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12 Attorneys for Plaintiffs
13 BITE TECH, INC. and CUSTMBITE LLC

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA

16 BITE TECH, INC.,
17 a Minnesota corporation, and
18 CUSTMBITE LLC,
19 a New Jersey limited liability corporation,

20 Plaintiffs,

21 v.

22 X2 IMPACT, INC.,
23 a Washington corporation,

24 Defendant.

25 C 12 5888
26 Case No.

27 COMPLAINT FOR DAMAGES AND
28 INJUNCTIVE RELIEF

DEMAND FOR JURY TRIAL

FILED
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CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
A

NC

1 Plaintiffs Bite Tech, Inc. ("Bite Tech") and CustMbite LLC ("CustMbite") (together,
2 "Plaintiffs") allege as follows:

3 PARTIES

4 1. Plaintiff Bite Tech is a Minnesota corporation with its principal place of business
5 at 20 Glover Avenue, Norwalk, Connecticut 06850. Bite Tech is qualified and duly authorized to
6 conduct business in the State of California.

7 2. Plaintiff CustMbite is a New Jersey limited liability corporation, with its principal
8 place of business at 10 Loughlin Ave., Cos Cob, Connecticut 06807.

9 3. On information and belief, Defendant X2 Impact, Inc. ("X2") is a Washington
10 corporation doing business in this judicial district, and has a principal place of business at 837 N.
11 34th St. Suite 210, Seattle, Washington 98103.

12 JURISDICTION AND VENUE

13 4. This is a civil action arising under the patent laws of the United States, 35 U.S.C.
14 §§ 1 *et seq.* This Court has jurisdiction over the subject matter of this action pursuant to
15 28 U.S.C. § 1331 and 1338(a).

16 5. Personal jurisdiction as to each defendant is proper in the State of California and in
17 this judicial district. Defendant maintains ongoing business activity in this State and in this
18 judicial district, including its provision and/or sale of X2 impact sensing mouthguards to
19 universities in Santa Clara County, and therefore have sufficient contacts with the State of
20 California to satisfy the requirements of due process and Rule 4(k)(2) of the Federal Rules of
21 Civil Procedure.

22 6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and
23 1400(b).

24 INTRADISTRICT ASSIGNMENT

25 7. Under Civil L. R. 3-2(c), this action shall be assigned on a district-wide basis,
26 notwithstanding the fact that a substantial part of the events that give rise to the claims alleged
27 herein occurred in Santa Clara County, in the San Jose Division of this Court.

28

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 7,950,394)

8. Plaintiffs reallege and incorporate by reference the allegations stated in paragraphs 1 through 6 of this Complaint.

9. CustMbite is the sole owner of U.S. Patent No. 7,950,394 (“the ‘394 Patent”), issued on May 31, 2011, titled “Mouthguard Formed of Propylene/alpha-olefin Polymer Elastomer.” A true and correct copy of the ‘394 Patent is attached as Exhibit A.

10. Bite Tech is the exclusive licensee of the ‘394 Patent, pursuant to the Purchase Agreement between Bite Tech and CustMbite dated November 4, 2011.

11. X2, by engaging in the unauthorized manufacture (or causing to be manufactured), use, sale and/or offer for sale of impact-sensing mouthguards (including, but not limited to the “X-Guard” mouthguard), has committed acts of direct infringement of the ‘394 Patent in violation of 35 U.S.C. § 271.

12. X2 has committed acts of contributory and/or inducement of infringement of Claim 1 of the ‘394 Patent by selling, supporting, and/or encouraging the infringing use of X2 impact sensing mouthguards by third parties. Such impact sensing mouthguard products are not staple articles or commodities suitable for non-infringing uses. On information and belief, X2 knew or should have known of the ‘394 Patent. These acts constitute violations of 35 U.S.C. § 271.

13. X2’s infringement of the ‘394 Patent is, has been, and continues to be willful and deliberate. Despite knowing of the ‘394 Patent, X2 has continued to directly and indirectly infringe one or more claims of the ‘394 Patent, entitling Plaintiffs to increased damages under 35 U.S.C. § 284 and to attorneys’ fees and expenses incurred in prosecuting this action under 35 U.S.C. § 285.

14. Such infringement has injured and damaged Plaintiffs. Unless enjoined by this Court, X2 will continue its infringement, irreparably injuring Plaintiffs.

15. As a direct and proximate result of X2’s infringement of the ‘394 Patent, Plaintiffs have been and continue to be damaged in an amount yet to be determined.

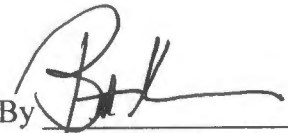
PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays that this Court enter judgment as follows:

- (A) Adjudicating and declaring that X2 has infringed, actively induced infringement of, and/or contributorily infringed the '394 Patent;
- (B) Preliminarily and permanently enjoining X2, its officers, agents, servants, employees, attorneys and all persons in active concert or participation with it from further infringement of the '394 Patent or, to the extent not so enjoined, ordering X2 to pay compulsory ongoing royalties for any continuing infringement of the '394 Patent;
- (C) Ordering that X2 account, and pay actual damages (but no less than a reasonable royalty), to Plaintiffs for X2's infringement of the '394 Patent;
- (D) Declaring that the X2 willfully infringed the '394 Patent and ordering that X2 pay treble damages to Plaintiffs as provided by 35 U.S.C. § 284;
- (E) Ordering that X2 pay Plaintiffs' costs, expenses, and interest, including prejudgment interest, as provided for by 35 U.S.C. § 284;
- (F) Declaring that this is an exceptional case and awarding Plaintiffs their attorneys' fees and expenses as provided for by 35 U.S.C. § 285;
- (G) Granting Plaintiffs such other and further relief as the Court deems just and appropriate, or that Plaintiffs may be entitled to as a matter of law or equity.

Dated: November 16, 2012

MORGAN, LEWIS & BOCKIUS LLP

By 
Brett M. Schuman
Attorneys for Plaintiffs

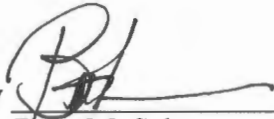
DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs hereby requests a trial by jury.

Dated: November 16, 2012

MORGAN, LEWIS & BOCKIUS LLP

By



Brett M. Schuman
Attorneys for Plaintiffs



US007950394B2

(12) **United States Patent**
Elkin et al.

(10) **Patent No.:** **US 7,950,394 B2**
(45) **Date of Patent:** **May 31, 2011**

(54) **MOUTHGUARD FORMED OF
PROPYLENE/ALPHA-OLEFIN POLYMER
ELASTOMER**

(76) Inventors: **Monroe Elkin**, New Brunswick, NJ
(US); **Manese Rabeony**, Piscataway, NJ
(US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 857 days.

(21) Appl. No.: **11/128,883**

(22) Filed: **May 13, 2005**

(65) **Prior Publication Data**

US 2005/0256276 A1 Nov. 17, 2005

Related U.S. Application Data

(60) Provisional application No. 60/571,325, filed on May
14, 2004, provisional application No. 60/579,539,
filed on Jun. 14, 2004.

(51) **Int. Cl.**
A61C 5/14 (2006.01)

(52) **U.S. Cl.** **128/861; 523/120**

(58) **Field of Classification Search** **128/861,**
128/859; 602/902; 206/63.5, 368; 523/120
See application file for complete search history.

(56) **References Cited**

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Primary Examiner — Patricia M Bianco

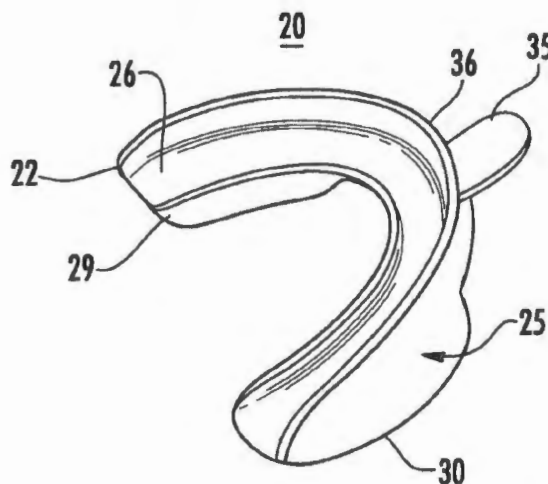
Assistant Examiner — Camtu T Nguyen

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Newman P.C.

(57) **ABSTRACT**

A self-customizable dental appliance adapted to lie within the
mouth of a person with a connecting arch or a u-shaped style
base with upstanding labial and lingual walls. The appliance
is formed of a semi-crystalline polypropylene alpha-olefin
copolymer containing stereoregular polymerized units of
identical tacticity. In one embodiment, the appliance is
formed of elastomeric propylene-ethylene copolymers.

1 Claim, 1 Drawing Sheet



U.S. Patent

May 31, 2011

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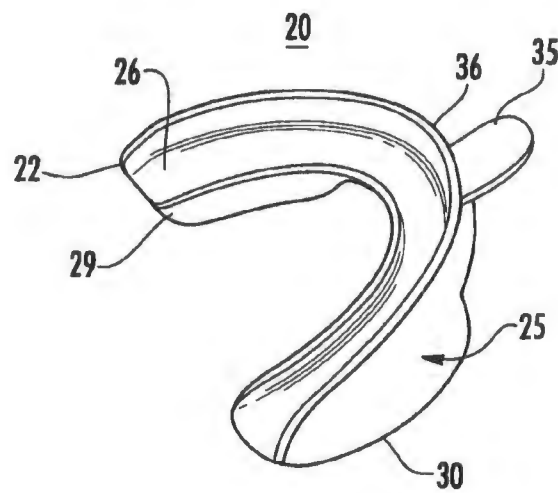
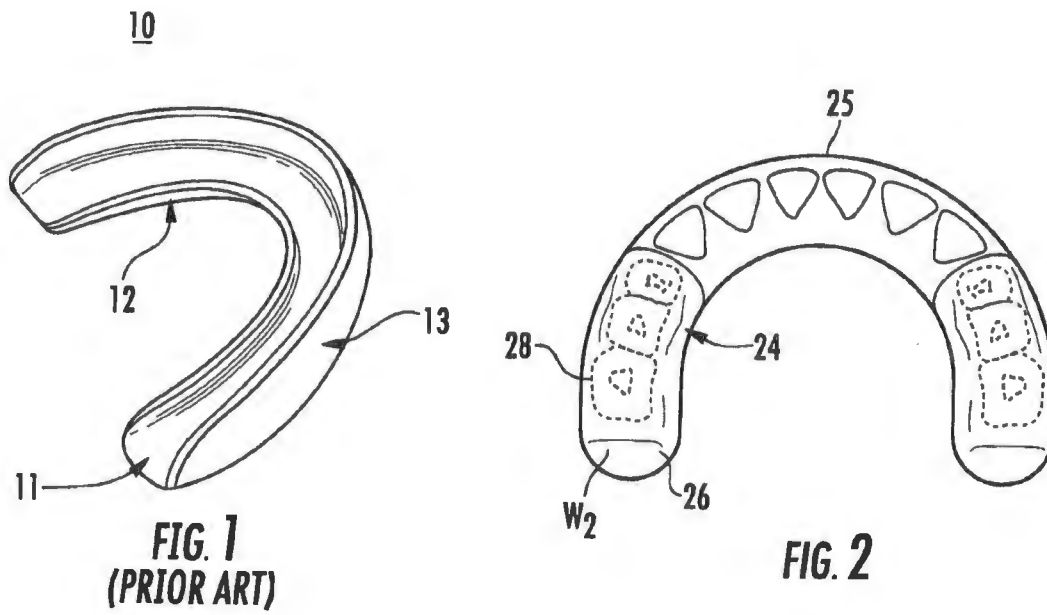


FIG. 3

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MOUTHGUARD FORMED OF PROPYLENE/ALPHA-OLEFIN POLYMER ELASTOMER

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application No. 60/571,325 filed May 14, 2004 the entirety of which is hereby incorporated by reference into this application and U.S. Provisional Patent Application No. 60/579,539 filed Jun. 14, 2004 the entirety of which is also hereby incorporated by reference into this application.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to athletic mouthguards and dental appliances, and specifically to self-customizable mouthguards and dental appliances.

2. Description of Related Art

It is known that mouthguards have been used to protect athletes in contact sports from injury to the teeth and also to protect the temporomandibular joint from destructive forces. Recent evidence also indicates that mouthguards may be beneficial in minimizing or preventing concussion. Performance of mouthguards is described in Elkin, M., Increased Athletic Performance using Mouthguards—True or False?, J. New Jersey Dental Assoc., 1996; Stenger, J. M., Mouthguards protection against shock to the head, neck and teeth, J. Am. Dental Assoc., 1964; Duda, M., Which Athletes Should Wear Mouthguards?, Phys. and Sports Med., 1987; and Hickey, J. C., The Relation of mouth protectors to cranial pressure and deformation, J. Am. Dental Assoc., 1967.

Athletes tend to clench their teeth upon exertion. This clenching creates considerable forces on the upper and lower jaws and can lead to damage to the teeth, headaches, neck pain and injury to the temporomandibular joint. Therefore, dental appliances and/or mouthguards have been created to place pads between the upper and lower dentition to prevent this clenching and possible damage to the teeth and other structures.

Historically, mouthguards have been made of ethylene vinyl acetate (EVA). Due to the user clenching and chewing on the appliance, it is subject to degradation. EVA is translucent or white and cannot be made clear. EVA also has a mild ester-like odor and will degrade to hazardous vinyl acetate, acetic acid, carbon monoxide and hazardous hydrocarbon oxidation products. While the mechanical and physical properties of EVA generally fulfill the safety requirements for a custom fitted mouthguard, attempts to mass-produce EVA as a Boil-and-Bite, "do-it-yourself" mouthguard have had limited success and acceptance (see Bishop, B. M., Davis, E. H., von Fraunhofer, J. A., "Materials for mouth protectors" *J. Prosthet. Dent.* 1985; 53:256-61 and Chalmers, D. J., "Mouthguards: Protection for mouth in the rugby union" *Sports Med.* 1998; 25(5):339-49; Winters, Sr., J. E. "Role of properly fitted mouthguards in prevention of sport-related Concussion" *J. Athletic Training* 2001; 36(3): 339-341). These mouthguards do not fit well and their poor retention plus their lack of proper extension into the buccal vestibule have led Park et al. to state unless dramatic improvements are made, they should not be promoted to customers as they are now (see Park, J. B., Shaull, K. L., Overton, B., Donly, K. I., "Improving mouthguard" *J. Prosthet. Dent.* 1994; 72: 373-80).

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Currently, commercially available mouthguards are (arbitrarily) classified as:

1. Stock over-the-counter—one size fits all. They must be held in place by clenching the teeth together—an obvious contraindication for continuous, vigorous sports requiring unobstructed airways.
2. Boil-and-Bite, mouth formed—these are placed in boiling water and then fitted into the mouth. When athletes attempt to fit these mouthguards, the resulting fit is often inadequate, loose and uncomfortable (see American Society for Testing and Materials. Standard practice for care and use of mouthguards (F 687-80). Reapproved 1992. Philadelphia (PA): American Society for Testing and Materials, 1992).

Attempts been made in engineering EVA for a better fit, comfort and protection; these include sophisticated multi-layer composites with a different softening temperature, custom gel fit liner, grip fit technology, or blending EVA with various polymers such as Kraton and polyurethane. (See Kitzels et al., "Quadruple composite performance enhancing mouthguard (U.S. Pat. No. 6,675,807); Wagner, E. C. "Custom fit mouthguard" (U.S. Pat. No. 5,566,684); Gel Max Shock Doctor's Mouthguard. www.shockdoc.com; Shock Doctor's 7001 V3.0 Mouthguard. www.shockdoc.com; Shock Doctor's V3 Mouthguard. www.shockdoc.com); and Brett et al., "Mouthguard and method of making" U.S. Pat. No. 6,584,978.). Despite these efforts, comfortable custom fitted mouthguards are still difficult to achieve and many athletic trainers and sports participants still prefer the custom-fabricated mouthguards, i.e. from dentist made study casts of the teeth. They are comfortable, fit better with good retention, and allow the user to breathe and speak more easily. Despite the cost, experts in the medical, dental and sports professions are still recommending the custom fitted mouthguard as the best choice and protection (see Chalmers, D. J., "Mouthguards: Protection for mouth in the rugby union" *Sports Med.* 1998; 25(5):339-49; Winters, Sr., J. E. "Role of properly fitted mouthguards in prevention of sport-related Concussion" *J. Athletic Training* 2001; 36(3): 339-341).

FIG. 1 illustrates a conventional noncustom mouthguard 10 which generally includes a horseshoe or u-shaped base or occlusal pad 11 with a lingual wall 12 and a labial wall 13.

U.S. Pat. No. 6,491,036 discloses a low density polyethylene dental appliance and mouthguard including a nucleating agent. A suitable material is EXACT® from ExxonMobil Chemical Company of Houston, Tex. 77253-3272. This material has ethylene crystallinity which produces a non-elastomeric material with little flexibility or no shrinkage.

There is a need for mouthguards and dental appliances of custom fit without the need to have it formed by a dentist. There is a need for self-customizing dental appliance or mouthguard which is aesthetic, offers protection for the teeth, exhibiting strong tensile strength, high impact properties, flexibility, and have little or no odor.

SUMMARY OF THE INVENTION

The present invention relates to a self-customizable dental appliance comprised of polyolefin-based thermoplastic elastomer. The dental appliance is securely adapted and fitted to the teeth for absorbing forces upon contact with the dental appliance. The dental appliance can have a horseshoe or u-shaped base with an occlusal pad and upstanding labial and lingual walls. A channel between the walls accommodates the teeth of a user. Optionally, the appliance can include a high density material. The use of a high-density material increases

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the crystalline temperature so that the self-customizable appliance will harden faster for a customized fit.

The self-customizable dental appliance of the present invention exhibits strong tensile strength, high impact properties, flexibility, and has little or no odor. The self-customizable appliance of the present invention can be made clear or colored for identification. The self-customizable appliance of the present invention is nonhazardous. The self-customizable appliance of the present invention can be easily molded by the user of the dental appliance. The self-customizable dental appliance has the advantages of (a) giving the user ample time, (for example, 2 to 3 minutes) to properly fit the mouthguard at a workable temperature below 60° C., during which the material must remain soft and elastic/extensible to conform the contour of the mouth and teeth; (b) providing shrink without any distortion once the mouthguard is comfortably in place; and (c) possessing a good balance of hardness, soft feel and shock absorbing power.

The invention will be more fully described by reference to the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a prior art mouthguard made of an elastomer and not designed for a custom fit.

FIG. 2 is a bottom plan view of the self-customizable dental appliance, mouthguard or splint placed on the upper teeth.

FIG. 3 is a perspective view of the custom fit dental appliance, mouthguard or splint which has been formed to fit the shape of the teeth and gums which has been formed with occlusal posterior pads and a connective arch.

DETAILED DESCRIPTION

Reference will now be made in greater detail to a preferred embodiment of the invention, an example of which is illustrated in the accompanying drawings. Wherever possible, the same reference numerals will be used throughout the drawings and the description to refer to the same or like parts.

FIGS. 2 through 3 illustrate dental appliance 20 in accordance with the teachings of the present invention. Dental appliance 20 can be formed as a mouthguard or dental splint. Dental appliance 20 is formed of base 22. Lingual wall 24 and buccal wall 25 extend from base 22. Channel 26 is formed between lingual wall 24 and buccal wall 25. Channel 26 has a width W, which is less than width W₂ of teeth 28. For example, channel 26 can have a width in the range of about 1 mm to about 12 mm.

Dental appliance 20 can include a layer of material to form occlusal lifting pad 30. Occlusal lifting pad 30 can have a height in the range of about 3 mm to about 4 mm. Occlusal lifting pad 30 is positioned between the maxilla and mandible adjacent to molars and/or bicuspsids for opening the bite of a user.

Dental appliance 20 is formed of a material which is self-customizable by a user of dental appliance 20. Dental appliance 20 can be formed of a semi-crystalline polyolefin polymer or polymer blend. Suitable polyolefin polymers include propylene-ethylene copolymer. The semi-crystalline polymer can be a thermoplastic polymer. The semi-crystalline polyolefin polymer can have low density. Suitable polymers for forming dental appliance 20 can include low density polypropylene. Optionally, a high density polypropylene can be used with the low density polyolefin.

Suitable polyolefin polymers include propylene-ethylene copolymers produced in the presence of a metallocene catalyst and activator as described in U.S. Pat. No. 6,525,157

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hereby incorporated by reference into this application. The copolymer can comprise about 5 to 25% by weight of ethylene-derived units and about 55 to 75% by weight of propylene derived units.

Suitable thermoplastic polymer blends comprise a composition formed of an isotactic polypropylene component and an alpha olefin and propylene copolymer, the copolymer comprising crystallizable alpha olefin sequences as described in U.S. Pat. No. 6,635,715 and U.S. Pat. No. 6,642,316 hereby each incorporated by reference into this application. The composition can be formed by blending at least a first polymer component and a second polymer component, the blend comprising: from about 2% to about 95% by weight of the first polymer component, the first polymer component comprising isotactic polypropylene and having a melting point greater than about 110° C., and copolymerizing propylene and ethylene using a chiral metallocene catalyst system, the copolymer having crystallinity from about 2% to about 65% from isotactic polypropylene sequences, a propylene content of from about 75% to about 90% by weight, a melting point of from 50° C. to 105° C., and wherein a glass transition temperature of the second polymer component is retained in the polymer blend. Alternatively, the polymer blend can be an uncrosslinked blend composition comprising a dispersed phase of a crystalline polymer component in a continuous phase of a crystallizable polymer component wherein: a) the crystalline polymer component is dispersed in phases less than 3 μm×3 μm×100 μm in size, b) the blend composition has greater than 65% propylene units by weight, c) the blend comprises greater than 1% but less than 40% by weight is based on the total weight of the blend of a crystalline first polymer component and less than 99% but greater than 60% by weight based on the total weight of the blend of a crystallizable second polymer component, such crystallinity being due to stereoregular polymerized propylene units, d) both first and second polymer component contain stereoregular polymerized propylene units of identical tacticity, e) the blend has a tensile elongation greater than 650%, wherein the first polymer component is a propylene homopolymer and has a melting point by DSC equal to or above 115° C., and the second polymer component is a copolymer of the propylene units and from about 8% to about 25% by weight ethylene units and has a melting point equal to or less than about 100° C.

A suitable material is Vistamaxx from ExxonMobil Chemical Company of Houston, Tex. 77253-3272.

Other polymers can be blended or laminated with the propylene-ethylene copolymer to provide enhanced properties. For example, suitable polymers can include elastomers, plasticizers, and rubber.

Colorants can be added to the propylene-ethylene copolymer to achieve a suitable aesthetic appearance. For example, the colorants can be clear. A suitable colorant is sold by Milliken Chemical under the trade designation CLEAR-INT® (Milliken Chemical Division of Milliken & Company (Spartanburg, S.C.)). Light reflective material can also be added or attached to the propylene-ethylene copolymer to achieve additional aesthetic appearance.

A method forming a self-customizable dental appliance comprises the steps of placing the dental appliance 20 in a hot medium. For example, after molding into dental appliance 20, the user simply places dental appliance 20 into a hot liquid, for example, dental appliance 20 can be placed into water having a temperature of about 60° C. to about 100° C. for a few seconds. The appliance is then removed and self-customized to the user's mouth, teeth and gums to provide a custom fit. Alternatively, dental appliance 20 can be placed in a wet paper towel and heated in a microwave oven. For example,

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dental appliance 20 can be heated for about 30 seconds to about 90 seconds in a microwave oven on a high setting. In one example, dental appliance 20 can be heated for about 60 seconds in a microwave on a high setting. Dental appliance 20 can be cooled for a short period of time, for example about 5 seconds. After placing dental appliance 20 in the mouth for customizing, dental appliance 20 can be left in the mouth until comfortable or placed in cold water for two minutes and returned to the mouth.

Dental appliance 20 can have a height of H, which is substantially the height of teeth 28, and after molding, dental appliance can be retained against teeth 28 due to the self-customizable fit.

Dental appliance 20 has improved shrinkage to product a custom fit in comparison with EVA mouthguards. Dental appliance 20 has increased overall fitting time in comparison with EVA mouthguards.

The following Example is illustrative of the present invention as described in the claims which follow thereafter:

Example

Dental appliance 20 was made from a thermoplastic polyolefin elastomer referred to as Vistamaxx™ which is manufactured by ExxonMobil Chemical. Table 1 compares the physical and mechanical property range of Vistamaxx with a mouthguard formed of EVA 28% vinyl acetate. The results show that the physical and mechanical properties match or surpass EVA. Dental appliance 20 provides a slower rate of crystallization or fitting time, i.e., the time interval before the material stiffens at body temperature. EVA hardens within 10 to 20 seconds. Any attempt to fit the mouthguard within this time interval results in an ill-fitted mouthguard with poor retention. Dental appliance 20 takes 2 to 3 minutes for the mouthguard to harden. This gives the user ample time to properly fit the mouthguard. During this time interval, the material remains soft and extensible. In addition, the high shrinkage of dental appliance 20 allows the mouthguard to shrink, giving a snug fit with excellent retention to the teeth and jaw within 5 minutes.

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TABLE I

Physical and Mechanical Properties	Dental Appliance 20	Conventional Mouthguard EVA (28% Vinyl acetate)
Density, g/cc	0.86-0.89	0.95
Melting Point° C.	55-160	70
Tensile Strength (psi)	2200-4500	2100
Die C Tear Strength (lb/in)	130-330	250
Elongation at Break (%)	100-1500	800
Flexural Modulus (psi)	1500-6500	2300
Hardness (Shore A)	50-90	80
Shrinkage to teeth	Excellent	Poor
Overall fitting time	2-3 minutes	10-20 seconds

It is to be understood that the foregoing description and specific embodiments are merely illustrative of the best mode of the invention and the principles thereof. Various modifications and additions may be made to the present invention by those skilled in the art without departing from the spirit and scope of this invention which is to be limited only by the scope of the appended claims.

What is claimed is:

1. A self-customizable mouthguard comprising one or more channels and an upstanding wall extending from said one or more channels having a u-shape formed of a semi-crystalline propylene ethylene copolymer comprising about 5% to about 25% by weight of ethylene-derived units and about 55% to about 95% by weight of propylene, wherein said semi-crystalline propylene ethylene copolymer is formed by copolymerizing propylene and ethylene using a chiral metallocene catalyst system, said semi-crystalline propylene-ethylene copolymer having crystallinity from about 2% to about 65% from polypropylene sequences, wherein said mouthguard is adapted to securely fit to teeth and wherein said mouthguard is configured to be molded by heating to a temperature of about 60° C. to about 100° C. and said mouthguard remains elastic/extensible at a workable temperature below 60° C. to conform said mouthguard to the contour of the mouth and teeth.

* * * * *