US00RE37382B1

(19) **United States**

(12) **Reissued Patent**

Yates

(10) **Patent Number: US RE37,382 E**

(45) **Date of Reissued Patent: Sep. 18, 2001**

(54) **GUM PAD FOR MUCOSAL DELIVERY OF MEDICATION**

(76) Inventor: **Alayne Yates**, 4176 Round Top Dr., Honolulu, HI (US) 96822

(21) Appl. No.: **09/208,875**

(22) Filed: **Dec. 10, 1998**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **5,741,500**
Issued: **Apr. 21, 1998**
Appl. No.: **08/680,135**
Filed: **Jul. 15, 1996**

(51) **Int. Cl.**[7] **A61K 9/70**

(52) **U.S. Cl.** **424/404**; 424/402; 424/426; 424/435; 424/444; 604/77; 128/848; 128/859

(58) **Field of Search** 424/402, 404, 424/426, 435, 444

(56) **References Cited**

U.S. PATENT DOCUMENTS

688,446		12/1901	Stempel	128/260
767,553		8/1904	Edgelow	128/260
1,622,616		3/1927	Temple	128/260
1,934,688		11/1933	Ackerman	32/1
3,386,440		6/1968	Cohen	128/268
3,416,527		12/1968	Hoef	128/260
3,444,858		5/1969	Russell	128/260
3,844,286		10/1974	Cowen	128/260
4,764,377		8/1988	Goodson	424/435
5,197,882		3/1993	Jernberg	433/215
5,326,685	*	7/1994	Gaglio	433/215
5,360,341		11/1994	Abramowitz	433/215
5,741,500	*	4/1998	Yates	424/404
5,762,952		6/1998	Barnhart	424/448
5,849,322		12/1998	Ebert et al.	424/435
5,874,095		2/1999	Deckner et al.	424/401

OTHER PUBLICATIONS

"Topical Application of Hydantoins in Gingival Disorders", by Savini et al., from *Phenytoin–Induced Teratology*, ed. Hassell et al., Raven Press, New York, 1980.

"Systemic Delivery of Therapeutic Peptides and Proteins", by Banga & Chien, from *Int'l. Jour. of Pharmaceutics*, Elsevier Press, 1988.

"Clinical Pharmacology Approaches . . . ", by Pollock et al., from *Jour. of Controlled Release*, Elsevier, 1990.

"Systemic Delivery . . . Across Absorptive Mucosae", by Syani & Chien, from *Critical Reviews . . . Drug Carrier Systems*, Begell House, Inc., 1996.

"Influence of the Buccal Application Site of a Bioadhesive . . . ", by Bouckaert, from *Int'l. Jour. of Pharmaceutics*, Elsevier, 1996.

"Application of a Local Drug Delivery System . . . ", by Minabe et al., from *Jour. of Periodontology*, 1989.

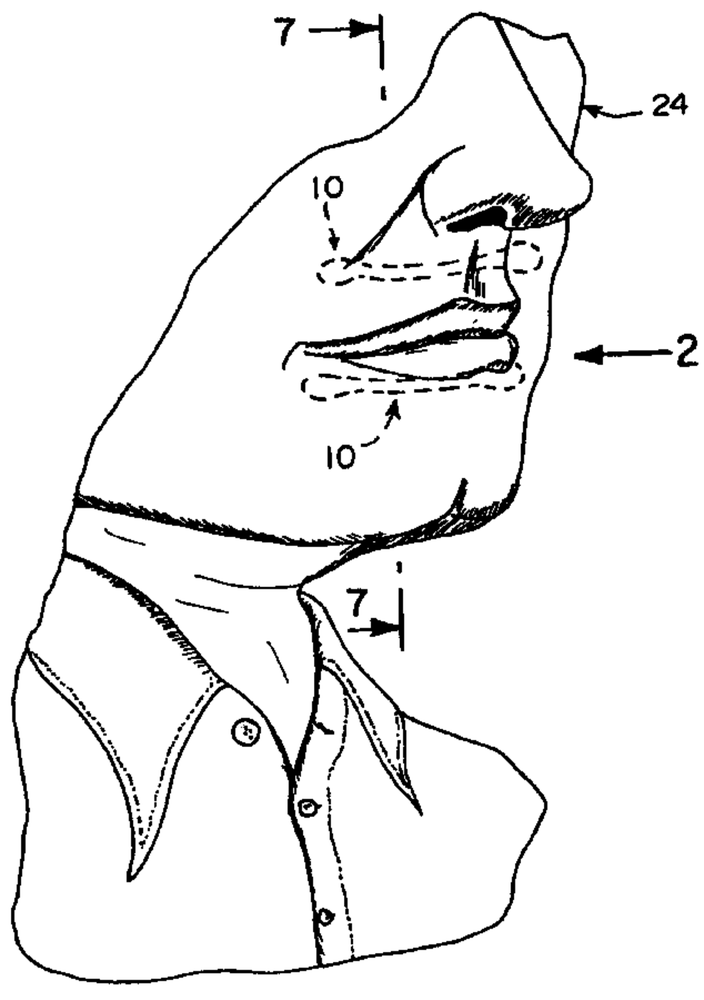
* cited by examiner

Primary Examiner—Jose' G. Dees
Assistant Examiner—Kathryne E. Shelborne
(74) *Attorney, Agent, or Firm*—Leighton K. Chong

(57) **ABSTRACT**

A gum **[**growth**]** pad **(10) [**comprising**]** *has* a nonporous first layer **(12)[**. An**]** *and an* absorbent second layer **(14) [**is**]** placed upon the nonporous first layer **(12)**. A *gum tissue* growth medication **(16)** in a liquid form **[**is**]** *may be* impregnated within the absorbent second layer **(14)** and then dried. A semi-permeable third layer **(18)** covers the absorbent second layer **(14)** with the dried gum tissue growth medication **(16)**. A facility **(20)** is for sealing the nonporous first layer **(12)** to the semi-permeable third layer **(18)** about a periphery thereof.

20 Claims, 2 Drawing Sheets



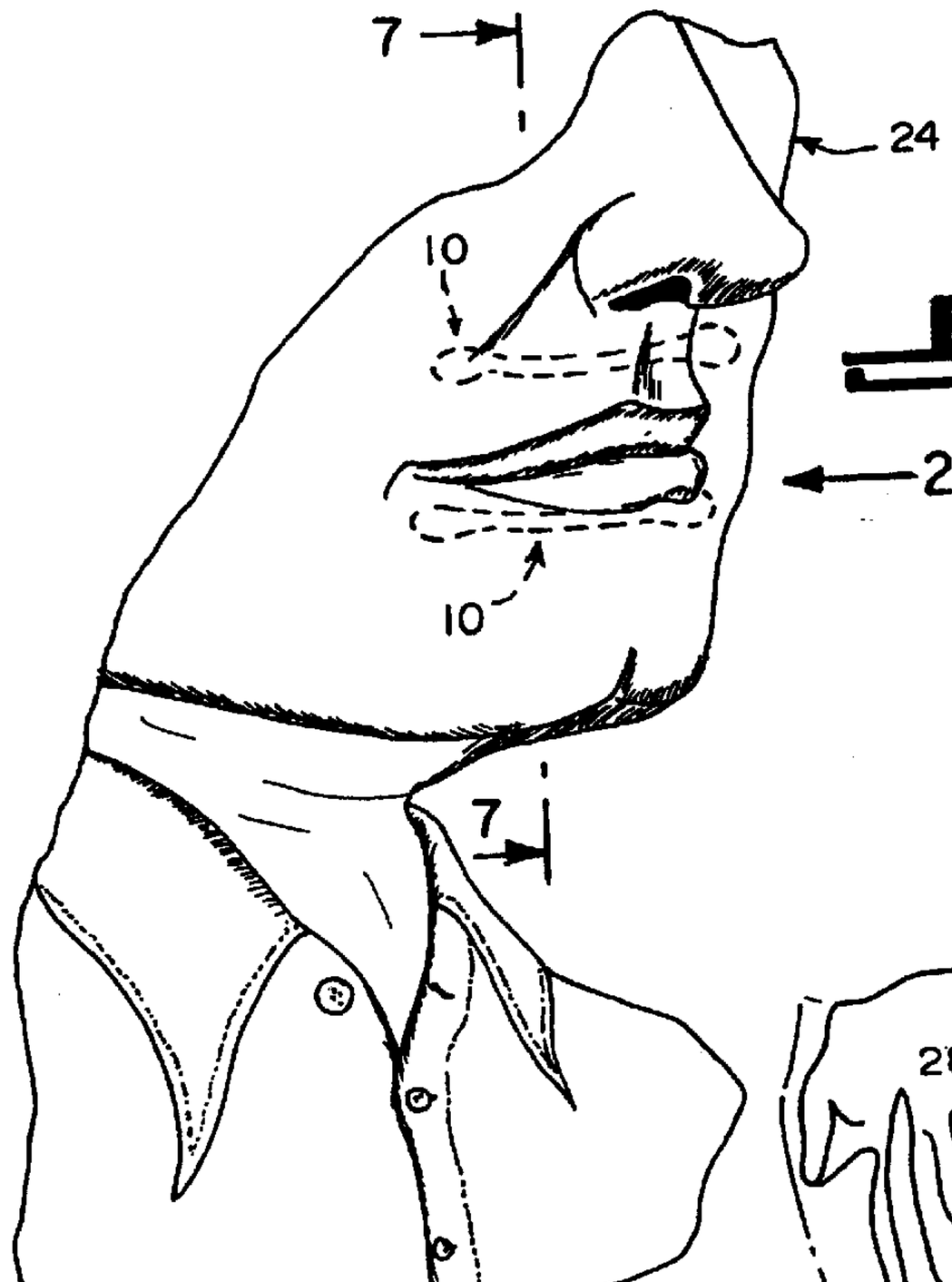


Fig 1

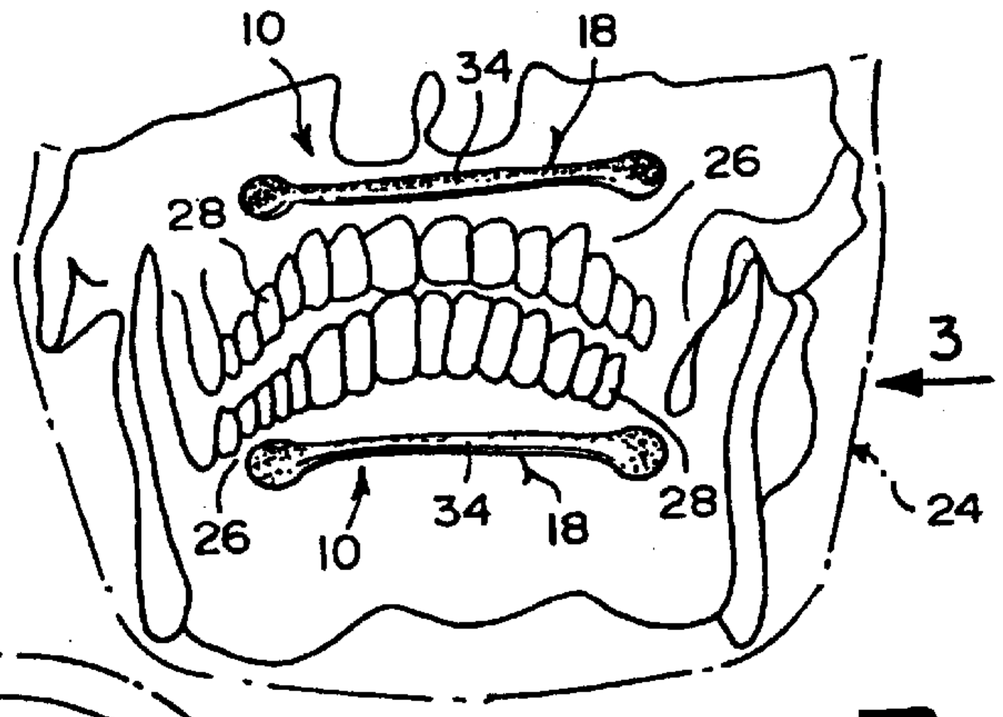


Fig 2

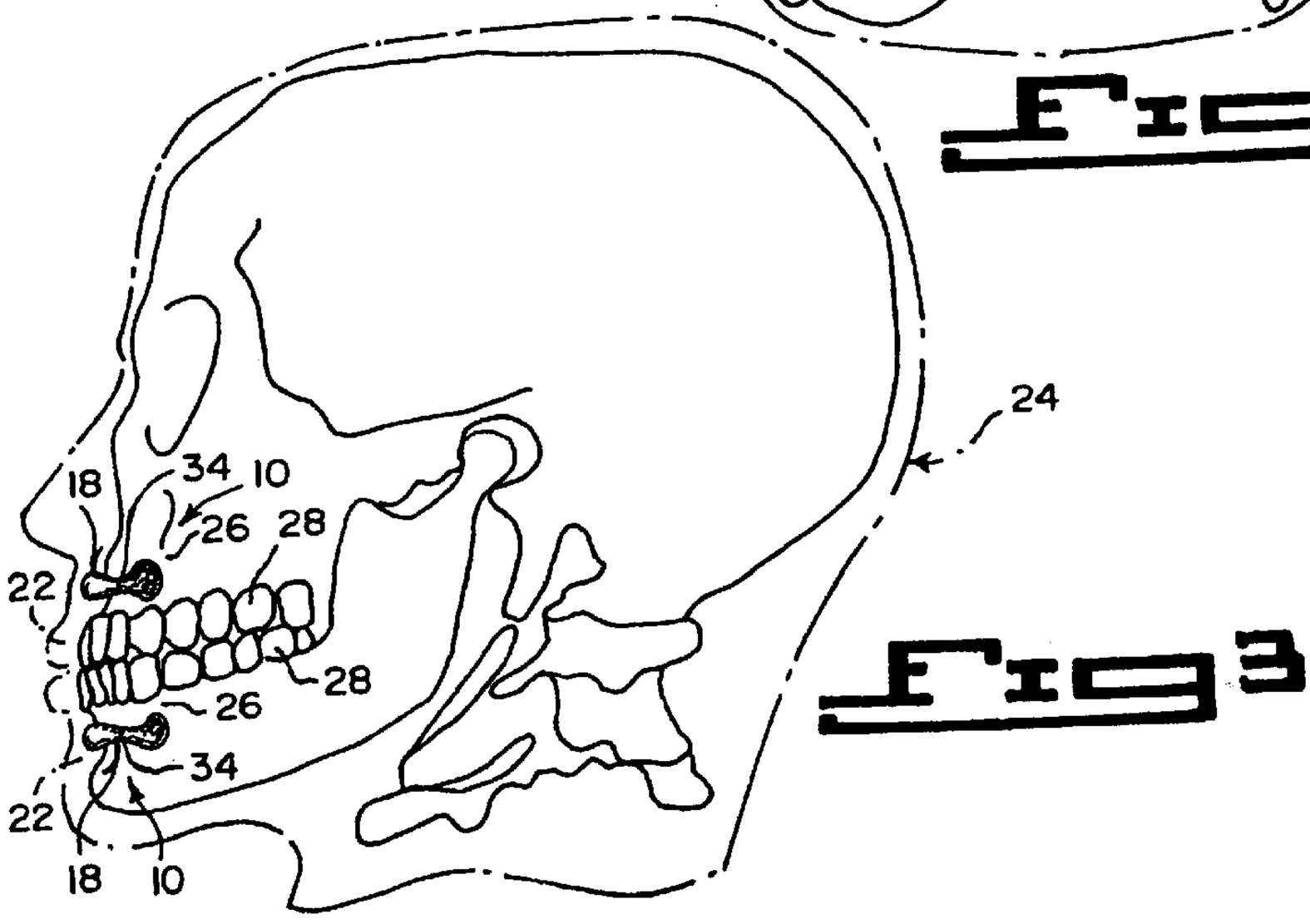


Fig 3

Fig 4

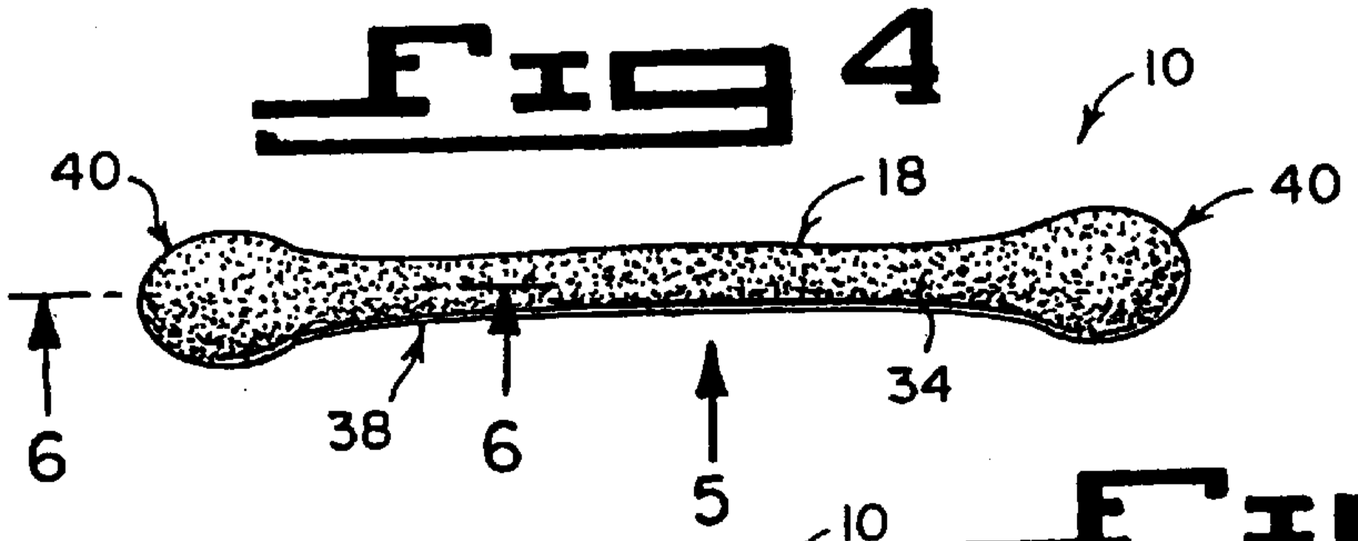
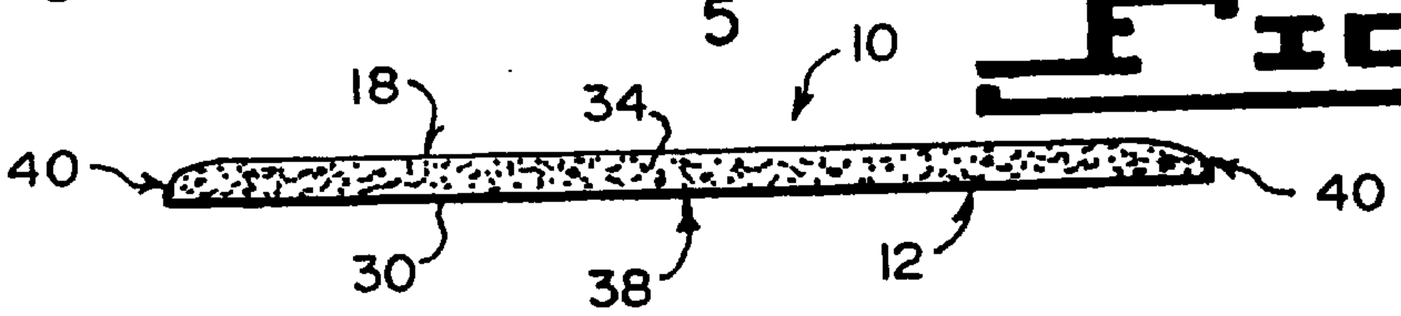


Fig 5



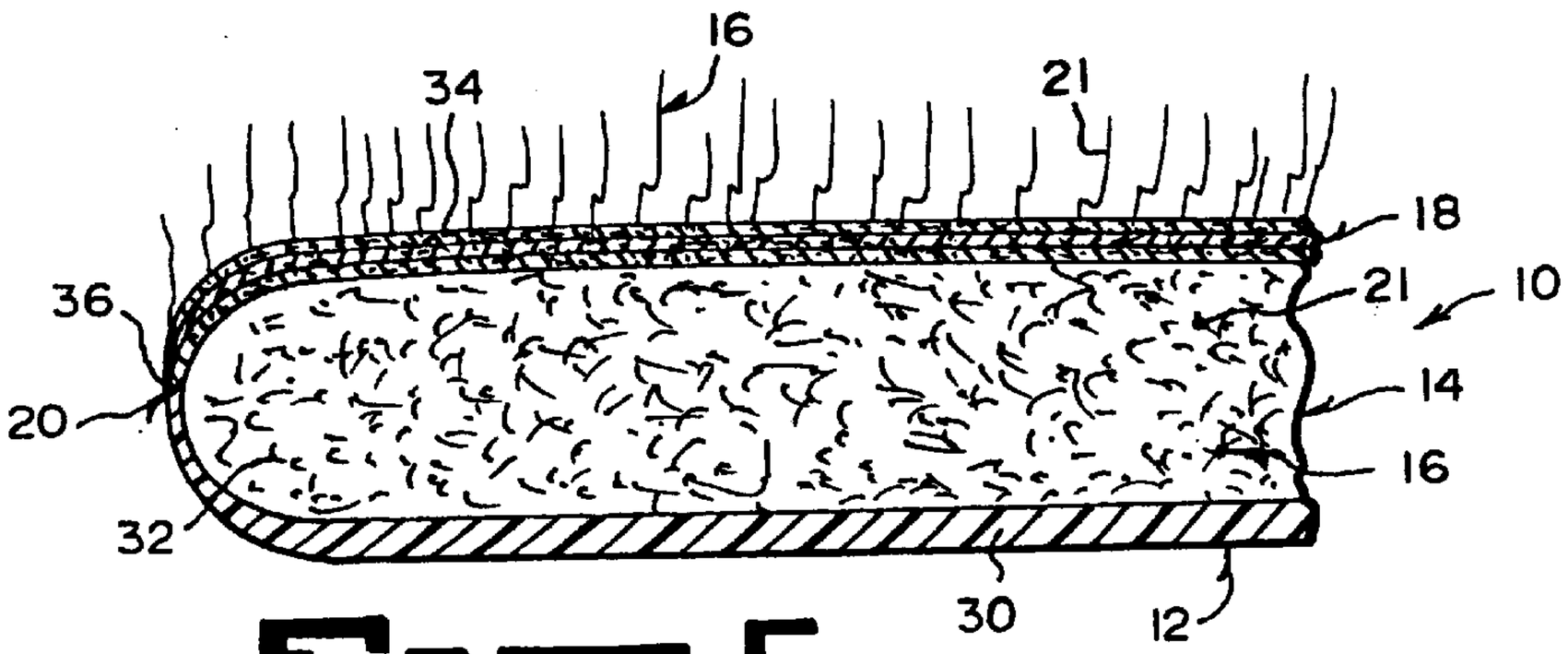


Fig 6

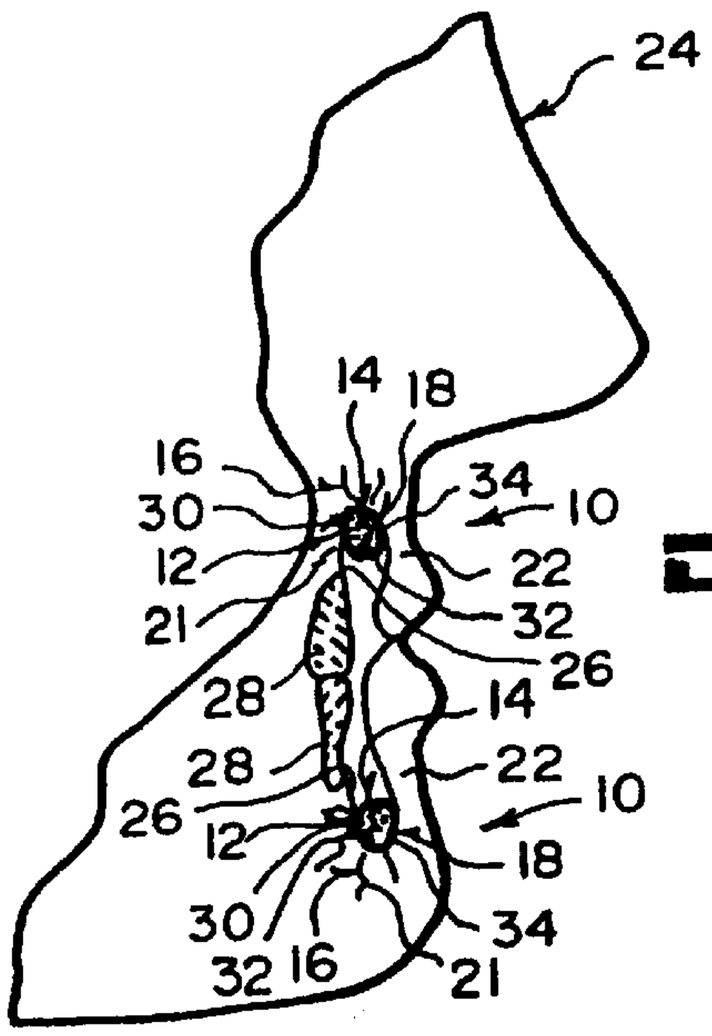


Fig 7

GUM PAD FOR MUCOSAL DELIVERY OF MEDICATION

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

This is a reissue patent application from U.S. Pat. No. 5,741,500, issued on Apr. 21, 1998.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The instant invention relates generally to holding devices and more specifically it relates to a gum [growth] pad.

2. Description of the Prior Art

Numerous holding devices have been provided in prior art. For example, U.S. Pat. Nos. 3,510,053 to Focke; 5,197,882 to Jernberg; 5,267,862 to Parker and 5,326,685 to Gaglio et al. are all illustrative to such prior art. While these units may be suitable for the particular purpose to which they address, they would not be as suitable for the purposes of the present invention as heretofore described.

U.S. Pat. No. 3,510,053 of Focke, Heinz, *for* "Pouch Made of a Single- or Multiple-Ply Synthetic Plastics Sheet Material, Preferably for Tobacco[U.S. Pat. No. 3,510,053 The invention]", provides a pouch made of a single- or multiple-ply synthetic plastics sheet material, particularly polyethylene, for the reception of a material such as tobacco. The pouch is preferably formed by longitudinally folding over a continuous sheet of plastic material, so that it has a short wall and a longer wall which [latter] serves as a wrap-around flap. The pouch is sealed at three edges and has an opening sealed by a substantially air-tight closure so constructed that it can be easily torn open.

U.S. Pat. No. 5,197,882 of Jernberg[, Gary R.], *for* "Periodontal Barrier and Method for Aiding Periodontal Tissue Regeneration Agents[U.S. Pat. No. 5,197,882 A]", *discloses a* periodontal barrier and method incorporating chemo-therapeutic agents [is disclosed] for aiding and guiding periodontal tissue regeneration.

U.S. Pat. No. 5,267,862 of Parker[, Jonathan A.], *for* "Intraoral Appliance[U.S. Pat. No. 5,267,862 Dental]", *discloses dental* appliances formed using this method [provide] *with* projections of the appliance itself which provide the necessary gripping forces rather than extraneous wires or other parts. The projections are formed by cutting grooves in casts of the teeth arches which will result in a projection, which will bear against the teeth, when the cast surface is duplicated in plastic. A first embodiment forms upper and lower plastic components, each having projections from the casts using the lost wax technique. These components are joined together in a predetermined relationship using a wax bit registration taken while the patient held his jaw in the predetermined relationship, and a dental articulator. A second method forms the plastic components directly over the casts. In this method the components are joined together, while mounted over the patient's arches, with the patient holding his jaw in the predetermined relationship. Both methods can be used to produce a single component with no joining of components then being required.

U.S. Pat. No. 5,326,685 of Gaglio[, Thomas J. Santoriello, Luigi] *et al., for* "Viscous Fluid Dispensing Apparatus[U.S. Pat. No. 5,326,685 This is]", *discloses* an applicator for applying a viscous fluid to a surface. There is a flexible backing material of a closed-cell material and a flexible

dispensing material of an open-celled material disposed over and carried by the flexible backing material. The open-celled material has an internal structural spacing sized relative to the viscosity of the fluid, so as to absorb and allow the fluid to slowly pass therethrough. Preferably, the flexible backing material and the flexible dispensing material are sealed together about the periphery thereof to form a hollow pocket. The fluid in the form of a gel, salve or the like, is disposed in the hollow pocket. The pocket can be filled with an oxidizing agent and used for tooth whitening and/or gum treatment. The pocket can be attached to an adhesive backing to make adhesive bandages which apply various medications to the underlying skin area. This approach can be employed for treating wounds and blemishes. The pockets can also be used for dispensing a variety of other materials including makeup remover, moisturizer, polishes, cleansers and the like.

SUMMARY OF THE INVENTION

A primary object of the present invention is to provide a gum [growth] pad that will overcome the shortcomings of the prior art devices.

Another object is to provide a gum [growth] pad that fits snugly and comfortably between the gums and buccal mucosa, since it does not buckle or rotate when in place and does not interfere with speech.

An additional object is to provide a gum [growth] pad that will deliver medication at a controlled rate directly onto the gums, by diffusing slowly through a semi-permeable membrane and into the saliva.

A still additional object is to provide a gum [growth] pad that is placed high up or low down, abutting the junction between the buccal mucosa and the gum, to allow greater contact between the medication and the gum tissue, with less likelihood of the medication being swallowed.

A further object is to provide a gum [growth] pad that is simple and easy to use.

A still further object is to provide a gum [growth] pad that is economical in cost to manufacture.

Further objects of the invention will appear as the description proceeds.

To the accomplishment of the above and related objects, this invention may be embodied in the form illustrated in the accompanying drawings, attention being called to the fact, however, that the drawings are illustrative only, and that changes may be made in the specific construction illustrated and described within the scope of the appended claims.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

Various other objects, features and attendant advantages of the present invention will become more fully appreciated as the same becomes better understood when considered in conjunction with the accompanying drawings, in which like reference characters designate the same or similar parts throughout the several views, and wherein:

FIG. **1** is a perspective view of a head and upper torso of a person with parts broken away, showing the instant invention in dotted lines in place.

FIG. **2** is a front view taken, in the direction of arrow **2** in FIG. **1**, with the exterior of the head shown in phantom.

FIG. **3** is a side view taken in the direction of arrow **3** in FIG. **2**, showing the outline of the head complete.

FIG. **4** is an enlarged elevational view of the instant invention per se.

FIG. **5** is a side view taken in the direction of arrow **5** in FIG. **4**.

FIG. **6** is a further enlarged cross sectional view taken along line **6—6** in FIG. **4**, showing the internal structure thereof.

FIG. **7** is a diagrammatic cross sectional view taken along line **7—7** in FIG. **1**, showing the positioning of the instant invention between the buccal mucosa and the gums of the teeth.

Similar reference characters denote corresponding features consistently throughout the attached drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now descriptively to the drawings, in which similar reference characters denote similar elements throughout the several views. FIGS. **1** through **7** illustrate a gum **[**growth**]** pad **10** comprising a nonporous first layer **12** with an absorbent second layer **14** placed upon the nonporous first layer **12**. A medication **16** in a liquid form is impregnated within the absorbent second layer **14** and then dried. A semi-permeable third layer **18** covers the absorbent second layer **14** with the dried medication **16**. A facility **20** is for sealing the nonporous first layer **12** to the semi-permeable third layer **18** about a periphery thereof. The medication **16 [**is**]** *may be* a gum tissue growth substance **21**. The nonporous first layer **12** is applied high up or low down against the gum tissue **26** of the teeth **28** in the mouth of a person **24**, with the semi-permeable third layer **18** against the buccal mucosa **22**. Saliva in the mouth of the person **24** will penetrate through to the semi-permeable third layer **18** and cause the dried gum tissue growth substance **21** in the absorbent second layer **14** to liquify and diffuse through the semi-permeable third layer **18**, to enhance the growth of the gum tissue **26**, reverse age related gum recession, protect against gingival disease and loss of teeth **28**. The nonporous first layer **12** contributes stability, but allows flexibility, so that the pad **10** can adapt to the cavity without buckling or curling.

As best seen in FIG. **3**, the nonporous first layer **12** is a synthetic thermoplastic sheet **30**. The absorbent second layer **14** is a sponge-like cushion **32**. The semi-permeable third layer **18** is a thin membrane sheet **34**. The sealing facility **20** is a hot-bond adhesive **36**.

The gum **[**growth**]** pad **10**, as best seen in FIGS. **4** and **5**, has an elongated generally tubular shaped body **38** with bulb shaped ends **40**, to supply a large posterior area of the gum tissue **26** and help stabilize placement between the buccal mucosa **22** and the gum tissue **26** of the teeth **28**. The nonporous first layer **12** is flat, while the semi-permeable third layer **18** is curved on the tubular shaped body **38**, so as to fit snugly and comfortably between the buccal mucosa **22** and the gum tissue **26** in the mouth of the person **24**.

The gum tissue growth substance **21** can be a drug diphenylantoin sodium known **[**as**]** *by* the trademark name DILANTIN, which is ordinarily used to treat and prevent seizures, with a well known side effect for gingival hyperplasia. DILANTIN has recently been shown to stimulate the formation of bone, as well as gum tissue.

The gum tissue growth medication **16** can also be an immuno-suppressant agent, such as cyclosporin or nifedipine. Immuno-suppressant agents are also known to stimulate gum growth. The gum tissue growth medication **16** can also be a nerve growth factor, a protein gene product, or a bone growth protein. Bone growth protein stimulates the repair of bone and tooth-anchoring connective tissue. All these substances have the potential of preventing and treating periodontal disease.

OPERATION OF THE INVENTION

To use the gum **[**growth**]** pad **10**, the following steps should be taken:

1. Apply the nonporous first layer **12** high up or low down against the gum tissue **26** of the teeth **28** in the mouth of the person **24**.
2. Make sure that the semi-permeable third layer **18** is against the buccal mucosa **22**.
3. The dried gum tissue growth substance **21** in the absorbent second layer will become liquified when saliva in the mouth of the person **24** penetrates through the semi-permeable third layer **18**.
4. The liquified gum tissue growth substance **21** will diffuse through the semi-permeable third layer **18**, to enhance the growth of the gum tissue **26**.
5. The gum **[**growth**]** pad **10** will not interfere with speech and cause no discomfort.
6. Application of the gum **[**growth**]** pad **10**, two to three times weekly, will regenerate the tooth anchoring connective gum tissue **26** to help protect against gingival disease.

LIST OF REFERENCE NUMBERS

10 gum **[**growth**]** pad
12 nonporous first layer of **10**
14 absorbent second layer of **10**
16 medication of **10** in **14**
18 semi-permeable third layer of **10**
20 sealing facility of **10**
21 gum tissue growth substance for **16**
22 buccal mucosa of **24**
24 person
26 gum tissue of **24**
28 teeth of **24**
30 synthetic thermoplastic sheet for **12**
32 sponge-like cushion for **14**
34 thin membrane sheet for **18**
36 hot-bond adhesive for **20**
38 elongated generally tubular shaped body for **10**
40 bulb shaped end on **38**

It will be understood that each of the elements described above, or two or more together may also find a useful application in other types of methods differing from the type described above.

While certain novel features of this invention have been shown and described *and* are pointed out in the annexed claims, it is not intended to be limited to the details above, since it will be understood that various omissions, modifications, substitutions and changes in the forms and details of the device illustrated and in its operation can be made by those skilled in the art without departing in any way from the spirit of the present invention.

Without further analysis, the foregoing will so fully reveal the gist of the present invention that others can, by applying current knowledge, readily adapt it for various applications without omitting features that, from the standpoint of prior art, fairly constitute essential characteristics of the generic or specific aspects of this invention.

What is claimed is new and desired to be protected by Letters Patent is set forth in the appended claims:

1. A gum **[**growth**]** pad comprising:

a) a nonporous first layer;

b) an absorbent second layer placed upon and in contact with said nonporous first layer;

c) a dried medication capable of being liquified by saliva impregnated within said absorbent second layer;

d) a semi-permeable third layer covering said absorbent second layer with said dried medication forming a pocket completely filled by said absorbent second layer; and

e) means for sealing said nonporous first layer to said semi-permeable third layer about a periphery thereof.

2. A gum **[**growth**]** pad as recited in claim **1**, wherein said medication is a gum tissue growth substance, whereby said nonporous first layer is applied high up/low down against the gum tissue of the teeth in the mouth of a person, with said semi-permeable third layer against the buccal mucosa, so that saliva in the mouth of the person will penetrate through to said semi-permeable third layer and cause said dried gum tissue growth substance in said absorbent second layer to liquify and diffuse through said semi-permeable third layer, to enhance the growth of the gum tissue, reverse age related gum recession, protect against gingival disease and loss of teeth, wherein said nonporous first layer contributes stability, but allows flexibility, so that said pad can adapt to the cavity without buckling and curling.

3. A gum **[**growth**]** pad as recited in claim **1**, wherein said nonporous first layer is a synthetic thermoplastic sheet.

4. A gum **[**growth**]** pad as recited in claim **1**, wherein said absorbent second layer is a sponge cushion.

5. A gum **[**growth**]** pad as recited in claim **1**, wherein said semi-permeable third layer is a thin membrane sheet.

6. A gum **[**growth**]** pad as recited in claim **1**, wherein said sealing means is a hot-bond adhesive.

7. A gum **[**growth**]** pad as recited in claim **1**, further having an elongated generally tubular shaped body with bulb shaped ends, to supply a large posterior area of the gum tissue and help stabilize placement between the buccal mucosa and the gum tissue of the teeth.

8. A gum **[**growth**]** pad as recited in claim **7**, wherein said nonporous first layer is flat, while said semi-permeable third layer is curved on said tubular shaped body, so as to fit snugly and comfortably between the buccal mucosa and the gum tissue in the mouth of the person.

9. A gum **[**growth**]** pad as recited in claim **2**, wherein said gum tissue growth substance is a drug diphenylhydantoin sodium, which is ordinarily used to treat and prevent seizures, with a well known side effect for gingival hyperplasia, whereby drug diphenylantoin sodium stimulates the formation of bone, as well as gum tissue.

10. A gum **[**growth**]** pad as recited in claim **2**, wherein said gum tissue growth substance is an immuno-suppressant agent, such as cyclosporin and nifedipine that will stimulate gum growth.

11. A gum **[**growth**]** pad as recited in claim **2**, wherein said gum tissue growth substance is a nerve growth factor.

12. A gum **[**growth**]** pad as recited in claim **2**, wherein said gum growth substance is a protein gene product.

13. A gum **[**growth**]** pad as recited in claim **2**, wherein said gum tissue growth substance is a bone growth protein that will stimulate the repair of bone and tooth-anchoring corrective tissue.

14. The method of delivering medication at a controlled rate directly onto human tissue within the mouth of a person utilizing a pad, said pad consisting essentially of a nonporous first layer, an absorbent second layer on one side of said nonporous first layer, and a semi-permeable third layer covering the absorbent second layer forming a sealed pocket completely filled with said absorbent second layer, said method comprising the steps of:

a) impregnating said absorbent second layer with medication in a liquid form and then drying said medication; and

b) placing said pad within the mouth of said person with the semi-permeable third layer in contact with the tissue to receive said medication for permitting the saliva within said mouth to penetrate said semi-permeable third layer causing the dried medication to liquify and diffuse through said semi-permeable third layer.

15. The method of claim **14** in which said pad is placed between the buccal mucosa and the gum tissue in said mouth.

16. The method of claim **15** in which said medication is diphenylantoin sodium.

17. The method of claim **15** in which said pad includes means for stabilizing said pad within said mouth.

18. The method of claim **17** in which said stabilizing means comprises said pad having a generally tubular shaped body with the first layer being flat and having bulb shaped ends.

19. A gum pad comprising:

a) a nonporous first layer which is stable and flexible such that it can be mounted in place on the gums in the mouth of a person;

b) a second layer placed upon and in contact with said nonporous first layer;

c) a medication carried in said second layer which is capable of being liquified by saliva and transported in liquified form by diffusion from said second layer;

d) a semi-permeable third layer covering said second layer which is permeable to saliva from the mouth of the person, such that, when said gum pad is mounted with said nonporous first layer on the gums of the person and with said semi-permeable third layer in contact with buccal mucosa tissue facing toward the gums, saliva can penetrate through said semi-permeable layer to said medication-carrying second layer and liquify the medication therein and transport it in liquified form by diffusion through said semi-permeable third layer to the buccal mucosa tissue of the person; and

e) means for sealing said nonporous first layer to said semi-permeable third layer so as to enclose the second layer, therein.

20. A method of delivering medication at a controlled rate onto buccal mucosa tissue within the mouth of a person by utilizing a pad, said pad consisting essentially of a nonporous first layer, a medication-carrying second layer on one side of said nonporous first layer, and a semi-permeable third layer covering the second layer and sealed to said nonporous first layer so as to enclose the second layer therein, said method comprising the steps of:

a) impregnating said second layer with medication which is capable of being liquified by saliva and transported in liquified form by diffusion from said second layer; and

b) placing said pad within the mouth of the person with the semi-permeable third layer in contact with the buccal mucosa tissue in order to have saliva from within the mouth of the person penetrate the semi-permeable third layer to liquify the medication in the second layer and cause the saliva-liquified medication to diffuse through the semi-permeable third layer onto the buccal mucosa tissue.

* * * * *