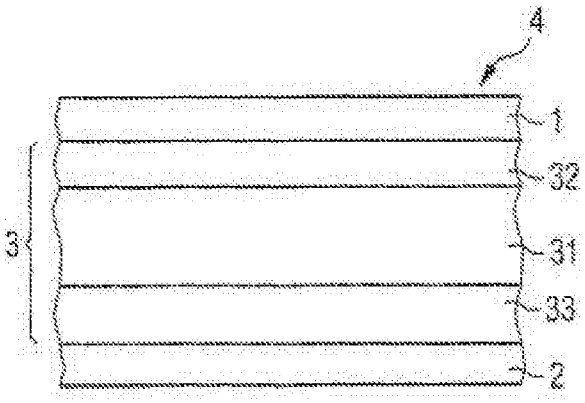
Priority number(s): DE20101009230 20100225

Also published as: US2014151923 (A1) US2012315484 (A1) WO2011104014 (A1) EP2539147 (A1) EP2539147 (B1) more

Abstract of DE102010009230 (A1)

Die Erfindung betrifft ein Folienverbundmaterial (em Kartenkörper, vorzugsweise in einem Kartenkörper eines tragbaren Datenträgers, mit - mindestens einer ersten Kunststoff-Aussenschicht (1), - mindestens einer Kunststoff-Innenschicht (3), - mindestens einer zweiten Kunststoff-Aussenschicht (2), wobei alle Schichten (1, 3, 2) gemeinsam einen Coextrusionsverbund bilden, dadurch gekennzeichnet, dass - der Kunststoff der mindestens einen ersten Aussenschicht (1) ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren ist, - der Kunststoff der mindestens einen Innenschicht (3) ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem thermoplastischen Polymer ist, - der Kunststoff der mindestens einen zweiten Aussenschicht (2) ein thermoplastisches

Polymer oder ein Gemisch von thermoplastischen Polymeren ist.; Die Erfindung betrifft auch ein Verfahren zur Herstellung des Folienverbundmaterials, sowie einen Kartenkörper (5), der das Folienverbundmaterial (4) als mindestens eine Schicht in seinem Schichtverbund aufweist, und ein Verfahren zur Herstellung des Kartenkörpers (5).



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(19) Deutsches Patent- und Markenamt

(10) **DE 10 2010 009 230 A1** 2011.08.25

(12) # Offenlegungsschrift

(21) Aktenzeichen: **10 2010 009 230.4**
(22) Anmeldetag: **25.02.2010**
(43) Offenlegungstag: **25.08.2011**

(51) Int Cl.: ***B32B 27/08*** (2006.01)
B32B 27/00 (2006.01)
B32B 27/36 (2006.01)
B32B 27/40 (2006.01)
B32B 27/20 (2006.01)
B32B 37/15 (2006.01)
G06K 19/02 (2006.01)

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(72) Erfinder:
Riedl, Josef, 85395, Attenkirchen, DE; Braun, Andreas, 80798, München, DE

(56) Für die Beurteilung der Patentfähigkeit in Betracht gezogene Druckschriften:

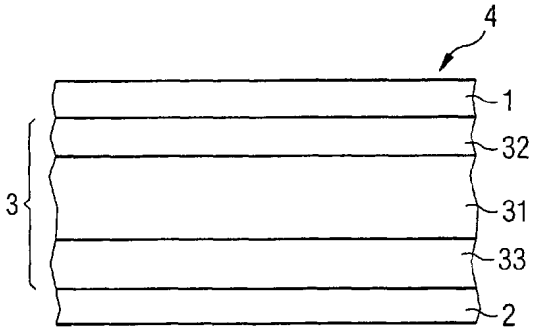
US	**2005/01 42 371**	**A1**
EP	**0 384 252**	**B1**
EP	**0 430 282**	**A2**
WO	**01/85 451**	**A1**

Rechercheantrag gemäß § 43 Abs. 1 Satz 1 PatG ist gestellt.

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Bezeichnung: **Hochflexibles Folienverbundmaterial und seine Verwendung in Kartenkörpern**

(57) Zusammenfassung: Die Erfindung betrifft ein Folienverbundmaterial (4), insbesondere zur Verwendung als Schicht in einem Kartenkörper, vorzugsweise in einem Kartenkörper eines tragbaren Datenträgers, mit
– mindestens einer ersten Kunststoff-Außenschicht (1),
– mindestens einer Kunststoff-Innenschicht (3),
– mindestens einer zweiten Kunststoff-Außenschicht (2),
wobei alle Schichten (1, 3, 2) gemeinsam einen Coextrusionsverbund bilden, dadurch gekennzeichnet, dass
– der Kunststoff der mindestens einen ersten Außenschicht (1) ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren ist,
– der Kunststoff der mindestens einen Innenschicht (3) ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem thermoplastischen Polymer ist,
– der Kunststoff der mindestens einen zweiten Außenschicht (2) ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren ist.
Die Erfindung betrifft auch ein Verfahren zur Herstellung des Folienverbundmaterials, sowie einen Kartenkörper (5), der das Folienverbundmaterial (4) als mindestens eine Schicht in seinem Schichtverbund aufweist, und ein Verfahren zur Herstellung des Kartenkörpers (5).



Beschreibung

[0001] Die Erfindung betrifft ein Folienverbundmaterial, ein Verfahren zur Herstellung des Folienverbundmaterials, sowie einen Kartenkörper, insbesondere einen Kartenkörper für einen tragbaren Datenträger, der das Folienverbundmaterial enthält, und ein Verfahren zur Herstellung des Kartenkörpers.

[0002] Bei der Fertigung von Kartenkörpern, insbesondere für tragbare Datenträger, wie z. B. Chipkarten, werden mehrere übereinander liegende Kunststofffolien miteinander laminiert. Als Kunststofffolien werden wegen ihrer guten Laminierbarkeit meist thermoplastische Folien verwendet, z. B. Folien aus Polyvinylchlorid, Polycarbonat, Polypropylen, Polyethylenterephthalat oder thermoplastischen Polyurethanen. Ein Nachteil von Kartenkörpern aus derartigen thermoplastischen Folien sind ihre mangelhaften mechanischen Eigenschaften hinsichtlich Biegebeanspruchung und schlagartiger Krafteinwirkung. Es kommt dabei zu Spannungen im Kartenkörper, und schließlich zu Rissen. Auch der Einbau elektronischer Module führt meist zu Spannungen, einer Schwächung des Kartenkörpers, und letztendlich zu einer erhöhten Anfälligkeit für Risse und Brüche.

[0003] Zur Verbesserung der mechanischen Eigenschaften solcher Kartenkörper ist es vorteilhaft, im Rahmen des Laminierprozesses Folien aus thermoplastischem Elastomer, beispielsweise auf Urethanbasis, einzusetzen. Diese Folien sind außerordentlich elastisch und können die Biegebeanspruchbarkeit und Bruchfestigkeit des Kartenaufbaus deutlich verbessern. In der Druckschrift EP 0 430 282 A2 ist ein Kartenkörper in der Form einer mehrschichtigen Ausweiskarte beschrieben, bei der zwischen dem Kartenkern und entsprechenden Deckfolien jeweils eine Schicht aus thermoplastischem Elastomer vorgesehen ist.

[0004] Die Verarbeitung von Folien aus thermoplastischem Elastomer, sogenannten TPE-Folien, im Rahmen eines Laminierprozesses bei der Herstellung eines Kartenkörpers ist jedoch sehr schwierig. Aufgrund ihrer hohen Elastizität sind die Folien sehr "lappig". Die mangelnde Steifigkeit führt zu Problemen bei der Verarbeitung in den Produktionsmaschinen, und die geringe Dimensionsstabilität kann auch Passerprobleme beim Bedrucken der Folien verursachen. Zusätzlich neigt das Material beim Laminieren zum Verlaufen. Femer besitzen solche Folien einen niedrigen Glasübergangsbereich, der unter 0°C, wobei es in diesem Temperaturbereich flexibel bleibt und nicht spröde wird. Darüberhinaus neigen die Folien beim Stapeln aufgrund ihrer glatten Oberflächen zu Verblockungen, so dass die Folien im Stapel nur schwer vereinzelt und transportiert werden können. Um beim Laminieren solcher Folien mit anderen Materialien wie Polycarbonat, Polyethylenterephthalat, Polyethylenterephthalat-Copolyestern oder Elends aus Polyester und Polycarbonat eine ausreichende Verbindungssteifigkeit zu erreichen, ist es zudem erforderlich, den Glaspunkt des jeweils anderen Materials zu erreichen. Da dieser Glaspunkt regelmäßig weit über dem Glasübergangsbereich von thermoplastischen Elastomeren liegt, führt dies in Verbindung mit der Abhängigkeit von der Stärke des Abfalls der Viskosität im entsprechenden Temperaturbereich häufig zum Ausschwimmen des thermoplastischen Elastomers. Dies hat zur Folge, dass die verwendeten Laminiermaschinen oft gereinigt werden müssen. Unter Umständen können sogar die an dem thermoplastischen Elastomer anliegenden Folien ebenfalls zu fließen beginnen, und ein darauf befindliches Druckbild deformieren. Es besteht zwar die Möglichkeit, bei niedrigeren Temperaturen zu laminieren, um hierdurch das Ausschwimmen der Folien zu vermeiden, aber beim Laminieren bei niedrigen Temperaturen wird in der Regel kein ausreichend guter Laminatverbund erreicht.

[0005] Diese Probleme treten bereits auf, wenn man die für die Herstellung von Datenträgern üblichen Foliendicken von 100 µm bis 300 µm verwendet. Um einen Datenträger deutlich gegen Bruchgefahr zu schützen, reicht es aber meist schon aus, dass man nur circa 30 µm bis 50 µm dicke Schichten aus thermoplastischem Elastomer beidseitig, möglichst weit außen liegend, in den Aufbau einbringt. Diese Dicken sind aber in den üblichen Verarbeitungsprozessen schwierig zu handhaben. Selbst sehr steife Folien wie Polycarbonat-Folien sind bei Schichtdicken von 50 µm oder darunter nicht mehr zu verarbeiten.

[0006] Es ist daher erstrebenswert, die positiven Eigenschaften von vergleichsweise steifen thermoplastischen Folien und von Folien aus thermoplastischem Elastomer in einem einzigen Folienmaterial zu kombinieren. Ein Lösungsansatz in dieser Richtung ist in dem Dokument EP 0 384 252 B1 offenbart. Der darin beschriebene Folienverbundwerkstoff weist eine Vielzahl von Schichten auf, wobei eine mittlere Schicht aus thermoplastischem Elastomer hergestellt ist. An diese Schicht schließen sich Schichten aus thermoplastischen Kunststoffen an. Bei der Herstellung des Verbundwerkstoffs werden auf eine Folie, welche die mittlere Schicht bildet, die weiteren Schichten aufgebracht. Ein Aufbringungsverfahren ist die gemeinsame Extrusion.

[0007] Aufgabe der vorliegenden Erfindung ist es, ein hochflexibles Folienmaterial bereitzustellen, das zur Verwendung als Schicht in einem Kartenkörper geeignet ist. Insbesondere sollte das Folienmaterial im Rahmen

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der Fertigung eines Kartenkörpers gut verarbeitet werden können und gute mechanische Eigenschaften des Kartenkörpers garantieren. Erwünschte Eigenschaften eines derartigen Folienmaterials sind

- eine hohe Flexibilität, um die gewünschte Biegebeanspruchbarkeit, insbesondere dynamische Biegebeanspruchbarkeit, der Karte zu gewährleisten;
- die Fähigkeit, Spannungen, Risse und Brüche in der Karte zu vermeiden, insbesondere auch beim Einbau von elektronischen Modulen in die Karte;
- eine gute Laminierbarkeit mit gängigen Kartenmaterialien, insbesondere thermoplastischen Folien, bevorzugt ohne Hilfsschichten;
- eine gute Bedruckbarkeit, bevorzugt ohne Druckvorbehandlung;
- eine gute Dimensionsstabilität bei Herstellung und Verarbeitung;
- eine einfache, und bevorzugt preiswerte, Herstellbarkeit;
- eine gute Handhabbarkeit bei der Weiterverarbeitung, insbesondere ein Vermeiden von Verblocken, und
- eine problemlose Integrierbarkeit in den üblichen Prozess der Datenträgerherstellung.

[0008] Aufgabe der vorliegenden Erfindung ist es auch, einen Kartenkörper, insbesondere einen Kartenkörper für einen tragbaren Datenträger, bereitzustellen, der die Nachteile des Stands der Technik vermeidet. Insbesondere sollte der Kartenkörper den Einbau elektronischer Module gut tolerieren und eine gute Resistenz gegenüber Spannungsrissen und Brüchen, beispielsweise bei Biegebeanspruchung und schlagartiger Krafteinwirkung, aufweisen.

[0009] Die Aufgaben werden gelöst durch das Folienverbundmaterial, das Verfahren zur Herstellung eines Folienverbundmaterials, den Kartenkörper und das Verfahren zur Herstellung eines Kartenkörpers mit den Merkmalen, wie sie in den jeweiligen unabhängigen Ansprüchen angegeben sind. Spezielle Ausführungsformen der vorliegenden Erfindung sind in den abhängigen Ansprüchen angegeben.

[0010] Erfindungsgemäß wird ein Folienverbundmaterial bereitgestellt, das mindestens drei, bevorzugt fünf, und gegebenenfalls mehr als fünf Schichten aufweist, d. h. mindestens eine Innenschicht und eine erste und eine zweite Außenschicht, die die Innenschicht an ihren beiden Oberflächen bedecken. Die Schichten bestehen jeweils aus einem Kunststoffmaterial, d. h. aus Kunststoff, der gegebenenfalls mit üblichen Additiven versetzt ist. Der Kunststoff der ersten und der zweiten Außenschicht ist jeweils ein thermoplastisches Polymer oder ein Gemisch aus thermoplastischen Polymeren. Der Kunststoff der mindestens einen Innenschicht ist ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem thermoplastischen Polymer. Ein derartiges Folienverbundmaterial vereinigt die vorteilhaften Elastizitätseigenschaften des Elastomers mit den vorteilhaften Eigenschaften des Thermoplasten, beispielsweise hinsichtlich Laminierbarkeit und Handhabbarkeit. Die Herstellung eines solchen Verbundmaterials wirft technische Probleme auf, da die verwendbaren Materialien sorgfältig aufeinander abgestimmt werden müssen, um die gewünschten Folieneigenschaften zu erzielen. Eine wichtige Rolle spielt auch die Wahl der jeweiligen Schichtdicken, der geeigneten Prozessparameter und Extruderkonfigurationen, und die passende Zusammenstellung der Rezepturen.

[0011] Die Kunststoff-Innenschicht des Folienverbundmaterials besteht bevorzugt aus mehr als einer Schicht, besonders bevorzugt aus drei Teilschichten, einer inneren Kunststoff-Innenschicht und zwei äußeren Kunststoff-Innenschichten. Der Grund für diesen Aufbau aus mehreren Teilschichten liegt in erster Linie darin, dass die optimalen Extrusionstemperaturen und Schmelzeviskositäten von Thermoplasten und thermoplastischen Elastomeren relativ weit auseinander liegen. Eine Extrusion eines Folienverbundmaterials mit einer Innenschicht aus mindestens einem thermoplastischen Elastomer und Außenschichten aus mindestens einem Thermoplasten ist daher technisch sehr schwierig und liefert typischerweise keine guten und reproduzierbaren Folienqualitäten. Erfindungsgemäß werden die Schmelzeviskositäten und Extrusionstemperaturen der die einzelnen Schichten bildenden Materialien durch Abmischungen stufenweise aneinander angeglichen. Dadurch können Extruder, die die jeweils benachbarten Schichten des herzustellenden Folienverbundmaterials extrudieren, mit ähnlichen bzw. stufenweise angeglichenen Prozessparametern betrieben werden, was wiederum eine bessere, homogenere Überlagerung der Schmelzeschichten und eines verbesserte Haftfestigkeit der Schichten aneinander bewirkt.

[0012] Die beiden Kunststoff-Außenschichten können gleich oder verschieden sein. Typischerweise bestehen die Kunststoff-Außenschichten des Folienverbundmaterials aus denselben Materialien und weisen dieselbe Dicke auf, d. h. das Folienverbundmaterial ist hinsichtlich seiner Außenschichten symmetrisch. Dies ist jedoch nicht zwingend, d. h. die Außenschichten können sich sowohl hinsichtlich ihrer Kunststoffe, als auch hinsichtlich ihrer Dicken, als auch hinsichtlich eventueller Additive unterscheiden.

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[0013] Die Kunststoff-Innenschicht besteht aus einem Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem Thermoplasten, wobei, um eine passende Abstufung der Eigenschaften benachbarter Schichten zu erzielen, der Thermoplast bevorzugt derselbe Thermoplast ist, der in der benachbarten Außenschicht verwendet wurde. Zumindest im Falle von nur einer einzigen Kunststoff-Innenschicht ist es daher sehr vorteilhaft, für die beiden Kunststoff-Außenschichten jeweils dasselbe thermoplastische Material zu verwenden.

[0014] Wenn die Kunststoff-Innenschicht des Folienverbundmaterials aus mehreren Teilschichten aufgebaut ist, enthält jede der Teilschichten jeweils ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem Thermoplasten, wobei der Anteil an dem thermoplastischen Elastomer umso höher ist, je weiter innen in dem Folienverbundmaterial die jeweilige Teilschicht liegt. Im Sinne einer Erzielung guter Folienqualitäten und einer guten Haftfestigkeit der Schichten aneinander ist es bevorzugt, für alle Teilschichten der Innenschicht dasselbe thermoplastische Elastomer bzw. Gemisch von thermoplastischen Elastomeren zu verwenden. Gleichermaßen ist es bevorzugt, für alle Teilschichten der Innenschicht dasselbe thermoplastische Polymer bzw. Gemisch von thermoplastischen Polymeren zu verwenden. Falls die erste Kunststoff-Außenschicht und die zweite Kunststoff-Außenschicht verschiedene thermoplastische Polymere enthalten, ist es bevorzugt, eine schrittweise Angleichung der Zusammensetzung nach innen vorzunehmen. Für ein Folienverbundmaterial mit einer Innenschicht aus drei Teilschichten würde dies bedeuten, dass die erste äußere Kunststoff-Innenschicht bevorzugt denselben Thermoplasten enthält wie die erste Kunststoff-Außenschicht, und die zweite äußere Kunststoff-Innenschicht bevorzugt denselben Thermoplasten enthält wie die zweite Kunststoff-Außenschicht. Die innere Kunststoff-Innenschicht würde dann bevorzugt sowohl den Thermoplasten der ersten Kunststoff-Außenschicht als auch den Thermoplasten der zweiten Kunststoff-Außenschicht enthalten.

[0015] Die Teilschichten einer Kunststoff-Innenschicht weisen zwar bevorzugt dieselben Typen von thermoplastischen Elastomer und Thermoplast auf, können sich jedoch ohne weiteres hinsichtlich ihrer Dicken und ihrer Zusatzstoffe unterscheiden. Bei einer Innenschicht aus drei Teilschichten ist bevorzugt die innerste Schicht die dickste Teilschicht. Typischerweise ist das Folienverbundmaterial bezüglich seiner Innenschichten symmetrisch. Derartige Materialien können am einfachsten hergestellt werden.

[0016] Die thermoplastischen Elastomere und Thermoplasten müssen miteinander verträglich und gut miteinander mischbar sein. Außerdem sollten ihre Extrusionstemperaturen und Schmelzeviskositäten so ähnlich wie möglich sein. Als Kunststoff für die Außenschichten ist es bevorzugt, Polyester (bevorzugt PETG), Polycarbonat oder Elends aus Polyester und Polycarbonat zu verwenden. Als thermoplastisches Elastomer für die Innenschicht bzw. die Innenschichten sind thermoplastische Urethan-Elastomere, insbesondere thermoplastische Urethan-Elastomere auf der Basis von aromatischen Estern oder Ethern, bevorzugt. Aliphatische thermoplastische Elastomere auf Urethanbasis haben zwar den Vorteil, UV-stabil zu sein, sind aber mit den bevorzugten Thermoplasten kaum durch Coextrusion zu verarbeiten. Reproduzierbare Folienqualitäten sind nur schwer zu erhalten. Die aromatischen Typen haben zwar den Nachteil einer geringen UV-Stabilität, aber dieser Nachteil kann durch Zugabe von UV-Stabilisatoren, wie sie auf dem Markt gängig sind, leicht behoben werden. Zur stufenweisen Angleichung der Eigenschaften weist jede Innenschicht eine Zumischung eines Thermoplasten auf, bevorzugt des Thermoplasten der angrenzenden Außenschicht.

[0017] Thermoplastische Elastomere gibt es mit verschiedenen Shore D-Härten, wobei die jeweilige Härte auf den Thermoplasten der angrenzenden bzw. nächstliegenden Außenschicht abgestimmt sein sollte. Wenn die Thermoplasten Polyester sind, wird als thermoplastische Elastomer bevorzugt ein thermoplastisches Elastomer mit einer Shore D-Härte von 35 bis 50 verwendet, und wenn der Thermoplast ein Polycarbonat ist, wird als Elastomer bevorzugt ein Elastomer mit einer Shore D-Härte im Bereich von 40 bis 70, insbesondere zwischen 50 und 65, verwendet. Ferner sollten die thermoplastischen Elastomere möglichst viele der folgenden Eigenschaften aufweisen: sie sollten eine Reißdehnung zwischen 300% und 700%, insbesondere zwischen 350% und 500%, haben; sie sollten eine Schmelzeviskosität in Abhängigkeit von der Schmelzetemperatur besitzen, und bevorzugt einen MFI von 7 bis 11 cm^3/10 min haben; ihre Verarbeitungstemperaturen sollten zwischen 190°C und 240°C, insbesondere zwischen 210°C und 240°C, liegen; sie sollten hydrolysebeständig sein; sie sollten eine Affinität zu den für die Außenschichten verwendeten Thermoplasten besitzen, insbesondere zu Polyester und/oder Polycarbonaten.

[0018] Das erfindungsgemäße Folienverbundmaterial kann in transparenten, farbigen oder farblosen, und opaken Ausführungsformen hergestellt werden. Opake Ausführungsformen enthalten neben den Kunststoff-Komponenten, und gegebenenfalls sonstigen Additiven, Füllstoffe wie beispielsweise Titandioxid (Weiß) und Ruß (Schwarz). Auch Buntpigmente wie diverse Metalloxide können enthalten sein. Beispielsweise enthalten

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opake Ausführungsformen als Füllstoff als Weißpigment TiO2BaSO4. Insbesondere bei verstreckten Folien kann die Opazität auch durch Vakuoolen erzeugt werden.

[0019] Wird das Folienverbundmaterial als eine Außenschicht eines Kartenkörpers verwendet, ist es bevorzugt transparent. Bevorzugte Kunststoff-Zusammensetzungen (ohne Berücksichtigung von Additiven) für ein fünfschichtiges transparentes Folienverbundmaterial sind jeweils 0% thermoplastisches Elastomer und 100% Thermoplast für die erste und die zweite Außenschicht, jeweils 20% bis 50% thermoplastisches Elastomer und 80% bis 50% Thermoplast für die erste und die zweite äußere Innenschicht, und 30% bis 70%, bevorzugt 50% bis 70%, thermoplastisches Elastomer und 70% bis 30%, bevorzugt 50% bis 30%, Thermoplast für die innere Innenschicht.

[0020] Wird das erfindungsgemäße Folienverbundmaterial im Inneren eines Kartenaufbaus verwendet, ist es bevorzugt opak. Bevorzugte Zusammensetzungen (unter Berücksichtigung von Kunststoffen und Füllstoffen) für ein fünfschichtiges opakes Folienverbundmaterial sind: jeweils 0% Elastomer, 85% bis 95% Thermoplast und 5% bis 15% Füllstoff für die erste und die zweite Außenschicht; jeweils 20% bis 50% Elastomer, 75% bis 35% Thermoplast und 5% bis 15% Füllstoff für die erste und die zweite äußere Innenschicht, und 50% bis 70% thermoplastisches Elastomer, 45% bis 15% Thermoplast und 5% bis 15% Füllstoff für die innere Innenschicht.

[0021] Die Angaben sind in Gewichtsprozent, etwaige Additive wie UV-Stabilisatoren, Farbstoffe, Laseradditive etc. sind dabei nicht berücksichtigt.

[0022] Das erfindungsgemäße Folienverbundmaterial kann auch mehr als drei Teilschichten aus Elastomer-Thermoplast-Gemischen aufweisen. Unabhängig von der exakten Zusammensetzung und der Art der verwendeten Thermoplasten und Elastomere ist es stets wesentlich, dass der Gehalt an thermoplastischem Elastomer in einer inneren Teilschicht mindestens so hoch, und bevorzugt höher, als der Gehalt an thermoplastischem Elastomer in der angrenzenden äußeren Teilschicht ist.

[0023] Neben den Kunststoffen selbst können die Materialien für die einzelnen Schichten die gängigen Additive enthalten, beispielsweise die bereits genannten Füllstoffe und UV-Stabilisatoren, oder auch Farbpigmente, Flammhemmstoffe, optische Aufheller, Oxidationsstabilisatoren und Laseradditive. Der Zusatz von Hilfsstoffen wird bevorzugt gering gehalten, um die Abstimmung der Kunststoffmaterialien aufeinander möglichst wenig zu stören. Die jeweiligen Außenschichten des Folienverbundmaterials können auch einen Zusatz an Antiblockmitteln enthalten.

[0024] Die Gesamtdicke des erfindungsgemäßen Folienverbundmaterials liegt typischerweise zwischen 50 µm und 350 µm, wobei die Dicke variiert, je nachdem, an welcher Stelle der Schichtfolge eines Kartenkörpers das Folienverbundmaterial vorgesehen werden soll. Wird das Folienverbundmaterial als eine innere Schicht, d. h. als ein Teil des Kernschichtaufbaus, verwendet, sind Gesamtschichtdicken im Bereich von etwa 150 µm bis 350 µm, beispielsweise 240 µm, bevorzugt. Wird das Folienverbundmaterial als Deckschicht verwendet, sind Gesamtschichtdicken im Bereich von etwa 80 µm bis 130 µm, beispielsweise 105 µm, bevorzugt. Dabei entfallen, wenn die Gesamtschichtdicke als 100% bezeichnet wird, jeweils etwa 10% bis 30% auf die erste und die zweite Kunststoff-Außenschicht, und dementsprechend etwa 80% bis 40% auf die Kunststoff-Innenschicht. Eine besonders bevorzugte Schichtdicken-Verteilung ist, mit einer Abweichung von jeweils etwa ±3%, jeweils 10% für die erste und die zweite Kunststoff-Außenschicht, jeweils 20% für die erste und die zweite äußere Kunststoff-Innenschicht, und 40% für die innere Kunststoff-Innenschicht.

[0025] Die Herstellung des erfindungsgemäßen Folienverbundmaterials erfolgt durch Coextrusion. Dabei werden die für die einzelnen Schichten des erfindungsgemäßen Folienverbundmaterials vorgesehenen Kunststoffmaterialien, gegebenenfalls unter Zusatz der entsprechenden Additive, jeweils in geeigneten Extrudern geschmolzen und die Schmelze einem Feedblock oder einer Breitschlitzdüse zugeführt. Die Folienmaterialien werden im Feedblock oder der Breitschlitzdüse vor dem Austritt so zusammengeführt, dass die Schichtfolge des vorstehend beschriebenen Folienverbundmaterials entsteht. Bei der Herstellung ist insbesondere zu beachten:
Die thermoplastischen Elastomere, insbesondere die bevorzugten thermoplastischen Elastomere auf Urethanbasis, sind hygroskopisch. Die Elastomere müssen daher vor der Verarbeitung gut vorgetrocknet werden, d. h. die Restfeuchte sollte unter 0,05% liegen, da es sonst zu einem Abbau durch Hydrolyse während des Verarbeitungsprozesses im Extruder kommen kann.

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[0026] Die thermoplastischen Elastomere werden bei erhöhen Temperaturen thermisch abgebaut. Daher muss ihre Verweilzeit in den Extrudern möglichst kurz gehalten werden, d. h. für eine kontinuierliche Förderung der Schmelze ohne Unterbrechung gesorgt werden.

[0027] Die Folienverbundmaterialien müssen eine Mindestgesamtmenge an thermoplastischem Elastomer enthalten, damit die Folie eine ausreichende Elastizität besitzt, um später im Aufbau eines Kartenkörpers die auftretenden Spannungen und mechanischen Belastungen ausgleichen zu können. Typischerweise sind etwa 40% thermoplastisches Elastomer erforderlich, aber je nach Kartenaufbau und thermoplastischem Elastomer kann der Wert niedriger oder höher sein. Es müssen Extruderkonfigurationen vorgesehen werden, die in der Lage sind, kontinuierlich die entsprechenden Schichtdicken zu fördern. In der Regel ist es vorteilhaft, die Schichtdicken der Schichten mit thermoplastischem Elastomer so groß wie möglich zu machen, und den Anteil an thermoplastischem Elastomer an den jeweiligen Schichten ebenfalls so groß wie möglich zu machen.

[0028] Thermoplaste und thermoplastische Elastomere (insbesondere die bevorzugten thermoplastischen Polyester und thermoplastischen Elastomere auf Urethanbasis) haben relativ weit auseinander liegende optimale Extrusionstemperaturen und Schmelzeviskositäten. Die Rezepturen müssen daher so eingestellt werden, dass durch die Abmischungen von Thermoplasten und thermoplastischen Elastomeren die Extrusionstemperaturen und die Schmelzeviskositäten benachbarter Schichten angeglichen werden, so dass eine homogene Überlagerung der Schmelzeschichten gewährleistet ist. Beispielhafte Rezepturen wurden bereits weiter oben angegeben. Beispielhafte Verarbeitungsparameter werden bei Fig. 1 angegeben.

[0029] Bei einem fünfschichtigen Folienverbundmaterial erfolgt die Extrusion (Temperatur der Extrusionsdüse bzw. die Schmelzetemperaturen der einzelnen Schmelzeströme) der ersten und der zweiten Kunststoff-Außenschicht bevorzugt bei 200 bis 280°C, besonders bevorzugt bei 210 bis 260°C, die Extrusion der ersten und der zweiten äußeren Kunststoff-Innenschicht bevorzugt bei einer Temperatur von 200 bis 270°C, besonders bevorzugt bei 210 bis 260°C, und die Extrusion der inneren Kunststoff-Innenschicht bevorzugt bei 190 bis 270°C, besonders bevorzugt bei 220 bis 250°C.

[0030] Bei dem erfindungsgemäßen Folienverbundmaterial werden hervorragende Verbundwerte der Schichten untereinander erreicht, d. h. die Haftfestigkeit der Schichten aneinander beträgt typischerweise mindestens 30 N/cm.

[0031] Das erfindungsgemäße Folienverbundmaterial ist insbesondere dazu geeignet, als Schicht im Schichtaufbau eines Kartenkörpers verwendet zu werden, um die mechanischen Eigenschaften des Kartenkörpers zu verbessern.

[0032] Kartenkörper, insbesondere Kartenkörper für Chipkarten und andere Datenträger, bestehen typischerweise aus einer Vielzahl von Schichten, die miteinander durch Laminieren verbunden sind. Die einzelnen Schichten bestehen meist aus thermoplastischen Polymermaterialien, wie Polyvinylchlorid, Polycarbonat oder Polyethylenterephthalat. Zwischen den Schichten bzw. in Aussparungen der Schichten können sich elektronische Bauteile und aufgedruckte Antennen befinden. Als mindestens eine der Schichten des Kartenkörpers wird dabei ein erfindungsgemäßes Folienverbundmaterial verwendet. Insbesondere wird das erfindungsgemäße Folienverbundmaterial als eine oder als beide Deckschichten (Overlay-Folie) des Kartenkörpers eingesetzt. Alternativ oder zusätzlich kann das erfindungsgemäße Folienverbundmaterial innerhalb des Kartenaufbaus (Inlett-Folie) vorgesehen werden, also eine Kernschicht bilden.

[0033] Zur Herstellung des Kartenkörpers werden die Kunststofffolien, die den späteren Kartenkörper bilden sollen, miteinander laminiert. Das Laminieren kann in einem einzigen Arbeitsgang erfolgen, d. h. es werden alle Folienmaterialien, die den Kartenkörper bilden sollen, gestapelt und in einem Arbeitsgang laminiert. Alternativ kann das Laminieren in zwei oder mehr Arbeitsgängen durchgeführt werden, das heißt es wird nur jeweils ein Teil der Folien gemeinsam zu einem Teilstapel laminiert, und die Teilstapel dann später in einem weiteren Arbeitsgang zu dem Kartenkörper gestapelt und laminiert. Ein guter Laminatverbund wird dabei durch ein Laminieren bei einer Temperatur zwischen 120°C und 200°C erreicht, insbesondere zwischen 130°C und 180°C, bevorzugt zwischen 140°C und 160°C.

[0034] Vorzugsweise wird das Laminieren in einer Heizstation und einer Kühlstation durchgeführt, wobei der Druck in der Heizstation und der Druck in der Kühlstation geeignet gewählt wird. Die Laminierzeit liegt in der Heiz- und/oder Kühlstation vorzugsweise jeweils zwischen 10 Minuten und 25 Minuten.

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[0035] Die erfindungsgemäßen Kartenkörper haben typischerweise Gesamtdicken im Bereich von etwa 0,5 bis 1,0 mm. Die Gesamtdicke des erfindungsgemäßen Folienverbundmaterials liegt in der Regel zwischen 80 µm und 350 µm, je nach dem, an welcher Stelle des Schichtverbunds des Kartenkörpers das Folienverbundmaterial eingesetzt werden soll. Inlett-Folien sind für gewöhnlich dicker als Overlay-Folien, wobei die Gesamtdicke für Inlett-Folien typischerweise im Bereich von 150 µm bis 350 µm liegt, und die Gesamtdicke für Overlay-Folien typischerweise im Bereich von 80 µm bis 130 µm liegt. Die erfindungsgemäßen Folienverbundmaterialien verschmelzen dank ihrer Außenschichten aus thermoplastischem Kunststoff sehr gut mit benachbarten Schichten des Kartenkörper-Schichtaufbaus, so dass ein stabiler Kartenkörper-Laminatverbund erhalten wird. Gleichzeitig sorgen die Außenschichten aus Thermoplast, wenn das erfindungsgemäße Folienverbundmaterial als Overlay-Folie verwendet wird oder wenn beispielsweise eine erfindungsgemäße Folie als Kernfolie eingesetzt wird, dafür, dass die Kartenkörper problemlos bedruckt und gehandhabt werden können, und nicht zu einem Verblocken neigen.

[0036] Die Erfindung wird nachfolgend anhand von Figuren noch weiter veranschaulicht. Es wird darauf hingewiesen, dass die Figuren nicht maßstabsgetreu und nicht proportionsgetreu sind. Außerdem wird darauf hingewiesen, dass die Figuren die Erfindung lediglich näher erläutern sollen und in keiner Weise beschränkend zu verstehen sind. Gleiche Bezugsziffern bezeichnen gleiche Elemente.

[0037] Es zeigen:

[0038] Fig. 1 einen Schnitt durch ein erfindungsgemäßes Folienverbundmaterial mit einer Kunststoff-Innenschicht, die aus einer inneren Innenschicht und zwei äußeren Innenschichten besteht, einer ersten Kunststoff-Außenschicht und einer zweiten Kunststoff-Außenschicht,

[0039] Fig. 2 einen Schnitt durch ein erfindungsgemäßes Folienverbundmaterial mit einer Kunststoff-Innenschicht, einer ersten Kunststoff-Außenschicht und einer zweiten Kunststoff-Außenschicht,

[0040] Fig. 3 einen Schnitt durch ein erfindungsgemäßes Folienverbundmaterial mit einer Kunststoff-Innenschicht, die aus einer inneren Innenschicht und zwei äußeren Innenschichten besteht, sowie mit zwei ersten Kunststoff-Außenschichten und zwei zweiten Kunststoff-Außenschichten,

[0041] Fig. 4 einen Schnitt durch einen erfindungsgemäßen Kartenkörper mit zwei erfindungsgemäßen Folienverbundmaterialien als Deckschichten und mit Chipmodul,

[0042] Fig. 5 einen Schnitt durch einen erfindungsgemäßen Kartenkörper mit zwei erfindungsgemäßen Folienverbundmaterialien als Teilschichten des Kartenkerns und mit Chipmodul, und

[0043] Fig. 6 einen Schnitt durch einen erfindungsgemäßen Kartenkörper mit zwei erfindungsgemäßen Folienverbundmaterialien als Deckschichten, sowie zwei erfindungsgemäßen Folienverbundmaterialien als Teilschichten des Kartenkerns, und mit Chipmodul.

[0044] Fig. 1 zeigt eine erste Ausführungsform eines erfindungsgemäßen Folienverbundmaterials **4** im Schnitt. Bei dieser Ausführungsform besteht die Kunststoff-Innenschicht aus einer inneren Teilschicht **31**, einer ersten äußeren Teilschicht **32** und einer zweiten äußeren Teilschicht **33**. Darauf befinden sich eine erste Kunststoff-Außenschicht **1** und eine zweite Kunststoff-Außenschicht **2**. Diese Kunststoff-Außenschichten enthalten als die Kunststoffkomponente (neben gegebenenfalls vorhandenen Additiven) ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren. Die Innenschichten **31**, **32**, **33** enthalten als die Kunststoffkomponente (neben gegebenenfalls vorhandenen Additiven) jeweils ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem thermoplastischen Polymer. Die innere Innenschicht **31** hat einen höheren Gehalt an thermoplastischem Elastomer als die äußeren Innenschichten **32**, **33**. In der Innenschicht **3** bzw. den Teilschichten **31**, **32**, **33** wird dasselbe thermoplastische Polymer oder Gemisch von thermoplastischen Polymeren verwendet wie in den Außenschichten **1**, **2**. Durch die Abstufung in den Zusammensetzungen der Schichten von reinem Thermoplasten außen bis zu einem Gemisch mit einem hohen Elastomeranteil in der innersten Schicht, sind jeweils benachbarte Schichten einander relativ ähnlich bzw. einander angeglichen, und bei der Extrusion kann eine homogene Überlagerung der Schmelzeschichten und eine gute Haftung der einzelnen Teilschichten aneinander erreicht werden.

[0045] Die Herstellung des Folienverbundmaterials **4** kann beispielsweise erfolgen, indem Granulate mit drei verschiedenen Zusammensetzungen bzw. Abmischungen (Granulat A für die erste und die zweite Kunststoff-Außenschicht **1**, **2**; Granulat B für die erste und die zweite äußere Kunststoff-Innenschicht **32**, **33**; Granulat

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C für die innere Kunststoff-Innenschicht **31**) in drei Extrudern A, B, C geschmolzen werden, und die entsprechenden Schmelzeströme (Material A aus Extruder A, Material B aus Extruder B, Material C aus Extruder C) jeweils durch eine Breitschlitzdüse extrudiert und zu dem dargestellten Schichtaufbau zusammengeführt werden. Alternativ besteht die Möglichkeit, daß die Schichten im Feedblock vor dem Extrudieren durch die Breitschlitzdüse zusammengeführt werden. Ferner besteht die alternative Möglichkeit, daß die Schichten erst in der Breitschlitzdüse, einer sogenannten Mehrkanaldüse, selbst, vor dem Schmelzeaustritt zusammengeführt werden. In der dargestellten Ausführungsform ist das Folienverbundmaterial symmetrisch im Aufbau, d. h. die Außenschichten **1**, **2** und die Teilschichten der Innenschicht **32**, **33** haben jeweils die gleiche Zusammensetzung und die gleiche Dicke. Dies ist jedoch nicht zwingend. Bei unsymmetrischen Folienverbundmaterialien sind zur Herstellung entsprechend mehr Extruder erforderlich und eine andere entsprechende Feedblockkonstellation.

[0046] Nachfolgend sind konkrete Beispielrezepturen für ein transparentes Folienverbundmaterial und ein opakes Folienverbundmaterial angegeben.

Transparente Folie, Materialstärke 105 bis 110 µm, Schichtdicken-Verhältnis 1/32/31/33/2 = 10/20/40/20/10:

Schichten **1**, **2**:	4% S462 + 4% S465 + 92% PETG
Schichten **32**, **33**:	4% S465 + 32% 9665 DU + 64% PETG
Schicht **31**:	4% S465 + 65% 9665 DU + 31% PETG

Opake Folie, Materialstärke 120 µm, Schichtdicken-Verhältnis 1/32/31/33/2 = 10/20/40/20/10:

Schichten **1**, **2**:	20% S469-YE + 80% PETG
Schichten **32**, **33**:	55% PETG + 25% DP 9665 DU + 20% S469-YE
Schicht **31**:	30% PETG + 50% DP 9665 DU + 20% S469-YE

[0047] Desmopan 9665 DU, der Firma Bayer Material Science, ist ein thermoplastisches Elastomer auf Urethanbasis (Ethertype) mit einer Shore D-Härte von 75 (Shore A-Härte 98) und einer Reißdehnung von 350% (Folie M5e). Es ist UV-stabilisiert, mikroben- und hydrolysebeständig.

[0048] 5469-YE der Firma Sukano ist ein Weiß-Additiv.

[0049] S462 der Firma Sukano ist ein Antiblockmittel.

[0050] S465 der Firma Sukano ist ein Laseradditiv.

[0051] Nachfolgend sind beispielhafte Extrudereinstellungen zur Herstellung des Folienverbundmaterials **4** angegeben.

Verarbeitungsparameter:

bevorzugte Verarbeitungstemperaturen Extruder C				
Zone 1	Zone 2	Zone 3 bis n	Schmelzeleitungen, -pumpe, -filter	Feedblock/Düse
30°C–80°C	180°C–270°C	190°C–270°C	190°C–270°C	190°C–270°C

besonders bevorzugte Verarbeitungstemperaturen Extruder C				
Zone 1	Zone 2	Zone 3 bis n	Schmelzeleitungen, -pumpe, -filter	Feedblock/Düse
40°C–70°C	200°C–250°C	210°C–250°C	210°C–250°C	220°C–250°C

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bevorzugte Verarbeitungstemperaturen Extruder B				
Zone 1	Zone 2	Zone 3 bis n	Schmelzeleitungen, -pumpe, -filter	Feedblock/Düse
30°C–70°C	190°C–270°C	200°C–270°C	200°C–270°C	200°C–270°C

besonders bevorzugte Verarbeitungstemperaturen Extruder B				
Zone 1	Zone 2	Zone 3 bis n	Schmelzeleitungen, -pumpe, -filter	Feedblock/Düse
40°C–60°C	200°C–260°C	210°C–260°C	210°C–260°C	210°C–260°C

bevorzugte Verarbeitungstemperaturen Extruder A				
Zone 1	Zone 2	Zone 3 bis n	Schmelzeleitungen, -pumpe, -filter	Feedblock/Düse
30°C–70°C	200°C–280°C	200°C–280°C	200°C–280°C	200°C–280°C

besonders bevorzugte Verarbeitungstemperaturen Extruder A				
Zone 1	Zone 2	Zone 3 bis n	Schmelzeleitungen, -pumpe, -filter	Feedblock/Düse
40°C–60°C	210°C–260°C	210°C–260°C	210°C–260°C	210°C–260°C

[0052] Die jeweils günstigen Extrudereinstellungen können in Abhängigkeit von den eingesetzten Extrudern (Durchsatz, Schneckengeometrien) variieren. Sie stellen Angaben zur Orientierung dar, die ein Fachmann gegebenenfalls durch wenige Routineversuche an die vorgegebenen Extruderkonfigurationen anpassen kann.

[0053] Fig. 2 zeigt eine andere Ausführungsform des erfindungsgemäßen Folienverbundmaterials **4**. Diese Ausführungsform hat den einfachsten Schichtaufbau mit einer einzigen Innenschicht **3** und zwei Außenschichten **1**, **2**. Die Außenschichten **1**, **2** bestehen wiederum aus einem thermoplastischen Polymer oder einem Gemisch von thermoplastischen Polymeren. Wie bei allen Ausführungsformen sind Polyester, Polyestergemische, insbesondere PETG, Polycarbonat, Polycarbonat-Gemische und Elends aus Polyester und Polycarbonat bevorzugte thermoplastische Polymere. Die Innenschicht **3** besteht aus einem Gemisch aus mindestens einem thermoplastischen Elastomer, bevorzugt einem Elastomer auf Urethanbasis, mit einem Anteil an thermoplastischem Polymer. Das für die Innenschicht **3** verwendete thermoplastische Polymer ist identisch mit dem thermoplastischen Polymer oder Polymer-Gemisch, das für die Außenschichten **1**, **2** verwendet wird. Für alle Ausführungsformen des erfindungsgemäßen Folienverbundmaterials sind Urethan-Elastomere auf der Basis von aromatischen Estern oder aromatischen Ethern wegen ihrer besonderen Eignung zur Coextrusion mit Thermoplasten besonders bevorzugt. Ganz besonders bevorzugt sind sie für ein nur dreischichtiges Folienverbundmaterial, wie in Fig. 2 dargestellt, da bei nur einer einzigen Innenschicht weniger Abstufungsmöglichkeiten als beispielsweise bei einer dreischichtigen Innenschicht, wie in Fig. 1 dargestellt, bestehen. Es ist daher schwieriger, verträgliche Übergänge zwischen den einzelnen Schichten zu schaffen.

[0054] Fig. 3 zeigt eine weitere Ausführungsform des erfindungsgemäßen Folienverbundmaterials **4**, bei der die Innenschicht **3** wie bei dem in Fig. 1 dargestellten Folienverbundmaterial aufgebaut ist, aber die erste Außenschicht **1** und die zweite Außenschicht **2** jeweils aus einer äußeren Außenschicht **12**, **22** und einer inneren Außenschicht **11**, **21** aufgebaut sind. Das Folienverbundmaterial weist also insgesamt sieben Schichten auf. Grundsätzlich gilt, dass die Herstellung des Folienverbundmaterials umso schwieriger wird, je mehr Schichten das Folienverbundmaterial aufweist. Daher sind Varianten mit Außenschichten **1**, **2**, die aus mehreren Teilschichten aufgebaut sind, weniger bevorzugt. Sie sind vor allem dann sinnvoll, wenn in eine äußere Teilschicht **12**, **22** ein Bestandteil eingebracht werden soll, der mit einem Bestandteil der Innenschicht **3** unverträglich ist, oder wenn beispielsweise eine separate Teilschicht mit einem Antiblockmittel ausgestattet werden soll. Die entsprechenden Zusätze sind dann nur in der äußeren ersten Außenschicht **12** und/oder der äußeren zweiten Außenschicht **22** vorhanden.

[0055] Die Fig. 4, Fig. 5 und Fig. 6 zeigen jeweils beispielhafte Schichtaufbauten für erfindungsgemäße Kartenkörper **5**. Allgemein bestehen erfindungsgemäße Kartenkörper aus einem Kartenkern **6**, der typischerweise aus ein bis sieben Schichten aufgebaut ist. In den Figuren sind jeweils drei Kemschichten, eine Kerninnen-

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schicht **9**, eine erste Kernaußenschicht **7** und eine zweite Kernaußenschicht **7'**, dargestellt. Bei Kartenkörpern des Stands der Technik bestehen die Kartenkerne aus thermoplastischen Folien, typischerweise aus PVC, PET, ABS, Polyester, PC, PEC und dergleichen. Derartige Folien können auch für erfindungsgemäße Kartenkerne verwendet werden. Zwischen den Folienschichten und/oder in Aussparungen der Folienschichten können sich elektronische Bauteile wie elektronische Module und Antennen befinden. Auch andere Merkmale, wie beispielsweise Sicherheitselemente oder Aufdrucke, können vorgesehen werden. Der Schichtaufbau der Kartenkörper **5** wird jeweils außenseitig durch eine Deckschicht **8**, **8'** abgeschlossen. Die den Schichtaufbau bildenden Folien werden bevorzugt durch Laminieren miteinander verbunden, weshalb alle verwendeten Materialien gut miteinander laminierbar sein sollten.

[0056] Fig. 4 zeigt eine Ausführungsform eines erfindungsgemäßen Kartenkörpers **5** mit einem Kartenkern **6**, bestehend aus einer PVC- oder PET-Folie **9**, auf die eine Spule (nicht gezeigt) aufgedruckt ist, und zwei PVC-Folien **7**, **7'**. Der Schichtaufbau wird abgeschlossen durch die beiden Deckfolien **8**, **8'**, die aus dem erfindungsgemäßen Folienverbundmaterial **4**, wie es vorstehend beschrieben wurde, bestehen.

[0057] In Ausnehmungen der Folien **7**, **8** befindet sich ein Chipmodul **15**, das mittels einer Modulauflage **16** aus Modulkleber mit dem Kartenkörper verklebt ist. Kontakte **17** stellen den elektrischen Kontakt zu der auf die Folie **9** aufgedruckten Spule (nicht gezeigt) her.

[0058] Wenn das erfindungsgemäße Folienverbundmaterial **4**, wie in Fig. 4 dargestellt, als Deckschicht (Overlay-Folie) verwendet wird, ist es bevorzugt transparent. Die Verwendung des erfindungsgemäßen Folienverbundmaterials ausschließlich als Deckschicht hat den Vorteil, dass die Verklebung des Chipmoduls **15** ausschließlich mit Standard-Kartenfolien erfolgt, so dass weiterhin der übliche Standard-Modulkleber für die Modulauflage **16** verwendet werden kann.

[0059] Fig. 5 zeigt eine andere Ausführungsform eines erfindungsgemäßen Kartenkörpers **5**. Hier besteht der Kartenkern **6** aus einer PVC- oder PET-Folie **9** mit einer aufgedruckten Antennenspule (nicht gezeigt), an die sich beidseitig die Schichten **7**, **7'** aus dem erfindungsgemäßen Folienverbundmaterial **4** anschließen. Der Schichtaufbau wird abgeschlossen durch die beiden Deckschichten **8**, **8'** aus PVC-Folie. Wie bei der in Fig. 4 dargestellten Ausführungsform ist ein Chipmodul **15** mittels einer Modulauflage **16** in den Kartenkörper **5** eingeklebt und weist Kontakte **17** zur Kontaktierung der Antennenspule auf.

[0060] Wenn das erfindungsgemäße Folienverbundmaterial **4**, wie in der in Fig. 5 dargestellten Ausführungsform, eine Teilschicht bzw. Teilschichten des Kerns **6** bildet, wird es bevorzugt opak ausgeführt. Diese Ausführungsform hat den Vorteil, dass das erfindungsgemäße Folienverbundmaterial, da es sich im Verklebungsbereich des Chipmoduls befindet, Spannungen, die beim Implantieren des Moduls durch die Temperatureinwirkung (Hotmelt-Verklebung) im Material aufgebaut werden, besonders gut ausgleichen kann.

[0061] Eine weitere altemative Ausführungsform eines erfindungsgemäßen Kartenkörpers **5** ist in Fig. 6 dargestellt. Hier besteht der Kartenkem **6** aus der Kerninnenschicht **9** aus PVC- oder PET-Folie, der ersten Kernaußenschicht **7** und der zweiten Kernaußenschicht **7'**, beide aus erfindungsgemäßem Folienverbundmaterial **4** in opaker Ausführung. Die beiden Deckschichten **8**, **8'** bestehen ebenfalls aus erfindungsgemäßem Folienverbundmaterial **4**, diesmal in transparenter Ausführung. Ein Chipmodul **15** ist wie bei den Ausführungsformen von Fig. 4 und Fig. 5 in den Kartenkörper implantiert und verklebt. Diese Ausführungsform mit erfindungsgemäßem Folienverbundmaterial **4** sowohl als Kern-Teilschicht als auch als Deckschicht verleiht dem Kartenkörper **5** besonders vorteilhafte mechanische Eigenschaften. Einerseits werden beim Implantieren des Moduls durch die Temperatureinwirkung aufgebaute Spannungen durch die erfindungsgemäßen Kern-Teilschichten gut ausgeglichen, und andererseits sorgen die weit außen liegenden Deckfolien **8**, **8'** aus erfindungsgemäßem Folienverbundmaterial **4** für eine hohe Bruchfestigkeit, fehlende Verblockungsneigung, gute Bedruckbarkeit und Steifigkeit.

[0062] In den Fig. 4, Fig. 5 und Fig. 6 sind die Kartenaufbauten jeweils symmetrisch dargestellt, was jedoch nicht zwingend ist. Möglich sind beispielsweise auch Ausführungsformen, bei denen das erfindungsgemäße Folienverbundmaterial **4** nur als eine der Deckschichten und/oder als eine Kern-Teilschicht verwendet wird. Bei Verwendung als Deckschicht ist die Schichtdicke des Folienverbundmaterials **4** typischerweise maximal halb so groß wie bei der Verwendung als Kern-Teilschicht.

[0063] Durch den Einsatz des erfindungsgemäßen Folienverbundmaterials als Deckschicht(en) und/oder als Kernschicht(en) in einem Kartenkörper können die mechanischen Eigenschaften von Kartenkörpern gegenüber Kartenkörpem des Stands der Technik maßgeblich verbessert werden. Die Kartenkörper können stär-

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keren und häufigeren Biegebelastungen ausgesetzt werden, ohne dass es zu Spannungen, Rissen oder Brüchen des Kartenkörpers kommt. Auch Spannungen, die durch den Einbau elektronischer Module, die stets eine Schwächung des Kartenkörpers bewirken, entstehen, können ausgeglichen und somit die mechanischen Eigenschaften des Kartenkörpers verbessert werden. Das erfindungsgemäße Folienverbundmaterial kann in den Kartenkörpern anstelle jeder beliebigen Standardfolie eingesetzt werden.

[0064] Insbesondere Kartenaufbauten, bei denen das erfindungsgemäße Folienverbundmaterial im Inneren des Kartenaufbaus eingesetzt wird, wie in Fig. 5 beispielhaft dargestellt, haben ausgezeichnete mechanische Eigenschaften, wie hervorragende Festigkeit und Steifigkeit. Dies zeigt sich besonders bei schlagartigen Krafteinwirkungen, die ansonsten im Regelfall zum Kartenbruch führen. Verantwortlich dafür ist die größere Dicke der Folienverbundmaterial-Kernschichten, und damit der höhere Anteil des erfindungsgemäßen Folienverbundmaterials am Kartenkörper insgesamt.

[0065] Das erfindungsgemäße Folienverbundmaterial ist auch in sich selbst sehr stabil, d. h. es besteht ein fester Verbund zwischen seinen einzelnen Teilschichten, ohne die Gefahr einer Trennung der Teilschichten voneinander bei Belastung. Diese Stabilität wird durch geeignete Abstufungen der Zusammensetzungen der Teilschichten, die ähnliche Verarbeitungseigenschaften benachbarter Teilschichten zur Folge haben, erzielt.

[0066] Das erfindungsgemäße Folienverbundmaterial kann preisgünstig hergestellt werden, und es steht ein breites Spektrum an geeigneten thermoplastischen Elastomeren mit unterschiedlichen Eigenschaften auf dem Markt zur Verfügung. Das Folienverbundmaterial ist einfach im Coextrusionsverfahren zu verarbeiten und zeichnet sich auch durch eine besonders einfache Handhabung bei der Weiterverarbeitung aus, d. h. es kann beispielsweise problemlos bedruckt und mit allen gängigen Kartenmaterialien laminiert werden. Es neigt auch nicht zum Verblocken. Das Folienmaterial kann mit einem hohen Anteil an thermoplastischem Elastomer hergestellt werden, wodurch es sehr elastisch ist und, bei Verwendung als Schicht in einem Kartenkörper, die mechanischen Eigenschaften des Kartenkörpers gegenüber Kartenkörpern ohne das erfindungsgemäße Folienverbundmaterial deutlich verbessert.

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ZITATE ENTHALTEN IN DER BESCHREIBUNG

Diese Liste der vom Anmelder aufgeführten Dokumente wurde automatisiert erzeugt und ist ausschließlich zur besseren Information des Lesers aufgenommen. Die Liste ist nicht Bestandteil der deutschen Patent- bzw. Gebrauchsmusteranmeldung. Das DPMA übernimmt keinerlei Haftung für etwaige Fehler oder Auslassungen.

Zitierte Patentliteratur

- EP 0430282 A2 [0003]
- EP 0384252 B1 [0006]

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Patentansprüche

1. Folienverbundmaterial (**4**), insbesondere zur Verwendung als Schicht in einem Kartenkörper, vorzugsweise in einem Kartenkörper eines tragbaren Datenträgers, mit
– mindestens einer ersten Kunststoff-Außenschicht (**1**),
– mindestens einer Kunststoff-Innenschicht (**3**),
– mindestens einer zweiten Kunststoff-Außenschicht (**2**),
wobei alle Schichten (**1**, **3**, **2**) gemeinsam einen Coextrusionsverbund bilden, **dadurch gekennzeichnet**, dass
– der Kunststoff der mindestens einen ersten Außenschicht (**1**) ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren ist,
– der Kunststoff der mindestens einen Innenschicht (**3**) ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem thermoplastischen Polymer ist,
– der Kunststoff der mindestens einen zweiten Außenschicht (**2**) ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren ist.

2. Folienverbundmaterial (**4**) nach Anspruch 1, dadurch gekennzeichnet, dass die Kunststoff-Innenschicht (**3**) aus einer inneren Schicht (**31**) und einer ersten äußeren (**32**) und einer zweiten äußeren (**33**) Schicht besteht.

3. Folienverbundmaterial (**4**) nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Kunststoff-Innenschicht (**3**) dasselbe thermoplastische Polymer oder Gemisch von thermoplastischen Polymeren enthält wie die erste (**1**) und/oder die zweite (**2**) Außenschicht.

4. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass der Kunststoff der ersten (**1**) und/oder der zweiten (**2**) Außenschicht ein Polyester oder ein Gemisch von Polyestern, bevorzugt PETG, ein Polycarbonat oder ein Gemisch von Polycarbonaten, oder ein Blend aus Polyester und Polycarbonat ist.

5. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass das mindestens eine thermoplastische Elastomer der Innenschicht (**3**) ein Urethan-Elastomer, bevorzugt ein Urethan-Elastomer auf der Basis von aromatischen Estern oder aromatischen Ethern ist.

6. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass wenn der Kunststoff der ersten und/oder der zweiten Außenschicht ein PET-Copolyester ist, das thermoplastische Elastomer der Innenschicht (**3**) ein Elastomer mit einer Shore D-Härte von 35 bis 50 ist, und wenn der Kunststoff der ersten und/oder der zweiten Außenschicht ein Polycarbonat ist, das thermoplastische Elastomer der Innenschicht (**3**) ein Elastomer mit einer Shore D-Härte von 50 bis 70 ist.

7. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass das thermoplastische Elastomer ein Elastomer ist, das eine Shore D-Härte zwischen 40 und 70, bevorzugt zwischen 50 und 65, und/oder eine Reißdehnung zwischen 300% und 700%, bevorzugt zwischen 350% und 500%, und/oder eine Schmelzeviskosität (MFI) von 7 bis 10 cm^3/10 min und/oder eine Verarbeitungstemperatur zwischen 190°C und 240°C, bevorzugt zwischen 210°C und 240°C, hat.

8. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass das Folienverbundmaterial transparent ist und eine erste Kunststoff-Außenschicht (**1**), eine erste äußere Kunststoff-Innenschicht (**32**), eine innere Kunststoff-Innenschicht (**31**), eine zweite äußere Kunststoff-Innenschicht (**33**) und eine zweite Kunststoff-Außenschicht (**2**) aufweist, wobei
der Kunststoff der ersten und der zweiten Außenschicht 1, 2 zu 100% ein Thermoplast ist,
der Kunststoff der ersten und der zweiten äußeren Innenschicht (**32**, **33**) zu 50 bis 80% aus Thermoplast und zu 20 bis 50% aus Elastomer besteht, und
der Kunststoff der inneren Innenschicht (**31**) zu 30 bis 70%, bevorzugt 30 bis 50%, aus Thermoplast und zu 70 bis 30%, bevorzugt 70 bis 50%, aus Elastomer besteht.

9. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass das Folienverbundmaterial opak ist und eine erste Kunststoff-Außenschicht (**1**), eine erste äußere Kunststoff-Innenschicht (**32**), eine innere Kunststoff-Innenschicht (**31**), eine zweite äußere Kunststoff-Innenschicht (**33**) und eine zweite Kunststoff-Außenschicht (**2**) aufweist, wobei
das Material der ersten und der zweiten Kunststoff-Außenschicht **1**, **2** zu 85% bis 95% aus Thermoplast und zu 5 bis 15% aus Füllstoff, Rest gegebenenfalls übliche Additive, besteht,

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das Material der ersten und der zweiten äußeren Kunststoff-Innenschicht (**32**, **33**) zu 20 bis 50% aus Elastomer, zu 75 bis 25% aus Thermoplast und zu 5 bis 15% aus Füllstoff, Rest gegebenenfalls übliche Additive, besteht und
das Material der inneren Kunststoff-Innenschicht zu 50 bis 70% aus Elastomer, zu 15 bis 45% aus Thermoplast und zu 5 bis 15% aus Füllstoff, Rest gegebenenfalls übliche Additive, besteht.

10. Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass die Dicke der Kunststoff-Innenschicht (**3**) 40 bis 80% der Gesamtdicke des Folienverbundmaterials (**4**) ausmacht.

11. Verfahren zur Herstellung eines Folienverbundmaterials (**4**) nach einem der Ansprüche 1 bis 10, aufweisend ein Coextrudieren mindestens eines ersten Außenschicht-Kunststoffmaterials, mindestens eines zweiten Außenschicht-Kunststoffmaterials, und mindestens eines Innenschicht-Kunststoffmaterials, dadurch gekennzeichnet, dass
– alle Kunststoffmaterialien extrudiert und so zusammengeführt werden, dass ein Folienverbundmaterial (**4**) gebildet wird, bei dem eine Kunststoff-Innenschicht (**3**) beidseitig von einer ersten (**1**) und einer zweiten (**2**) Kunststoff-Außenschicht bedeckt wird,
– das mindestens eine erste Außenschicht-Kunststoffmaterial als Kunststoff ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren aufweist,
– das mindestens eine zweite Außenschicht-Kunststoffmaterial als Kunststoff ein thermoplastisches Polymer oder ein Gemisch von thermoplastischen Polymeren aufweist, und
– das mindestens eine Innenschicht-Kunststoffmaterial als Kunststoff ein Gemisch aus mindestens einem thermoplastischen Elastomer und mindestens einem thermoplastischen Polymer aufweist.

12. Verfahren nach Anspruch 11, dadurch gekennzeichnet, dass Kunststoffmaterialien mit Merkmalen, wie sie in einem der vorangehenden Ansprüche angegeben sind, verwendet werden.

13. Verfahren nach Anspruch 11 oder 12, dadurch gekennzeichnet, dass eine Kunststoff-Innenschicht (**3**) aus einer inneren Schicht (**31**) und einer ersten äußeren (**32**) und einer zweiten äußeren (**33**) Schicht gebildet wird, und die erste und die zweite Kunststoff-Außenschicht (**1**, **2**) bei einer Düsentemperatur von 200 bis 280°C, bevorzugt 210 bis 260°C, extrudiert werden, die erste und die zweite äußere Kunststoff-Innenschicht (**32**, **33**) bei einer Düsentemperatur von 200 bis 270°C, bevorzugt 210 bis 260°C, extrudiert werden, und die innere Kunststoff-Innenschicht (**31**) bei einer Düsentemperatur von 190 bis 270°C, bevorzugt 220 bis 250°C, extrudiert wird.

14. Kartenkörper (**5**), insbesondere für einen tragbaren Datenträger, mit einer Mehrzahl von miteinander laminierten Kunststoffschichten, umfassend
– einen Kartenkern (**6**) aus mindestens einer Keminnenschicht (**9**),
– mindestens zwei Deckschichten (**8**, **8'**), um beide Oberflächen des Kartenkerns (**6**) zu bedecken, und
– gegebenenfalls mindestens eine Kernaußenschicht (**7**, **7'**) zwischen der Kerninnenschicht (**9**) und mindestens einer der Deckschichten (**8**, **8'**),
dadurch gekennzeichnet, dass mindestens eine der Deckschichten (**8**, **8'**) und/oder mindestens eine Kernaußenschicht (**7**, **7'**) ein Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 10 oder ein nach einem Verfahren der Ansprüche 11 bis 13 erhältliches Folienverbundmaterial (**4**) ist.

15. Verfahren zur Herstellung eines Kartenkörpers (**5**), insbesondere für einen tragbaren Datenträger, mit einer Mehrzahl von Kunststoffschichten, umfassend:
– einen Kartenkern (**6**) aus mindestens einer Keminnenschicht (**9**),
– mindestens zwei Deckschichten (**8**, **8'**), um beide Oberflächen des Kartenkerns (**6**) zu bedecken, und
– gegebenenfalls mindestens eine Kernaußenschicht (**7**, **7'**) zwischen der Kerninnenschicht (**9**) und mindestens einer der Deckschichten (**8**, **8'**),
bei dem die Kunststoffschichten in einem Arbeitsvorgang oder in mehreren Arbeitsvorgängen miteinander laminiert werden, dadurch gekennzeichnet, dass als mindestens eine der Deckschichten (**8**, **8'**) und/oder als mindestens eine Kernaußenschicht (**7**, **7'**) ein Folienverbundmaterial (**4**) nach einem der Ansprüche 1 bis 10 oder ein nach einem Verfahren nach einem der Ansprüche 11 bis 13 erhältliches Folienverbundmaterial (**4**) verwendet wird.

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16. Verfahren nach Anspruch 15, dadurch gekennzeichnet, dass das Laminieren bei einer Temperatur von zwischen 120°C und 200°C erfolgt, bevorzugt zwischen 130°C und 180°C, besonders bevorzugt zwischen 130°C und 150°C liegt.

Es folgen 2 Blatt Zeichnungen

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Anhängende Zeichnungen

FIG 1

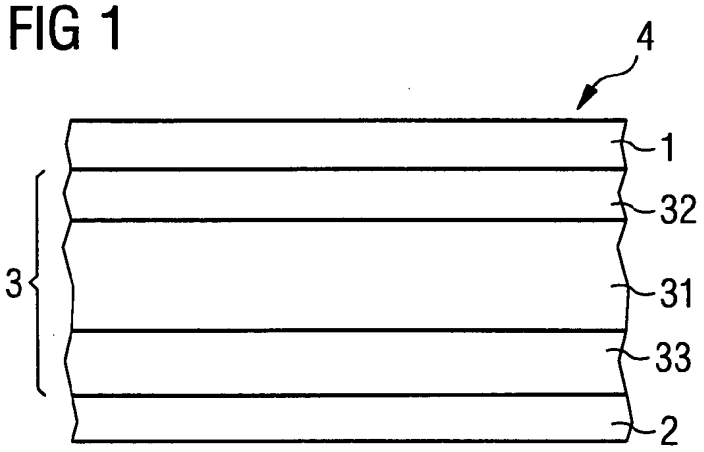


FIG 2

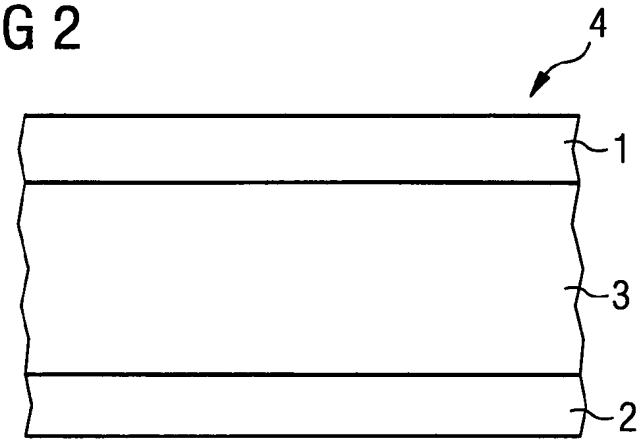
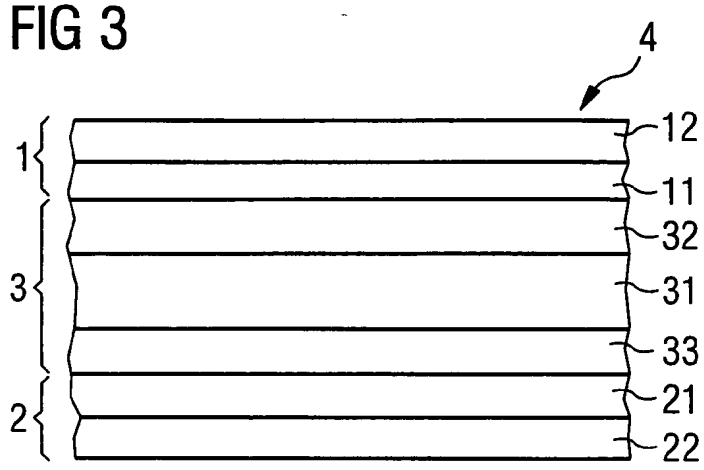


FIG 3



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FIG 4

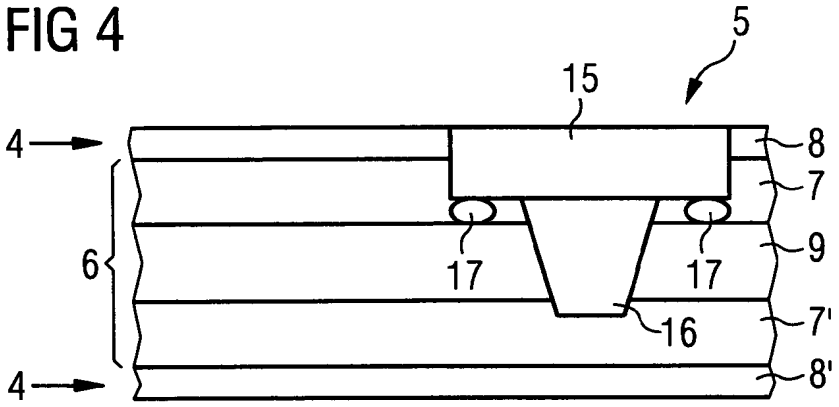


FIG 5

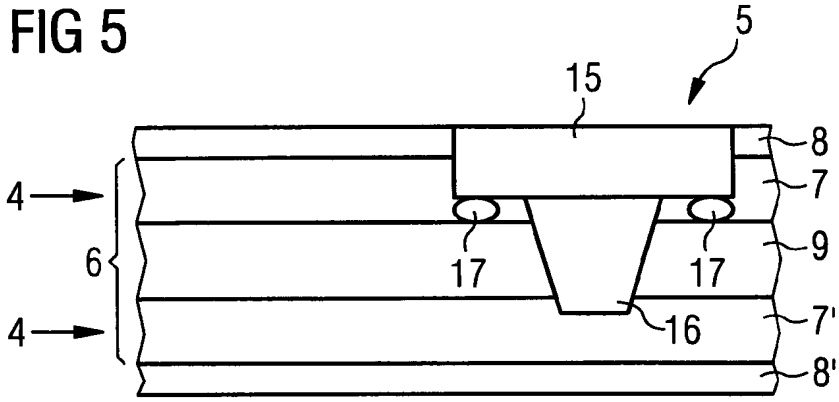
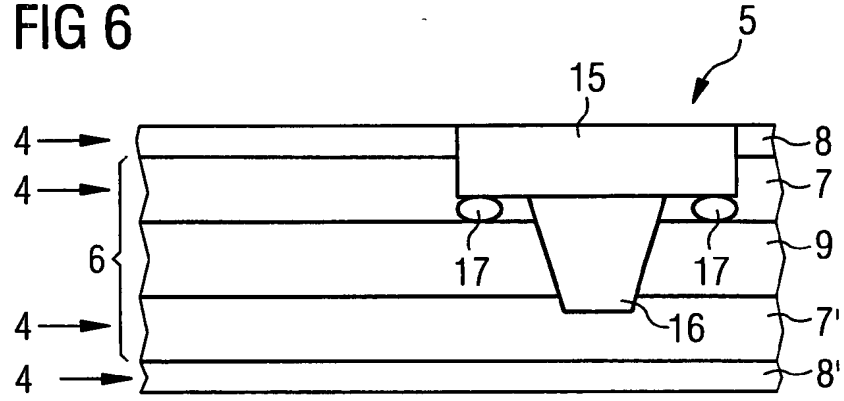


FIG 6



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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.
BMS121016PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2012/037745	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

ClearCorrect Exhibit 1010, Page 1352 of 1447

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/037745

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
22 January 2013	30/01/2013

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

3

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/037745

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

ClearCorrect Exhibit 1010, Page 1354 of 1447

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/US2012/037745	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.

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/470,681	Filing Date 05/14/2012	☐ 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 **11/22/2016**

	(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))	* 31	Minus	** 31	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 3	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

	(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))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ 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.
** 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
MELINDA L. OLIVER

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.

Approved for use through 07/31/2016. 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 1 of 3

Complete if Known	
Application Number	13470681
Filing Date	05-14-2012
First Named Inventor	LI; Chunhua
Art Unit	3732
Examiner Name	MAI; Hao D.
Attorney Docket Number	22773-826.201

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-8496473	07-30-2013	PHAN; Loc X. et al.	
	002	US-20010041320	11-15-2001	PHAN; Loc et al.	
	003	US-20040146670	07-29-2004	CHIN; Albert et al.	
	004	US-20070148608	06-28-2007	TADROS; Safwat et al.	
	005	US-20080299507	12-04-2008	LI; Chunhua et al.	
	006	US-20090087808	04-02-2009	SOO; Chia et al.	
	007	US-20090239188	09-24-2009	TING; Kang et al.	
	008	US-20160228215	08-11-2016	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	DE-102004014023-A1	10-20-2005	KRD COATINGS GMBH [DE]		☒
	002	DE-102010009230-A1	08-25-2011	GIESECKE & DEVRIENT GMBH [DE]		☒
	003	WO-2013172812-A1	11-21-2013	BAYER MATERIALSCIENCE AG [DE], et al.		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HDM/

Examiner Signature	/Hao D Mai/ (01/06/2017)	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 07/31/2016. 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 3

Complete if Known	
Application Number	13470681
Filing Date	05-14-2012
First Named Inventor	LI; Chunhua
Art Unit	3732
Examiner Name	MAI; Hao D.
Attorney Docket Number	22773-826.201

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	Baird Equity Research. Align Technology, Inc. (ALGN): Analyst Day Recap. May 30, 2014. 12 pages.	☐
	002	Baird Equity Research. Align Technology, Inc. (ALGN): Impressive Quarter/Guide, Momentum Stronger than We Realized. October 18, 2013. 15 pages.	☐
	003	International Preliminary Report on Patentability dated 11/18/2014 for International PCT Patent Application No. PCT/US2012/037745.	☐
	004	International Search Report and Written Opinion dated 01/30/2013 for International PCT Patent Application No. PCT/US2012/037745.	☐
	005	STIFEL. TAM Survey. Properly Aligning Expectations Ahead of 4Q13 Guidance. Align Technology, Inc. October 10, 2013. 12 pages.	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HDM/

Examiner Signature	/Hao D Mai/ (01/06/2017)	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 07/31/2016. 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	3

Complete if Known	
Application Number	13470681
Filing Date	05-14-2012
First Named Inventor	LI; Chunhua
Art Unit	3732
Examiner Name	MAI; Hao D.
Attorney Docket Number	22773-826.201

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)	2016-11-22
Name/Print	Patrick Medley	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.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/470,681	LI ET AL.	
	Examiner	Art Unit	
	HAO D. MAI	3732	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Hao Mai*. (3)_____.

(2) *Melissa Harwood*. (4)_____.

Date of Interview: *05 January 2017*.

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: *38*.

Identification of prior art discussed: *N/A*.

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...)

Proposed examiner's amendment to correct typographical error was discussed and authorized by Applicant's counsel.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of 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

/HAO D MAI/ Examiner, Art Unit 3732	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	HAO D MAI	3732

CPC						
Symbol					**Type**	**Version**
A61C		7	/	08	F	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		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

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/HAO D MAI/ Examiner.Art Unit 3732	01/06/2017	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/CRIS L RODRIGUEZ/ Supervisory Patent Examiner.Art Unit 3732	01/07/2017	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	HAO D MAI	3732

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION												
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED							
		A	6	1	C	7 / 08 (2006.01.01)								
CROSS REFERENCE(S)		B	3	2	B	25 / 08 (2006.01.01)								
		B	3	2	B	25 / 20 (2006.01.01)								
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)	B	3	2	B	27 / 08 (2006.01.01)								
		B	3	2	B	27 / 28 (2006.01.01)								
		B	3	2	B	27 / 30 (2006.01.01)								
		B	3	2	B	27 / 32 (2006.01.01)								
		B	3	2	B	27 / 34 (2006.01.01)								
		B	3	2	B	27 / 36 (2006.01.01)								
		B	3	2	B	27 / 40 (2006.01.01)								

/HAO D MAI/ Examiner.Art Unit 3732 (Assistant Examiner)	01/06/2017 (Date)	**Total Claims Allowed:** 31
/CRIS L RODRIGUEZ/ Supervisory Patent Examiner.Art Unit 3732 (Primary Examiner)	01/07/2017 (Date)	O.G. Print Claim(s) 1 O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	HAO D MAI	3732

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	21	17	16	33										
2	2	22	18	24	34										
3	3	23	19	25	35										
4	4		20	26	36										
5	5		21	27	37										
6	6		22	28	38										
7	7		23	29	39										
8	8		24	30	40										
9	9		25	31	41										
10	10		26												
11	11		27												
12	12		28												
17	13		29												
18	14	13	30												
19	15	14	31												
20	16	15	32												

/HAO D MAI/ Examiner.Art Unit 3732 (Assistant Examiner)	01/06/2017 (Date)	**Total Claims Allowed:** 31	
/CRIS L RODRIGUEZ/ Supervisory Patent Examiner.Art Unit 3732 (Primary Examiner)	01/07/2017 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	HAO D MAI	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014	07/28/2014	02/23/2015	08/10/2015	06/16/2016	01/06/2017
1	1	÷	✓	✓	✓	✓	✓	✓	✓	=
2	2	÷	✓	✓	✓	✓	✓	✓	✓	=
3	3	÷	✓	✓	✓	✓	✓	✓	✓	=
4	4	÷	✓	✓	✓	✓	✓	✓	✓	=
5	5	÷	✓	✓	✓	✓	✓	✓	✓	=
6	6	÷	✓	✓	✓	✓	✓	✓	✓	=
7	7	÷	✓	✓	✓	✓	✓	✓	✓	=
8	8	÷	✓	✓	✓	✓	✓	✓	✓	=
9	9	÷	✓	✓	✓	✓	✓	✓	✓	=
10	10	÷	✓	✓	✓	✓	✓	✓	✓	=
11	11	÷	✓	✓	✓	✓	✓	✓	✓	=
12	12	÷	✓	✓	✓	✓	✓	✓	✓	=
17	13	÷	✓	✓	✓	✓	✓	✓	✓	=
18	14	÷	✓	✓	✓	✓	✓	✓	✓	=
19	15	÷	✓	✓	✓	✓	✓	✓	✓	=
20	16	÷	✓	✓	✓	✓	✓	✓	✓	=
21	17	÷	✓	✓	✓	✓	✓	✓	✓	=
22	18	÷	✓	✓	✓	✓	✓	✓	✓	=
23	19	÷	✓	✓	✓	✓	✓	✓	✓	=
	20	÷	N	N	N	N	N	N	-	-
	21	÷	N	N	N	N	N	N	-	-
	22	÷	N	N	N	N	N	N	-	-
	23	÷	N	N	N	N	N	N	-	-
	24	÷	N	N	N	N	N	N	-	-
	25	÷	N	N	N	N	N	N	-	-
	26	÷	N	N	N	N	N	N	-	-
	27	÷	N	N	N	N	N	N	-	-
	28	÷	N	N	N	N	N	N	-	-
	29	÷	N	N	N	N	N	N	-	-
13	30								✓	=
14	31								✓	=
15	32								✓	=
16	33								✓	=
24	34								✓	=
25	35								✓	=
26	36								✓	=

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	**Art Unit**
	HAO D MAI	3732

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/27/2012	09/28/2012	09/10/2013	01/11/2014	07/28/2014	02/23/2015	08/10/2015	06/16/2016	01/06/2017
27	37								✓	=
28	38									=
29	39									=
30	40									=
31	41									=

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	17	A61C7/08.cpc. and (layer and co$1polyester and polyurethane)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:43
L2	7328	B32B25/08,20.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:45
L3	11	B32B25/08,20.cpc. and (orthodontic or dental)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:46
L4	115346	B32B27/08,281,286,308,32,34,36,365,40.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:47
L5	145	B32B27/08,281,286,308,32,34,36,365,40.cpc. and (orthodontic or dental)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:47
L6	9	B32B27/08,281,286,308,32,34,36,365,40.cpc. and (orthodontic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:48
L7	14	B32B27/08,281,286,308,32,34,36,365,40.cpc. and (orthodontic or dental) and (co$1polyester and polyurethane)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2017/01/06 10:48
L8	9	(("8496473") or ("20010041320") or	US-	OR	OFF	2017/01/06

		("20040146670") or ("20070148608") or ("20080299507") or ("20090087808") or ("20090239188") or ("20160228215")).PN.	PGPUB; USPAT; USOCR; FPRS; EPO; JPO			10:55
L11	1	("20040146670").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	OFF	2017/01/06 10:58

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L12	993	A61C7/08.cpc.	US-PGPUB; USPAT	ADJ	ON	2017/01/06 11:02
L13	1718	B32B25/08,20.cpc.	US-PGPUB; USPAT	ADJ	ON	2017/01/06 11:02
L14	24092	B32B27/08,281,286,308,32,34,36,365,40.cpc.	US-PGPUB; USPAT	ADJ	ON	2017/01/06 11:02
L15	1	(l12 or l13 or l14) and (orthodontic layer co$1polyester polyurethane).clm.	US-PGPUB; USPAT	WITH	ON	2017/01/06 11:03
L16	25	(l12 or l13 or l14) and (orthodontic layer).clm.	US-PGPUB; USPAT	WITH	ON	2017/01/06 11:03
L17	29	(l12 or l13 or l14) and (layer co$1polyester polyurethane).clm.	US-PGPUB; USPAT	WITH	ON	2017/01/06 11:03
L18	4	(l12 or l13 or l14) and (layer co$1polyester polyurethane).clm. and (dental or orthodontic)	US-PGPUB; USPAT	WITH	ON	2017/01/06 11:04

1/6/2017 11:05:01 AM
C:\Users\hmai1\Documents\EAST\Workspaces\13470681.wsp

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

107046 7590 01/18/2017
WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER
MAI, HAO D

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 01/18/2017

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

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	$960	$0	$0	$960	04/18/2017

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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (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 01/18/2017
WSGR / Align Technology , Inc.
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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

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	$960	$0	$0	$960	04/18/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MAI, HAO D	3732	433-006000

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 03-02 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:
❑ Issue Fee
❑ Publication Fee (No small entity discount permitted)
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
❑ A check is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
❑ Applicant certifying micro entity status. See 37 CFR 1.29
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.
❑ Applicant asserting small entity status. See 37 CFR 1.27
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.
❑ Applicant changing to regular undiscounted fee 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. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

ClearCorrect Exhibit 1010, Page 1372 of 1447

UNITED STATES PATENT AND TRADEMARK OFFICE

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Address: COMMISSIONER FOR PATENTS
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13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

107046 7590 01/18/2017
WSGR / Align Technology , Inc.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
MAI, HAO D	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 01/18/2017

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.

PTOL-85 (Rev. 02/11)

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 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, 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. 13/470,681	Applicant(s) LI ET AL.	
	Examiner HAO D. MAI	Art Unit 3732	AIA (First Inventor to File) 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 *11/22/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-19 and 30-41*. 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 _____.

/HAO D MAI/
Examiner, Art Unit 3732

DETAILED ACTION

Declaration under 37 CFR 1.132

1. The declaration under 37 CFR 1.132 filed 11/22/2016 is sufficient to overcome the rejection of claims 1-19 and 30-37 based upon evidence of unobvious or unexpected advantageous properties of a layered material of a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer in a removable orthodontic tooth positioning appliance.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Melissa Harwood on 01/05/2017

The application has been amended as follows:

Claim 38, line 8, is amended as follows:

compression set greater than 40% after 2<u>4</u> hours at 70 ℃, wherein the first and second soft

Allowable Subject Matter

3. Claims 1-19 and 30-41 are allowed.

4. The following is an examiner's statement of reasons for allowance:

Regarding claims 1 and 13, the prior arts fail to disclose or reasonably teach of an orthodontic appliance comprising, *inter alia*: a hard inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm, wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn, in combination with the elements and their arrangements as set forth in the claims.

Regarding claim 38, the prior arts fail to disclose or reasonably teach of an orthodontic appliance comprising, *inter alia*: a shell having a plurality of teeth receiving cavities shaped to apply a repositioning force to the patient's teeth, wherein the shell is formed from a multilayer material configured to reduce degradation of the repositioning force over time when the shell is worn on the patient's teeth, the multilayer material comprising a first soft polymer layer and a second soft polymer layer each having a compression set greater than 40% after 24 hours at 70℃, wherein the first and second soft polymer layers each comprise a thermoplastic polyurethane elastomer; and a single hard polymer layer disposed between the first and second soft polymer layers and having a stress relaxation greater than 10% at 24 hour testing between 90% to 100% humidity, wherein the single hard polymer layer comprises a co-polyester, in combination with the elements and their arrangements as set forth in the claims.

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

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. 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.

/Hao D Mai/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13470681	LI ET AL.
	Examiner	Art Unit
	Hao Mai	3732

CPC- SEARCHED		
Symbol	Date	Examiner
A61C 7/00, 08, 14, 146; 9/00; 19/063	2/23/2015	JO
A61K 6/0023, 083, 09, 10	2/23/2015	JO
Updated Search	08/10/2015	HDM
Update Search	06/16/2016	HDM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
433	2, 6, 18, 24	9/28/2012	JO
264	16, 17, 18	9/28/2012	JO
Updated	All	9/10/2013	JO
Updated	All	1/11/2014	JO
Updated	All	7/28/2014	JO
Updated	All	2/23/2015	JO

SEARCH NOTES		
Search Notes	Date	Examiner
EAST; Inventor; Forward/backward; PLUS search	9/28/2012	JO
Updated EAST search	9/10/2013	JO
Updated EAST search	1/11/2014	JO
Updated EAST search	7/28/2014	JO
Updated EAST search	2/23/2015	JO
Update Search	08/10/2015	HDM
Update Search	06/16/2016	HDM
Interference Text Search	01/06/2017	HDM

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
A61C	7/08	01/06/2017	HDM
B32B	25/08, 20	01/06/2017	HDM
B32B	27/08, 281, 286, 308, 32, 34, 36, 365, 40	01/06/2017	HDM

/JUSTIN O'DONNELL/ Examiner.Art Unit 3732	

Notice of References Cited	Application/Control No. 13/470,681	Applicant(s)/Patent Under Reexamination LI ET AL.	
	Examiner HAO D. MAI	Art Unit 3732	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-2015/0140300 A1	05-2015	Pudleiner; Heinz	B32B27/08	428/215
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

I 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: /Danielle Hoffman/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5655
Chunhua Li et al.	
Application No.: 13/470,681	Examiner: Hao D. Mai
Filed: May 14, 2012	Art Unit: 3732
For: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	REQUEST FOR CORRECTED FILING RECEIPT
Customer No.: 107046	

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

Commissioner:

Attached is a copy of the official Filing Receipt received from the U.S. Patent and Trademark Office in the above-referenced application for which issuance of a Corrected Filing Receipt is respectfully requested.

This Request for Corrected Filing Receipt is being made to change the inventorship as follows:

Chunhua Li, Cupertino, CA;

Yan Chen, Cupertino, CA;

to the correct inventorship of

Chunhua Li, Cupertino, CA;

Yan Chen, Cupertino, CA;

Dr. Heinz Pudleiner, Krefeld, GERMANY;

Klaus Meyer, Dormagen, GERMANY;

Joerg Nickel, Dormagen, GERMANY;

Craig Pehlert, Lenox, MA;

Applicants submit herewith an Application Data Sheet with the correct list of inventorship.

Applicants believe no fee is required for submission of this request. The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 23-2415.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

Dated: March 31, 2017

/Charles C. Hagadorn, III/

Charles C. Hagadorn, III
Registration No. 62,367

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Chunhua Li et al.	Group Art Unit: 3732
Serial Number: 13/470,681	Examiner: Hao D. Mai
Filing Date: May 14, 2012	**CONFIRMATION NO: 5655**
Title: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

Mail Stop: Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

REQUEST FOR CORRECTION OF INVENTORSHIP IN A PATENT APPLICATION UNDER 37 C.F.R. § 1.48

Commissioner:

Applicants hereby request that the inventorship of the above-referenced patent application be amended pursuant to 37 C.F.R. § 1.48 to name only the actual inventors.

The Office is requested to amend the inventorship to **ADD** the following omitted inventors:

Dr. Heinz Pudleiner, Krefeld, GERMANY

Klaus Meyer, Dormagen, GERMANY

Joerg Nickel, Dormagen, GERMANY

Craig Pehlert, Lenox, MA

According to 37 C.F.R.§ 1.48(a), *Correction of inventorship for Nonprovisional application,* Applicant provides herewith:

1. An Application Data Sheet as required by 37 C.F.R. § 1.76;
2. A Request for Corrected Filing Receipt;
3. An Oath or Declaration by the actual inventors as required by 37 C.F.R. § 1.63, or as permitted by §§ 1.42, 1.43, or 1.47; and
4. The processing fee set forth in 37 C.F.R. § 1.17(i)(1).

Applicants hereby state that the error in inventorship occurred without deceptive intent on the part of the named inventors, or on the part of the inventors being added.

CONCLUSION

For the reasons noted above, Applicants respectfully request that co-inventors **Dr. Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert** be added as inventors in the present application. Applicants also request that a corrected official Filing Receipt be issued.

The Commissioner is hereby authorized to charge the above-referenced fees of **$140.00** and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 22773-826.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: March 31, 2017

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

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

PTO/SB/01A (09-12)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

As the below named inventor(s), I/we declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 13/470,681

filed on May 14, 2012

☐ As amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. The above-identified application was made or authorized to be made by me/us.

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.

All statements made herein of my/our own knowledge are true, all statements made herein 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 are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon. 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), or both.

FULL NAME OF INVENTOR(S)

Inventor one: Chunhua Li Date: 3/30/17

Signature: _____ Citizen of: US

Inventor two: Yan Chen Date: 3/30/2017

Signature: _____ Citizen of: US

☒ Additional inventors or a legal representative are being named on two (2) additional form(s) attached hereto.

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

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

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Heinz	Pudleiner

Inventor's Signature: Heinz Pudleiner — Date: 04.03.2017

Residence: City	State	Country	Citizenship
Krefeld		DE	DE

Mailing Address: Bethelstr. 39

City	State	Zip	Country
Krefeld		47800	DE

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Klaus	Meyer

Inventor's Signature: Klaus Meyer — Date: 6.3.2017

Residence: City	State	Country	Citizenship
Dormagen		DE	DE

Mailing Address: Kamillenstr. 40

City	State	Zip	Country
Dormagen		41539	DE

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Joerg	Nickel

Inventor's Signature: Jörg Nickel — Date: 04.03.2017

Residence: City	State	Country	Citizenship
Dormagen		DE	DE

Mailing Address: Krokusweg 2

City	State	Zip	Country
Dormagen		41539	DE

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 21 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 (1-800-786-9199) and select option 2.

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Craig	Pehlert		
Inventor's Signature [signature]			Date 03/28/17
Lenox Residence City	MA State	US Country	US Citizenship
29 St Ann's Avenue Mailing Address			
Lenox City	MA State	01240 Zip	US Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

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 21 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 (1-800-786-9199) and select option 2

PTO/SB/14 (11-08)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.201
	Application Number	13/470,681
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.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Chunhua		Li	

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

City	Cupertino	State/Province	CA	Country of Residence	US

Citizenship under 37 CFR 1.41(b) US

Mailing Address of Applicant:

Address 1	19688 Vicksburg Dr.		
Address 2			
City	Cupertino	State/Province	CA
Postal Code	95014	Country	US

Applicant 2

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Yan		Chen	

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

City	Cupertino	State/Province	CA	Country of Residence	US

Citizenship under 37 CFR 1.41(b) US

Mailing Address of Applicant:

Address 1	10461 Pineville Ave.		
Address 2			
City	Cupertino	State/Province	CA
Postal Code	95014	Country	US

Applicant 3

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
Dr.	Heinz		Pudleiner	

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

City	Krefeld	Country Of Residence	DE

PTO/SB/14 (11-08)
Approved for use through 04/30/2017. OMB 0651-0032
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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.201
	Application Number	13/470,681
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

Citizenship under 37 CFR 1.41(b)	DE				
Mailing Address of Applicant:					
Address 1	Bethelstr. 39				
Address 2					
City	Krefeld	**State/Province**			
Postal Code	47800	**Country**	DE		

Applicant 4

Applicant Authority	(•) Inventor	( ) Legal Representative under 35 U.S.C. 117	( ) Party of Interest under 35 U.S.C. 118	
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**	DE		
Citizenship under 37 CFR 1.41(b)	DE				
Mailing Address of Applicant:					
Address 1	Kamillenstr. 40				
Address 2					
City	Dormagen	**State/Province**			
Postal Code	41539	**Country**	DE		

Applicant 5

Applicant Authority	(•) Inventor	( ) Legal Representative under 35 U.S.C. 117	( ) Party of Interest under 35 U.S.C. 118	
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**	DE		
Citizenship under 37 CFR 1.41(b)	DE				
Mailing Address of Applicant:					
Address 1	Krokusweg 2				
Address 2					
City	Dormagen	**State/Province**			
Postal Code	41539	**Country**	DE		

Applicant 6

Applicant Authority	(•) Inventor	( ) Legal Representative under 35 U.S.C. 117	( ) Party of Interest under 35 U.S.C. 118	
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
Citizenship under 37 CFR 1.41(b)	US				

PTO/SB/14 (11-08)
Approved for use through 04/30/2017. OMB 0651-0032
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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	22773-826.201
	Application Number	13/470,681
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

Mailing Address of Applicant:			
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	22773-826.201	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	8	**Suggested Figure for Publication (if any)**	2

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).
Enter either 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		

PTO/SB/14 (11-08)
Approved for use through 04/30/2017. OMB 0651-0032
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	22773-826.201
	Application Number	13/470,681
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. 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(a).

Remove

Application Number	Country[i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			○ Yes ◉ No

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

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1

If the Assignee is an Organization check here. ☒

Organization Name	Align Technology, Inc.		
Mailing Address Information:			
Address 1	2560 Orchard Parkway		
Address 2			
City	San Jose	**State/Province**	CA
Country[i]	US	Postal Code	95131
Phone Number		Fax Number	
Email Address			

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

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Charles C. Hagadorn, III/	Date (YYYY-MM-DD)	2017-03-31

PTO/SB/14 (11-08)
Approved for use through 04/30/2017. OMB 0651-0032
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	22773-826.201
	Application Number	13/470,681
Title of Invention	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	

First Name	Charles C.	Last Name	Hagadorn, III	Registration Number	62367

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 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 Acknowledgement Receipt

EFS ID:	28805426
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
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/Danielle Hoffman
Filer Authorized By:	Charles C. Hagadorn III
Attorney Docket Number:	22773-826.201
Receipt Date:	31-MAR-2017
Filing Date:	14-MAY-2012
Time Stamp:	17:29:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$140
RAM confirmation Number	040317INTEFSW00004537232415
Deposit Account	232415
Authorized User	Charlie Hagadorn

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	Request under Rule 48 correcting inventorship	22773-826-201_Req_for_Corr_Inventorship_filed_03-31-17.pdf	28467 c1e0a1a0bc46123ef382ae2d9832e3ff6746befb	no	2
Warnings:					
Information:					
2	Oath or Declaration filed	22773-826-201_Declarations_filed_03-31-17.pdf	1918870 11660d510878c832bb31432bd751661895e14e36	no	3
Warnings:					
Information:					
3	Application Data Sheet	22773-826-201_Corr_ADS_filed_03-31-17.pdf	1785956 4db1901d13e51c77497821e3b61062302a6fcc6e	no	6
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
4	Request for Corrected Filing Receipt	22773-826-201_Req_for_Corr_FR_filed_03-31-17.pdf	22466 2f236ac306d5c7e84e7353362f4b9060fa65d7f6	no	2
Warnings:					
Information:					
5	Request for Corrected Filing Receipt	22773-826-201_Filing_Receipt_filed_03-31-17.pdf	576303 26d52f71b86cfb58257f326a00d0f270d6518e6d	no	3
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30329 81d252d950bb1924a34e105725d834e260c6c1b3	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	4362391

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.

Electronic Patent Application Fee Transmittal

Application Number:	13470681
Filing Date:	14-May-2012
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Filer:	Charles C. Hagadorn III/Danielle Hoffman
Attorney Docket Number:	22773-826.201

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:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**140**

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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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/470,681	05/14/2012	3732	1920	22773-826.201 (022900US)	29	3

CONFIRMATION NO. 5655

UPDATED FILING RECEIPT

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

OC000000055532754

Date Mailed: 07/23/2012

Chunhua Li, Cupertinio CA;
Yan Chen, Cupertino, CA;
Dr. Heinz Pudleiner, Krefeld, GERMANY;
Klaus Meyer, Dormagen, GERMANY;
Joerg Nickel, Dormagen, GERMANY;
Craig Pehlert, Lenox, MA;

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**

Applicant(s)

~~Chunhua Li, Cupertino, CA;~~
~~Yan Chen, Cupertino, CA;~~

Assignment For Published Patent Application

Align Technology, Inc., San Jose, CA

Power of Attorney: The patent practitioners associated with Customer Number 107046

Domestic Priority data as claimed by applicant

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 05/24/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/470,681**

Projected Publication Date: 11/14/2013

Non-Publication Request: No

Early Publication Request: No

ClearCorrect Exhibit 1010, Page 1400 of 1447

Title

MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS

Preliminary Class

433

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 (1-866-999-4158).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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ClearCorrect Exhibit 1010, Page 1401 of 1447

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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NOT GRANTED

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Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 04/04/2017

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01 FC : 1819 600.00 DA

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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/470,681	05/14/2012	3732	1920	22773-826.201	29	3

CONFIRMATION NO. 5655

UPDATED FILING RECEIPT

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

OC000000090385182

Date Mailed: 04/11/2017

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)

Chunhua Li, Cupertino, CA;
Yan Chen, Cupertino, CA;
Heinz Pudleiner, Krefeld, GERMANY;
Klaus Meyer, Dormagen, GERMANY;
Joerg Nickel, Dormagen, GERMANY;
Craig Pehlert, Lenox, MA;

Assignment For Published Patent Application

Align Technology, Inc., San Jose, CA

Power of Attorney: The patent practitioners associated with Customer Number 107046

Domestic Applications for which benefit is claimed - None.
A proper domestic benefit claim must be provided in an Application Data Sheet in order to constitute a claim for domestic benefit. See 37 CFR 1.76 and 1.78.

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: No

Permission to Access Search Results: No

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:

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/470,681**

Projected Publication Date: Not Applicable

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:

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

NOT GRANTED

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

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community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/470,681	05/14/2012	Chunhua Li	22773-826.201

CONFIRMATION NO. 5655

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

37 CFR 1.48 ACKNOWLEDGEMENT LETTER

OC000000090385183

Date Mailed: 04/11/2017

NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(a)

This is in response to the applicant's request under 37 CFR 1.48(a) submitted on 03/31/2017.

The request under 37 CFR 1.48(a) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

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**.

/mmasfaw/

Electronic Acknowledgement Receipt

EFS ID:	28934761
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
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:	22773-826.201
Receipt Date:	14-APR-2017
Filing Date:	14-MAY-2012
Time Stamp:	17:40:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$960
RAM confirmation Number	041717INTEFSW00003565232415
Deposit Account	232415
Authorized User	Charlie Hagadorn

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	Issue Fee Payment (PTO-85B)	22773-826-201_IssueFeeTransmittal.pdf	208247 3151ab37a5798dbc855e975230513a091d90db8d	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30417 f90db4e8ed65c1cc994f2d14e828ebe9d36b818e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	238664		

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.

Electronic Patent Application Fee Transmittal

Application Number:	13470681
Filing Date:	14-May-2012
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:	22773-826.201

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	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (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 01/18/2017
WSGR / Align Technology , Inc.
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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Kevin J. Chance	(Depositor's name)
/Kevin J. Chance/	(Signature)
April 14, 2017	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/14/2012	Chunhua Li	22773-826.201	5655

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	$960	$0	$0	$960	04/18/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MAI, HAO D	3732	433-006000

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 03-02 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 Goodrich & Rosati
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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 23-2415 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
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.
☐ Applicant asserting small entity status. See 37 CFR 1.27
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.
☐ Applicant changing to regular undiscounted fee 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 /Charles Hagadorn, III/ Date April 14, 2017
Typed or printed name Charles Hagadorn, III Registration No. 62,367

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

ClearCorrect Exhibit 1010, Page 1413 of 1447

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/470,681	05/23/2017	9655691	22773-826.201	5655

107046 7590 05/03/2017

WSGR / Align Technology , Inc.
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 220 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;
Yan Chen, Cupertino, CA;
Heinz Pudleiner, Krefeld, GERMANY;
Klaus Meyer, Dormagen, GERMANY;
Joerg Nickel, Dormagen, GERMANY;
Craig Pehlert, Lenox, MA;

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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 _____August 8, 2017_____

WILSON SONSINI GOODRICH & ROSATI

By:_____/Hillary Pratt/_____

PATENT
Attorney Docket No.: 22773-826.201
Align Reference No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Patent Application of: Chunhua Li et al. Applicant: Patent No.: 9,655,691 Issue Date: May 23, 2017 Serial No.: 13/470,681 Filed: May 14, 2012 Title: MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS	Group Art Unit: 3732 Examiner: Hao D. Mai Confirmation No.: 5655

REQUEST FOR CERTIFICATE OF CORRECTION OF THE ISSUED PATENT FOR OFFICE MISTAKE (37 CFR §1.322)

Commissioner for Patents
Office of Patent Publication
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

It is noted that errors of a clerical nature appear in this patent due to mistakes on the part of the Office, as more fully described below. The Patentee believes that correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination of the patent. A certificate of correction is therefore requested. Attached hereto is Form PTO/SB/44 which is suitable for printing.

The errors and reasons for which correction is requested is located at:

Column 10, line 24 at Claim 12: Please delete the period in "70° C." to read: "70° C"

Column 10, line 41, Claim 14: Please delete the period in "70° C." to read: "70° C"

Column 12, line 1, Claim 23: Please delete the period in "70° C." to read: "70° C"

Column 12, line 18, Claim 25: Please delete the period in "70° C." to read: "70° C"

Column 12, line 37, Claim 28: Please delete the period in "70° C." to read: "70° C"

The term "70° C" was correctly listed on the Claims provided with the Response to Non-Final Office Action filed November 22, 2016, a copy of which is attached hereto. Accordingly, Patentee believes the error is attributable to the Patent Office. No fees are required for the submission of this Request.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees, or credit any overpayment to Deposit Account No. 23-2415 (Docket No. 22773-826.201).

Respectfully submitted,

/Charles C. Hagadorn, III/

Dated: August 7, 2017

Charles C. Hagadorn, III
Registration No. 62,367

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
Tel.: (206) 883-2500
Customer No. 107046

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on November 22, 2016

WILSON SONSINI GOODRICH & ROSATI

By: /William D. Tronvig/

Attorney Docket No.: 22773-826.201
Client Ref. No.: 1228.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 5655
Chunhua Li et al.	
Application No.: 13/470,681	Examiner: Hao D. Mai
Filed: May 14, 2012	Art Unit: 3732
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 June 22, 2016, please enter the following amendments and remarks. The fee for a Petition for Extension of Time of 2 months accompanies this response.

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

Remarks begin on page 10 of this paper.

Electronic Acknowledgement Receipt

EFS ID:	27595146
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
Title of Invention:	MULTILAYER DENTAL APPLIANCES AND RELATED METHODS AND SYSTEMS
First Named Inventor/Applicant Name:	Chunhua Li
Customer Number:	107046
Filer:	Melissa Mitchell Harwood/William Tronvig
Filer Authorized By:	Melissa Mitchell Harwood
Attorney Docket Number:	22773-826.201
Receipt Date:	22-NOV-2016
Filing Date:	14-MAY-2012
Time Stamp:	19:32:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$600
RAM confirmation Number	112316INTEFSW00007121232415
Deposit Account	232415
Authorized User	Melissa Harwood

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		2016_11_22_AMD_DEC_22773_826_201.pdf	1181392 ded372202e74a4b479ae09c5fc6d580a11291f99	yes	31

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Affidavit-traversing rejectns or objectns rule 132	21	31
	Applicant Arguments/Remarks Made in an Amendment	10	20
	Claims	2	9
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30818 20067b96e144cf4916437036071dcb3a96c752f2	no	2

Warnings:

Information:

Total Files Size (in bytes):	1212210

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 1-19 and 30-41 will be pending in the present application. No claims have been amended. New claims 38-41 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.

Examiner Interview

Applicants thank Examiners Mai and Rodriguez for participating in an in-person interview on October 26, 2016. Additional participants in the interview included Applicants' representatives, Melissa Harwood and Esther Kepplinger, as well as Arthur Hsieh and Chunhua Li. The Examiner's rejections of the claims made in a Non-Final Office Action mailed on June 22, 2016, and the submission of a declaration demonstrating the unexpected results of the present invention were discussed.

Claim Rejections – 35 U.S.C. § 103

Claims 1-5, 9-15, 18-19, 30-32, and 34-36 stand rejected under pre-AIA 35 U.S.C. § 103(a) as allegedly being obvious over US 2009/0246724 (hereinafter "Chen") in view of US 7,641,828 (hereinafter "DeSimone"), and further in view of US 4,791,156 (hereinafter "Hostettler") as evidenced by Boedeker.com, "Polycarbonate specifications" (hereinafter "Boedeker") and plastics.ides.com/generics/57/c/t/polyurethane-thermoset-elastomer-tsu-properties-processing (hereinafter "Plastics").

In particular, with regard to the hard inner layer, the Examiner asserts that although "Chen fails to disclose the hard inner polymer layer comprising a co-polyester," that it "would have been obvious to one of ordinary skill in the art at the time of invention to utilize the materials taught by DeSimone to form Chen's hard layer since DeSimone teaches that such materials are suitable for the intended use of such hard layer with predictable results and/or reasonable expectation of success." Office Action at 3-4. With regard to the soft outer layer, the

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Examiner asserts that "Chen also discloses that it is well known to use thermoplastic polyurethane for such appliance." *Id.* at 4.

Applicants respectfully disagree with the Examiner's assertions at least because (1) the cited references provide no reason to select a polymer of DeSimone for use in Chen; (2) 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 the presently claimed orthodontic appliances; (3) the presently claimed orthodontic appliances were found to exhibit unexpectedly good results when compared with the most relevant art; and (4) the presently claimed orthodontic appliances gave rise to considerable commercial success. These positions are supported by the present specification and further supported by the attached November 21, 2016 Declaration under 37 C.F.R. § 1.132 of Dr. Chunhua Li ("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 of appliances comprising material according to the present claims, which is referred to herein as ST30—a material that has soft outer layers comprising a thermoplastic polyurethane elastomer and a hard inner layer comprising a co-polyester—to the prior art, including a thermoplastic polyurethane referred to as EX30, which was the standard of care prior to the release of ST30.

1. Obvious to Try Rejection—The Examiner Provides No Reason Why the Skilled Artisan Would Select a Polymer of DeSimone for use in Chen

Independent claims 1 and 13 stand rejected over Chen, DeSimone, and Hostettler, as evidenced by Boedeker and Plastics. Office Action at 2. Of these, Hostettler, Boedeker, and Plastics are unrelated to orthodontic, tooth-moving appliances (e.g., Hostettler relates to dentures), and are used only in relation to flexural modulus and hardness. With regard to Chen and DeSimone, the Examiner proposes a combination of three different embodiments: the EX30 thermoplastic polyurethane appliance of Chen paragraph [0003], the multilayer polycarbonate/PVC material of Chen paragraph [0032], and the co-polyester mentioned in column 5, line 66 of DeSimone. Each embodiment provides only one element of the proposed combination. Moreover, the Examiner fails to identify any reason why one of ordinary skill

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would have selected these elements in combination with one another and the cited references themselves fail to provide such guidance.

The Examiner improperly relies on Chen for teaching the use of a thermoplastic polyurethane elastomer as a soft outer layer, however, Chen does not teach the use of a thermoplastic polyurethane elastomer as a soft outer layer. Chen refers to thermoplastic polyurethane only in paragraph [0003], discussing the existence of dental appliances consisting of polymers such as thermoplastic polyurethane. No mention of layered materials is made in reference to thermoplastic polyurethane elastomer. Neither of the other two paragraphs cited to in Chen (i.e., paragraphs [0032] and [0036]) discusses the use of a thermoplastic polyurethane elastomer in a soft (or other) layer. Nor does Chen describe this elsewhere. Thus, contrary to the Examiner's assertions, Chen fails to disclose the use of a thermoplastic polyurethane elastomer as a soft outer layer.

The Examiner improperly uses an "obvious to try" approach and fails to provide any reason why one of ordinary skill in the art would select a co-polyester material from DeSimone for use in the multi-layer material of Chen. In fact, DeSimone lists hundreds of materials, from which the Examiner points to a single reference of "co-polyester." (DeSimone, col. 5). Notably, neither Chen nor DeSimone provide any sort of guidance suggesting why one might select any one of these numerous materials of DeSimone over any other disclosed material. The references do not provide a finite number of identified, predictable solutions to the problem and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success. The obvious to try rationale is improper when what would have been obvious to try would have been to vary all parameters and try each of numerous possible choices until one possibly arrived at a successful result and where the prior art gave no indication of which parameters were critical or no direction as to of which of many possible choices is likely to be successful. *In re Kubin* (Fed. Cir. 2009). There is no guidance in the references about which of many choices might be successful. There is no indication that the hard layers described in DeSimone would have the properties recited in Chen nor any other basis for selecting them from the list of hundreds of materials. In the absence of any such guidance, the

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selection of the co-polyester material from DeSimone for use in Chen represents nothing more than an "obvious to try" rationale or impermissible hindsight bias.

2. No 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 presently claimed orthodontic appliances 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 multi-layer 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"), which is a product according to the instant claims comprising a layered material with a hard co-polyester layer between two soft layers of thermoplastic polyurethane elastomer. 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 of the present claims met Align's criteria for a multi-layer orthodontic appliance. *Id.* at ¶¶4-5. The tested materials included many multi-layer (e.g., three-layer) materials, yet of those tested only the materials of 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 ¶6.

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 presently claimed orthodontic appliances. Li Declaration at ¶7. As mentioned above, the

presently claimed multi-layer, 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 of the instant claims met Align's development criteria. *Id.* at 5. It was not a simple or predictable process to identify those materials that would work together to create the multi-layer 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 sufficient modulus of elasticity, 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 a suitable material. 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 presently claimed orthodontic appliances. 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 presently claimed orthodontic appliances. 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 polymers for use in the claimed multi-layer orthodontic appliances. *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 presently claimed orthodontic appliances based on the teachings of Chen, DeSimone and Hostettler. *Id.* at ¶10.

During the course of their evaluations, Applicants determined that merely combining the materials into multiple layers was insufficient to improve performance relative to the EX30 material. *Id.* at ¶6-7. In fact, many three-layer materials tested proved inferior to the EX30 material. These three-layer materials included combinations of materials disclosed in Chen and/or DeSimone. *Id.* In particular, the sole exemplified multi-layer 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 multi-layer configuration, would be inferior to EX30. *Id.* 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.

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 described in the present claims. *Id.* at ¶¶7-10.

3. Unexpected Results

Applicants have also established that the presently claimed appliances 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, called ST30, that has soft outer layers comprising a thermoplastic polyurethane elastomer and a hard inner layer comprising a co-polyester. Li Declaration at ¶¶11-16.

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As described in the Li Declaration, each study found that ST30 appliances provided strongly superior performance. 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 ¶¶13-14. 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 ¶15, Appendix B. Overall, patients treated with ST30 appliances showed a 75% improvement in tooth movement predictability over patients treated with EX30 appliances. *Id.* at ¶16. This surprising improvement would not have been predicted by a person of ordinary skill in the art. *Id.*

The unexpected results described above are commensurate in scope with independent claims 1, 13, and 38. Each claim describes orthodontic appliances with a hard co-polyester layer between soft layers of thermoplastic polyurethane elastomer. This corresponds to the material tested in the studies, ST30. Li Declaration at ¶¶4, 11. Accordingly, the unexpected results demonstrated by the studies, as described in the Li Declaration, correspond to the present claims.

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 as of the present filing date, and a person of ordinary skill would have considered it the closest relevant art. Thus, the skilled artisan would consider the superiority of the presently claimed orthodontic appliances relative to EX30 to be predictive of similar superiority of ST30 relative to other prior art appliances. Li Declaration at ¶16. During the course of Applicants' evaluations, they determined that merely combining the materials into multiple layers was insufficient to improve performance relative to the EX30 material. *Id.* at ¶6 In fact, many three-layer materials tested proved inferior to the EX30 material. *Id.* Based on these evaluations, none of these inferior multi-layer 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 was superior to many three-layer 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**.

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 presently claimed appliances produce unexpectedly positive results relative to the closest relevant art.

4. 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 ¶18. 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, Baird Q3 2013 Report at 9 (submitted herewith in an accompanying IDS). This striking commercial success was due to the superior performance of ST30 appliances to EX30 and other appliances on the market. Li Declaration at ¶¶18-19.

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 as disclosed and claimed, 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 herewith in an accompanying IDS). 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.

Independent claims 1, 13, and 38 are not obvious over the combination of Chen, DeSimone, and Hostettler, as evidenced by Boedeker, and Plastics for at least the reasons described above. Claims 2-5, 9-15, 19, 30-32, 34-36, and 39-41 depend from claims 1, 13, and 38 respectively, 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 1-5, 9-15, 18-19, 30-32, and 34-36 under pre-AIA 35 U.S.C. § 103(a) is respectfully requested.

Claims 6-8, 16-17, 33, and 37 stand rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chen in view of DeSimone and Hostettler, as applied to claims 1 and 13 above, and further in view of U.S. Pub. No. 2010/0055639 (hereinafter "Lewis").

Lewis fails to remedy the deficiencies of Chen, DeSimone, and Hostettler as described above. Accordingly, as claims 6-8, 16-17, 33, and 37 depend respectively from allowable claims 1 and 13, they are allowable for similar reasons, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claims 6-8, 16-17, 33, and 37 under pre-AIA 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: November 22, 2016

/Melissa M. Harwood/

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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. (Previously Presented) A removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of a patient's teeth and apply a resilient positioning force to the patient's teeth, the appliance comprising:

a hard inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn.

2. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises a blend of polymeric materials including the co-polyester and one or more of: a polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate, or a combination thereof.

3. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises a plurality of co-extruded or laminated polymer layers.

4. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises at least two layers including a first layer comprising the co-polyester and a second layer comprising one or more of: a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

5. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer has a thickness in a range from 400 μm to 1100 μm.

6. (Previously Presented) The appliance of claim 1, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

7. (Previously Presented) The appliance of claim 1, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a thermoplastic co-polyester elastomer, or a polyester elastomer.

8. (Previously Presented) The appliance of claim 1, wherein at least one of the first soft outer polymer layer and the second soft outer polymer layer comprises at least two layers including a first layer comprising the thermoplastic polyurethane elastomer and a second layer selected from the group consisting of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

9. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each have a thickness in a range from 35 μm to 80 μm.

10. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer, the first soft outer polymer layer, and the second soft outer polymer layer combined have a thickness of 500 μm to 1200 μm.

11. (Previously Presented) The appliance of claim 1, wherein the hard inner 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%, or a light transmission between 400 nm and 800 nm of greater than about 75%.

12. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each independently comprise at least one of: 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, or a light transmission between 400 nm and 800 nm of greater than about 75%.

13. (Previously Presented) 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 inner polymer layer comprising a co-polyester and having a hard polymer layer elastic modulus; and

a first soft outer polymer layer and a second soft outer polymer layer each comprising a thermoplastic polyurethane elastomer and each having a soft polymer elastic modulus less than the hard polymer layer elastic modulus, a flexural modulus of greater than about 35,000 psi, a hardness of about 60A to about 85D, and a thickness in a range from 25 μm to 100 μm,

wherein the hard inner polymer layer is disposed between the first soft outer polymer layer and the second soft outer polymer layer so as to reduce degradation of the resilient positioning force applied to the teeth when the appliance is worn.

14. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises a blend of polymeric materials including the co-polyester and one or more of: a polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, or a polytrimethylene terephthalate.

15. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises at least two layers including a first layer comprising the co-polyester and a second layer selected from the group consisting of: a polyester, a co-polyester, a thermoplastic polyurethane, a polypropylene, a polyethylene, an acrylic, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate.

16. (Previously Presented) The orthodontic system of claim 13, wherein each of the first soft outer polymer layer and the second soft outer polymer layer comprises a blend of polymeric materials including the thermoplastic polyurethane elastomer and one or more of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic

vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof.

17. (Previously Presented) The orthodontic system of claim 13, wherein at least one of the first soft outer polymer layer and the second soft outer polymer layer comprises at least two layers including a first layer comprising the thermoplastic polyurethane elastomer and a second layer selected from the group consisting of: a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

18. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner 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%, or a light transmission between 400 nm and 800 nm of greater than about 75%.

19. (Previously Presented) The orthodontic system of claim 13, wherein the first soft outer polymer layer and the second soft outer polymer layer each independently comprise at least one of: 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, or a light transmission between 400 nm and 800 nm of greater than about 75%.

20.-29. (Canceled)

30. (Previously Presented) The appliance of claim 1, wherein the hard inner polymer layer comprises a tensile strength at yield of between about 4000 pounds per square

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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%.

31. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer and the second soft outer polymer layer each comprise 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, and a light transmission between 400 nm and 800 nm of greater than about 75%.

32. (Previously Presented) The appliance of claim 1, wherein one or more of the first soft outer polymer layer or the second soft outer polymer layer comprise a plurality of polymer layers.

33. (Previously Presented) The appliance of claim 1, wherein the first soft outer polymer layer comprises a different material than the second soft outer polymer layer.

34. (Previously Presented) The orthodontic system of claim 13, wherein the hard inner polymer layer comprises 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%.

35. (Previously Presented) The orthodontic system of claim 13, wherein the first soft outer polymer layer and the second soft outer polymer layer each comprise 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, and a light transmission between 400 nm and 800 nm of greater than about 75%.

36. (Previously Presented) The orthodontic system of claim 13, wherein one or more of the first soft outer polymer layer or the second soft outer polymer layer comprise a plurality of polymer layers.

37. (Previously Presented) The orthodontic system of claim 13, wherein the first soft outer polymer layer comprises a different material than the second soft outer polymer layer.

38. (New) An orthodontic appliance for repositioning a patient's teeth, the appliance comprising:

a shell having a plurality of teeth receiving cavities shaped to apply a repositioning force to the patient's teeth, wherein the shell is formed from a multilayer material configured to reduce degradation of the repositioning force over time when the shell is worn on the patient's teeth, the multilayer material comprising:

a first soft polymer layer and a second soft polymer layer each having a compression set greater than 40% after 2 hours at 70 ºC, wherein the first and second soft polymer layers each comprise a thermoplastic polyurethane elastomer; and

a single hard polymer layer disposed between the first and second soft polymer layers and having a stress relaxation greater than 10% at 24 hour testing between 90% to 100% humidity, wherein the single hard polymer layer comprises a co-polyester.

39. (New) A plurality of orthodontic appliances as in claim 38, wherein the teeth receiving cavities of each of the plurality of orthodontic appliances are configured to move the patient's teeth along a path from a starting position to a final position when the plurality of

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orthodontic appliances is worn in succession, each appliance of the plurality of orthodontic appliances providing an incremental movement along said path.

40. (New) The orthodontic appliance of claim 38, wherein the shell consists essentially of the multilayer material.

41. (New) The orthodontic appliance of claim 40, wherein the first and second soft polymer layers each consists essentially of the thermoplastic polyurethane elastomer, and the single hard polymer layer consists essentially of the co-polyester.

Electronic Acknowledgement Receipt

EFS ID:	30015158
Application Number:	13470681
International Application Number:	
Confirmation Number:	5655
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/Hillary Pratt
Filer Authorized By:	Charles C. Hagadorn III
Attorney Docket Number:	22773-826.201
Receipt Date:	08-AUG-2017
Filing Date:	14-MAY-2012
Time Stamp:	13:07:44
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	Request for Certificate of Correction	Request.pdf	8524 cfd38f1311a68157d245ab4bedc3897b0595e3fc	no	2

Warnings:

Information:					
2	Request for Certificate of Correction	Pg1.pdf	153765 e31dc8746b163bafea11ab38163c7f1282ea7e05	no	2
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3	Request for Certificate of Correction	SecondPage.pdf	153663 80d2521ce55752cbddf8d36b403d79ea12439df2	no	2
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,655,691

APPLICATION NO.: 13/470,681

ISSUE DATE : May 23, 2017

INVENTOR(S) : Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 10, line 24, at Claim 12:

Please delete the period in "70° C." to read:

-- 70° C --

Column 10, line 41, at Claim 14:

Please delete the period in "70° C." to read:

-- 70° C --

Column 12, line 1, at Claim 23:

Please delete the period in "70° C." to read:

-- 70° C --

Column 12, line 18, Claim 25:

Please delete the period in "70° C." to read:

-- 70° C --

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, California 94304-1050

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. 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 1.0 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: Attention Certificate of Corrections Branch, 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.

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.

PTO/SB/44 (09-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,655,691

APPLICATION NO.: 13/470,681

ISSUE DATE : May 23, 2017

INVENTOR(S) : Chunhua Li, Yan Chen, Heinz Pudleiner, Klaus Meyer, Joerg Nickel, and Craig Pehlert

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 12, line 37, at Claim 28:

Please delete the period in "70° C." to read:

-- 70° C --

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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.
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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.

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107046 e 2017-08-25

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

Paper No.

Application No.:	**13/470,681**	**Date Mailed:**	**2017-08-25** **ELECTRONIC**
First Named Inventor:	Chunhua Li	Examiner:	MAI, HAO D
Attorney Docket No.:	22773-826.201	Art Unit:	3732
Confirmation No.:	5655	Filing Date:	05/14/2012

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

Commissioner for Patents

PTO-90c (Rev.08-06)

Response to the Request for Certificate of Correction	Patent No. 9655691	Applicant(s) LI ET AL.
	Issue Date 23 May, 2017	Docket No. 22773-826.201

This is in response to the request for a Certificate of Correction filed 08 August, 2017

☒ **Request Denied** – Consideration has been given to your request for the issuance of a Certificate of Correction under the provisions of 37 CFR 1.322 and/or 37 CFR 1.323. The Request is improper and denied for the reason(s) below:

1. ☐ Assignees' names and addresses (assignment data) printed in a patent, are based solely on information supplied in the appropriate space for identifying the assignment data on the Issue Fee Transmittal Form (PTOL-85b). Any request for a patent to be corrected to state the name of the assignee, must state that the assignment was submitted for recordation as set forth in in 37 CFR 3.11 before issuance of the patent. Petition under 3.81 is to be filed for consideration of correction to assignee. The petition fee set forth in 37 CFR 1.17(i)(1) (currently $140, $70, $35 for large, small and micro entities, respectively.

2. ☐ The alleged error in , is in fact an Amendment and/or Change made by the examiner and considered to be in accordance with the permissible amendments enumerated in the Manual of Patent Examining Procedure (MPEP) Section 1302.04. Applicant did not file objection or amendment under 37 CFR 1.312 prior to payment of the issue fee.

3. ☐ A petition under CFR 1.182 is required to correct the alleged errors in spelling or order of inventor's names, since inventor's names are printed solely in accordance with the type-written names, and in the order of the type-written names on the Application Data Sheet (ADS). The required fee currently under rule 1.17(f) (small entity $200, large entity $400, micro entity fee $100).

4. ☐ With respect to the alleged error in changing the inventor name on the patent due to clerical error in ADS/OATH of related patents. The inventor's name is printed in accordance with the OATH/ADS submitted at the time of filing the application. However, your attention is directed to C.F.R. 1.324, wherein a request is being made to change, add or delete inventor(s), after issuance of the patent.

5. ☐ With respect to the alleged error in , comparison of the printed patent with the corresponding location in the application file reveals that there is no discrepancy.

6. ☐ With respect to 37 CFR 1.72, the title should be brief but technically accurate and descriptive and should contain fewer than 500 characters. Inasmuch as the words "new," "improved," "improvement of," and "improvement in" are not considered as part of the title of an invention, these words should not be included at the beginning of the title of the invention and will be deleted when the Office enters the title into the Office's computer records, and when any patent issues.

7. ☐ The fee for correction under 37 CFR 1.323 is set forth in 37 CFR 1.20(a). ☐ Partial fee ☐ No fee was received with your request. Full fee payment is required before further action is taken on this request.

8. ☐ With respect to the request for corrected Letters Patent (Grant), corrections to the original Letters Patent are made under the provisions of Rule 1.322(b), not Rule1.323, unless a petition is granted.

9. ☒ Other Comments: Insertion of period after "C" is an editing change. According to USPTO Data Entry Manual, abbreviations for C" for Celsius/Centigrade and F" for Fahrenheit should never be deleted. If a period is not present after C or F, add a period. No correction is in order.

Further correspondence concerning this matter should be filed and directed to the Certificates of Correction Branch.

Legal Instrument Examiner: **/DEBORAH POLLARD/** Phone: (703)756-1955

Certificates of Correction Branch email: CustomerServiceCoC@uspto.gov CoC Central Phone Number: (703) 756-1814

If applicable, information regarding a petition under 37 CFR 1.183 should be directed to the attention of the Commissioner for Patents using the FAX number (571) 273-8300