COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

DECLARATION IN SUPPORT OF CONVENTION OR NON-CONVENTION APPLICATION FOR A PATENT

Insert title of invention.

In support of the Application made for a patent for an invention entitled: "SOFT CONTACT LENS HYDRATION DEVICE AND KIT"

Insert full name(s) and address(es) of Declarant(s) being the applicant(s) or person(s) authorized to sign on behalf of an applicant company.

I Howard R. Lambert,
~~We~~ Senior Patent Attorney
Allergan, Inc.,
2525 Dupont Drive,
Irvine, CA 92715,
United States of America

do solemnly and sincerely declare as follows:-

Cross out whichever of paragraphs 1(a) or 1(b) does not apply.

1(a) relates to application made by individual(s).
1(b) relates to application made by company; insert name of applicant company.

1. (a) ~~I am / We are the applicant ..... for the patent~~

or (b) I am authorized by

Allergan, Inc.

the applicant ..... for the patent to make this declaration on ~~its~~ their behalf.

Cross out whichever of paragraphs 2(a) or 2(b) does not apply.

2(a) relates to application made by inventor(s)
2(b) relates to application made by company(s) or person(s) who are not inventor(s); insert full name(s) and address(es) of inventors.

2. (a) ~~I am / We are the actual inventor ..... of the invention~~

or (b)

Martin M. Pollak,
16 Springwood Path,
Laurel Hollow,
New York 11791
United States of America

~~is~~ are the actual inventor ..... of the invention and the facts upon which the applicant ..... ~~is~~ are entitled to make the application are as follows:- Applicant is the assignee of the invention from the actual inventor by reason of an assignment by the actual inventor dated 12th October, 1987.

State manner in which applicant(s) derive title from inventor(s)

Cross out paragraphs 3 and 4 for non-convention applications. For convention applications insert basic country(s) followed by date(s) and basic applicant(s).

3. The basic application ..... as defined by Section 141 of the Act ~~was~~ were made

in United States of America on the 17th September, 1987

by MARTIN M. POLLAK

in ..... on the .....

by .....

in ..... on the .....

by .....

4 The basic application ~~referred to in paragraph 3 of this Declaration~~ ~~was~~ were the first application ..... made in a Convention country in respect of the invention the subject of the application.

Insert place and date of signature.

Declared at Irvine, CA 92715 this 28th day of August 1990

Signature of Declarant(s) (no attestation required).

Howard R. Lambert
Allergan, Inc.

Note: Initial all alterations.

DAVIES & COLLISON, MELBOURNE and CANBERRA.

(12) PATENT ABRIDGMENT (11) Document No. AU-B-25323/88
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 605454

(Modified Examination)

(54) Title
SOFT CONTACT LENS HYDRATION DEVICE AND KIT

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097868 17.09.87 US UNITED STATES OF AMERICA

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(57) Claim

1. A hydration device comprising an enclosure possessing means for permitting contact of a dehydrated contact lens in resident association with a mold element in which the lens was formed with hydration liquid, said device containing at least one such combined lens/mold element assembly.

4. A kit for effecting the hydration of a dehydrated contact lens and the separation of the lens from the cavity of a mold element in which the lens was formed which comprises:

a) at least one lens hydration device possessing an enclosure capable of containing at least one dehydrated contact lens in resident association with the cavity of a mold element in which the lens was formed, said device possessing means for permitting contact of said lens with hydration liquid;

b) at least one dehydrated contact lens in

.../2

resident association with the cavity of a mold element in which the lens was formed; and,

c) a quantity of hydration liquid.

PCT

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International Bureau

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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A45C 1/04, B65D 85/30	A1	(43) International Publication Date: 23 March 1989 (23.03.89)

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(71) Applicant: ALLERGAN, INC. [US/US]; 2525 Dupont Drive, Irvine, CA 92715 (US).

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(74) Agent: SKOLER, George, A.; 3010 Westchester Avenue, Purchase, NY 10577 (US).

(81) Designated States: AU, BR.

Published
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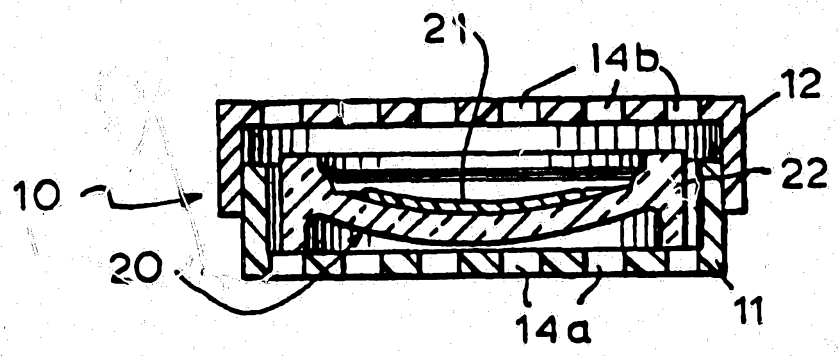
(54) Title: SOFT CONTACT LENS HYDRATION DEVICE AND KIT



(57) Abstract

A hydration device (10) and kit are provided for effecting the hydration of a dehydrated soft contact lens (21) resident within the cavity of a mold element (22) in which the lens was formed.

SOFT CONTACT LENS HYDRATION DEVICE AND KIT

This invention relates to the field of soft contact lenses, i.e., those formed from hydrogels, and receptacles therefor. More particularly, the present invention is directed to a dehydrated contact lens in resident association with the cavity of a mold member in which the lens was formed and a hydration device for the dehydrated lens/mold member combination, optionally provided as part of a kit for hydrating the lens and rendering it suitable for wearing.

The term "hydrogel" is descriptive of any water absorptive, optically clear material which is suitable for the fabrication of a contact lens. Illustrative of such materials are the water swellable, water-insoluble shape-retaining polymers disclosed, inter alia, in U.S. Patent Nos. 2,976,576, 3,220,960 and 3,822,089. These and related polymers are prepared from liquid polymerizable reaction mixtures containing monomer(s), initiator, catalyst, etc. Upon undergoing polymerization, the mixtures provide sparingly cross-linked water-absorptive polymeric hydrogels. In the hydrated state, contact lenses formed from such hydrogels are soft and pliable, have high oxygen permeability and as such are relatively comfortable to wear.

Contact lenses can be fabricated employing any of several known and conventional methods. The lenses can be machined, or lathed, to specification from a plastic lens blank. This is a fairly labor- and skill-intensive technique. Soft contact lenses can also be manufactured by various molding techniques which offer obvious advantages of economy. In one method, a plastic lens is cast molded in a static mold (see, for example, U.S. Patent No. 4,121,896 for

a male-female mold assembly which can be used in such a method). In another type of molding method, a plastic lens is formed in a rotating mold (see, for example, the centrifugal lens casting apparatus, molds and procedures described in U.S. Patent Nos. 4,517,138, 4,517,139, 4,517,140 and 4,568,501).

Whatever the fabrication technique used, the contact lens must undergo one or more post-lens forming operations to prepare it for wearing. Thus, the lens is washed, generally several times, with a hydrating liquid such as physiological saline (0.09 wt.% saline) in order to leach, or extract, any residual unreacted material, e.g., monomer(s), initiator, catalyst, etc., and at the same time swell the lens and render it compatible with the fluids of the eye. Where a lens has been formed by molding, the dehydrated lens, still resident within a mold member used in forming the lens, is introduced into a quantity of hydrating liquid, e.g., physiological saline as just mentioned, which causes the lens to swell and separate from the mold member. Thereafter, the lens is washed, visually inspected, sterilized, packaged, e.g., in a rubber-stoppered glass vial sealed with a metal crimp (usually one of aluminum), and the package is labeled. These post-lens forming operations are carried out at the lens manufacturing site and account for a significant percentage of the cost of a molded contact lens.

In recent years, accumulated medical evidence has strongly pointed to the considerable benefits to eye health to be gained by replacing contact lenses on a fairly frequent and regular basis. Lens care regimens involving surfactants and/or enzymatic protein removal procedures are at best only moderately successful in maintaining lenses in

an optimum state of cleanliness. Even this degree of lens maintenance becomes greatly compromised when the wearer fails to adhere to the proper regimen.

Dirty lenses contribute to visual and physiological problems. This is especially true with extended wear lenses because wearers often are unaware of a problem with a dirty lens and may continue to wear a lens despite its having accumulated excessive dirt and proteinaceous debris.

Considerations of economy aside, the ideal answer to this problem would be to provide the contact lens wearer with the capability for disposing the lenses on a frequent scheduled basis and replacing them with new, clean factory fresh lenses. This approach has already been promoted in various forms by contact lens suppliers. Thus, in one case, patients are dispensed several sets of lens in conventional sterile glass vials, such as those described above, which are normally used to store and ship lenses to practitioners. The high cost of the post-lens forming operations previously referred to tends to make such frequent replacement of lenses prohibitively expensive thereby discouraging the implementation of what is otherwise a sound and beneficial opthalmic practice.

U.S. Patent No. 4,429,786 describes an integrated contact lens maintenance kit and carrying apparatus for the storage and carrying of a user's contact lenses as well as a plurality of liquids normally utilized with such lenses. U.S. Patent No. 4,568,517 describes a kit for disinfecting lenses with a hydrogen peroxide solution and for neutralizing the hydrogen peroxide solution. The kit comprises means for washing the lens and a tablet or

particulate neutralizer. No mention is made in either of these patents of hydrating a molded dehydrated soft contact lens resident within the cavity of a mold element or of separating the lens from the mold.

It is an object of the present invention to provide a device for facilitating the hydration of a molded soft contact lens resident in th cavity of a mold element in which the lens was formed, the separation of the lens from the mold and, optionally, one or more additional post-lens forming treatments such as extraction of residual material(s), disinfection, cleaning, and the like.

Another object of the invention is to provide a disposable kit for effecting hydration of a dehydrated molded soft contact lens residing within the cavity of a mold element in which the lens was formed, the kit being primarily intended for use away from the site at which the lens is manufactured.

It is a particular object of the invention to provide such a disposable kit together with a quantity of combined dehydrated lens/mold elements and hydration devices and, optionally, one or more other components useful in such other post-lens forming treatments as previously mentioned.

SUMMARY OF THE INVENTION

By way of satisfying these and other objects of the invention, there is provided a lens hydration device possessing an enclosure containing at least one dehydrated contact lens in resident association with the cavity of a mold element in which the lens was formed, said hydration device possessing means for permitting contact of the lens with hydration liquid.

The invention further comprises a kit for effecting the hydration of a dehydrated contact lens and the separation of the lens from the cavity of a mold element in which the lens was formed, the kit comprising:

a) at least one lens hydration device possessing an enclosure capable of containing at least one dehydrated contact lens in resident association with the cavity of a mold element in which the lens was formed, said device possessing means for permitting contact of said lens with hydration liquid;

b) at least one dehydrated contact lens in resident association with the cavity of a mold element in which the lens was formed; and,

c) a quantity of hydration liquid.

Use of the lens hydration device and kit of this invention makes it possible to shift the hydration and demolding operations and, optionally, other post-lens forming operations, procedures which contribute appreciably to the cost of factory-finished lenses, from the lens manufacturing site to the contact lens wearer. Thus, in avoiding the cost of factory labor associated with some or all of such post-lens forming operations as hydrating the lens out of the mold, washing the hydrated lens, sterilizing the lens, packaging the lens in the sort of bulky glass vials typically used for this purpose and labeling the lens package, the foregoing lens hydration device and kit make it economically feasible for a contact lens wearer to discard worn lenses on a regular and frequent basis.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates in enlarged cross-section, a lens hydration device containing a dehydrated soft contact lens within the cavity of a mold element in which the lens was formed;

Fig. 2 illustrates the various components of one embodiment of a dehydrated soft contact lens treatment kit in accordance with this invention; and,

Fig. 3 illustrates a convenient package arrangement for storing the various components of a dehydrated soft contact lens treatment kit shown in Fig. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As indicated above, the present invention contemplates a dehydration device and kit for carrying out hydration and, optionally, other post-lens forming operations upon a molded soft contact lens. Illustrative of such lenses are those formed from a lens-forming reaction mixture containing hydrophilic monomers, e.g., those which form slightly or moderately crosslinked, three dimensional networks as disclosed in aforesaid U.S. Patent Nos. 2,976,576, 3,220,960 and 3,822,089. These materials upon undergoing polymerization provide "sparingly" cross-linked, water-absorptive shape- retaining articles such as contact lenses of 2-hydroxyethyl methacrylate polymers. The invention contemplates lenses manufactured from these and any other kinds of water-swellable materials.

Following lens formation employing either of the molding procedures referred to above, the dehydrated lens is hydrated (which also causes the lens to separate from the mold element) and any unreacted monomer(s) and/or other extraneous material(s) are removed therefrom.

Referring, now, to Fig. 1, hydration device 10 includes lower and upper members 11 and 12, respectively, which cooperate to form an enclosure 13 of dimensions sufficient to accommodate at least one dehydrated contact lens/mold element combination 20. Members 11 and 12 can be clear or opaque, hinged or non-hinged, i.e., detachable, and can be provided with any suitable means to effect their interengagement, e.g., threading, a snap-lock, friction fitting (as shown), etc. Perforations 14a and 14b defined within lower and upper members 11 and 12, respectively, permit passage of hydration liquid, e.g., physiological saline, into and through enclosure 13. As shown in Fig. 2, a portion 15 of upper member 12 can be texturized to facilitate labelling with a pencil or indelible ink so as to identify the combined contact lens/mold element assembly 20 enclosed in the hydration device.

While members 11 and 12 can be fabricated from a wide variety of materials, they are preferably manufactured by injection molding a thermoplastic resin such as polyethylene, polypropylene, polycarbonate, polyester, polyamide, etc. The upper and lower members of the hydration device can, if desired, be molded as a single unit joined through a flexible hinge.

Enclosure 13 of hydration device 10 is occupied by dehydrated contact lens 21 resident in the cavity of mold element 22. Combined dehydrated lens/mold element assembly 20 can be provided as a separate unit or, as illustrated, it can be provided already present within the enclosure of hydration device 10.

In a preferred embodiment of the present invention, a quantity of hydration devices 10 and combined dehydrated contact lens/mold element assemblies 20 are provided in kit form together with a quantity of hydration liquid and, if desired, one or more other lens treating materials such as disinfectant, sterilizer, cleaner, preservative, and the like. The individual components of one such kit are shown in Fig. 2 and include a quantity of combined dehydrated contact lens/mold element assemblies 20 which can be provided in stoppered tubular containers 30a and 30b suitably labeled to indicate the diopters of the lens and/or other lens identifying indicia. Alternatively, the combined dehydrated contact lens/mold element assemblies can be packaged in individually separable and labeled bubble packets formed as part of a perforate sheet 35 or strip. Yet another alternative is to provide combined lens/mold assemblies 20 already contained within labelled hydration device 10. The kit further includes a quantity of hydration liquid 40, e.g., physiological saline, which may or may not be concentrated and which may or may not contain a buffering agent and/or other optional ingredient(s).

Optional components of the kit can include one or more vessels 50, preferably of flame-proof or fire-resistant glass, for holding hydration fluid and/or other liquid(s), soft-tipped tweezers 60 for holding the contact lenses and one or more lens treatment materials, liquid or otherwise. Thus, e.g., the kit of this invention can include, besides hydration liquid, one or more soft contact lens cleaning, disinfectant, sterilizing, preserving, storing and/or peroxide removal compositions. Examples of such optional

compositions include the oxygen-releasing salt-containing isotonic lens cleaning and sterilizing solutions of U.S. Patent No. 3,873,696; the nonionic surfactant-containing lens cleaning and storing compositions of U.S. Patent No. 3,882,036; the hydrogen peroxide decomposition catalysts of U.S. Patent No. 3,912,451; the quaternary ammonium compound-containing lens sterilizing compositions of U.S. Patent No. 4,029,817; the polyoxyethylene-polyoxypropylene block copolymer-containing cold disinfectant solutions of U.S. Patent No. 4,356,100; the dimethyldiallylammonium chloride homopolymer-containing lens disinfectant compositions of U.S. Patent Nos. 4,367,548 and 4,443,429; the amphoteric surfactant, non-ionic surfactant and chlorhexidine-containing (and, optionally, thimerosal-containing) lens disinfecting and/or preserving solutions of U.S. Patent No. 4,354,952; the ascorbic acid-containing ambient temperature lens disinfectant compositions of U.S. Patent No. 4,367,157; the pentanedial-containing and, optionally, thimerosal-containing, lens disinfecting and preserving solutions of U.S. Patent Nos. 4,381,314 and 4,444,784; the lens cleaning solutions based on peroxide, transition metal salts, amphoteric or anionic surfactants described in U.S. Patent No. 4,414,127; the ascorbic acid and potentiating compound (e.g., trimethoprim or thimerosal)-containing ambient temperature lens disinfectant solutions of U.S. Patent No. 4,401,582; the C_{5-12} fatty acid-containing disinfecting solutions of U.S. Patent No. 4,410,442; the mixture of surfactants employed as lens cleaning compositions as described in U.S. Patent No. 4,440,662; the glycerol monolaurate and antimicrobial agent-containing lens disinfecting compositions of U.S.

Patent No. 4,485,029; the contact lens preserving solutions containing an ene-diol compound, e.g., ascorbic acid or dihydroxymaleic acid, and a source of copper ion as disclosed in U.S. Patent No. 4,490,389; the mixture of anionic and nonionic surfactants, said to exhibit a synergistic lens cleaning effect, described in U.S. Patent No. 4,500,441; the nonionic surfactant and chlorhexidine salt-containing lens cleaning solutions of U.S. Patent No. 4,504,405; the trimethoprim-containing lens preservative compositions of U.S. Patent Nos. 4,510,065, 4,529,535, 4,543,200 and 4,560,491 which additionally contain other ingredients such as EDTA, benzyl alcohol and adjuvant bactericides, e.g., sorbic acid or ascorbic acid; the lens disinfecting and sterilizing compositions containing hydrogen peroxide, surfactant and aqueous alcoholic mixture of a tertiary amine and a fatty acid alkanolamide as described in U.S. Patent Nos. 4,518,585 and 4,557,898; the sodium pyruvate-containing solutions (for decomposing a hydrogen peroxide lens sterilizing solution) disclosed in U.S. Patent No. 4,521,375; the biguanide-containing lens disinfecting and/or preserving solutions of U.S. Patent No. 4,537,746; a neutralizer such as sodium sulfite or sodium thiosulfate, and optionally, buffering agents, for addition to an aqueous hydrogen peroxide lens disinfectant solution to convert the latter into a saline lens storage solution as described in U.S. Patent No. 4,568,517; a catalyst such as catalase for addition to a hydrogen peroxide lens disinfecting solution to decompose the latter following the

disinfection procedure; and, the peroxidase-containing lens disinfecting system of U.S. Patent No. 4,588,586, the disclosures of which are incorporated by reference herein.

The necessary as well as some optional components of the contact lens kit herein are shown in Fig. 3 assembled in a convenient packaging unit 70 containing recesses for each component. Thus, each of the kit components shown in Fig. 1 is shown occupying a suitably dimensioned recess in packaging unit 70, e.g., fabricated from an impact-absorbing material such as a polyolefin foam or styrenic resin foam, which can be snugly fitted within an exterior paper carton for shipment and/or storage.

The principal operations involving the components of the dehydrated contact lens treatment kit of Figs. 2 and 3 are hydration and extraction. In the first of these operations, the combined dehydrated soft contact lens/mold element assembly 20 is enclosed within enclosure 13 of hydration device 10 with upper member 12 thereof being suitably marked with pencil or indelible ink to identify the lens within. The device is then immersed in boiling water or physiological saline for 3-5 minutes or so to hydrate lens 21 and release it from mold element 22. Following removal of the hydration device from the boiling liquid, the mold and lens are removed therefrom, preferably with soft-tipped tweezers 60. The mold element is discarded and the lens is returned to cavity 13 of hydration device 10 for the extraction procedure. In the latter operation, water or saline 40 is heated to 60 $\pm$ 10°C. and the hydration device with its hydrated lens is immersed therein for four hours.

Thereafter, the lens is placed in vessel 50 containing a small quantity of saline 40 for about one hour. The hydrated, extracted lens may thereafter be washed, sterilized, etc., prior to being worn.

Although illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to these precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention.

WHAT IS CLAIMED IS:

1. A hydration device comprising an enclosure possessing means for permitting contact of a dehydrated contact lens in resident association with a mold element in which the lens was formed with hydration liquid, said device containing at least one such combined lens/mold element assembly.

2. The hydration device of Claim 1 wherein the enclosure is defined by upper and lower interengaging members either or both of which possess one or more passages for admitting hydration liquid therein.

3. The hydration device of Claim 1 wherein the dehydrated contact lens is resident within the cavity of a mold element employed in a centrifugal lens casting procedure.

4. A kit for effecting the hydration of a dehydrated contact lens and the separation of the lens from the cavity of a mold element in which the lens was formed which comprises:

a) at least one lens hydration device possessing an enclosure capable of containing at least one dehydrated contact lens in resident association with the cavity of a mold element in which the lens was formed, said device possessing means for permitting contact of said lens with hydration liquid;

b) at least one dehydrated contact lens in resident association with the cavity of a mold element in which the lens was formed; and,

c) a quantity of hydration liquid.

5. The kit of Claim 4 wherein the dehydrated contact lens is resident within the cavity of a mold element employed in a centrifugal lens casting procedure.

6. The kit of Claim 4 wherein the enclosure of the hydration device is defined by upper and lower interengaging members either or both of which possess one or more passages for admitting hydration liquid therein.

7. The kit of Claim 4 wherein a plurality of such combined dehydrated lens/mold element assemblies and hydration devices are provided.

8. The kit of Claim 7 wherein the combined dehydrated lens/mold element assemblies are stored within a tubular container.

9. The kit of Claim 7 wherein one or more combined dehydrated lens/mold element assemblies are packaged in a packet.

10. The kit of Claim 7 wherein one or more combined dehydrated lens/mold element assemblies are packaged in individually separable packets formed as part of a sheet or strip of said packets.

11. The kit of Claim 7 wherein at least a portion of an exterior surface of the hydration devices is capable of receiving lens-identifying indicia applied thereto.

12. The kit of Claim 4 further comprising one or more vessels for holding hydration liquid and/or other lens treating composition(s).

13. The kit of Claim 4 further comprising means for gripping the contact lens.

14. The kit of Claim 13 wherein the gripping means is a set of soft-tipped tweezers.

15. The kit of Claim 4 comprising at least one additional material or composition for treating the contact lens.

16. The kit of Claim 15 wherein said additional material or composition is one for cleaning, sterilizing, preserving, storing, removing peroxide, or performing any combination of the aforesaid operations.

17. The kit of Claim 4 further comprising a packaging unit for receiving the kit components.

18. The kit of Claim 17 wherein the packaging unit is an impact-absorbing material or construction containing recesses for the kit components.

19. The kit of Claim 18 wherein the impact-absorbing material is a polyolefin foam or a styrenic polymer foam.

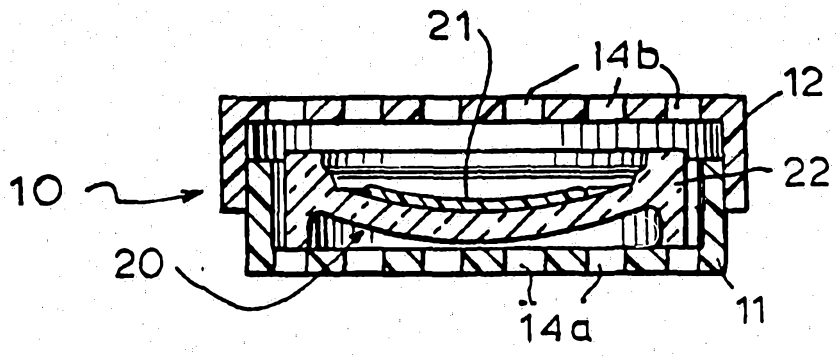


Fig. 1

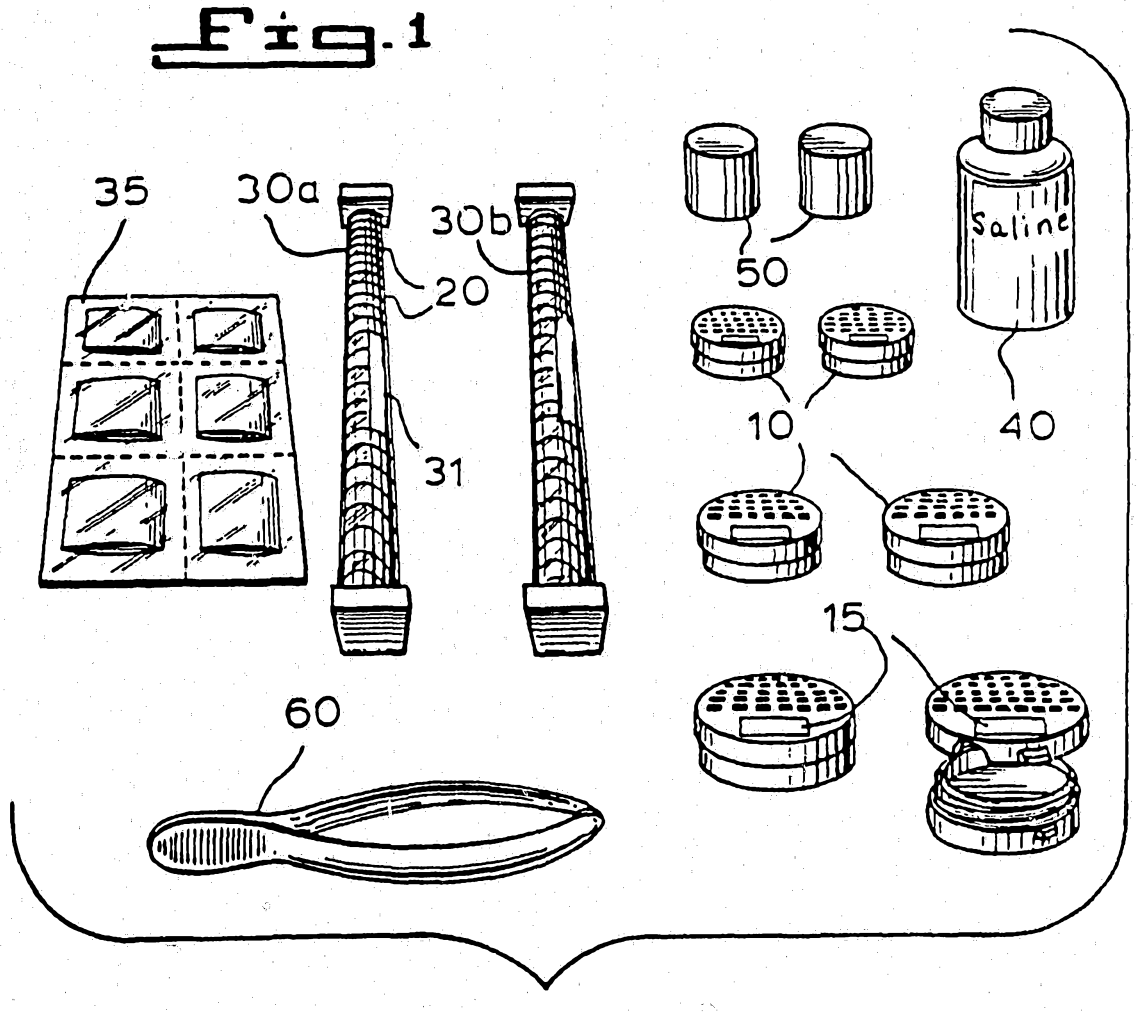
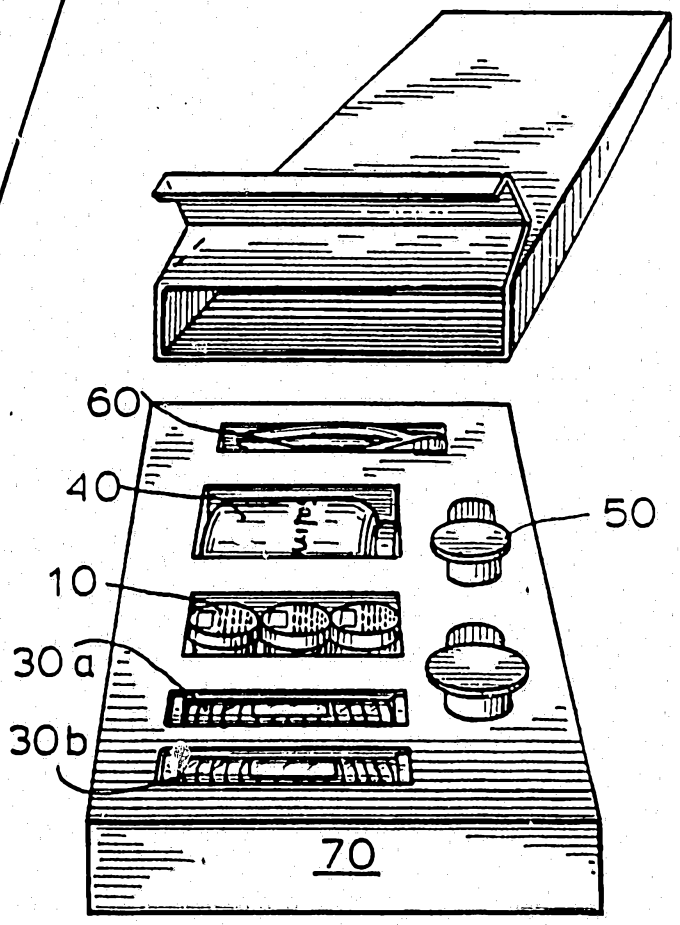


Fig. 2

Fig. 3



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/03157

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A45C 1/04; B65D 85/30

U.S. CL.: 206/5.1, 223, 523

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	206/5.1, 223, 523

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US,A, 3,036,083 OBITTS 13 November 1962 (13.11.62)	
A	US,A, 3,089,500 STALCUP 14 May 1963 (14.05.63)	
A	US,A, 3,115,146 ERWIN 24 December 1963 (24.12.63)	
A	US,A, 3,124,240 CROAN 10 March 1964 (10.03.64)	
A	US,A, 3,150,406 OBITTS 29 September 1964 (29.09.64)	
A	US,A, 3,168,100 RICH 02 February 1965 (02.02.65)	
A	US,A, 3,186,540 BREGER 01 June 1965 (01.06.65)	
A	US,A, 3,369,656 SKINNER, JR. 20 February 1968 (20.02.68)	
	(cont'd on supplemental sheet (2))	

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
07 November 1988	19 JAN 1989
International Searching Authority	**Signature of Authorized Officer**
ISA/US	Stephen Garbe

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US,A, 3,429,432 CABERNOCH ET AL 25 February 1969 (25.02.69)	
A	US,A, 3,645,284 KREZANOSKI ET AL 29 February 1972 (29.02.72)	
A	US,A, 4,294,349 IBSEN ET AL 13 October 1981 (13.10.81)	
A	US,A, 4,337,858 THOMAS ET AL 06 July 1982 (06.07.82)	
A	US,A, 4,392,569 SHOUP 12 July 1983 (12.07.83)	

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [1] not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [2], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4 ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US,A, 4,415,076 CAMPBELL 15 November 1983 (15.11.83)	
A	US,A, 4,429,786 HUCAL 07 February 1984 (07.02.84)	
A	US,A, 4,444,307 JERMYN 24 April 1984 (24.04.84)	
A	US,A, 4,568,517 KASPAR ET AL 04 February 1986 (04.02.86)	
A	US,A, 4,574,944 GREGORY 11 March 1986 (11.03.86)	