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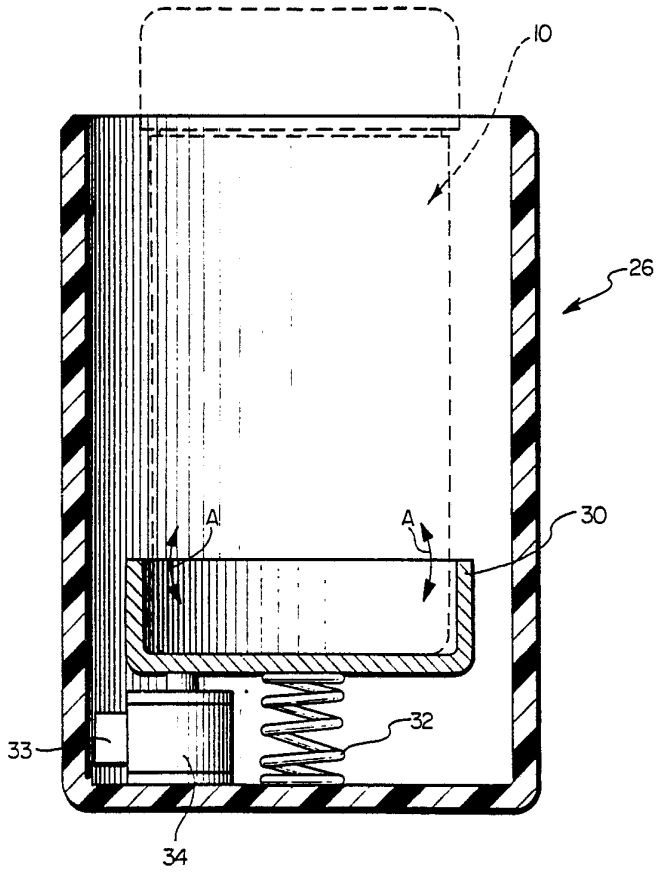
(54) Title: IMPROVED METHOD AND APPARATUS FOR THE STERILIZATION OF CONTACT LENSES UTILIZING MECHANICAL AGITATION

(57) Abstract

Contact lenses are disinfected in a method including treating the contact lenses with an aqueous system of hydrogen peroxide in the presence of a hydrogen peroxide decomposition catalyst, and mechanically agitating the system in order to accelerate decomposition of the hydrogen peroxide. In a preferred embodiment of the method, the initial concentration of hydrogen peroxide in the system is approximately 3-4 % and the mechanical agitation promotes decomposition of the hydrogen peroxide to a concentration of 50 parts per million or less within 6 hours following initial contact of the catalyst with the system. The catalytic decomposition can be performed in a conventional lens sterilization vessel (12) which is secured to a drive mechanism (26) for repeated motion of the reaction vessel (12) in order to maintain continuous agitation of the sterilization system (10) therein.



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IMPROVED METHOD AND APPARATUS FOR THE STERILIZATION OF CONTACT LENSES UTILIZING MECHANICAL AGITATION

BACKGROUND OF THE INVENTION

This invention relates to sterilization of contact lenses using hydrogen peroxide as the disinfectant, and more particularly relates to improved catalytic control of the decomposition of hydrogen peroxide in the lens disinfection process.

The well-known, commercialized soft contact lens disinfection process employing hydrogen peroxide solution as a bactericide is described for example in U.S. patents 4,750,610; 4,013,410 and 3,912,451. Recent improvements in contact lens cases for conducting such disinfection process are described in co-pending U.S. Patent application Serial No. 364,471 filed June 9, 1989, the disclosure of which is incorporated by reference herein. In such process, the contact lenses are immersed overnight in a weak bactericidal solution of hydrogen peroxide, approximately 3%, which solution is also subjected to a platinum catalyst to promote gradual decomposition of the hydrogen peroxide, viz.,

into water and liberated oxygen. This decomposition is critical, since significant hydrogen peroxide residues upon contact lenses can cause harm and irritation to the eyes of contact lens wearers. It has generally been recommended not only to allow sufficient time for nearly complete decomposition of the hydrogen peroxide, but additionally to employ a rinsing solution to flush any potential hydrogen peroxide residues from the lenses before insertion into the eyes.

In addition to the decomposition of the hydrogen peroxide, it is also important that the lenses be exposed to the relevant maximum strength of the disinfectant solution for sufficient time to destroy the harmful bacteria. Thus, the decomposition must not be too rapid, otherwise the lenses will not be thoroughly disinfected. The decomposition process, however, must be complete after a period of time to protect the eyes.

One object of the present invention is to improve the catalytic control over the hydrogen peroxide lens disinfection process, while additionally ensuring that upon completion of the lens disinfection process, the terminal hydrogen peroxide concentration is sufficiently reduced for safe contact by residues adhering to the disinfected lenses with the eyes of the wearer.

SUMMARY OF THE INVENTION

In accordance with the present invention, contact lenses are disinfected in a method including treating the contact lenses with an aqueous system of hydrogen peroxide in the presence of a hydrogen peroxide decomposition catalyst, and mechanically agitating the system in order to accelerate decomposition of the hydrogen peroxide. Since the initial concentration of hydrogen peroxide is desirably maintained above 1% for

lens disinfection during the initial period of lens contact in the system, for example a period of one-half to one full hour, and since the catalytic decomposition of the hydrogen peroxide by many catalytic elements during this initial period is not limited by transport of the hydrogen peroxide molecules to the catalytic surface, the activation of mechanical agitation of the disinfection system can be optionally delayed without lengthening the desired decomposition progress. In preferred embodiments of the method, the initial concentration of hydrogen peroxide in the system is approximately 3-4% and even delayed mechanical agitation promotes decomposition of the hydrogen peroxide to a concentration of less than 50 parts per million within less than 6 hours following initial contact of the catalyst with the system. Generally, even the delayed mechanical agitation can achieve reduction of the hydrogen peroxide concentration to less than 10 ppm in a shorter period of total elapsed time of catalyst contact with the system, so that the required duration of the lens disinfection operation can be reduced.

The catalytic decomposition can be performed in a conventional lens sterilization vessel which is secured to a drive mechanism for repeated motion of the reaction vessel in a time delayed manner, in order to maintain continuous agitation of the sterilization system therein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevation view illustrating of a conventional contact lens sterilization case containing a hydrogen peroxide system, which is inserted into a receptacle which has an electrically powered motion generator of any conventional design which agitates the vessel and the contained sterilization system;

FIG. 2 is a sectional view of the receptacle in FIG. 1 showing the inserted lens case in phantom illustration and an oscillatory motion generated to agitate the lens case in one embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, a typical sterilizing appliance or lens case which can be employed in accordance with the present invention is designated generally by reference numeral 10. Appliance 10 includes a generally cylindrical reaction vessel 12 which has an open top on which the cap member 14 is removably threaded. The reaction vessel 12 is designed to contain a contact lens sterilizing solution of aqueous hydrogen peroxide 16. The conventional solution 16 is approximately 3%-4% hydrogen peroxide buffered for sterilization of typical soft contact lenses. Initial concentration of the hydrogen peroxide solution can be varied to suit the sterilization application and decomposition catalyst.

Depending from and welded to the cap 14 is a lens support structure generally designated by reference numeral 18 which projects downwardly into the container 12 to immerse a pair of contact lenses 20 in the sterilization solution when the cap 14 is mounted thereon as shown. The support structure includes a pair of pivotal lens holder cover members 22 which enclose a respective lens 20 within the support structure while enabling the passage of the sterilization solution therethrough in conventional manner. A hydrogen peroxide decomposition catalyst element 24 is removably inserted and retained at the bottom of the container 12 in conventional manner. Examples of typical lens cases of the general type referred to above can be found in

United States Patent Nos. 4,956,156; 4,013,410; and 4,750,610, the disclosure of which are incorporated herein by reference.

In the present invention, suitable hydrogen peroxide decomposition catalysts include metals from Periods 4, 5 and 6 of the Periodic Chart of Elements and the Lanthanide elements which are disposed on a carrier or substrate to extend the active surface of the catalytic metal. Among the metal hydrogen peroxide decomposition catalysts belonging to the aforementioned Periods 4, 5 and 6 are, for example, Pt, Pd, Ir, Rh, Re, Au, Ag, Cu, Cr, Os, Co, Fe, Mo, W, Mn, Ce and Th.

Particularly for commercial reasons, platinum is the preferred hydrogen peroxide decomposition catalytic metal. Preferably, the platinum is disposed on an inexpensive support material which can be fabricated to provide a resulting catalytic element with extensive active surface area. Particularly suitable materials for the substrate support include polymeric materials on which the catalytic platinum can be securely disposed. The platinum metal can be deposited on the polymeric substrate using metal deposition techniques such as chemical deposition, vapor deposition, vacuum metalization, electroplating, or sputtering as more fully described in the aforementioned U.S. Patent 3,912,451.

In use, the contact lenses 20 are placed within the lens support structure 22. Hydrogen peroxide sterilization solution is then poured into the vessel 12 which contains the catalytic element. Alternatively, the catalytic element may be carried on the lens support structure so that the lenses and the catalytic element are immersed in the hydrogen peroxide solution at the same time as more fully described in co-pending U.S. Patent Application Serial No. 07/361,471 filed June 9,

1989, entitled Apparatus for Sterilizing Contact Lenses which is incorporated by reference herein.

Optionally, after appropriate delay time of, for example, 1/2 to 1 hour, the lens case or vessel 12 is then subjected to repeated mechanical agitation preferably in continuous oscillating motion indicated by arrow A, for example, by securing the vessel to an electrically driven oscillator mechanism 26, or similar motion generator. The mechanism 26 may be of various designs, its purpose being to produce agitation of the lens case 10. For example, the unit 26 as illustrated includes a housing 28 in which there is mounted a support 30 for the lens case 10. The support 30 is resiliently mounted by a mounting means or spring 32. A timer module 33 delays activation of an electrically driven oscillator 34 which imparts oscillating motion A to the support 30 which in turn produces the desired oscillation of the lens case 10. The mechanical agitation of the vessel and contained aqueous system then promotes accelerated diffusion and transport of the progressively diluted hydrogen peroxide molecules into contact with the decomposition catalyst to reduce the concentration of any residual hydrogen peroxide remaining after sterilization treatment of the contact lenses.

The following examples are illustrative of embodiments in accordance with the present invention but do not indicate limitation upon the scope of the claims.

EXAMPLES

The following table indicates the comparative performance of hydrogen peroxide decomposition within contact lens sterilization systems conducted both with and without mechanical agitation. In each of the indicated systems a pair of soft contact lenses was

subjected to hydrogen peroxide decomposition sterilization using a typical hydrogen peroxide buffered solution of approximately 3.75% in a conventional appliance as illustrated in FIG. 1 containing a typical catalytic element provided by sputtered platinum deposited on phenylene oxide polymeric support commercially supplied by General Electric Company under the trademark Noryl™, in conventional manner. The mechanically agitated or vibrated system designated A was evaluated by mounting the contact lens case on a small electrically driven vibration generator. The system designated B was not mechanically agitated.

Vibrated System	H_2O_2 Concentration at 6 hr. duration
A	6.9 ppm
Unvibrated System	
B	250.8 ppm

In both of systems A and B, the hydrogen peroxide concentration was reduced from initial concentration of approximately 3.75% to approximately 1% in generally the same time of approximately 23-25 minutes, however, hydrogen peroxide concentration of the vibrated system A was further reduced after six hours to less than 7 parts per million, while the hydrogen peroxide concentration of the unvibrated system B after six hours was reduced only to a level of approximately 251 parts per million, representing a potential risk of eye irritation to a contact lens wearer and exceeding the guideline maximum of 50 parts per million hydrogen peroxide for safe eye contact.

While particular embodiments of the present invention have been described herein, it will be obvious

to those skilled in the art that changes and modifications in various aspects may be made without departing from the broad scope of the invention. Consequently, the scope of the invention is not limited by any particular embodiment but is defined by the appended claims and the equivalents thereof.

The Invention is Claimed as Follows:

1. A method for disinfecting contact lenses comprising:

a) treating contact lenses with an aqueous system including hydrogen peroxide in the presence of a hydrogen peroxide decomposition catalyst; and

b) simultaneously mechanically agitating said system in order to accelerate decomposition of said hydrogen peroxide.

2. A method according to claim 1, wherein the initial concentration of said hydrogen peroxide in said system is approximately 3-4% and said mechanical agitation promotes decomposition of said hydrogen peroxide to a concentration less than 50 ppm within less than 6 hours following an initial contact of said catalyst with said system.

3. A method according to claim 1, further comprising delaying activation of said simultaneous mechanical agitation following initiation of said treating step (a).

4. Apparatus for disinfecting contact lenses, comprising:

a) a reaction vessel for containing contact lenses and an aqueous system including hydrogen peroxide in the presence of a hydrogen decomposition catalyst; and

b) agitation means for agitating said system in order to accelerate decomposition of said hydrogen peroxide.

5. Apparatus according to claim 4, wherein said agitation means comprises drive means for driving repeated motion of said reaction vessel in order to maintain continuous agitation of said system therewithin.

6. Apparatus according to claim 4, further comprising timing means for delaying activation of said

agitation means following initiation of said disinfecting.

FIG. 1

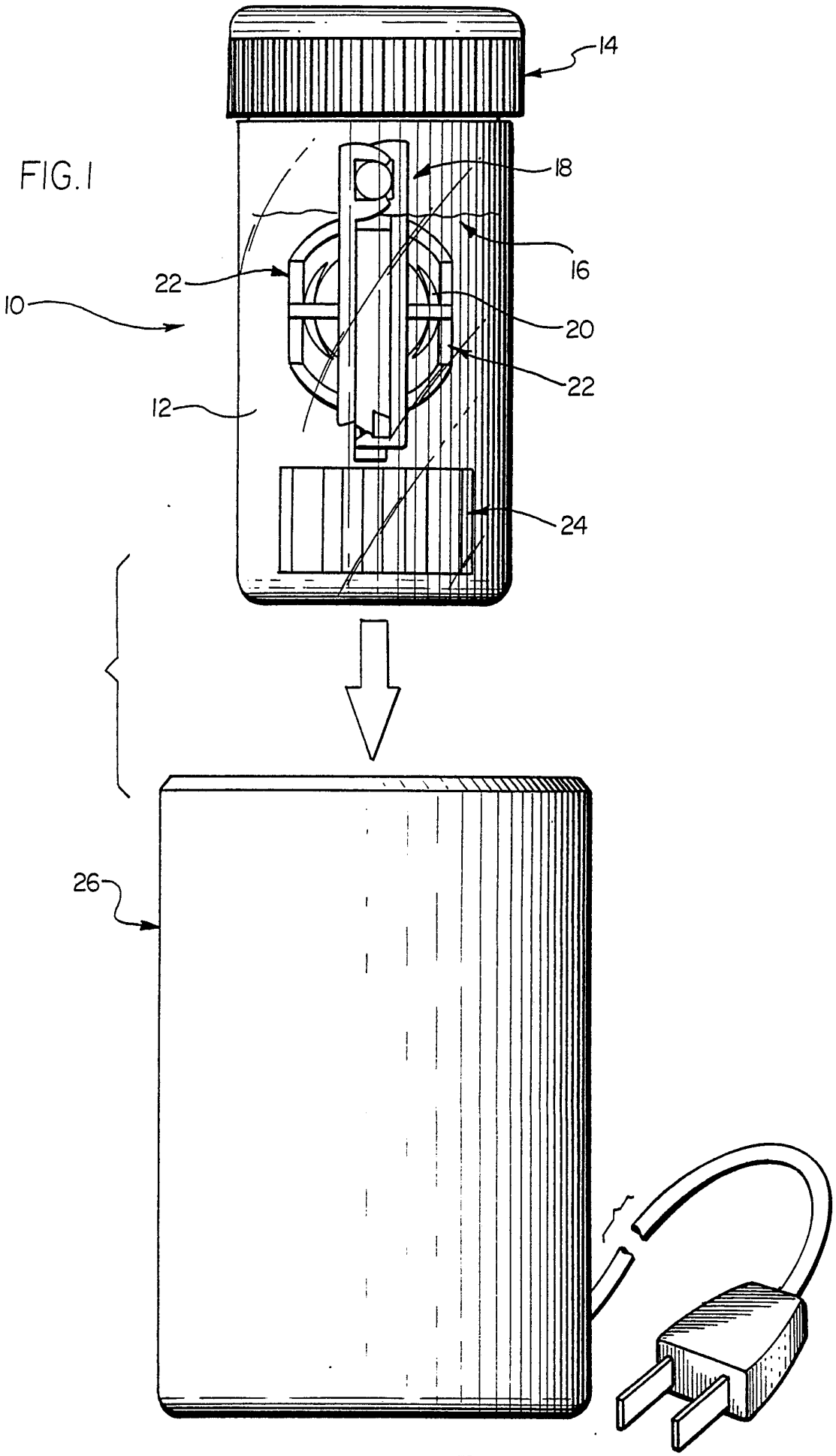
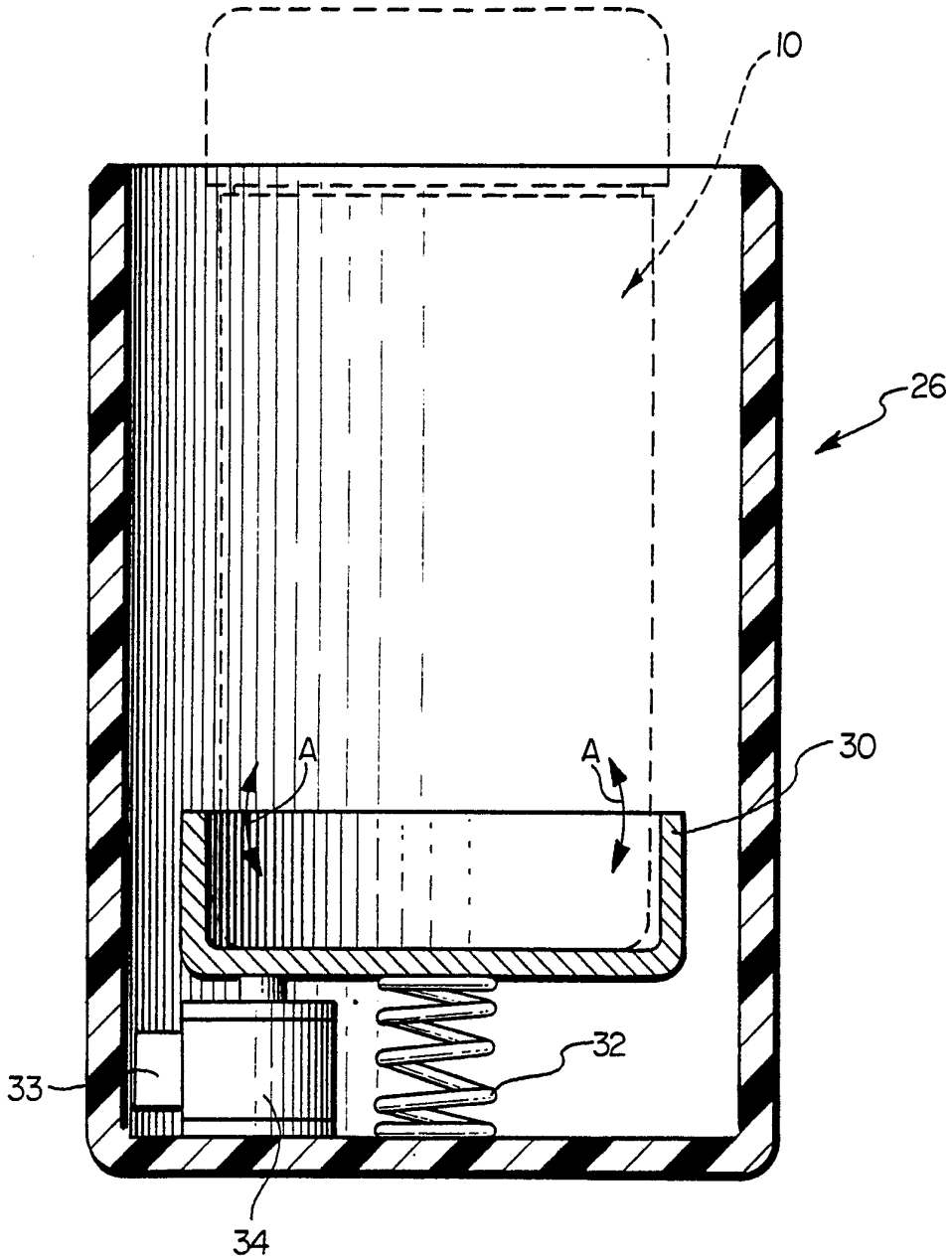


FIG. 2



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00271

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[3]

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

IPC (5): A61L 2/00
US CL : 422/28, 300, 301; 134/118,901

II. FIELDS SEARCHED

Minimum Documentation Searched[4]

Classification System	Classification Symbols
U.S.	422/28, 300, 301; 134/1, 35, 42, 118, 189, 901; 366/114, 210, 216

Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched[5]

APs
search terms: conatct lenses, oscillate, agitate, clean, disinfect, sterilize, catalyst, hydrogen peroxide

III. DOCUMENTS CONSIDERED TO BE RELEVANT[14]

Category*	Citation of Document,[16] with indication, where appropriate, of the relevant passages[17]	Relevant to Claim No.[18]
x/y	US, A, 4, 852, 592 (DiGangi et al.) 01 August 1989, see abstract, col. 3, lines 16-25, col. 6, lines 14-23, 45-58, col. 8, lines 24-25, 29-30, 64-68, col. 9, lines 1-8.	1, 3-6/2
x/y	US, A, 4, 852, 591 (Wisotzki et al.) 01 August 1989, see abstract, col. 2, lines 33-42, col. 3, lines 17-20, col. 4, lines 30-31.	1, 3-6/2
x	US, A, 4, 779, 633 (Thomas et al.) 25 October 1988, see abstract, col. 2, lines 32-44, col. 4, lines 48-55.	4-6
x	US, A, 3, 871, 395 (Murry) 18 March 1975, see column 6, lines 16, 65, 68, col. 7, line 1.	4-6
A	US, A, 4, 735, 223 (Ituarte) 05 April 1988, see entire document.	1-6
A	US, A, 4, 907, 613 (Litzaw) 13 March 1990, see entire document.	1-6
A	US, A, 4, 784, 167 (Thomas et al.) 15 November 1988, see entire document.	1-6

* Special categories of cited documents:[16]

"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[2]	Date of Mailing of this International Search Report[2]
20 FEBRUARY 1992	03MAR 1992
International Searching Authority[1]	Signature of Authorized Officer[20]
ISA/US	Theresa A. Trembley

Form PCT/ISA/210 (second sheet)(May 1986) ß

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 4, 653, 519 (Kanner) 31 March 1987, see entire document.	1-6
A	US, A, 3, 973, 760 (Browning et al.) 10 August 1976, see entire document.	1-6
A	US, A, 4, 889, 693 (Su et al.) 26 December 1989, see entire document.	1-6
A	US, A, 4, 396, 583 (LeBoeuf) 02 August 1983, see entire document.	1-6
A	US, A, 4, 597, 399 (Rabenau et al.) 01 July 1986, see entire document.	1-6

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 (1), 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 Search 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.