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U.S. UTILITY Patent Application

PATENT NUMBER and ISSUE DATE
8,268,299

APPLICATION NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
11/858,781					

(FACE)

NOTICE OF ALLOWANCE MAILED		Assistant Examiner	CLAIMS ALLOWED	
			Total Claims	Print Claim for O.G
ISSUE FEE			DRAWING	
Amount Due	Date Paid		Sheets Drwg. / Figs.Drwg. / Print Fig.	
☐ TERMINAL DISCLAIMER		Primary Examiner	Application Examiner	
		PREPARED FOR ISSUE		

FILED WITH: ☐ DISK (CRF) ☐ CD-ROM

(Attached in pocket on right inside flap)

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3205US
	Application Number	
Title of Invention	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
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☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3205US
	Application Number	
Title of Invention	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS	

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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	26356		
Email Address	gregg.brown@alconlabs.com	Add Email	Remove Email

Application Information:

Title of the Invention	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS		
Attorney Docket Number	3205US	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3205US
	Application Number	
Title of Invention	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	26356		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	60/827411	2006-09-28
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	60/826529	2006-09-21

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			◉ Yes ○ No

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3205US
	Application Number	
Title of Invention	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS	

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here. ☒			
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Country [i] US		Postal Code	76134
Phone Number	817-551-8663	Fax Number	817-551-4610
Email Address	gregg.brown@alconlabs.com		

Additional Assignee Data may be generated within this form by selecting the **Add** button. Add

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Gregg C. Brown, Reg. 30,613/			Date (YYYY-MM-DD)	2007-09-20
First Name	Gregg C.	Last Name	Brown	Registration Number	30613

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

described and claimed herewith and further identified as Attorney Docket No. 3205 US the specification of which (check one)

(X) is attached hereto.

( ) was filed by an authorized person on my behalf on _____, as Application Serial No. _____ and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known to me to be material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):			Priority Claimed	
Application Number	**Country**	**Filed (Month/Day/Year)**	**Yes**	**No**

I hereby claim the benefit under 35 USC §119(e) of any United States provisional application(s) listed below.

Prior Provisional Application(s):		Priority Claimed	
Application Number	**Filed (Month/Day/Year)**	**Yes**	**No**
60/827,411	**09/28/06**	**X**	
60/826,529	**09/21/06**	**X**	

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, Section 112. I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. Application(s):		Status: Patent, Pending, Abandoned
Application Number	**Filed (Month/Day/Year)**	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint those patent practitioners associated with Customer No. **26356** as my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith.

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Docket No. 3205 US

SELF-PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

Cross-Reference to Related Applications

The present application claims priority based on U.S. Provisional Patent Application Serial Nos. 60/827,411 filed September 28, 2006, and 60/826,529, filed September 21, 2006.

Background of the Invention

The present invention is directed to self-preserved pharmaceutical compositions. More specifically, the invention is directed to the provision of aqueous, multi-dose pharmaceutical compositions that have been formulated so as to have sufficient antimicrobial activity to satisfy the preservation efficacy requirements of the United States Pharmacopeia ("USP") and analogous guidelines in other countries, without requiring a conventional antimicrobial preservative, such as benzalkonium chloride, polyquaternium-1, hydrogen peroxide (e.g., sodium perborate), or chorine-containing agents. The ability to achieve self-preservation is based on a unique combination of formulation components and criteria.

Many pharmaceutical compositions are required to be sterile (i.e., free of bacteria, fungi and other pathogenic microorganisms). Examples of such compositions include: solutions and suspensions that are injected into the bodies of humans or other mammals; creams, lotions, solutions or other preparations that are topically applied to wounds, abrasions, burns, rashes, surgical incisions, or other conditions where the skin is not intact; and various types of compositions that are applied either directly to the eye (e.g., artificial tears, irrigating solutions, and drug products), or are applied to devices that will come into contact with the eye (e.g., contact lenses).

The foregoing types of compositions can be manufactured under sterile conditions via procedures that are well known to those skilled in the art. However, once the packaging for a product is opened, such that the composition contained therein is exposed to the atmosphere and other sources of potential microbial contamination (e.g., the hands of a human patient), the sterility of the product may be

compromised. Such products are typically utilized multiple times by the patient, and are therefore frequently referred to as being of a "multi-dose" nature.

Due to the frequent, repeated exposure of multi-dose products to the risk of microbial contamination, it is necessary to employ a means for preventing such contamination from occurring. The means employed may be: (i) a chemical agent that prevents the proliferation of microbes in a composition, which is referred to herein as an "antimicrobial preservative"; or (ii) a packaging system that prevents or reduces the risk of microbes reaching a pharmaceutical composition within a container.

Prior multi-dose ophthalmic compositions have generally contained one or more antimicrobial preservatives in order to prevent the proliferation of bacteria, fungi and other microbes. Such compositions may come into contact with the cornea either directly or indirectly. The cornea is particularly sensitive to exogenous chemical agents. Consequently, in order to minimize the potential for harmful effects on the cornea, it is preferable to use anti-microbial preservatives that are relatively non-toxic to the cornea, and to use such preservatives at the lowest possible concentrations (i.e., the minimum amounts required in order to perform their anti-microbial functions).

Balancing the anti-microbial efficacy and potential toxicological effects of anti-microbial preservatives is sometimes difficult to achieve. More specifically, the concentration of an antimicrobial agent necessary for the preservation of ophthalmic formulations from microbial contamination may create the potential for toxicological effects on the cornea and/or other ophthalmic tissues. Using lower concentrations of the anti-microbial agents generally helps to reduce the potential for such toxicological effects, but the lower concentrations may be insufficient to achieve the required level of biocidal efficacy (i.e., antimicrobial preservation).

The use of an inadequate level of antimicrobial preservation may create the potential for microbial contamination of the compositions and ophthalmic infections resulting from such contaminations. This is also a serious problem, since ophthalmic infections involving *Pseudomonas aeruginosa* or other virulent microorganisms can lead to loss of visual function or even loss of the eye.

Thus, there is a need for a means of enhancing the activity of anti-microbial agents so that very low concentrations of the agents can be utilized without increasing the potential for toxicological effects or subjecting patients to unacceptable risks of microbial contamination and resulting ophthalmic infections.

Ophthalmic compositions are generally formulated as isotonic, buffered solutions. One approach to enhancing the anti-microbial activity of such compositions is to include multi-functional components in the compositions. In addition to performing their primary functions, these multi-functional components also serve to enhance the overall anti-microbial activity of the compositions.

The following publications may be referred to for further background regarding the use of multi-functional components to enhance the antimicrobial activity of ophthalmic compositions:

1. U.S. Patent No. 5,817,277 (Mowrey-McKee, et al; tromethamine);
2. U.S. Patent No. 6,503,497 (Chowhan, et al.; borate/polyol complexes);
3. U.S. Patent No. 5,741,817 (Chowhan, et al.; low molecular weight amino acids such as glycine);
4. U.S. Patent No. 6,319,464 (Asgharian; low molecular weight amino alcohols);
5. U.S. Patent Application Publication No. US 2002/0122831 A1 (Mowrey-McKee, et al.; bis-aminopolyols);
6. U.S. Patent No. 6,348,190 (Illes, et al.; zinc); and
7. JP 2003-104870 (zinc).

The use of zinc to enhance the antimicrobial activity of pharmaceutical compositions, including ophthalmic solutions, is well known. See, for example, the following articles and patent publications, as well as U.S. Patent No. 6,348,190 and JP 2003-104870, cited above:

McCarthy, "Metal Ions and Microbial Inhibitors", Cosmetic & Toiletries, 100:69-72 (Feb. 1985);

Zeelie, et al., "The Effects of Selected Metal Salts on the Microbial Activities of Agents used in the Pharmaceutical and Related Industries", Metal Compounds in Environment and Life, 4:193-200 (1992);

Zeelie, et al., "Effects of Copper and Zinc Ions on the Germicidal Properties of Two Popular Pharmaceutical Antiseptic Agents, Cetylpyridinium Chloride and Povidone-iodine", Analyst, 123:503-507 (March 1998);

McCarthy, et al., "The Effect of Zinc Ions on the Antimicrobial Activity of Selected Preservatives", Journal of Pharmacy and Pharmacology, Vol. 41 (1989);

U.S. Patent No. 6,482,799 (Tuśe, et al.);

U.S. Patent No. 5,320,843 (Raheja, et al.);

U.S. Patent No. 5,221,664 (Berkowitz, et al.);

U.S. Patent No. 6,034,043 (Fujiwara, et al.);

U.S. Patent No. 4,522,806 (Muhlemann, et al.);

U.S. Patent No. 6,017,861 (Fujiwara, et al.); and

U.S. Patent No. 6,121,315 (Nair, et al.).

The present invention is directed to the provision of improved preservative systems containing zinc ions.

The compositions of the present invention are multi-dose products that do not require a conventional antimicrobial preservative (e.g., benzalkonium chloride), and yet are preserved from microbial contamination. Such compositions have been referred to in the art as being "preservative free" (see, e.g., U.S. Patent No. 5,597,559 issued to Olejnik, et al.). Compositions that are preserved from microbial contamination as a result of the inherent antimicrobial activity of one or more components of the compositions are also referred to in the art as being "self-preserved" (see, e.g., U.S. Patent No. 6,492,361 issued to Muller, et al.).

The following publication may be referred to for further background regarding pharmaceutical compositions that are "preservative-free" or "self-preserving": Kabara, et al., Preservative-Free and Self-Preserving Cosmetics and Drugs – Principles and Practice, Chapter 1, pages 1-14, Marcel Dekker, Inc. (1997).

The multi-dose compositions of the present invention, which do not contain a conventional antimicrobial preservative, are referred to herein as being "self-preserved".

Summary of the Invention

The present invention is directed to the self-preservation of aqueous ophthalmic compositions via the use of very low concentration of zinc ions. The present invention is based in part on the finding that in order to utilize low concentrations of zinc ions to self-preserve multi-dose ophthalmic compositions having ophthalmically acceptable pH and osmolality values, certain formulation parameters must be maintained. Specifically, the concentration of buffering anions utilized to maintain the pH within an ophthalmically acceptable range must be limited to an amount of 15 millimolar ("mM") or less in order to avoid interfering with the anti-microbial activity of the zinc ions.

In addition, it has been determined that the antimicrobial activity of the zinc-containing compositions of the present invention can be further enhanced by the use of zinc ions in combination with borate or a borate/polyol complex, and that if such a combination is utilized, the use of propylene glycol is strongly preferred, so as to avoid ionic interactions between anionic species generated by other polyols (e.g., sorbitol) and the zinc cations.

It has also been determined that the performance of the zinc-based preservative systems of the present invention is further enhanced by: (i) limiting the amount of multivalent metal cations other than zinc (e.g., calcium and magnesium) in the compositions of the present invention; and (ii) limiting the amount of ionized salts (e.g., sodium chloride and potassium chloride) in said compositions. As described in greater detail below, the compositions of the present invention are preferably free of or substantially free of both ionized salts and multivalent metal cations other than zinc.

The self-preserved, multi-dose compositions of the present invention have several advantages over existing ophthalmic formulations that are either: (i) packaged as a "single dose" or "unit of use" product, so as to avoid the inclusion of any antimicrobial preservative (e.g., BION®TEARS Lubricant Eye Drops, which is marketed by Alcon Laboratories, Inc.), or (ii) preserved by means of a so-called "disappearing" preservatives, such as the chlorite-based system described in U.S. Patent Nos. 5,424,078; 5,736,165; 6,024,954; and 5,858,346 (e.g., the artificial tears product "REFRESH™ Tears", which is marketed by Allergan), or the peroxide-containing system described in U.S. Patent Nos. 5,607,698; 5,683,993; 5,725,887; and

5,858,996 (e.g., the artificial tear product "GenTeal™ Tears", which is marketed by CIBAVision).

Unlike these existing products, the multi-dose ophthalmic compositions of the present invention are able to satisfy the USP preservative efficacy requirements, as well as analogous requirements in other countries, including the Japanese Pharmacopoeia ("JP") and European Pharmacopoeia ("EP") preservative efficacy standards, without employing any conventional antimicrobial preservatives, such as chlorite or hydrogen peroxide.

The above-discussed findings regarding the zinc may be applied to enhance the antimicrobial activity of various types of pharmaceutical compositions. However, the present invention is particularly directed to the provision of aqueous ophthalmic solutions that are effective in preventing microbial contamination in the absence of conventional antimicrobial preservatives, such as benzalkonium chloride ("BAC"), polyquaternium-1, chlorite or hydrogen peroxide.

Brief Description of the Drawings

Figures 1-3 are graphs showing the interaction of boric acid and various polyols.

Detailed Description of the Invention

The pharmaceutical compositions of the present invention contain zinc ions at a concentration of 0.04 to 0.9 millimoles/liter ("mM"), preferably 0.04 to 0.4 mM and most preferably 0.1 to 0.4 mM. The use of this very low concentration is particularly desirable in ophthalmic pharmaceutical compositions containing therapeutically active agents, such as prostaglandin analogues used to control intraocular pressure (e.g., travoprost), because at higher concentrations the zinc ions may produce an astringent effect when applied to the eye. The zinc ions are preferably provided in the form of zinc chloride, at a concentration of 0.0005 to 0.012 percent by weight/volume ("w/v%"), preferably 0.0005 to 0.005 w/v% and most preferably 0.001 to 0.005 w/v%.

The zinc may be provided in various forms, such as zinc chloride, zinc sulfate, zinc acetate or zinc carbonate. The use of zinc chloride is preferred.

As indicated above, the present invention is based on part on a finding that anionic agents utilized to buffer the compositions of the present invention may interfere with the ability of zinc to exert antimicrobial activity. Such interference can be very detrimental to the ability of the compositions to maintain sufficient antimicrobial activity to meet preservative efficacy standards, particularly in view of the very low concentrations of zinc utilized in the present invention. Accordingly, it has been determined that the total concentration of anionic species in the compositions of the present invention should be limited. Specifically, it is preferred that the total concentration of anionic species, particularly buffering anions, should be limited to an amount of less than 15 mM, more preferably less than 10 mM, and most preferably less than 5 mM. For simplicity and clarity, the concentration of buffering anionic species in this patent application will be represented by the concentration of monovalent cations (such as sodium) that are present or needed to bring the pH to the specified value.

As utilized herein, the phrase "less than" relative to a specified concentration (e.g., 15 mM) means that the specified component (e.g., buffering anions) is either not present in the composition at all or is present at a concentration less than the specified limit (e.g., 15 mM).

It has been determined that multivalent buffering anions, particularly citrate and phosphate, have a significant adverse effect on the antimicrobial activity of the zinc-based preservative systems described herein. The compositions of the present invention therefore preferably do not contain any multivalent buffering anions, other than borate-polyol complexes, which may be multivalent under certain conditions (e.g., pH and/or borate: polyol ratio), or are substantially free of such buffering anions. As utilized herein, the phrase "substantially free of multivalent buffering anions" means that the composition either does not contain any multivalent buffering anions or contains an amount of said anions that does not inhibit the ability of the composition to satisfy specified preservative efficacy standards (e.g., USP, EP or JP). The amount of multivalent buffering anions in the compositions of the present invention is preferably less than 5 mM, with said concentration being determined in the same manner as specified in the preceding paragraph.

As indicated above, it has been determined that the antimicrobial activity of the zinc-based preservative systems of the present invention is also adversely affected by other divalent cations, such as calcium and magnesium. The antimicrobial activity of divalent zinc ions (Zn^{2+}) is based upon the ability of the ions to competitively bind and

inactivate macromolecular complexes that are critical to the central metabolic activity of the prokaryotic cell. In order for Zn^{2+} to kill, it must first gain access to the cytoplasm and its charge density prevents its diffusion across the membrane at a physiologically significant rate. Therefore, the ability of Zn^{2+} ions to enter the cell must be facilitated by membrane transport proteins. Access to these transport proteins can be competitively inhibited by multivalent metal cations, particularly Mg^{2+}, Ca^{2+}, Mn^{2+}, Ni^{2+}, and Co^{2+}. Thus, increasing the extracellular concentration of these inhibitory cations diminishes the capacity of Zn^{2+} ions to gain access to the cytoplasm and subsequently reduces its cytotoxic activity to the microorganism.

In view of the potential interference of multivalent metal cations other than zinc, the compositions of the present invention preferably do not contain such cations or are substantially free of said cations. As utilized herein, the phrase "substantially free of multivalent metal cations other than zinc" means that the composition either does not contain such cations or contains an amount of said cations that does not inhibit the ability of the composition to satisfy specified preservative efficacy standards (e.g., USP, EP or JP). The amount of multivalent metal cations other than zinc in the compositions of the present invention is preferably less than 5 mM.

It has also been determined that ionized salts (e.g., sodium chloride and potassium chloride) adversely affect the antimicrobial activity of the preservative systems described herein. Accordingly, the compositions of the present invention preferably do not contain ionized salts, or are substantially free of ionized salts. As utilized herein, the phrase "substantially free of ionized salts" means that the composition either does not contain any ionized salt or contains an amount of ionized salt that does not inhibit the ability of the composition to satisfy specified efficacy standards (e.g., USP, JP or EP). The amount of ionized salt contained in the compositions of the present invention is preferably less than 50 mM.

As used herein, the term "borate" includes boric acid, sodium borate and potassium borate. The use of borates containing divalent cations (e.g., calcium borate) may adversely affect the antimicrobial action of zinc ions, by competing with zinc for binding sites on the cell walls of bacterial and other microbes, and is therefore should be avoided. For the same reason, the self-preserved compositions of the present invention are preferably free of or substantially free of other sources of divalent cations, such as calcium chloride.

The self-preserved compositions of the present invention preferably contain one or more borates in an amount of from about 0.1 to about 2.0% w/v, more preferably 0.3 to 1.5% w/v, and most preferably 0.5 to 1.2% w/v.

As used herein, the term "polyol" includes any compound having at least one hydroxyl group on each of two adjacent carbon atoms that are not in *trans* configuration relative to each other. The polyols can be linear or cyclic, substituted or unsubstituted, or mixtures thereof, so long as the resultant complex is water soluble and pharmaceutically acceptable. Examples of such compounds include: sugars, sugar alcohols, sugar acids and uronic acids. Preferred polyols are sugars, sugar alcohols and sugar acids, including, but not limited to: mannitol, glycerin, xylitol, sorbitol and propylene glycol.

As indicated above, the use of propylene glycol is particularly preferred in order to limit the presence of anionic species. Boric acid interacts with polyols, such as glycerol, propylene glycol, sorbitol and mannitol, to form borate polyol complexes. The type and ratio of such complexes depends on the number of OH groups of a polyol on adjacent carbon atoms that are not in trans configuration relative to each other. For example, propylene glycol has only one OH group on each of two adjacent carbon atoms that are not in trans configuration. Consequently, one molecule of boric acid will interact and form a complex with one or two molecules of propylene glycol, resulting in a monovalent anion. However, in the case of sorbitol, mannitol and other sugar-type polyols, this interaction is much more complex, because one molecule of such polyols can complex with two molecules of borate and then further complex with two additional molecules of the polyol, resulting in a multivalent anion.

When borate is present in the compositions of the present invention, the compositions preferably also contain one or more polyols, at a total concentration of 0.25 to 2.5% w/v. The polyol preferably is propylene glycol at a concentration of 0.25 to 1.80% w/v, preferably 0.25 to 1.25% w/v. Although less preferable than propylene glycol, sorbitol and mannitol are also preferred polyols, and preferably are used at a concentration of 0.05 to 0.75% w/v, preferably 0.05 to 0.5% w/v.

The compositions of the present invention preferably contain borate or a borate/polyol complex, most preferably a borate/polyol complex wherein the polyol portion of the complex is propylene glycol or a combination of propylene glycol and sorbitol. The preference for propylene glycol is based on a discovery that sorbitol and other polyols have a greater tendency to form anionic species at pH values of 7.5 or

less, and that such anionic species may interfere with the antimicrobial activity of zinc. The graphs shown in Figures 1-3 demonstrate that sorbitol has a much higher tendency to form anionic species in the presence of boric acid, compared to propylene glycol.

The data shown in Figures 1-3 were compiled as follows: A 1 Kg solution containing the given concentrations of boric acid and propylene glycol or sorbitol or mannitol was prepared and the initial pH of the solution was determined. 1 N NaOH was then added to adjust the pH. The cumulative amount of sodium hydroxide used to adjust pH to different values was then recorded.

As explained above, boric acid interacts and forms an ionic complex with species containing several hydroxyl groups, such as mannitol and sorbitol. However, the interaction between boric acid and propylene glycol is more limited than with other polyols. This is represented by the amount of sodium hydroxide needed to adjust pH, as shown in Figure 1. Sorbitol and mannitol significantly shift the curve relative to the amount of NaOH required to lower pH, whereas propylene glycol only slightly shifts the curve. This is further evident in Figure 2.

The present invention is particularly directed to the provision of multi-dose, self-preserved ophthalmic compositions that have sufficient antimicrobial activity to allow the compositions to satisfy the USP preservative efficacy requirements, as well as other preservative efficacy standards for aqueous pharmaceutical compositions, without a conventional antimicrobial preservative.

The preservative efficacy standards for multi-dose ophthalmic solutions in the U.S. and other countries/regions are set forth in the following table:

Preservative Efficacy Test ("PET") Criteria
(Log Order Reduction of Microbial Inoculum Over Time

	Bacteria	Fungi
USP 27	A reduction of 1 log (90%), by day 7; 3 logs (99.9%) by day 14; and no increase after day 14	The compositions must demonstrate over the entire test period, which means no increases of 0.5 logs or greater, relative to the initial inoculum.
Japan	3 logs by 14 days; and no increase from day 14 through day 28.	No increase from initial count at 14 and 28 days
Ph. Eur. A[1]	A reduction of 2 logs (99%) by 6 hours; 3 logs by 24 hours; and no recovery after 28 days	A reduction of 2 logs (99%) by 7 days, and no increase thereafter
Ph. Eur. B	A reduction of 1 log at 24 hours; 3 logs by day 7; and no increase thereafter	A reduction of 1 log (90%) by day 14, and no increase thereafter
FDA/ISO 14730	A reduction of 3 logs from initial challenge at day 14; and a reduction of 3 logs from rechallenge	No increase higher than the initial value at day 14, and no increase higher than the day 14 rechallenge count through day 28.

[1]There are two preservative efficacy standards in the European Pharmacopoeia ' "A" and "B".

The standards identified above for the USP 27 are substantially identical to the requirements set forth in prior editions of the USP, particularly USP 24, USP 25 and USP 26.

The compositions of the present invention may optionally also include one or more low molecular weight amino alcohols as buffering agents. The amino alcohols which may be utilized in the present invention are water-soluble and have a molecular weight in the range of from about 60 to about 200. The following compounds are representative of the low molecular weight amino alcohols which may be utilized in the present invention: 2-amino-2-methyl-1-propanol (AMP), 2-dimethylamino-methyl-1-propanol (DMAMP), 2-amino-2-ethyl-1,3-propanediol (AEPD), 2-amino-2-

methyl-1,3-propanediol (AMPD), 2-amino-1-butanol (AB). "AMP (95%)", which refers to 95% pure AMP and 5% water, is the most preferred low molecular weight amino alcohol of the present invention. These amino alcohols are available commercially from Angus Chemical Company (Buffalo Grove, Illinois). Tromethamine may also be utilized in the compositions of the present invention.

The amount of amino alcohol used will depend on the molecular weight of the amino alcohol selected, and the presence (or absence) of other ingredients in the composition (e.g., chelating agents, buffering agents and/or tonicity agents). The amino alcohol will generally be present in an amount necessary to enhance the antimicrobial activity of an aqueous self-preserved pharmaceutical composition of the type described herein. The amount of amino alcohol required for a particular composition can be determined through comparative testing. The above-described amino alcohols are also utilized in the compositions of the present invention to neutralize the pH of the borate or borate/polyol complex, or bring the composition to the desired pH level. The amount of amino alcohol required for this purpose is a function of the particular borate or borate/polyol mixture selected and the concentration thereof. In general, the self-preserved compositions of the present invention may optionally contain one or more amino alcohols at a total concentration of from about 0.01 to about 2.0 percent by weight/volume ("%w/v"), and preferably from 0.1 to 1.0 %w/v.

The zinc, zinc/borate, zinc/polyol and zinc/borate/polyol systems described herein may be included in various types of pharmaceutical compositions to enhance anti-microbial activity and self-preserve the compositions, such as ophthalmic, otic, nasal and dermatological compositions, but is particularly useful in ophthalmic compositions. Examples of such compositions include: ophthalmic pharmaceutical compositions, such as topical compositions used in the treatment of glaucoma, infections, allergies or inflammation; compositions for treating contact lenses, such as cleaning products and products for enhancing the ocular comfort of patients wearing contact lenses; and various other types of ophthalmic compositions, such as ocular lubricating products, artificial tears, astringents, and so on. The compositions may be aqueous or non-aqueous, but will generally be aqueous.

The compositions of the present invention may contain various types of therapeutic agents. However, the invention is most useful relative to therapeutic agents that are nonionic, since nonionic agents do not interfere with the antimicrobial activity of zinc cations in solution. Cationic therapeutic agents may also be utilized in

the compositions, particularly if the agent is included in the compositions in free base form or in the form of a salt with a monovalent anion, such as a hydrochloride salt. Cationic therapeutic agents that are included in the compositions in the form of a salt of a multivalent anion may interfere with the antimicrobial activity of the zinc preservative systems described herein, depending on the concentration of the anion. Such interference must be considered when selecting therapeutic agents that are suitable for use in the compositions of the present invention. Similarly, the use of therapeutic agents that are anionic may be considered; however, such agents may interfere with the activity of zinc ions, depending on the concentration of the agent and its dissociation constant.

Examples of therapeutic agents that may be contained in the ophthalmic compositions of the present invention include prostaglandin analogs (e.g., latanoprost, travoprost and unoprostone), hypotensive lipids (e.g., bimatoprost), and glucocorticoids (e.g., prednisolone, dexamethasone and lotoporednol).

The present invention is particularly directed to the provision of self-preserved, multi-dose ophthalmic compositions in connection with the treatment of conditions wherein the cornea or adjacent ocular tissues are irritated, or conditions requiring frequent application of a composition, such as in the treatment of dry eye patients. The self-preserved compositions of the present invention are therefore particularly useful in the field of artificial tears, ocular lubricants, and other compositions used to treat dry eye conditions, as well as other conditions involving ocular inflammation or discomfort.

The compositions of the present invention will generally be formulated as sterile aqueous solutions. The compositions of the present invention are also formulated so as to be compatible with the eye and/or other tissues to be treated with the compositions. The ophthalmic compositions intended for direct application to the eye will be formulated so as to have a pH and tonicity that are compatible with the eye.

The compositions will have a pH in the range of 4 to 9, preferably 5.5 to 8.5, and most preferably 5.5 to 8.0. It has been determined that a slightly alkaline pH increases the antimicrobial activity of the compositions of the present invention. The use of a pH in the range of 7.0 to 8.0 is therefore preferred.

The compositions will have an osmolality of 200 to 350 milliosmoles per kilogram (mOsm/kg), more preferably 250 to 330 mOsm/kg. As indicated above, the use of nonionic osmolality-adjusting agents is preferred, as ionic salts such as sodium chloride have been found to reduce the antimicrobial activity of the zinc-based preservative systems described herein. The use of propylene glycol, glycerol, xylitol or combinations thereof as nonionic osmolality adjusting agents is particularly preferred. Boric acid may also be utilized as an osmolality-adjusting agent in the compositions of the present invention. Boric acid, if utilized, will be present in the compositions as a mixture of ionic and nonionic species.

The compositions of the present invention may contain various types of pharmaceutical excipients, such as surfactants, viscosity-modifying agents and so on, provided that such excipients are non-ionic. The use of excipients that are cationic or anionic is not preferred, since such ionic agents may interfere with the zinc-based preservation systems described herein. This is particularly true with respect to anionic excipients. Accordingly, the compositions of the present invention are preferably free of or substantially free of anionic excipients.

In the event cationic or anionic excipients are utilized, the amount of excipient contained in the compositions must be limited to an amount that does not inhibit the ability of the composition to meet the applicable preservative efficacy requirements (e.g., USP, JP and/or EP) and adjustments to the formulation properties may be required. For example, the nonionic surfactant polyoxyl 40 hydrogenated castor oil can be used for solubilization or stabilization of drugs, such as travoprost. However, it has been determined that 12-hydroxy stearic acid, an anionic compound that has been determined to be present as an impurity and potential degradation product of the excipient polyoxyl 40 hydrogenated castor oil, interacts with zinc and forms particles. In order to avoid particle formation throughout the commercial shelf-life of a composition containing these components, the pH of the composition needs to be in the range 5.0 to 6.0, preferably in the range 5.5 to 5.9. These finding are further illustrated in Example Y, below.

One or more conventional antimicrobial preservatives (e.g., benzalkonium chloride and polyquaternium-1) can be present in the compositions of the present invention, if desired, but the compositions preferably do not contain any conventional antimicrobial preservatives. If utilized, such preservatives can be present in conventional amounts, but in view of the self-preserving properties of the compositions of the present invention, such conventional antimicrobial preservatives

can also be utilized in much lower concentrations than would be required to satisfy preservative efficacy requirements if only the conventional antimicrobial preservative were present. Since the present compositions can be a self-preserved composition, if an anti-microbial preservative is present as an option, the amount can be an amount that would not be effective alone as an antimicrobial preservative agent. However, the overall composition would have sufficient antimicrobial activity to satisfy USP/FDA/ISO preservative efficacy requirements.

Preferably the conventional antimicrobial preservative, if present, is not anionic and if anionic, it is preferred that the amount should be low enough to not substantially interfere with the antimicrobial activity of the preservative systems described herein.

Applicants specifically incorporate the entire contents of all cited references in this disclosure. Further, when an amount, concentration, or other value or parameter is given as either a range, preferred range, or a list of upper preferable values and lower preferable values, this is to be understood as specifically disclosing all ranges formed from any pair of any upper range limit or preferred value and any lower range limit or preferred value, regardless of whether ranges are separately disclosed. Where a range of numerical values is recited herein, unless otherwise stated, the range is intended to include the endpoints thereof, and all integers and fractions within the range. It is not intended that the scope of the invention be limited to the specific values recited when defining a range.

Other embodiments of the present invention will be apparent to those skilled in the art from consideration of the present specification and practice of the present invention disclosed herein. It is intended that the present specification and examples be considered as exemplary only with a true scope and spirit of the invention being indicated by the following claims and equivalents thereof.

The following examples are presented to further illustrate selected embodiments of the present invention. The formulations shown in the examples were prepared using procedures that are well-known to persons of ordinary skill in the field of ophthalmic pharmaceutical compositions.

Antimicrobial preservative effectiveness as set forth by the examples *infra* was determined using an organism challenge test according to the methods described in the United States Pharmacopeia 24 (USP) for category 1A products. Samples were

inoculated with known levels of one or more of the following: gram-positive vegetative bacteria (*Staphylococcus aureus* ATCC 6538), gram-negative vegetative bacteria (*Pseudomonas aeruginosa* ATCC 9027 and *Escherichia coli* ATCC 8739), yeast (*Candida albicans* ATCC 10231) and mold (*Aspergillus niger* ATCC 16404). The samples were then pulled at specified intervals to determine if the antimicrobial preservative system was capable of killing or inhibiting the propagation of organisms purposely introduced into the formulation. The rate or level of antimicrobial activity determines compliance with the USP preservative efficacy standards for the cited categories of preparations. In some instances, the PET screen test was conducted for only 7 days, rather than 14 or 28 days, with additional time points of 6 and 24 hours being added to evaluate preservative efficacy relative to Ph. Eur. B. criteria. This modified PET screen test has been shown to be a reliable test for determining whether a composition will meet USP or Ph. Eur. B criteria.

Table 1

Preservative Standards for U.S. Category 1A Products presented as Log Reduction of Organism Population

Time Pulls	24 Hours	7 days	14 days	28 days
For Bacteria (*S. aureus, P. aeruginosa, and E. coli*)				
Ph. Eur. B	1.0	3.0	NI	NI
USP	NA	1.0	3.0	NI
For Fungi (*C. albicans and A. niger*)				
Ph. Eur. B	NA	NA	1.0	NI
USP	NA	NI	NI	NI

NI = No increase at this or any following time pulls

NA = Time point not required for applicable standard (e.g., USP or Ph. Eur. B)

As shown in Table 1, the USP 24 Antimicrobial Effectiveness Test requires that compositions containing Category 1A products have sufficient anti-bacterial activity to reduce an initial inoculum of approximately 10^5 to 10^6 bacteria by one log (i.e., a 90% reduction in the microorganism population) over a period of seven (7) days and by three logs (i.e., a 99.9% reduction in the microorganism population) over a period of fourteen (14) days, and requires that there cannot be any increase in the microorganism population following the conclusion of the fourteen day period. Relative to fungi, the USP standards require that the compositions maintain stasis (i.e., no growth) relative to the population of the initial inoculum over the entire 28 day test

period. A category 1A product is an injection, or other parenteral including emulsions, otic, sterile nasal products and ophthalmic products made with aqueous bases or vehicles.

The margin of error in calculating microorganism populations is generally accepted to be +/-0.5 logs. Accordingly, the term "stasis", as utilized herein relative to the above-discussed USP standards, means that the initial population cannot increase by more than 0.5 log orders, relative to the initial population.

Examples A - E

The formulations of Examples A-E were evaluated to determine the effect of buffering anions on preservative efficacy. As discussed in greater detail below, the formulations of Examples A and B do not contain buffering agents. Although these formulations satisfied the USP preservative efficacy requirements, the presence of a buffering system is highly desirable, so as to prevent pH drift over the life of a commercial product (i.e., a period of up to two years or more). The formulation of Example C include a borate/polyol buffering system, but the system has minimal buffering capacity. As with the formulations of Examples A and B, the formulation of Example C satisfied the USP requirements. The formulations of Examples D and E contain significantly greater concentrations of buffering agents and consequently a higher buffering capacity. However, the relatively large amount of buffering anions present resulted in a failure of the formulations to satisfy preservative efficacy requirements. Thus, a comparison of Examples A-E demonstrates the need to balance the requirements for an effective buffering system with the antimicrobial activity required to satisfy preservative efficacy requirements.

The formulation of Example A does not have any buffering ingredient. The amount of sodium hydroxide used in the formulation (0.2 mM) to adjust pH is minimal, which means that the buffering anion concentration is very low. This formulation containing 0.18 mM zinc (0.0025% zinc chloride) meets USP preservation criteria, but is not desirable from a commercial perspective due to the lack of buffering capacity.

Though the formulation of Example B contains boric acid, it does not have buffering capacity as the pKa of boric acid (alone) is much higher than 6. The amount of sodium hydroxide used in the formulation (0.3 mM) to adjust pH is minimal. This formulation containing 0.18 mM zinc (0.0025% zinc chloride) meets USP

preservation criteria, but is not commercially desirable due to the lack of buffering capacity.

The formulation of Example C includes two excipients, boric acid and propylene glycol, which together add significantly to the osmolality of the composition and provide minimal buffering capacity. The amount of sodium hydroxide required in this formulation to adjust pH (0.5 mM) is somewhat higher than for the formulations of Examples A and B, but still very low compared to the limits specified herein (i.e., less than 15 mM, more preferably less than 5 mM). This formulation, containing 0.18 mM Zinc (0.0025% zinc chloride), meets USP preservation criteria, but the buffering capacity is not ideal relative to commercial viability.

Adding boric acid and sorbitol in the amounts indicated for the formulations of Examples D and E provides significant buffering capacity, but results in very high buffering anion concentrations (i.e., 77 and 49 mM, respectively). Example D does not meet USP preservation criteria for either *S. aureus* or *E. coli* at days 7 and 14. Example E does not meet USP preservation criteria for *S. aureus* at day *14* or for *E. coli* at days 7 and 14. These results demonstrate that the addition of significant amounts of buffering anions disrupted the preservation activity of the compositions. Thus, although the buffering systems of the formulations in Examples D and E are commercially viable, the preservative systems do not satisfy USP requirements and consequently would not be acceptable for a commercial product subject to the USP requirements or similar requirements in countries other than the U.S.

Example	A	B	C	D	E
FID	107339	107340	107431	106737	106757
Lot Number	04-37152	04-37160-1	04-37290	04-36171	04-36176
Ingredient	**Concentration (w/v %)**				
Travoprost	0.004	0.004	0.004	0.004	0.004
Polyoxyl 40 Hydrogenated Castor Oil (HCO-40)	0.5	0.5	0.5	0.5	0.5
Zinc Chloride	0.0025	0.0025	0.0025	0.0025	0.0025
Boric Acid	None	1	1	1	0.5
Sorbitol	0.25	None	None	3.8	3.2
Propylene Glycol	0.75	None	0.75	None	None
Sodium Hydroxide, and/or Hydrochloric Acid	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 6.0
Purified Water	QS 100 %	QS 100 %	QS 100 %	QS 100 %	QS 100 %
Osmolality	113	Not tested	274	291	208
Monovalent cation (Na) conc. needed to adjust pH of buffering anions	0.2 mM	0.3 mM	0.5 mM	77 mM	49 mM
Microorganism	**Log Order Reductions**				
S. aureus					
7 D	5.0	5.0	4.7	0.9	1.1
14 D	5.0	5.0	4.7	1.8	2.3
28 D	5.0	5.0	4.7	4.4	4.7
P.aeruginosa					
7 D	5.0	5.0	4.9	2.1	4.0
14 D	5.0	5.0	4.9	4.3	4.9
28 D	5.0	5.0	4.9	5.1	4.9
E. coli					
7 D	5.0	5.0	4.5	0.9	0.9
14 D	5.0	5.0	5.1	1.4	2.1
28 D	5.0	5.0	5.1	5.2	4.9
C. albican					
7 D	1.4	0.0	0.0	0.3	0.1
14 D	3.3	0.6	0.2	0.4	0.6
28 D	3.4	4.9	0.9	0.7	1.5
A. niger					
7 D	0.0	1.4	0.7	3.4	2.7
14 D	0.7	2.2	0.2	3.7	3.7
28 D	0.6	2.3	0.5	4.9	4.3

Examples F through J

In these examples, the amount of sorbitol was reduced to 1%, while keeping the boric acid concentration at 1%, in order to reduce the concentration of buffering anionic species. In addition, examples G, I, and J contain 0.75% propylene glycol. All five examples have an anionic buffer concentration of about 19 mM.

The compositions of Examples F and G contain 0.18 mM of zinc. These have much better anti-microbial activity against *S. Aureus* than the formulations of Examples D and E, above. Specifically, the compositions of Examples F and G meet USP preservation criteria for *S. aureus*. However, although the antimicrobial activity against *E. coli* at zinc concentrations of 0.18 mM (Examples F and G) and 0.36 mM (Example H and I) is improved, compared to examples D and E, it is not sufficient to consistently meet USP preservation criteria at day 14. Increasing the zinc concentration to 1.8 mM (Example J) improved the antimicrobial activity of the solution, so as to allow it to meet USP criteria. However, as indicated above, such higher concentration of zinc are not preferred in ophthalmic products, as zinc may provide astringent activity at these concentrations.

All of the formulations of Examples F-J contained anionic buffer concentrations of 19 mM, which is greater than the preferred limit of 15 mM specified herein. The fact that these compositions were not able to consistently meet or exceed the USP preservative efficacy requirements, even at relatively high zinc concentrations, further demonstrates the importance of limiting the concentration of buffering anions.

Example	F	G	H	I	J
FID	106039	106755	107038	107039	107099
Lot Number	04-36405	04-36173	04-36479	04-36476	04-36632
Ingredient	**Concentration (w/v %)**				
Travoprost	0.004	0.004	0.004	0.004	0.004
Polyoxyl 40 Hydrogenated Castor Oil (HCO-40)	0.5	0.5	0.5	0.5	0.5
Zinc Chloride	0.0025	0.0025	0.005	0.005	0.025
Boric Acid	1	1	1	1	1
Sorbitol	1	1	1	1	1
Propylene Glycol	None	0.6	None	0.6	0.6
Sodium Hydroxide, and/or Hydrochloric Acid	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 6.0
Purified Water	QS 100 %	QS 100 %	QS 100 %	QS 100 %	QS 100 %
Osmolality	--	279	204	288	291
Monovalent cation (Na) conc. needed to adjust pH of buffering anions	19 mM	19 mM	19 mM	19 mM	19 mM
Microorganism	**Log Order Reductions**				
S. aureus					
7 D	2.1	2.2	1.7	3.4	4.4
14 D	3.7	4.4	4.0	3.7	5.1
28 D	5.0	5.2	5.0	5.0	5.1
P.aeruginosa					
7 D	2.6	3.2	3.0	3.4	4.9
14 D	4.6	5.1	4.7	4.6	4.9
28 D	5.0	5.1	5.0	5.0	4.9
E. coli					
7 D	1.7	1.7	1.4	1.5	3.4
14 D	2.3	2.8	3.0	2.3	4.9
28 D	5.1	5.2	5.1	5.1	4.9
C. albican					
7 D	0.2	0.3	0.2	0.2	0.7
14 D	0.1	0.4	0.2	0.9	1.0
28 D	0.4	0.7	0.6	1.3	1.2
A. niger					
7 D	3.0	2.7	3.0	3.0	3.4
14 D	3.1	3.6	3.7	3.0	3.6
28 D	3.7	4.3	3.8	3.8	3.6

Examples K through N

In these examples, the amount of sorbitol was reduced to 0.25%, while keeping the boric acid concentration at 1%, in order to reduce the concentration of buffering anionic species. In addition, the compositions of Examples L-N contain 0.75% propylene glycol. The formulations of Examples K and L have an anionic buffer concentration of about 4 mM, which is within the preferred range of less than 5 mM specified herein. The antimicrobial activity of these compositions against *E. coli* at a zinc concentration of 0.18 mM (0.0025 w/v%) is significantly improved, relative to the activity of the formulations in Examples F-J, and the compositions meet USP preservation criteria. In examples M and N, the pH was adjusted to 5.5 and 6.5, respectively, while maintaining the USP preservation efficacy. The results obtained with the formulations of Examples K through N, which are representative of the compositions of the present invention, further demonstrate the importance of limiting the concentration of buffering anions, relative to satisfying preservative efficacy requirements.

Example	K	L	M	N
FID	107046	**107047**	**109032**	**109033**
Lot Number	04-36523	37157-3	05-40452	05-40453
Ingredient				
Travoprost	0.004	0.004	0.004	0.004
Polyoxyl 40 Hydrogenated Castor Oil (HCO-40)	0.5	0.5	0.5	0.5
Zinc Chloride	0.0025	0.0025	0.0025	0.0025
Boric Acid	1	1	1	1
Sorbitol	0.25	0.25	0.25	0.25
Propylene Glycol	None	0.75	0.75	0.75
Sodium Hydroxide, and/or Hydrochloric Acid	Adjust pH to 6.0	Adjust pH to 6.0	Adjust pH to 5.5	Adjust pH to 6.5
Purified Water	QS 100 %	QS 100 %	QS 100 %	QS 100 %
Osmolality	176	272	283	278
Monovalent cation (Na) conc. needed to adjust pH of buffering anions	3.9 mM	4.1 mM	2 mM	7.5 mM
Microorganism		**Log Order Reductions**		
S. aureus				
7 D	2.6	4.1	3.2	3.4
14 D	4.7	5.0	4.8	4.8
28 D	5.0	5.0	4.8	4.8
P.aeruginosa				4.9
7 D	4.6	4.5	4.9	4.9
14 D	5.0	5.0	4.9	4.9
28 D	5.0	5.0	4.9	
E. coli				
7 D	2.7	1.9	3.4	3.4
14 D	5.1	5.0	4.9	4.9
28 D	5.1	5.0	4.9	4.9
C. albican				
7 D	0.1	0.2	0.1	0.2
14 D	0.1	0.6	0.3	0.4
28 D	0.4	1.0	0.9	1.3
A. niger				
7 D	2.2	2.3	2.7	2.6
14 D	2.3	3.8	3.1	2.6
28 D	3.0	3.5	3.8	2.8

Examples O and P

In these examples, the amount of boric acid was reduced. The formulations meet USP preservation criteria and are representative of the compositions of the present invention.

Example	O	P
FID	**107519**	**107520**
Lot Number	04-37442	04-37443
Ingredient	**Concentration (w/v %)**	
Travoprost	0.004	0.004
Polyoxyl 40 Hydrogenated Castor Oil (HCO-40)	0.5	0.5
Zinc Chloride	0.0025	0.0025
Boric Acid	0.3	0.15
Sorbitol	0.25	0.125
Propylene Glycol	1.6	1.6
Sodium Hydroxide, and/or Hydrochloric Acid	Adjust pH to 6.0	Adjust pH to 6.0
Purified Water	QS 100 %	QS 100 %
Osmolality	281	247
Sodium Hydroxide conc.	2.2 mM	0.5 mM
Monovalent cation (Na) conc. needed to adjust pH of buffering anions	2.2 mM	0.5 mM
Microorganism	**Log Order Reductions**	
S. aureus		
7 D	4.9	5.0
14 D	4.9	5.0
28 D	4.9	5.0
P.aeruginosa		
7 D	5.0	5.0
14 D	5.0	5.0
28 D	5.0	5.0
E. col		
7 D	5.1	5.1
14 D	5.1	5.1
28 D	5.1	5.1
C. albican		
7 D	0.3	0.2
14 D	0.9	1.0
28 D	1.5	2.0
A. niger		
7 D	2.6	2.6
14 D	3.0	2.3
28 D	3.7	2.6

Examples Q and R

The preservation of formulations containing 0.18 mM zinc (0.0025% zinc chloride), with or without boric acid. was evaluated. The results show that antimicrobial activity was greater with the presence of boric acid/polyols. However, the formulation of Example R exhibited sufficient activity to satisfy USP preservative efficacy requirements, even though it did not contain boric acid. The ability of the formulation of Example R to meet preservative efficacy requirements is believed to be attributable in part to the fact that the formulation: (i) did not contain any multivalent anionic buffering agents and (ii) contained a non-ionic agent (i.e., propylene glycol) as the principal osmolality adjusting agent. The formulations of Examples Q and R are representative of the compositions of the present invention.

Examples		Q	R
FID		112306	112308
Lot Number		07-47316	07-47318
Ingredients		Concentration (w/v %)	
Zinc Chloride		0.0025	0.0025
Tromethamine		None	0.13
Propylene Glycol		1.6	1.6
Boric Acid		0.25	None
Mannitol		0.1	None
Sodium Hydroxide, and/or Hydrochloric Acid		Adjust pH to 7.5	Adjust pH to 7.5
Purified Water		QS 100%	QS 100%
Osmolality (mOsm/kg)		261	232
Sodium Hydroxide concentration		4.4 mM NaOH	None
Monovalent Cation (sodium) needed to adjust pH of buffering anions		4.4 mM NaOH	*
Microorganism		Log Order Reductions	
S. Aureus	6 Hours	0.5	1.4
	24 Hours	2.6	3.5
	7 Days	5.1	5.1
	14 Days	NT	NT
	28 Days	NT	NT
Pseudomonas A	6 Hours	1.4	2.8
	24 Hours	4.0	3.8
	7 Days	5.1	5.1
	14 Days	NT	NT
	28 Days.	NT	NT
E. Coli	6 Hours	0.8	0.7
	24 Hours	1.5	1.7
	7 Days	5.1	5.1
	14 Days	NT	NT
	28 Days.	NT	NT
Candida A.	7 Days	0.9	0.3
	14 Days	NT	NT
	28 Days.	NT	NT
A. Niger	7 Days	1.7	0.4
	14 Days	NT	NT
	28 Days.	NT	NT

* This formulation does not contain any buffering anion. However, it contains a buffering cation, tromethamine. pH is adjusted using 8.8 mM HCl.

NT = Not Tested

Examples Q and S

A comparison of the formulations of Examples Q and S demonstrates that the preservation efficacy of formulations containing 0.18 mM zinc (0.0025% zinc chloride) is reduced in the presence of low levels of a multivalent metal cation, i.e., calcium. However, the amount of multivalent metal cation in the formulation of Example S (i.e., 2.3 mM), which is less than the upper limit specified herein (i.e., less than 5 mM), was not great enough to significantly inhibit the preservative efficacy of the formulation. The formulations of Examples Q and S are representative of the compositions of the present invention.

Examples		Q	S
FID		112306	112307
Lot Number		07-47316	07-47317
Ingredients		Concentration (w/v %)	
Zinc Chloride		0.0025	0.0025
Calcium Chloride		None	0.025
Propylene Glycol		1.6	1.6
Boric Acid		0.25	0.25
Mannitol		0.1	0.1
Sodium Hydroxide, and/or Hydrochloric Acid		Adjust pH to 7.5	Adjust pH to 7.5
Purified Water		QS 100%	QS 100%
Osmolality (mOsm/kg)		261	264
Sodium Hydroxide Conc.		4.4 mM	4.5 mM
Monovalent Cation (Sodium) needed to adjust pH of buffering anions		4.4 mM	4.5 mM
Microorganism		Log Order Reductions	
S. Aureus	6 Hours	0.5	0.2
	24 Hours	2.6	1.2
	7 Days	5.1	5.1
	14 Days	NT	NT
	28 Days	NT	NT
Pseudomonas A	6 Hours	1.4	0.6
	24 Hours	4.0	0.8
	7 Days	5.1	5.1
	14 Days	NT	NT
	28 Days.	NT	NT
E. Coli	6 Hours	0.8	0.6
	24 Hours	1.5	0.7
	7 Days	5.1	5.1
	14 Days	NT	NT
	28 Days.	NT	NT
Candida A.	7 Days	0.9	0.6
	14 Days	NT	NT
	28 Days.	NT	NT
A. Niger	7 Days	1.7	1.4
	14 Days	NT	NT
	28 Days.	NT	NT

NT = Not Tested

Examples Q, T and U

A comparison of the results obtained with the formulations of Examples Q, T and U demonstrates that preservation efficacy improves as the zinc chloride concentration is increased from 0.18 mM zinc (0.0025% zinc chloride) to 1.8 mM zinc (0.025% zinc chloride). All three formulations satisfied USP preservative efficacy requirements. However, the formulation of Example Q (0.18 mM zinc) did not clearly satisfy the Ph. Eur. B. requirements. The formulations of Examples T and U (0.88 and 1.8 mM of zinc, respectively) did clearly satisfy the Ph. Eur. B requirements; however, the use of higher concentrations of zinc (i.e., 1.8 mM in Example U) is not desirable, as such concentrations may product an astringent affect when applied to the eye. The zinc concentration utilized in the formulation of Example U is outside the range specified herein (i.e., 0.04 to 0.9 mM). Consequently, the formulations of Examples Q and T are representative of the compositions of the present invention, while the formulation of Example U is comparative.

Examples		Q	T	U
FID		112306	112294	112148
Lot Number		07-47316	07-47278	07-46931
Ingredients		Concentration (w/v %)		
Zinc Chloride		0.0025	0.012	0.025
Propylene Glycol		1.6	1.6	1.6
Boric Acid		0.25	0.25	0.25
Mannitol		0.1	0.1	0.1
Sodium Hydroxide, and/or Hydrochloric Acid		Adjust pH to 7.5	Adjust pH to 7.5	Adjust pH to 7.5
Purified Water		QS 100%	QS 100%	QS 100%
Osmolality (mOsm/kg)		261	261	265
Sodium Hydroxide Conc.		4.4 mM	4.4 mM	4.6 mM
Monovalent Cation (Sodium) needed to adjust pH of buffering anions		4.4 mM	4.4 mM	4.6 mM
Microorganism		Log Order Reductions		
S. Aureus	6 Hours	0.5	1.2	2.6
	24 Hours	2.6	3.5	4.3
	7 Days	5.1	5.0	5.0
	14 Days	NT	NT	NT
	28 Days	NT	NT	NT
Pseudomonas A	6 Hours	1.4	1.3	2.7
	24 Hours	4.0	3.3	4.5
	7 Days	5.1	4.9	5.0
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT
E. Coli	6 Hours	0.8	0.8	1.0
	24 Hours	1.5	1.6	1.8
	7 Days	5.1	5.0	5.0
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT
Candida A.	7 Days	0.9	2.8	5.0
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT
A. Niger	7 Days	1.7	1.3	1.6
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT

NT = Not Tested

Examples U, V and W

A comparison of the results obtained with the formulations of Examples U, V and W demonstrates the effect of pH on the antimicrobial activity of the zinc-based preservative systems of the present invention. Specifically, even at a high zinc concentration (i.e., 1.8 mM), the formulation of Example V (pH 5.5) did not satisfy the Ph. Eur. B. preservative efficacy requirements, but the same formulation did satisfy those requirements when the pH was increased to 6.5 (Example W) or 7.5 (Example U). These results demonstrate the preference for use of a slightly alkaline pH in the compositions of the present invention, as specified above. This preference is of even greater importance when concentrations of zinc lower than 1.8 mM are utilized, as in the compositions of the present invention.

Examples		V	W	U
FID		112286	112287	112148
Lot Number		07-47249	07-47632	07-46931
Ingredients		Concentration (w/v %)		
Zinc Chloride		0.025	0.025	0.025
Propylene Glycol		1.6	1.6	1.6
Boric Acid		0.25	0.25	0.25
Mannitol		0.1	0.1	0.1
Sodium Hydroxide, and/or Hydrochloric Acid		Adjust pH to 5.5	Adjust pH to 6.5	Adjust pH to 7.5
Purified Water		QS 100%	QS 100%	QS 100%
Osmolality (mOsm/kg)		263	265	265
Sodium Hydroxide Conc.		0.1 mM	1.0 mM	4.6 mM
Monovalent Cation (Sodium) needed to adjust pH of buffering anions		0.1 mM	1.0 mM	4.6 mM
Microorganism		Log Order Reductions		
S. Aureus	6 Hours	0.1	0.2	2.6
	24 Hours	0.2	2.3	4.3
	7 Days	4.2	5.0	5.0
	14 Days	NT	NT	NT
	28 Days	NT	NT	NT
Pseudomonas A	6 Hours	1.2	1.4	2.7
	24 Hours	2.1	3.2	4.5
	7 Days	4.9	4.9	5.0
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT
E. Coli	6 Hours	0.4	0.5	1.0
	24 Hours	0.9	1.3	1.8
	7 Days	2.2	5.0	5.0
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT
Candida A.	7 Days	1.0	2.0	5.0
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT
A. Niger	7 Days	2.3	2.0	1.6
	14 Days	NT	NT	NT
	28 Days.	NT	NT	NT

NT = Not Tested

Example X

The formulation of Example X, which is representative of the compositions of the present invention, contained zinc at a concentration of 0.29 mM, had an alkaline pH and satisfied the USP and Ph. Eur. B. preservative efficacy requirements. These results further demonstrate the basis for the above-specified preference for the use of a slightly alkaline pH in the compositions of the present invention.

Example		X
FID		112736
Lot Number		07-48252
Ingredients		Concentration (w/v %)
Zinc Chloride		0.004
Propylene Glycol		1.7
Boric Acid		0.25
Tromethamine, and/or HC1		Adjust pH to 8.0
Purified Water		QS 100%
Osmolality (mOsm/kg)		265
Tromethamine concentration mM		12.4
Monovalent Cation (Tromethamine) Needed to adjust pH of buffering anions*		8.2
Microorganism		Log Order Reductions
S. Aureus	6 Hours	1.9
	24 Hours	3.9
	7 Days	4.9
	14 Days	4.9
	28 Days	4.9
Pseudomonas A	6 Hours	2.2
	24 Hours	3.0
	7 Days	4.7
	14 Days	4.7
	28 Days.	4.7
E. Coli	6 Hours	0.8
	24 Hours	1.5
	7 Days	3.9
	14 Days	5.0
	28 Days.	5.0
Candida A.	7 Days	2.1
	14 Days	2.9
	28 Days.	4.1
A. Niger	7 Days	0.9
	14 Days	1.9
	28 Days.	1.8

* Calculated using pKa of 8.3

Example Y

12-Hydroxystearic acid (HSA) is an impurity and potential degradation product of the excipient polyoxyl 40 hydrogenated castor oil ("HCO-40"). Above a threshold concentration of HSA, zinc ions interact with HSA to form zinc di-12-hydroxystearate particles. This particulate matter formation is not acceptable for an ophthalmic solution. A study was conducted to assess the effect of pH on particulate matter formation in freshly prepared samples of the composition shown in Table Y-1 below. The potential for particulate formation was evaluated by adding varying amounts of HCO-40 to the composition. The results presented in Table Y-2 below show that as pH is decreased, a higher level of HSA is required to form particles. Thus, a lower pH is preferred for a composition containing the surfactant HCO-40 and zinc ions, so that the composition remains free from particulate matter formation throughout its shelf-life. The preferred pH range for such compositions is 5.0 to 6.0. The most preferred pH range for such compositions is 5.5 to 5.9.

Table Y-1:
Composition of used for the study effect of pH on zinc di-12-hydroxystearate particulate matter formation [a]

Component	Concentration W/V%
Travoprost	0.004%
Polyoxyl 40 Hydrogenated Castor Oil (HCO-40)	0.5%
Boric Acid	1.0%
Zinc Chloride	0.0025%
Sorbitol	0.25%
Propylene Glycol	0.75%
Sodium Hydroxide/ Hydrochloric Acid	Adjust pH.[b]
Purified Water	q.s. 100%

[a] These samples were spiked with HSA.
[b] pH was adjusted to pre-determined values between 5.5 to 6.5

Table Y-2

Relationship Between pH and Particulate Matter Formation (by Microscopic Observation) in Freshly Prepared Samples of Composition Containing HSA at Room Temperature

Total Concentration of HSA	pH at which Particulate Matter [a] was not formed	pH at which Particulate Matter [a] was formed
5 ppm	6.00	6.10[b]
6.5 ppm	5.75	5.90
8 ppm	5.58	5.75

[a] Based on microscopic observation of white crystalline particles.
[b] Particles observed visually; hence were not checked microscopically.

Example Z:

The formulation shown below represents a further example of a self-preserved pharmaceutical composition of the present invention.

Example	**Z**
Ingredients	**Conc. (w/v%)**
Olopatadine Hydrochloride	0.111
Propylene glycol	0.3
Boric Acid	1.0
Sodium Chloride	*0.17*
Zinc Chloride	0.0025
Sodium Hydroxide	
Hydrochloric Acid	Adjust pH 7.0
Purified Water	QS 100

II. Physical Parameters	
Osmolality (mOsm/kg)	267,268
Monovalent cation (Na) concentration needed to adjust pH of buffering anions	6.9 mM

PET Results	**6h**	**24h**	**7d**	**14d**	**28d**
S.aureus	0.0	0.2	4.4	4.9	4.9
P. aeruginosa	0.4	1.3	3.7	4.9	4.9
E. coli	0.7	0.8	5.0	5.0	5.0
C. albicans			0.1	0.5	1.3
A. niger			1.5	1.8	1.3

Examples AA through AD

The formulations in Examples AA and AB contain borate/polyol buffers, whereas the formulations in Example AC and AD contain citrate and phosphate buffers, respectively. All formulations contain 0.11 mM zinc (0.0015% zinc chloride). The formulations in Examples AA and AB, which are representative of the compositions of the present invention, satisfied USP preservative efficacy requirements for the microorganisms tested. The formulations in Examples AC and AD failed to satisfy the USP preservative efficacy requirements, relative to all microorganisms tested. The formulations in Examples AC and AD contained multivalent buffering anions (i.e., citrate and phosphate, respectively) at concentrations of greater than 5 mM. These results demonstrate the importance of limiting the concentration of multivalent buffering anions in the compositions of the present invention.

Example		AA	AB	AC	AD
FID		109997	110009	110002	110013
Lot Number		05-42424	05-42421	05-42428	05-42432
Ingredient					
Polyoxyl 40 Hydrogenated Castor Oil (HCO-40)		0.5	0.5	0.5	0.5
Zinc Chloride		0.0015	0.0015	0.0015	0.0015
Boric Acid		1	1	None	None
Propylene Glycol		0.4	0.4	0.4	0.4
Sodium Chloride		None	0.2	None	None
Sodium Citrate (Dihydrate)		None	None	0.215	None
Dibasic Sodium Phosphate (Anhydrous)		None	None	None	0.156
Sodium Hydroxide, and/or Hydrochloric Acid		Adjust pH to 7.0	Adjust pH to 7.0	Adjust pH to 7.0	Adjust pH to 7.0
Purified Water		QS 100 %	QS 100 %	QS 100 %	QS 100 %
Osmolality		210	270	76	85
Monovalent cation (Na) conc. needed to adjust pH of buffering anions		4.4 mM	4.7 mM	20.4 mM*	15.8 mM*
Microorganism		**Log Order Reductions**			
S. aureus	7 D	4.8	4.8	*0.9*	*0.9*
	14 D	4.8	4.8	4.8	3.5
	28 D	4.8	4.8	4.8	4.3
P.aeruginosa	7 D	4.9	4.9	*0.4*	*-0.3*
	14 D	4.9	4.9	*0.5*	*-0.4*
	28 D	4.9	4.9	*0.3*	*-0.2*
E. col	7 D	4.4	4.4	*-0.6*	*-0.9*
	14 D	4.4	4.4	*-0.4*	*-0.8*
	28 D	4.4	4.4	*-0.3*	*-0.5*
C. albican	7 D	NT	NT	NT	NT
	14 D	NT	NT	NT	NT
	28 D	NT	NT	NT	NT
A. niger	7 D	NT	NT	NT	NT
	14 D	NT	NT	NT	NT
	28 D	NT	NT	NT	NT

* Calculated based on Pka and concentration of buffer used.

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We Claim:

1. A multi-dose, self-preserved ophthalmic composition, comprising zinc ions at a concentration of 0.04 to 0.9 mM, wherein the concentration of anionic species present in the composition is less than 15 mM.

2. A composition according to Claim 1, wherein the composition further comprises an antimicrobial effective amount of borate.

3. A composition according to Claim 1, wherein the composition further comprises a borate/polyol complex.

4. A composition according to Claim 3, wherein the polyol utilized in the borate/polyol complex is propylene glycol.

5. A composition, according to Claim 3, wherein the polyol utilized in the borate/polyol complex is propylene glycol and sorbitol.

6. A composition according to Claim 1, wherein the composition comprises zinc ions at a concentration of 0.04 to 0.4 mM.

7. A composition according to Claim 6, wherein the concentration of buffering anions in the composition is less than 5 mM.

8. A composition according to Claim 1, wherein the concentration of multivalent metal cations other than zinc in the composition is less than 5 mM.

9. A composition according to Claim 1, wherein the concentration of ionized salts in the composition is less than 50 mM.

10. A composition according to Claim 1, wherein: (i) the concentration of zinc ions in the composition is 0.1 to 0.4 mM; (ii) the concentration of multivalent buffering anions in the composition is less than 5 mM; (iii) the concentration of multivalent metal cations in the composition is less than 5 mM; and (iv) the concentration of ionized salts in the composition is less than 50 mM.

11. In a method of enhancing the antimicrobial activity of an aqueous ophthalmic composition by including zinc ions in said composition, the improvement which comprises utilizing the zinc ions in the composition at a concentration of 0.04 to 0.9 mM and limiting the concentration of buffering anions in the composition to less than 15 mM.

12. The method of Claim 11, wherein the improvement further comprises including a borate/polyol complex in said composition.

13. The method of Claim 12, wherein the polyol utilized in said borate/polyol complex is propylene glycol.

14 The method of Claim 11, wherein the concentration of zinc ions in the composition is 0.04 to 0.4 mM.

15. The method of Claim 14, wherein the concentration of buffering anions is less than 5 mM.

16. The method of Claim 11, wherein the improvement further comprises limiting the concentration of multivalent cations other than zinc in the composition to less than 5 mM.

17. The method of Claim 11, wherein the improvement further comprises limiting the concentration of ionized salts in the composition to less than 50 mM.

18. The method of Claim 11, wherein zinc ions are utilized at a concentration of 0.1 to 0.4 mM, the concentration of multivalent buffering anions in the composition is limited to a concentration of less than 5 mM, the concentration of multivalent metal cations other than zinc in the composition is limited to a concentration of less than 5 mM, and the concentration of ionized salts in the composition is limited to a concentration of less than 50 mM.

Abstract

The present invention is directed to the provision of multi-dose, self-preserved ophthalmic compositions. The compositions possess sufficient antimicrobial activity to satisfy USP preservative efficacy requirements, as well as similar preservative standards (e.g., EP and JP), without requiring the presence of conventional anti-microbial preservative agents, such as benzalkonium chloride. The compositions are effectively preserved by a balanced ionic buffer system containing zinc ions at a concentration of 0.04 to 0.9 mM, preferably 0.04 to 0.4 mM. One aspect of the balanced buffer system is limitation of the amount of buffering anions present to a concentration of 15 mM or less, preferably 5 mM or less. In a preferred embodiment, the compositions also contain borate or, most preferably, one or more borate/polyol complexes. The use of propylene glycol as the polyol in such complexes is strongly preferred. Limiting the amount of divalent metals other than zinc and the amount of ionized salts present has also been determined to be important to maximize the antimicrobial activity of the balanced buffer systems.

FIG. 1

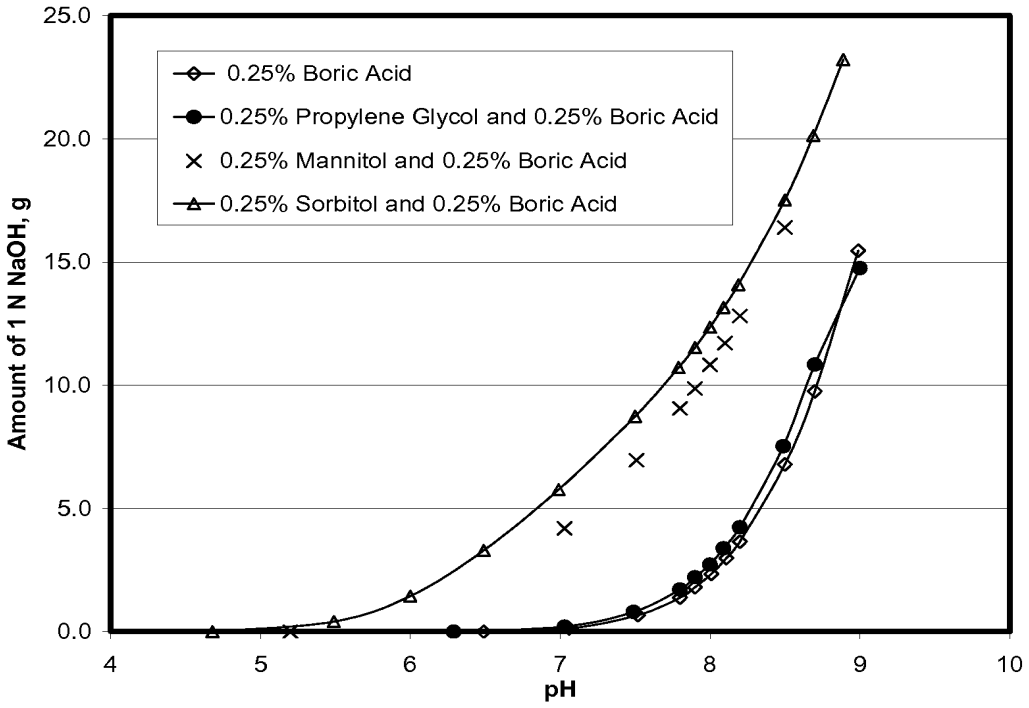

Figure 1: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of mannitol, sorbitol or propylene glycol.

FIG. 2

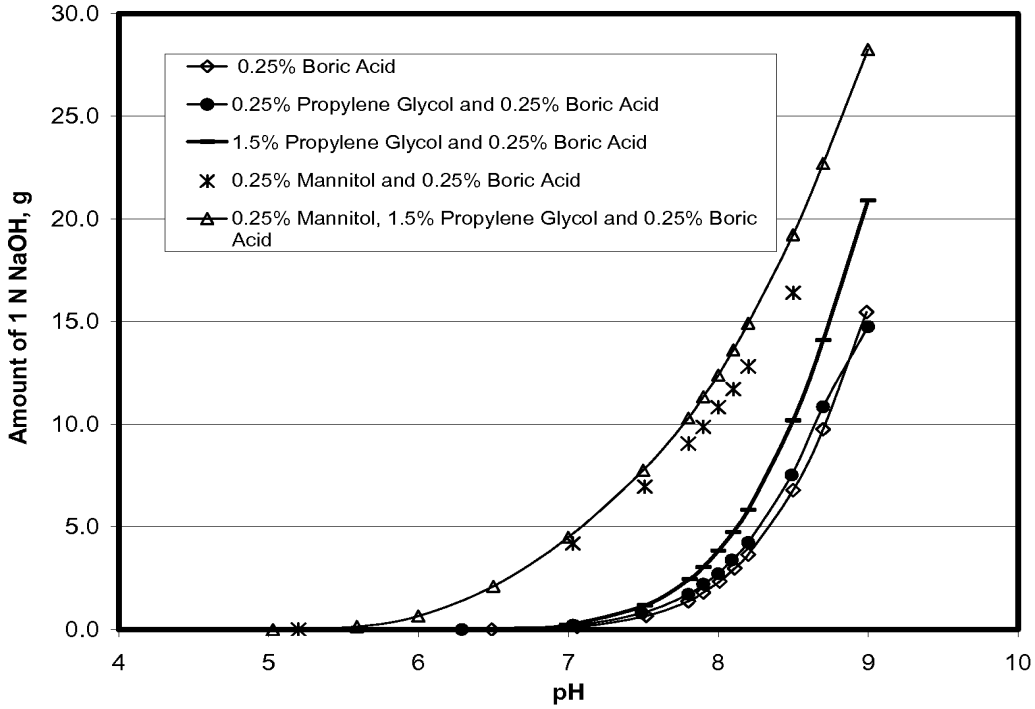

Figure 2: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of propylene glycol.

FIG. 3

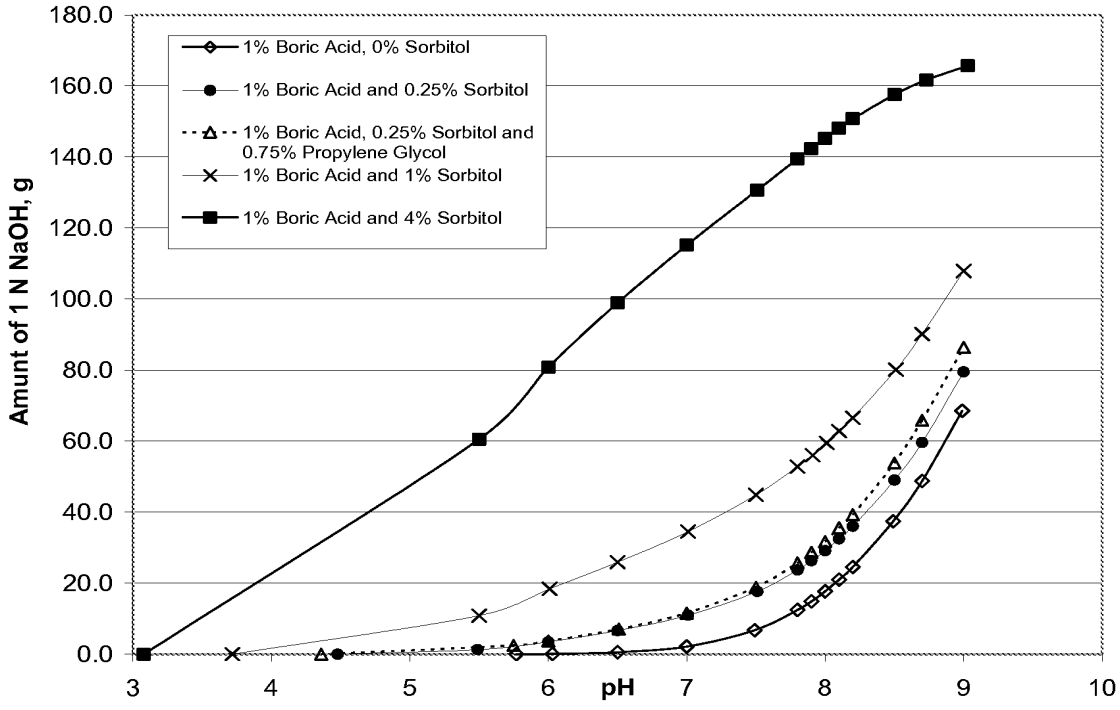

Figure 3: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution Boric Acid (1%) in presence of different concentrations of sorbitol...

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	SELF-PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Gregg C. Brown/Deborah Weinschenk
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Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	300	300
Utility Search Fee	1111	1	500	500
Utility Examination Fee	1311	1	200	200
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1000**

Electronic Acknowledgement Receipt

EFS ID:	2223087
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF-PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Gregg C. Brown/Deborah Weinschenk
Filer Authorized By:	Gregg C. Brown
Attorney Docket Number:	3205 US
Receipt Date:	20-SEP-2007
Filing Date:	
Time Stamp:	18:49:27
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$1000
RAM confirmation Number	3112
Deposit Account	010682
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	3205US9_20_07.pdf	1127175 8b41992af68ae8dfea2c348c240776814e4023d5	no	5
Warnings:					
Information:					
2	Oath or Declaration filed	3205USDec.pdf	156557 92ef16d17cdb0ed37b7df756a2f1418187f0ec73	no	4
Warnings:					
Information:					
3		3205US.pdf	312370 0c5a249cc88f982a3ba5cf3b1543b5100a17f078	yes	45

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	39
Claims	40	41
Abstract	42	42
Drawings	43	45

Warnings:					
Information:					
4	Fee Worksheet (PTO-06)	fee-info.pdf	8385 268b2332de16d0a38aa3cd4faa164b31734bf6d3	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1604487	

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	2223087
Application Number:	11858781
International Application Number:	
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Submitted with Payment	yes
Payment was successfully received in RAM	$1000
RAM confirmation Number	3112
Deposit Account	010682
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	3205US9_20_07.pdf	1127175 8b41992af68ae8dfea2c348c240776814e4023d5	no	5
Warnings:					
Information:					
2	Oath or Declaration filed	3205USDec.pdf	156557 92ef16d17cdb0ed37b7df756a2f1418187f0ec73	no	4
Warnings:					
Information:					
3		3205US.pdf	312370 0c5a249cc88f982a3ba5cf3b1543b5100a17f078	yes	45

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	39
Claims	40	41
Abstract	42	42
Drawings	43	45

Warnings:					
Information:					
4	Fee Worksheet (PTO-06)	fee-info.pdf	8385 268b2332de16d0a38aa3cd4faa164b31734bf6d3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1604487		

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9/20/07

PTO/SB/06 (12-04)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

11/858,781

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))							300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))							500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))							200
TOTAL CLAIMS (37 CFR 1.16(i))	18 minus 20 =		X 25=			X 50=	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =		X 100=			X 200=	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			N/A			N/A	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1000

APPLICATION AS AMENDED – PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
11/858,781	09/20/2007	1615	1000	3205US	18	2

CONFIRMATION NO. 3372

26356
ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

FILING RECEIPT

Date Mailed: 12/11/2007

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Bhagwati P. Kabra, Euless, TX;
Masood A. Chowhan, Arlington, TX;
L. Wayne Schneider, Crowley, TX;
Wesley Wehsin Han, Arlington, TX;

Assignment For Published Patent Application

ALCON MANUFACTURING, LTD., Fort Worth, TX

Power of Attorney: The patent practitioners associated with Customer Number 26356

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/827,411 09/28/2006
and claims benefit of 60/826,529 09/21/2006

Foreign Applications

If Required, Foreign Filing License Granted: 12/08/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 11/858,781**

Projected Publication Date: 03/27/2008

Non-Publication Request: No

Early Publication Request: No

Title

SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

Preliminary Class

424

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US

CONFIRMATION NO. 3372

26356
ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX76134

Title: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

Publication No. US-2008-0075790-A1
Publication Date: 03/27/2008

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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Pre-Grant Publication Division, 703-605-4283

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Bhagwati Kabra	)	Examiner: Arnold, Ernst V.
		)	
Serial No:	11/858,781 (Conf. #3372)	)	Group Art Unit: 1616
		)	
Filed:	September 20, 2007	)	Docket No.: 3205US

FOR: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. 1.56, 1.97, AND 1.98

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

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56, Applicants submit the attached PTO Form 1449 and copies of references prior to the mailing date of a first Office Action on the merits in the above-referenced application. In accordance with 37 CFR 1.98(a)(2), copies of foreign patents and non-patent literature are attached. No copies of the U.S. patents/patent application publications are provided.

Also included for the convenience of the Examiner is a copy of the International Search Report and Written Opinion of the International Searching Authority issued in connection with a corresponding PCT international application.

It is believed that no fee is required to make this a complete and timely filing. However, if it is determined that a petition or fee is required, the Commissioner is hereby authorized to charge any fee associated with this statement to our Deposit Account No. 010682.

Applicants request that the listed patents, articles, and other information be considered during prosecution of this application and that they appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

23 June 2008
Date

By: Scott A. Chapple
Scott A. Chapple
Registration No. 46,287

Address for Correspondence:
Alcon Research, Ltd.
Attn: Scott A. Chapple
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

PTO/SB/08a (03-08)
Approved for use through 06/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati Kabra
Art Unit	1615
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4522806		1985-06-11	Muhlemann et al.	
	2	5221664		1993-06-22	Berkowitz et al.	
	3	5320843		1994-06-14	Raheja et al.	
	4	5352708		1994-10-04	Woodward et al.	
	5	5424078		1995-06-13	Dziabo et al.	
	6	5597559		1997-01-28	Olejnik et al.	
	7	5607698		1997-03-04	Martin et al.	
	8	5683993		1997-11-04	Tsao	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1615
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	9	5725887		1998-03-10	Martin et al.	
	10	5736165		1998-04-07	Ripley et al.	
	11	5741817		1998-04-21	Chowhan et al.	
	12	5817277		1998-10-06	Mowrey-McKee et al.	
	13	5858346		1999-01-12	Vehige et al.	
	14	5858996		1999-01-12	Tsao	
	15	6017861		2000-01-25	Fujiwara et al.	
	16	6024954		2000-02-15	Park et al.	
	17	6034043		2000-03-07	Fujiwara et al.	
	18	6121315		2000-09-19	Nair et al.	
	19	6319464		2001-11-20	Asgharian	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1615
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	20	6348190		2002-02-19	Illes et al.	
	21	6482799		2002-11-19	Tuse et al.	
	22	6492361		2002-12-10	Muller et al.	
	23	6503497		2003-01-07	Chowhan et al.	
	24	6583124		2003-06-24	Asgharian	
	25	7074827		2006-07-11	Ueno	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020098160		2002-07-25	Chowhan et al.	
	2	20020122831		2002-09-05	Mowrey-McKee et al.	
	3	20060205725		2006-09-14	Ueno	

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(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati Kabra
Art Unit	1615
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2003-104870	JP		2001-09-28			☐
	2	98/10773	WO		1998-03-19	Richter Gedeon Vegyeszeti		☐
	3	2005/097067	WO		2005-10-20	Bausch & Lomb Incorporated		☐
	4	2007/106723	WO		2007-09-20	Bausch & Lomb Incorporated		☐
	5	2008/036847	WO		2008-03-27	Alcon Manufacturing, Ltd.		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Bruce et al., 4-2001, “Zinc and the eye”, Journal Of The American College Of Nutrition, 106-118	☐
	2	Kabara et al., 1997, Preservative-Free and Self-Preserving Cosmetics and Drugs – Principles and Practice, Chapter 1, pages 1-14, Marcel Dekker, Inc.	☐
	3	McCarthy et al., 1989, "The Effect of Zinc Ions on the Antimicrobial Activity of Selected Preservatives", Journal of Pharmacy and Pharmacology, Vol. 41, 114P	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1615
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	4	McCarthy, 1985, "Metal Ions as Microbial Inhibitors", Cosmetic & Toiletries, 100:69-72	☐
	5	PCT International Search Report for corresponding International Application No. PCT/US2007/079082 with mailing date April 7, 2008	☐
	6	PCT Written Opinion for corresponding International Application No. PCT/US2007/079082 with mailing date April 7, 2008	☐
	7	Zeelie et al., 1992, "The Effects of Selected Metal Salts on the Microbial Activities of Agents used in the Pharmaceutical and Related Industries", Metal Compounds in Environment and Life, 4:193-200	☐
	8	Zeelie et al., 1998, "Effects of copper and zinc ions on the germicidal properties of two popular pharmaceutical antiseptic agents cetylpyridinium chloride and povidone-iodine", Analyst, 123:503-507	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1615
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. No. 46,287/	Date (YYYY-MM-DD)	2008-06-24
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	3508453
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	24-JUN-2008
Filing Date:	20-SEP-2007
Time Stamp:	14:20:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement Letter	3205_US_IDSLtr_062408.pdf	42028 48c202e536b16b3a37ba906fcc88bff3ebde5fc9	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Filed	3205_US_IDS1449_062408.pdf	1104817 e83d19abb66eaad68b6866af953b9bc46c30801e	no	7
Warnings:					
Information:					
3	Foreign Reference	JP_2003_104870_A1.pdf	689401 9d9d6f5a2b26b618c33a6ab071ddbf0ebe1bd3e7	no	17
Warnings:					
Information:					
4	Foreign Reference	WO_98_010773_A1.pdf	1094400 70ef6115f96fbb92512528529584633aa07adcb9	no	31
Warnings:					
Information:					
5	Foreign Reference	WO_05_097067_A1.pdf	1851911 09ef491e2103f61292d1affcd377fedf0070e7f0	no	36
Warnings:					
Information:					
6	Foreign Reference	WO_07_106723_A2.pdf	2197756 e0118b98dd4e75ee4e52c42fdb4171cc8ae4b675	no	54
Warnings:					
Information:					
7	Foreign Reference	WO_08_036847_A2.pdf	1979616 49a025dda4e26b403fb1457c80745ccb493ea564	no	45
Warnings:					
Information:					
8	NPL Documents	Bruce_et_aL_2001_JACN_106-118.pdf	510498 a9d1fe8627b96d1971c2bd81f16d6484974c7057	no	7
Warnings:					
Information:					
9	NPL Documents	Kabara_et_al_1997_PreservativeFree_1-14.pdf	1119845 3806fb2237c7f67baf64bd21637384604ba0b8f3	no	24
Warnings:					
Information:					
10	NPL Documents	McCarthy_et_al_1989_JPP_41_114P.pdf	168868 924ab00001ceea122201e234ec44220037552168	no	1
Warnings:					
Information:					

11	NPL Documents	McCarthy_et_al_1985_CT_100_69-72.pdf	408963 f0bd918bda22e2284bb396b48e2ef8d97f0b6fbf	no	4
Warnings:					
Information:					
12	NPL Documents	PCT-US2007-079082_Search_Rpt.pdf	151432 06e90888972b442c4fac35314af65f82d139682c	no	4
Warnings:					
Information:					
13	NPL Documents	PCT-US2007-079082_Written_Opinion.pdf	168208 542b0e8aa688a9d8e4db617dd614f1ffe623ae1f	no	5
Warnings:					
Information:					
14	NPL Documents	Zeelie_et_al_1992_MCEL_4_193-200.pdf	567484 77004f2c72d772bbffe3db7fd7f7a82c36b43ed3	no	8
Warnings:					
Information:					
15	NPL Documents	Zeelie_et_al_1998_Analyst_123_503-507.pdf	405364 bc6f5ccea4c9ac7a998b12546f81d9365de7b950	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	12460591		

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

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Bhagwati Kabra	)	Examiner: Arnold, Ernst V.
		)	
Serial No:	11/858,781 (Conf. #3372)	)	Group Art Unit: 1616
		)	
Filed:	September 20, 2007	)	Docket No.: 3205US

FOR: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. 1.56

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

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56, Applicants submit the following patents, articles and other information listed on the attached PTO/SB/08a form.

It is believed that no fee is required to make this a complete and timely filing. However, if it is determined that a petition or fee is required, the Commissioner is hereby authorized to charge any fee associated with this statement to our Deposit Account No. 010682.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

11-11-08
Date

By: _____
Scott A. Chapple
Registration No. 46,287

Address for Correspondence:
Alcon Research, Ltd.
Attn: Scott A. Chapple
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

PTO/SB/08a (10-08)
Approved for use through 11/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati Kabra
Art Unit	1616
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5130298		1992-07-14	Cini et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1616
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1616
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. No. 46,287/	Date (YYYY-MM-DD)	2008-11-11
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	4267051
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	11-NOV-2008
Filing Date:	20-SEP-2007
Time Stamp:	11:48:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement Letter	3205_US_IDSLtr_111108.pdf	38889 476cef180547fbdd1908886378177304a261c7e6	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Filed (SB/08)	3205_US_IDS08a_111108.pdf	744064 50c7eb1c4c25d5879f3a1f50556b8cf5f12037d2	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	782953

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati Kabra et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1616

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendment; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

September 18, 2009.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

PRELIMINARY AMENDMENT

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

Dear Sir:

Please enter the following amendments prior to formal examination of the above-identified application.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1 (original): A multi-dose, self-preserved ophthalmic composition, comprising zinc ions at a concentration of 0.04 to 0.9 mM, wherein the concentration of anionic species present in the composition is less than 15 mM.

Claim 2 (original): A composition according to Claim 1, wherein the composition further comprises an antimicrobial effective amount of borate.

Claim 3 (original): A composition according to Claim 1, wherein the composition further comprises a borate/polyol complex.

Claim 4 (original): A composition according to Claim 3, wherein the polyol utilized in the borate/polyol complex is propylene glycol.

Claim 5 (original): A composition, according to Claim 3, wherein the polyol utilized in the borate/polyol complex is propylene glycol and sorbitol.

Claim 6 (original): A composition according to Claim 1, wherein the composition comprises zinc ions at a concentration of 0.04 to 0.4 mM.

Claim 7 (original): A composition according to Claim 6, wherein the concentration of buffering anions in the composition is less than 5 mM.

Claim 8 (original): A composition according to Claim 1, wherein the concentration of multivalent metal cations other than zinc in the composition is less than 5 mM.

Claim 9 (original): A composition according to Claim 1, wherein the concentration of ionized salts in the composition is less than 50 mM.

Claim 10 (original): A composition according to Claim 1, wherein: (i) the concentration of zinc ions in the composition is 0.1 to 0.4 mM; (ii) the concentration of multivalent buffering anions in the composition is less than 5 mM; (iii) the concentration of multivalent metal cations in the composition is less than 5 mM; and (iv) the concentration of ionized salts in the composition is less than 50 mM.

Claims 11-18 (cancelled)

Claim 19 (new): A multi-dose, self-preserved ophthalmic composition, comprising zinc ions at a concentration of 0.04 to 0.4 mM, wherein the concentration of anionic species present in the composition is less than 15 mM and wherein the composition exhibits sufficient antimicrobial activity to allow the compositions to satisfy the USP 27 preservative efficacy requirements.

Claim 20 (new): A composition according to Claim 19, wherein the composition further comprises a borate and a polyol for forming a borate/polyol complex.

Claim 21 (new): A composition according to claim 20, wherein the concentration of borate in the composition is 0.1 to about 2.0% w/v and the concentration of polyol in the composition is 0.25 to 2.5% w/v.

Claim 22 (new): A composition, according to Claim 21, wherein the polyol utilized in the borate/polyol complex is propylene glycol and/or sorbitol.

Claim 23 (new): A composition according to Claim 19, wherein the concentration of buffering anions in the composition is less than 5 mM.

Claim 24 (new): A composition according to Claim 19, wherein the concentration of ionized salts in the composition is less than 50 mM.

Claim 25 (new): A composition according to Claim 19, wherein: (i) the concentration of multivalent buffering anions in the composition is less than 5 mM; (ii) the concentration of multivalent metal cations in the composition is less than 5 mM; and (iii) the concentration of ionized salts in the composition is less than 50 mM.

Claim 26 (new): A multi-dose, self-preserved ophthalmic composition, comprising zinc ions at a concentration of 0.04 to 0.4 mM; and

a borate and a polyol for forming a borate/polyol complex, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v;

wherein: (i) the concentration of anionic species present in the composition is less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the compositions to satisfy the USP 27 preservative efficacy requirements.

Claim 27 (new): A composition, according to Claim 26, wherein the polyol utilized in the borate/polyol complex is propylene glycol and/or sorbitol.

Claim 28 (new): A composition according to Claim 27, wherein the concentration of buffering anions in the composition is less than 5 mM.

Claim 29 (new): A composition according to Claim 26, wherein the concentration of ionized salts in the composition is less than 50 mM.

Claim 30 (new): A composition according to Claim 28, wherein: (i) the concentration of multivalent buffering anions in the composition is less than 5 mM; (ii) the concentration of multivalent metal cations in the composition is less than 5 mM; and (iii) the concentration of ionized salts in the composition is less than 50 mM.

REMARKS

Claims 1-10 are original, claims 11-18 are canceled. Applicants have added new claims 19-30.

Applicants respectfully request consideration of the pending claims and believes no fee is due with this response. However, the Commissioner is authorized to charge any fees which may be required or to credit any overpayment to Deposit Account No. 010682 in the name of Alcon Laboratories, Inc.

Respectfully submitted,

ALCON RESEARCH, LTD.

17 September 2009
Date

Scott A. Chapple, Agent
Reg. No. 46,287

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Attorney Docket: 3205US

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	9	52	468
Independent claims in excess of 3	1201	1	220	220
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**688**

Electronic Acknowledgement Receipt

EFS ID:	6099781
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	18-SEP-2009
Filing Date:	20-SEP-2007
Time Stamp:	13:38:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$688
RAM confirmation Number	8721
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3205_US_PrelAm_091809.pdf	159810 f838c4f4a08bfb54fbe5fe4de8f10ccc49cd78ab	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	32261 f5468459d23fc0e29491bc70fd7932413ae8b8ab	no	2

Warnings:

Information:

Total Files Size (in bytes):	192071

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/858,781	09/20/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 09/18/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 22	Minus	** 29	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***4	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

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

Legal Instrument Examiner:
/RAMONA D. WILSON/

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 09/28/2009

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/28/2009	PAPER

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

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ERNST V. ARNOLD*. (3)_____.

(2) *Scott Chapple*. (4)_____.

Date of Interview: *22 September 2009*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *1,19 and 26*.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *As a courtesy to Applicant, the Examiner granted this pre-examination interview. Applicant discussed example 18 on page 23 of WO 2005097067 Xia et al. where 0.0065 wt% Zinc was used in the composition. Applicant discussed that their composition uses less zinc and that borate in combination with zinc enhances the zinc antimicrobial ability. The Examiner said that all of these points would be taken into consideration upon examination* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Ernst V Arnold/ Primary Examiner, Art Unit 1616	

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 04/14/2010

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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
04/14/2010	PAPER

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

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

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

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

Disposition of Claims

4)☒ Claim(s) 1-10 and 19-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 and 19-30 is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on 20 September 2007 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11-18 have been cancelled. Claims 1-10 and 19-30 are pending and under examination.

Drawings

The drawings are objected to because the Figure captions belong in the body of the specification under “Brief Description of the Drawings" section. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Figures 1,2 and 3 are directed to:

> Figure 1: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of mannitol, sorbitol or propylene glycol.

> Figure 2: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of propylene glycol.

> Figure 3: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution Boric Acid (1%) in presence of different concentrations of sorbitol...

But the specification states:

> **Brief Description of the Drawings**
>
> » Figures 1-3 are graphs showing the interaction of boric acid and various polyols.

The specification and the Figures are not in agreement.

Appropriate correction is required. The Examiner also assumes Applicant will note the plurality of periods in caption of Figure 3 and correct that as well.

Claim Rejections - 35 USC § 112

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

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

Claim 7 recites the limitation "the concentration of buffering anions" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the concentration of multivalent metal cations" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the concentration of ionized salts" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation " the concentration of buffering anions; the concentration of multivalent metal cations; the concentration of ionized salts" in lines 2-5. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation the concentration of buffering anions" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "the concentration of ionized salts" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation " the concentration of buffering anions; the concentration of multivalent metal cations; the concentration of ionized salts" in lines 1-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "the concentration of buffering anions" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "the concentration of ionized salts" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation " the concentration of buffering anions; the concentration of multivalent metal cations; the concentration of ionized salts" in lines 1-4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Olejnik et al. (US 5597559).

Olejnik et al. disclose ophthalmic formulations with zinc ions at an approximate concentration of human tear fluid, sorbitol, and borate with a pH of about 7.0 to 7.5 (Abstract and claims 1, 5-11 and 15). It is the Examiner's position that a an approximate concentration of human tear fluid anticipates the instant range of 0.04 to 0.9 mM in the absence of evidence to the contrary. Since the amount of anions is less than 15 mM then instant claim 1 is anticipated. Zinc chloride has a molecular weight of 136.3 g/mol. Since the amount of zinc salt can be 0.01 to 0.50 weight percent (claim 8) then the concentration of zinc ions can be calculated in 100 ml solution (assuming 100 ml aqueous solution is about 100 g) as:

(0.5 g ZnCl2/136.3 g/mol) = 0.0036 moles/0.1l = 0.03 M = 30 mM

(0.01 g ZnCl2/136.3 g/mol) = 0.000073 moles/0.1l = 0.0007 M = 0.7 mM

Olejnik et al. discloses that borate is antimicrobial and anticipates instant claim 2. Sorbitol is a polyol and inherently forms a complex with borate to anticipate instant claim 3. Polypropylene glycol is disclosed (claim 3). Since there are no other multivalent metal cations, then instant claim 8 is anticipated. The salt concentration is less than 50 mM and anticipates instant claims 9 and 10.

Olejnik et al. teach generating 0.05 to 3.0 wt% borate in the composition (claim 11) and has an embodiment with 0.12 wt% sodium borate (claim 14).

Olejnik et al. teach that the sorbitol can be present from 0.01 to 0.1 wt% (claims 1 and 5) and the polyalkylene glycol (a polyol) can be present from 0.5 to 2.0 wt% (claim 1) and polyethylene glycol (a polyol) can be present from 0.5 to 2.0 wt% (claim 4).

Claim Rejections - 35 USC § 103

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

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

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

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chowhan et al. (US 6503497) and Olejnik et al. (US 5597559) and Kross (US 5820822).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims:

> Claim 1 (original): A multi-dose, self-preserved ophthalmic composition, comprising zinc ions at a concentration of 0.04 to 0.9 mM, wherein the concentration of anionic species present in the composition is less than 15 mM.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Olejnik et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Chowhan et al. teach borate-polyol complexes in ophthalmic compositions (title abstract and claims 1-45). Chowhan et al. teach using from 0.5 to 6 wt% or the narrower reange of 1.0 to 2.5 wt% of a borate polyol complex to enhance the antimicrobial activityof the composition (claims 1 and 8). Sorbitol and propylene glycol and mannitol are taught as the polyols (claims 3-7). Chowhan et al. teach adding another antimicrobial agent (claim 17). There are no multivalent metal ions present; the concentration of ionized salt is less than 50 mM and the concentration of buffering anions is less than 5 mM.

Kross teaches that zinc chloride is a known antibacterial agent (Abstract ; column 9, lines 1-5; and claims 1-17).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Chowhan et al. is that Chowhan et al. do not expressly teach adding zinc ions at a concentration of 0.04 to 0.4 mM or 0.9 mM or meeting the USP 27 requirements. This deficiency in Chowhan et al. is cured by the teachings of Olejnik et al. and Kross.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add zinc ions in the amount instantly claimed, as

suggested by Olejnik et al. and Kross, to the composition of Chowhan, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Chowhan et al. teach one of ordinary skill in the art to add other antimicrobial agents and Olejnki et al. and Kross establish that not only is zinc known as an antimicrobial agent but it is also used in ophthalmic compositions. With respect to the concentration of the zinc ions present, Olejnik et al. teach an *approximate* concentration to human tear fluid as discussed above. With respect to the lower amount of 0.4 mM zinc ions it is the Examiner's position that this amount is obvious over Olejnik et al. From MPEP 2144.05: "Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)."

With respect to the USP 27 requirements, these are intrinsically met with the composition in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Primary Examiner, Art Unit 1616

Notice of References Cited	Application/Control No. 11/858,781	Applicant(s)/Patent Under Reexamination KABRA ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,820,822	10-1998	Kross, Robert D.	422/37
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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	P					
	Q					
	R					
	S					
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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08a (03-08)
Approved for use through 06/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati Kabra
Art Unit	1615
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4522806		1985-06-11	Muhlemann et al.	
	2	5221664		1993-06-22	Berkowitz et al.	
	3	5320843		1994-06-14	Raheja et al.	
	4	5352708		1994-10-04	Woodward et al.	
	5	5424078		1995-06-13	Dziabo et al.	
	6	5597559		1997-01-28	Olejnik et al.	
	7	5607698		1997-03-04	Martin et al.	
	8	5683993		1997-11-04	Tsao	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.A./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
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	First Named Inventor	Bhagwati Kabra
	Art Unit	1615
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	9	5725887		1998-03-10	Martin et al.	
	10	5736165		1998-04-07	Ripley et al.	
	11	5741817		1998-04-21	Chowhan et al.	
	12	5817277		1998-10-06	Mowrey-McKee et al.	
	13	5858346		1999-01-12	Vehige et al.	
	14	5858996		1999-01-12	Tsao	
	15	6017861		2000-01-25	Fujiwara et al.	
	16	6024954		2000-02-15	Park et al.	
	17	6034043		2000-03-07	Fujiwara et al.	
	18	6121315		2000-09-19	Nair et al.	
	19	6319464		2001-11-20	Asgharian	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	1615
	Examiner Name	Arnold, Ernst V.
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	20	6348190		2002-02-19	Illes et al.	
	21	6482799		2002-11-19	Tuse et al.	
	22	6492361		2002-12-10	Muller et al.	
	23	6503497		2003-01-07	Chowhan et al.	
	24	6583124		2003-06-24	Asgharian	
	25	7074827		2006-07-11	Ueno	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020098160		2002-07-25	Chowhan et al.	
	2	20020122831		2002-09-05	Mowrey-McKee et al.	
	3	20060205725		2006-09-14	Ueno	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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First Named Inventor	Bhagwati Kabra
Art Unit	1615
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2003-104870	JP		2001-09-28			☐
	2	98/10773	WO		1998-03-19	Richter Gedeon Vegyeszeti		☐
	3	2005/097067	WO		2005-10-20	Bausch & Lomb Incorporated		☐
	4	2007/106723	WO		2007-09-20	Bausch & Lomb Incorporated		☐
	5	2008/036847	WO		2008-03-27	Alcon Manufacturing, Ltd.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Bruce et al., 4-2001, "Zinc and the eye", Journal Of The American College Of Nutrition, 106-118	☐
	2	Kabara et al., 1997, Preservative-Free and Self-Preserving Cosmetics and Drugs – Principles and Practice, Chapter 1, pages 1-14, Marcel Dekker, Inc.	☐
	3	McCarthy et al., 1989, "The Effect of Zinc Ions on the Antimicrobial Activity of Selected Preservatives", Journal of Pharmacy and Pharmacology, Vol. 41, 114P	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.A./

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	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	4	McCarthy, 1985, "Metal Ions as Microbial Inhibitors", Cosmetic & Toiletries, 100:69-72	☐
	5	PCT International Search Report for corresponding International Application No. PCT/US2007/079082 with mailing date April 7, 2008	☐
	6	PCT Written Opinion for corresponding International Application No. PCT/US2007/079082 with mailing date April 7, 2008	☐
	7	Zeelie et al., 1992, "The Effects of Selected Metal Salts on the Microbial Activities of Agents used in the Pharmaceutical and Related Industries", Metal Compounds in Environment and Life, 4:193-200	☐
	8	Zeelie et al., 1998, "Effects of copper and zinc ions on the germicidal properties of two popular pharmaceutical antiseptic agents cetylpyridinium chloride and povidone-iodine", Analyst, 123:503-507	☐

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EXAMINER SIGNATURE

Examiner Signature	/Ernst Arnold/	Date Considered	04/12/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11858781	KABRA ET AL.
	Examiner	Art Unit
	ERNST V ARNOLD	1616

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST 424/642, 660; 514/912 text limited all databases	4/12/10	eva
inventor name PALM	4/12/10	eva

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

PTO/SB/08a (10-08)
Approved for use through 11/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Filing Date	2007-09-20
First Named Inventor	Bhagwati Kabra
Art Unit	1616
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/E.A./	1	5130298		1992-07-14	Cini et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.A./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati Kabra
	Art Unit	1616
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Ernst Arnold/	Date Considered	04/12/2010

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.A./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	689570	(zinc and (artificial with tear) or glaucoma or ophthlamic or eye)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:03
L2	460346	l1 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:03
L3	62	424/642.ccls. and l2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:04
L4	28	424/660.ccls. and l2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:05
L5	891	514/912.ccls. and l2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:08
L6	2	l4 and zinc.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:08
L7	16	l5 and zinc.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:08
L8	51	l3 and zinc.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:09
L9	2	"6503497".pn. and (zinc or borate or boric or polyol or (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:17

L10	0	"6503497".pn. and zinc	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:19
L11	0	"6143799".pn. and zinc	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:19
L12	0	"6849253".pn. and zinc	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:19
L13	4603	(zinc and concentration and (liquid or solution or gel)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:21
L14	4062	l13 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:21
L15	46	l14 and ophthalmic	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:21
L16	10	l14 and ophthalmic and human and tears	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 07:30
L17	7	(zinc and (antimicrobial or antibacterial) and (ophthlamic or eye) and (mM or millimolar)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:44
L18	5	l17 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:44
L19	52	(zinc and (antimicrobial or antibacterial) and (ophthlamic or eye)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:46

L20	42	l19 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:46
L21	283	((zinc and (antimicrobial or antibacterial) and (liquid or solution)).clm. and (zinc with chloride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:53
L22	229	l21 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:53
L23	124	((zinc and (antimicrobial or antibacterial) and (liquid or solution)).clm. and (zinc adj chloride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:54
L24	229	l22 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:54
L25	106	l23 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 08:54
L26	2	"5130298".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/04/12 09:15

4/ 12/ 2010 9:19:58 AM
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Inventor Information for 11/858781

Inventor Name	City	State/Country
KABRA, BHAGWATI P.	EULESS	TEXAS
CHOWHAN, MASOOD A.	ARLINGTON	TEXAS
SCHNEIDER, L. WAYNE	CROWLEY	TEXAS
HAN, WESLEY WEHSIN	ARLINGTON	TEXAS

Appln Info | Contents | Petition Info | Atty/Agent Info | Continuity/Reexam | Foreign D

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 05/17/2010

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IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
05/17/2010	PAPER

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

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ERNST V. ARNOLD*.

(2) *Scott Chapel*.

(3)*Bhagwati Kabra (on telephone)*.

(4)_____.

Date of Interview: *5/12/10*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *1) Applicant discussed their invention. 2) Discussed the rejections of record in detail. 3). Discussed importance of the buffering anions. 4). Discussed USP 27 standard and Olejnik does not meet it. 5) Discussed claim 26 and the Examiner will review the patentability of this claim and report to Applicant in 2 weeks time.*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Ernst V Arnold/ Primary Examiner, Art Unit 1616	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 05/28/2010

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
05/28/2010	PAPER

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

The time period for reply, if any, is set in the attached communication.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

All Participants:

(1) *ERNST V. ARNOLD*.

(2) *Scott Chapel*.

Status of Application: _____

(3) _____.

(4) _____.

Date of Interview: *26 May 2010*

Time: _____

Type of Interview:
☒ Telephonic
☐ Video Conference
☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☐ No
If Yes, provide a brief description: .

Part I.

Rejection(s) discussed:

Claims discussed:
26-30

Prior art documents discussed:

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
See Continuation Sheet

Part III.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.
☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

/Ernst V Arnold/
Primary Examiner, Art Unit 1616

(Applicant/Applicant's Representative Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed: As a follow up from the previous interview, the Examiner stated that claim 26, with appropriate arguments, would overcome the 103 rejection of record and appears to be allowable. The Examiner pointed out a possible 112 second paragraph issue with claims 29 and 30 where the concentration of the ionized salts in the composition is less than 50 mM. This could mean that there is 24 mM cationic species and 24 mM anionic species which would be greater than the "less than 15 mM" anionic species of claim 26. Applicant will consider some claim amendments and submit those amendments and arguments for the Examiner's consideration.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1616

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

June 8, 2010.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

AMENDMENT AND RESPONSE

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

Dear Sir:

This paper is submitted in response to the Office Action dated April 14, 2010, for which the three-month date for response is July 14, 2010.

Applicants believe that no extension of time is required. However, if the U.S. Patent Office deems any fees to be deficient or absent, consider this paragraph such a request and authorization to deduct said fees from Alcon Laboratories, Inc. Deposit Account No. **010682.**

Applicants respectfully request the Examiner to please enter the following amendments and consider the following remarks relative to the above-identified application.

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

Amendments to the Claims are reflected in the listing of claims that begins on page 3 of this paper.

Remarks begin on page 6 of this paper.

REMARKS

Applicants thank Examiner Arnold for the courtesies extended to the undersigned during a personal interview conducted on May 12, 2010 and a follow-up telephonic interview conducted on May 26, 2010. The Office Action objected to the drawings and rejected claims 1-10 and 19-30. By this amendment, Applicants have amended claims 28 and 30, cancelled claims 1-10 and 19-25 and have added new claims 31-40.

I. Objections to the Drawings

The Office Action objected to the Drawings suggesting that the description in the actual figures did not correspond to the description in the Brief Description of Drawings. Without acquiescing in this objection, Applicants have amended the Brief Description of Drawings to overcome the objection. Applicants also submit herewith replacement pages of drawings to place proper numbering at the top of the drawings and to remove the excess periods of the Fig. 3 description as suggested by the Office Action.

II. Claim Rejection under 35 USC 112

The Office Action rejected claims 7, 8, 9, 10, 23, 24, 25, 28, 29 and 30 under 35 USC 112. Claims 7, 8, 9, 10, 23, 24, 25 and 29 have been canceled making those rejections moot. Claims 28 and 30 have been amended to overcome their respective rejections.

III. Claim Rejections under 35 USC 103

The Office Action rejected claims 1-10 and 19-30 as being anticipated by or obvious in view of one or more of Olejnik et al. (US 5597559), Chowhan et al. (US 6503497) and Kross (US 5820822). Without acquiescing in these rejections, Applicants have canceled claims 1-10 and 19-25 and have added new claims 31-40.

THE INTERVIEWS: During the personal interview conducted on May 12, 2010 and the follow-up telephonic interview conducted on May 26, 2010, the patentability of the

claims was discussed. As suggested by Examiner's Interview Summary dated May 28, 2010, it was agreed that claim 26 of the present application and its dependents would be allowable upon the presentation of proper arguments. Applicants provide those arguments below. It was also agreed that Examiner Arnold would phone the undersigned if any issues remained after submission of the present amendment.

1) The inventors of the present application, through the maintenance of a low level of anionic species, have been able to achieve high levels of antimicrobial activity with very low levels of zinc. As recited in the claim 26, the composition includes, "zinc ions at a concentration of 0.04 to 0.4 mM".
2) Olejnik teaches away from the concentration of zinc recited in claim 26 of the present application. In particular, Olejnik teaches toward ionic salt concentrations of 0.01 to 0.50 weight percent (see col.2, lines 45-52 of Olejnik). Moreover, as evidenced by at least example 1, Olejnik teaches toward relatively high levels of ionic salt, particularly Potassium Chloride. Thus, Olejnik teaches away from the zinc level in claim 26 of the present application.
3) Additionally, Claim 26 of the present application is recited as satisfying the USP 27 preservative efficacy requirements. Olejnik is designed to have a much shorter duration of preservation than would be required by the USP. At column 6, lines 20-25, Olejnik reads, "Staphylococcus aureus and A. niger did not proliferate in the tear formulation, however, there was a resurgence in counts for E. Coli, P. aeruginosa and C. albican by seven day post inoculation." Moreover, at col. 10, line 66 to column 11, line 2, Olejnik reads, "Thus, the presently preferred formulation is suited to use in a multi-does container for a limited re-use period, preferably less than about 72 hours." The skilled artisan will quickly recognize that the USP standards require longer periods of preservation.

In summary, Olejnik does not contemplate a composition having the low levels of zinc and preservation efficacy recited in claim 26. In fact, Olejnik teaches away from such a composition. Moreover, the other references cited by the Office Action do not cure the lack of disclosure and improper teachings of Olejnik.

V. New Claims

Applicant have added claims 31 - 40 to address various aspects of the present invention and, in certain instances, to even further detail the inventive concept of the present application. Support for claims 31, 32 and 33 can be found at least at page 13, lines 10-15. Support for claim 34 can be found at least at page 14, lines 29-31. Support for claim 35 can be found at least at page 14, lines 22-24. Support for claims 36-40 can be found at the locations discussed above, original claim 10, page 9 and lines 1-4 and lines 26-33.

CONCLUSION

Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

Alcon Research, Ltd.

June 8, 2010

Scott A. Chapple
Reg. No. 46,287

Attachment: Replacement Drawings

Address for Correspondence:
Scott A. Chapple, IP Legal
Alcon Research, Ltd.
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Attorney Docket: 3205US

REPLACEMENT SHEET

1 / 3

FIG. 1

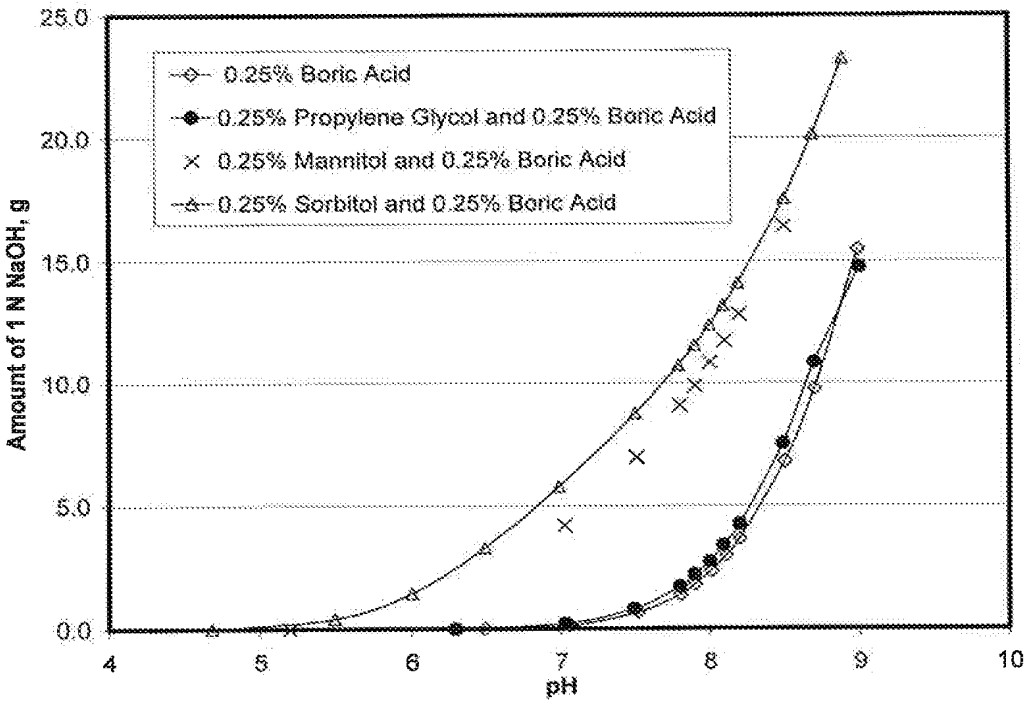

Figure 1: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of mannitol, sorbitol or propylene glycol.

REPLACEMENT SHEET

2 / 3

FIG. 2

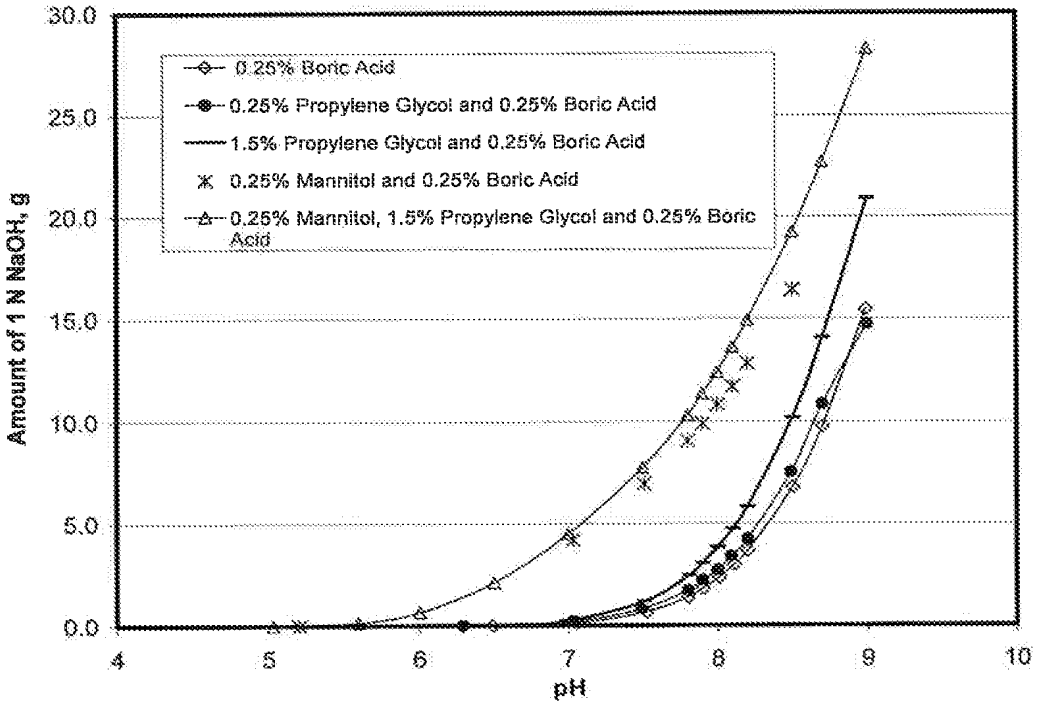

Figure 2: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of propylene glycol.

REPLACEMENT SHEET

3 / 3

FIG. 3

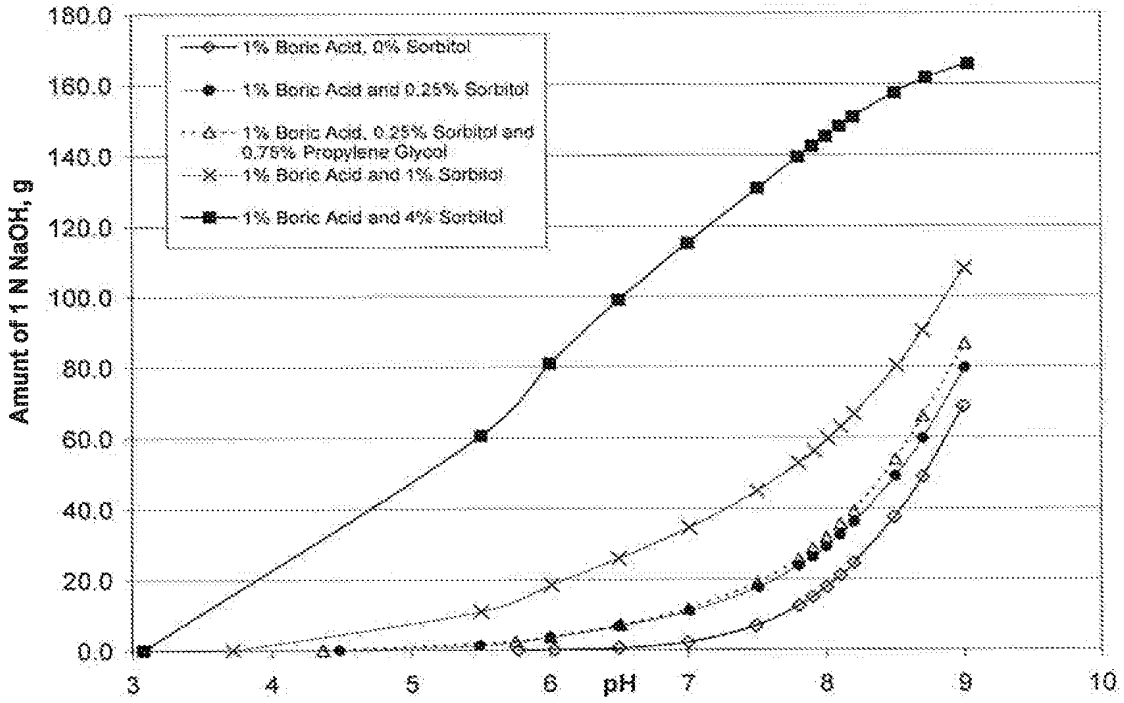

Figure 3: Amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution Boric Acid (1%) in presence of different concentrations of sorbitol.

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	10	52	520
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**520**

Electronic Acknowledgement Receipt

EFS ID:	7770887
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	08-JUN-2010
Filing Date:	20-SEP-2007
Time Stamp:	16:26:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$520
RAM confirmation Number	3096
Deposit Account	010682
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3205_US_Resp-Amend-ReplDwgs_060810.pdf	443005 f927f5f8106eb7f88c08a796057090b7217a4e92	yes	12

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	2
Claims	3	5
Applicant Arguments/Remarks Made in an Amendment	6	9
Drawings-only black and white line drawings	10	12

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	30380 a43632f947369bfb72382f6e6b6da6a73b21eea8	no	2

Warnings:

Information:

Total Files Size (in bytes):	473385

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

AMENDMENTS TO THE SPECIFICATION

Please revise the paragraph beginning at page 6, line 20 as follows:

~~Figures 1-3 are graphs showing the interaction of boric acid and various polyols.~~

Figure 1 is a graph showing the amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of mannitol, sorbitol or propylene glycol.

Figure 2 is a graph showing the amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution of Boric Acid (0.25%) in presence of propylene glycol.

Figure 3 is a graph showing the amount of 1 N Sodium Hydroxide needed to adjust pH of 1Kg solution Boric Acid (1%) in presence of different concentrations of sorbitol.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claims 1-25 (canceled)

Claim 26 (previously presented): A multi-dose, self-preserved ophthalmic composition, comprising

zinc ions at a concentration of 0.04 to 0.4 mM; and

a borate and a polyol for forming a borate/polyol complex, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v;

wherein: (i) the concentration of anionic species present in the composition is less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the compositions to satisfy the USP 27 preservative efficacy requirements.

Claim 27 (previously presented): A composition, according to Claim 26, wherein the polyol utilized in the borate/polyol complex is propylene glycol and/or sorbitol.

Claim 28 (currently amended): A composition according to Claim 27, wherein the composition has a concentration of buffering anions ~~in the composition~~ that is less than 5 mM.

Claim 29 (canceled)

Claim 30 (currently amended): A composition according to Claim 28, wherein: (i) the composition has a concentration of multivalent buffering anions ~~in the composition~~ that is less than 5 mM; and (ii) the composition has a concentration of multivalent metal cations ~~in the composition~~ that is less than 5 mM~~; and (iii) the concentration of ionized salts in the composition is less than 50 mM~~.

Claim 31 (new): A composition according to Claim 26 further comprising a therapeutic agent.

Claim 32 (new): A composition according to Claim 26 further comprising a therapeutic agent selected from the group consisting of bimatoprost, latanoprost, travoprost and unprostone.

Claim 33 (new): A composition according to Claim 32 wherein the composition includes the travoprost.

Claim 34 (new): A composition according to Claim 26 wherein the composition has a pH from 5.5 to 5.9.

Claim 35 (new): A composition according to Claim 26 further comprising a non-ionic surfactant.

Claim 36 (new): A composition according to Claim 26 further comprising:

a therapeutic agent; and

a non-ionic surfactant;

wherein:

i. the composition has a pH from 5.5 to 5.9;

ii. the composition has a concentration of multivalent buffering anions that is less than 5 mM;

iii. the composition has a concentration of multivalent metal cations that is less than 5 mM;

iv. the borate is present in the composition at a concentration of 0.5 to 1.2% w/v; and

v. the polyol includes propylene glycol and the propylene glycol is present in the composition at a concentration of 0.25 to 1.25% w/v.

Claim 37 (new): A composition according to Claim 36 wherein the therapeutic agent is selected from the group consisting of bimatoprost, latanoprost, travoprost and unprostone.

Claim 38 (new): A composition according to Claim 36 wherein the therapeutic agent is travoprost.

Claim 39 (new): A composition according to claim 38 wherein the non-ionic surfactant is polyoxyl 40 hydrogenated castor oil.

Claim 40 (new): A composition according to claim 36 wherein the zinc ions are provided by zinc chloride.

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1613	

DATE MAILED: 08/27/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	11/29/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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P.O. Box 1450
Alexandria, Virginia 22313-1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26356 7590 08/27/2010

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FORT WORTH, TX 76134

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	11/29/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ARNOLD, ERNST V	1613	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____ 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

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❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 08/27/2010

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1613	

DATE MAILED: 08/27/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 510 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 510 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *6/8/10*.

2. ☒ The allowed claim(s) is/are *26-28 and 30-40 [renumbered as 1-14]* .

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Ernst V Arnold/
Primary Examiner, Art Unit 1616

DETAILED ACTION

Claims 1-25 and 29 have been cancelled. Claims 31-40 are new. Claims 26-28 and 30-40 are pending and under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 6/8/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 1-3 and 8-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Olejnik et al. (US 5597559). Applicant's amendments have overcome this rejection. Claims 1-10 and 19-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chowhan et al. (US 6503497) and Olejnik et al. (US 5597559) and Kross (US 5820822). Applicant's arguments have overcome this rejection.

This application is in condition for allowance except for the following formal matters:

The figure captions remain in the Figures. There should be no captions in the Figures.

Drawings

The drawings are objected to because the Figure captions belong in the body of the specification under "Brief Description of the Drawings" section. Corrected drawing

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Double Patenting

The Examiner notes possible double patenting with later filed 12/441995 claims 1 and 3-5 drawn to a multi-dose, self preserved ophthalmic composition comprising a borate/polyol complex and zinc ions and later filed 12/441742 claims 1-4 drawn to a multi-dose, self preserved pharmaceutical compositions with zinc ions and borate/amino alcohol system. From MPEP 804: If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. Accordingly, this application is allowed without the need of a terminal disclaimer.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: the closest prior art of Chowhan et al. (US 2002/0123482) does not teach or suggest, alone or in combination, the instant multi-dose, self-preserved ophthalmic composition with less than 15 mM anionic species. Chowhan et al. teach a composition comprising zinc, boric acid and glycerin in claim 16:

16. An improved artificial tear solution for alleviating dry eye symptoms, said solution having the following formula:

Ingredient	Amount (w/v %)
Hydroxypropyl Methylcellulose (2910) (E4M)	0.3
Dextran 70	0.1
Polysorbate 80 (Tween 80)	0.005
Sodium Chloride	0.4
Boric Acid	0.8
Glycine	0.1
Potassium Chloride	0.038
Calcium Chloride (Dihydrate)	0.0053
Magnesium Chloride (Hexahydrate)	0.0065
Zinc Chloride	0.00015
Glycerin	0.2
Polyquaternium-1	0.00001–0.001
NaOH/HCl	q.s. pH 7.4
Purified Water	q.s. to 100

However, just the sodium chloride is present at about 68 mM and there is no teaching or suggestion to lower the anionic species (i.e., chloride) to less than 15 mM and still retain the USP 27 standard. In fact, it is surprising that Applicant can use about half as much zinc as Olejnik et al. (US 5597559) and obtain a much greater duration of preservative effect. In contrast Olejnik et al. teach only 72 hours of efficacy, which clearly does not meet USP 27 standards as shown by Applicant. Therefore, the Examiner deems the instant invention free of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 26-28 and 30-40 [renumbered as 1-14] are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1616

Notice of References Cited	Application/Control No. 11/858,781	Applicant(s)/Patent Under Reexamination KABRA ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0123482	09-2002	Chowhan et al.	514/59
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	6	chowhan.in. and zinc and borate and polyol	US-PGPUB; USPAT	OR	ON	2010/08/16 06:33
L3	0	"20080075790".pn. and ((zinc adj chloride) and (polyoxyl with castor) and travopost and unprostone and pH and surfactant)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:44
L4	0	"20080075790".pn. and ((zinc adj chloride) and (polyoxyl with castor) and travopost and unprostone)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:44
L5	0	"20080075790".pn. and ((zinc adj chloride) and travopost and unprostone)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
L6	0	"20080075790".pn. and ((zinc adj chloride) and travopost)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
L7	0	"20080075790".pn. and (zinc and travopost)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
L8	1	"20080075790".pn.	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
L9	1	"20080075790".pn. and zinc	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
L10	1	"20080075790".pn. and zinc and chloride	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45

L11	1	"20080075790".pn. and zinc and chloride and travoprost	US-PGPUB; USPAT	OR	ON	2010/08/16 07:46
L12	1	"20080075790".pn. and zinc and chloride and travoprost and castor	US-PGPUB; USPAT	OR	ON	2010/08/16 07:46
L13	17	424/78.04.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
L14	52	424/405.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
L15	54	424/641.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
L16	15	424/657.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
L17	17	424/659.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
L18	22	424/660.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54

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zinc borate "propylene glycol" Search

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Zinc Borate-Zinc Borate professional supplier!
Zinc Borate Inquire Now. Description: ItemModel 2335 237. B2O3 % 45.0-48.0 40.0-43.0 ZnO % 36.0-39.0 32.0-35.0. Surface water %AÜ 1.0 1.0 **...**
chinaqualitycrafts.com/view/11281522/Zinc_Borate.html - Cached

borate toxicity - quality **borate** toxicity products , find 33 good ...
Related Searches: **zinc borate** non toxicity oils Borate borate fertilizers **... Propylene glycol** base, Silicate Type, Less toxic than the antifreeze based on **...**
www.hardware-wholesale.com/buy-borate_toxicity/ - Cached

High strength dental impression composition - US Patent 4648906 ...
Zinc borate has been found to be especially effective in contributing gel strength **...** Example 1 is duplicated but using **propylene glycol** in place of the **...**
www.patentstorm.us/patents/4648906/description.html - Cached

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by MY Kahook - 2007 - Cited by 1 - Related articles
Feb 1, 2009 **...** The combination of **zinc**, **borate**, **propylene glycol** and sorbitol is known to be effective at preventing both bacterial and fungal **...**
www.expert-reviews.com/doi/pdf/10.1586/17469899.2.3.363 - Similar

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Michael Ash, Irene Ash - 2004 - Health & Fitness - 873 pages
1332-07-6 **Zinc borate** (anhyd.) 822-16-2 Sodium stéarate 1085-98-9 Dichlofluanid 1314-13-2 Sodium hydroxide 1332-14-5 Copper sulfate, tribasic 824-35-1 **...**
books.google.com/books?isbn=1890595667...

Zinc Acetate - **Zinc** Acetate Manufacturers,**Zinc** Acetate Suppliers ...
Engaged in trading of zinc acetate, zinc nitrate, **zinc borate**, magnesium oxide, **...** Manufacture and export acetic acid, ethylene glycol, **propylene glycol**, **...**
dir.indiamart.com › ... › Industrial Chemicals - Cached - Similar

Treated Wood
Jun 22, 2010 **...** Sodium borate and **zinc borate** are two available compounds. **..... propylene glycol** must be selected to assist the borate's diffusion through **...**

www.cwc.ca/DesignWithWood/Durability/.../Treated%20Wood?... - Cached

Handbook of Sealant Technology - Google Books Result
K. L. Mittal, A. Pizzi - 2009 - Science - 540 pages
... and wetting agent 1–5 wt% plasticizer 0–2 wt% **propylene glycol** 20–40 wt% **...** pigments 4–6 wt% expandable graphite 16–25 wt% **zinc borate**, glass fiber, **...**
books.google.com/books?isbn=0849391628...

Dry Eye Treatment
Polyethylene Glycol 400 0.4% (lubricant), **Propylene Glycol** 0.3% (lubricant), **...** a loosely crosslinked meshwork created by interactions between **borate** and HP-Guar, **...** (bicarbonate & **zinc** help mucus & surface cells) Preservative-Free. **...**
www.agingeye.net/dryeyes/dryeyesdrugtreatment.php - Cached - Similar

Ingredients
... Calcium Disodium EDTA, Sodium **Borate**, Triethanolamine, **Propylene Glycol**, **... Zinc** Stearate, Sodium Citrate, Citric Acid, Sodium **Borate**, Triethanolamine, **...**
www.camillebeckmanonline.com/ingredients.aspx - Cached

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1. **A study of the anti-wear and friction-reducing properties of the lubricant additive, nanometer zinc borate**
Tribology International, *Volume 31, Issue 5, May 1998, Pages 219-223*
J. X. Dong, Z. S. Hu
Preview PDF (420 K) | Related Articles

2. **Optical spectroscopy of zinc borate glass activated by Pr^{3+} ions**
Journal of Non-Crystalline Solids, *Volume 231, Issues 1-2, 1 July 1998, Pages 178-188*
L. Del Longo, M. Ferrari, E. Zanghellini, M. Bettinelli, J. A. Capobianco, M. Montagna, F. Rossi
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3. **Zinc borates as flame-retardant pigments in chlorine-containing coatings**
Progress in Organic Coatings, *Volume 42, Issues 1-2, June 2001, Pages 82-88*
C. A. Giúdice, J. C. Benítez
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4. **Charring of fire retarded ethylene vinyl acetate copolymer — magnesium hydroxide/zinc borate formulations**
Polymer Degradation and Stability, *Volume 69, Issue 1, June 2000, Pages 83-92*
Fabien Carpentier, Serge Bourbigot, Michel Le Bras, René Delobel, Michel Foulon
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5. **Synthesis of hydrophobic zinc borate nanodiscs for lubrication**
Materials Letters, *Volume 60, Issue 20, September 2006, Pages 2511-2515*
Yumei Tian, Yupeng Guo, Man Jiang, Ye Sheng, Bala Hari, Guangyu Zhang, Yanqiu Jiang, Bing Zhou, Yanchao Zhu, Zichen Wang
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6. **Optical properties of Eu^{3+}-doped zinc borate glasses**
Journal of Luminescence, *Volume 121, Issue 1, November 2006, Pages 123-131*
A. Ivankov, J. Seekamp, W. Bauhofer
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7. **Synthesis and characterization of two new bulky tris(mercaptoimidazolyl)borate ligands and their zinc and cadmium complexes**
Polyhedron, *Volume 20, Issue 28, 15 December 2001, Pages 3343-3348*
Selma Bakbak, Vinay K. Bhatia, Christopher D. Incarvito, Arnold L. Rheingold, Daniel Rabinovich
Preview PDF (135 K) | Related Articles

Graphical Abstract

Two new tridentate sulfur-donor ligands, the tris(mercaptoimidazolyl)borates $[Tm^{Bz}]^-$ and $[Tm^{p\text{-}Tol}]^-$, have been readily prepared in very good yield and used to synthesize the corresponding Group 12 complexes $(Tm^R)MBr$ (M=Zn, Cd). These compounds have been characterized by a combination of analytical and spectroscopic techniques and, in the case of both benzyl-substituted derivatives, by X-ray crystallography.

8. **Effect of Cl^- anions on zinc passivity in borate solution**
Corrosion Science, *Volume 42, Issue 1, January 2000, Pages 1-16*
E. E. Abd El Aal
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9. **Optical properties of zinc borate glasses**
Materials Letters, *Volume 49, Issues 3-4, June 2001, Pages 209-213*
A. Ivankov, J. Seekamp, W. Bauhofer
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10. **Applications of BN- and ZnF_2-containing zinc borate glasses to laser-annealed polycrystalline Si field effect transistors**
Materials Research Bulletin, *Volume 33, Issue 8, August 1998, Pages 1257-1263*
K. Kobayashi
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11. **Factors affecting the anodic behaviour of zinc electrode in borate solutions**
Corrosion Science, *Volume 48, Issue 2, February 2006, Pages 343-360*
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12. **Luminescence properties of Dy^{3+} ions in a variety of borate and fluoroborate glasses containing lithium, zinc, and lead**
Journal of Alloys and Compounds, *Volume 374, Issues 1-2, 14 July 2004, Pages 22-26*
C. K. Jayasankar, V. Venkatramu, S. Surendra Babu, P. Babu
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13. **Preparation of functionalized zinc borates and their coupling reaction with allylic acetates**
Tetrahedron Letters, *Volume 39, Issue 41, 8 October 1998, Pages 7537-7540*
Yuichi Kobayashi, Yuko Tokoro, Kengo Watatani
Preview PDF (201 K) | Related Articles

Graphical Abstract

Preparation of functionalized boronate esters **4** and coupling reaction of the corresponding zinc borates **1** with *sec* allylic acetates are described.

14. **Phosphate coatings on magnesium alloy AM60: Part 2: Electrochemical behaviour in borate buffer solution**
Surface and Coatings Technology, *Volume 192, Issues 2-3, 21 March 2005, Pages 239-246*
L. Kouisni, M. Azzi, F. Dalard, S. Maximovitch
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15. **Kinetics and mechanism of the bicarbonate dehydration of the half-sandwich zinc(II) complexes $[Tp^{Ph}]ZnX$ ($[Tp^{Ph}]$ = hydrotris(3-phenylpyrazolyl)borate; X^- = OH^-, N_3^-, NCS^-)**
Journal of Molecular Catalysis A: Chemical, *Volume 198, Issues 1-2, 1 May 2003, Pages 99-106*
Ying-Ji Sun, Lei Z. Zhang, Wei Sun, Peng Cheng, Hua-Kuan Lin, Shi-Ping Yan, Dai-Zheng Liao, Zong-Hui Jiang, Pan-Wen Shen
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16. **Syntheses and crystal structures of two new hydrated borates, $Zn_8[(BO_3)_3O_2(OH)_3]$ and $Pb[B_5O_8(OH)]\cdot 1.5H_2O$**
Journal of Solid State Chemistry, *Volume 179, Issue 12, December 2006, Pages 3911-3918*
Xuean Chen, Yinghua Zhao, Xinan Chang, Jianlong Zuo, Hegui Zang, Weiqiang Xiao
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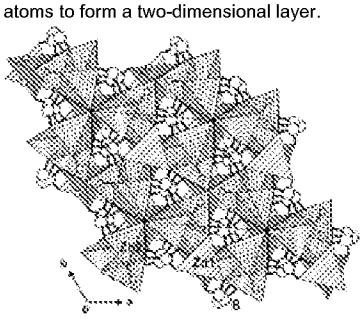
$Zn_8[(BO_3)_3O_2(OH)_3]$ represents a new structure type in which Zn-centered tetrahedra are connected

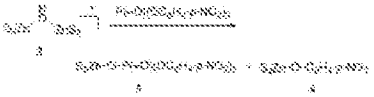
via common vertices to form a three-dimensional framework. The boron atoms are incorporated into the channels in the framework to strengen the structure via B–O bonds. $Pb[B_5O_8(OH)]\cdot 1.5H_2O$ is a new layered material containing double ring $[B_5O_8(OH)]^{2-}$ building units that share exocyclic oxygen atoms to form a two-dimensional layer.



17. **Phosphate triester hydrolysis promoted by S_3–zinc(II) complexes with a bridged hydroxide: The crystal structure of TtiZn–OP(O)$(OC_6H_4$-*p*-$NO_2)_2$, Tti = hydrotris(*N*-xylyl-2-thioimidazolyl) borate**
Inorganic Chemistry Communications, *Volume 9, Issue 12, December 2006, Pages 1215-1218*
Mohamed M. Ibrahim
Preview | PDF (206 K) | Supplementary Content | Related Articles

Graphical abstract

The bridged μ-hydroxo zinc(II) complex $[TtiZn(\mu OH)ZnTti]ClO_4$ (**2**) cleaves the P–O bond in tris(*p*-nitrophenyl)phosphate, affording a mixture of the monomeric phosphate diester complex TtiZn–OP(O)$(OC_6H_4$-*p*-$NO_2)_2$ (**3**) and phenoxide complex TtiZn–OC_6H_4-*p*-NO_2 (**4**). The coordination geometry in both complexes is best described as distorted tetrahedral with an S_3O ligand donor set.



18. **Development of zinc borates designed for functionalized hard nucleophiles in the coupling reaction with allylic alcohol derivatives**
Tetrahedron Letters, *Volume 39, Issue 41, 8 October 1998, Pages 7533-7536*
Yuichi Kobayashi, Kengo Watatani, Yuko Tokoro
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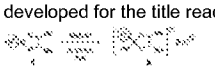
Graphical Abstract

Zinc borates **3** (R^T = aryl, alkenyl), prepared from the boronate esters **1** and MeZnCl, were developed for the title reaction.



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Journal of Inorganic Biochemistry, *Volume 94, Issue 3, 1 March 2003, Pages 214-220*
Yoka Kaup, Mirjam Schmid, Andrew Middleton, Ulrich Weser
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20. **Formation of borate zinc (ZnB_4O_7) nanotubes**
Journal of Crystal Growth, *Volume 286, Issue 1, 1 January 2006, Pages 184-187*
J.B. Chang, P.X. Yan, Q. Yang
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21. **Active site model of carbonic anhydrase: synthesis and crystal structure of the functional tetrahedral zinc complex with hydrotris(3-phenyl-5-methylpyrazolyl-1-yl)borate**
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Ke-Wu Yang, Yong-Zhen Wang, Zhong-Xian Huang, Jie Sun
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K. Varlot, M. Kasrai, G. M. Bancroft, E. S. Yamaguchi, P. R. Ryason, J. Igarashi
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23. **VO^{2+} ions in zinc lead borate glasses studied by EPR and optical absorption techniques**
Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy, Volume 61, Issues 11-12, September 2005, Pages 2595-2602
P. Giri Prakash, J. Lakshmana Rao
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Serge Bourbigot, Michel Le Bras, Robert Leeuwendal, Kelvin K. Shen, David Schubert
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Journal of Non-Crystalline Solids, Volume 220, Issues 2-3, 1 November 1997, Pages 217-221
M. Sbetti, E. Moser, M. Montagna, M. Ferrari, S. Chaussedent, M. Bettinelli
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William R. McWhinnie, Zahra Monsef-Mirzai, Michael C. Perry, Nirmala shaikh, Thomas A. Hamor
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27. **Fluorescence properties of Eu^{3+} ions doped borate and fluoroborate glasses containing lithium, zinc and lead**
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V. Venkatramu, P. Babu, C.K. Jayasankar
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28. **Spectroscopic investigation of zinc borate glasses doped with trivalent europium ions**
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A. Thulasiramudu, S. Buddhudu
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Zhi Zheng, Guangqiu Shen, Yong Wan, Lili Cao, Xiangdong Xu, Qixian Yue, Tianjian Sun
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B. Garba
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33. **Electronic spectroscopy of trivalent lanthanide ions in lead zinc borate glasses**
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N. Sooraj Hussain, N. Ali, A.G. Dias, M.A. Lopes, J.D. Santos, S. Buddhudu

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Journal of Non-Crystalline Solids, Volumes 232-234, 11 July 1998, Pages 581-586
F. Rocca, G. Dalba, R. Grisenti, M. Bettinelli, F. Monti, A. Kuzmin
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Solid State Communications, Volume 97, Issue 6, February 1996, Pages 521-525
Giorgio Pozza, David Ajò, Marco Bettinelli and, Adolfo Speghini, Maurizio Casarin
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Synthesis and characterization of cadmium, copper and zinc complexes with scorpionate

49. ligand hydrotris[3-(*p*-anisyl)-5-methylpyrazol-1-yl]borate [$HB\{pz^{An,Me}\}_3$]. X-ray structure of $[Cd(OAc)(Hpz^{Me,An})(HB\{pz^{An,Me}\}_3)]\cdot CH_2Cl_2$
Polyhedron, *Volume 20, Issues 3-4, 15 February 2001, Pages 291-295*
Yuan Deng, Ru-Ji Wang, Ting-Zhen Ding, Yong Li, Su-Qin Sun, Yu-Ping Feng, Yu-Fen Zhao
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Inorganica Chimica Acta, *Volume 337, 26 September 2002, Pages 459-462*
David T. Puerta, Seth M. Cohen
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Graphical Abstract

The dinuclear zinc(II) complex $[(Tp^{Me,Ph})_2Zn_2(H_3O_2)]ClO_4$ ($Tp^{Me,Ph}$=hydrotris(5,3-methylphenylpyrazolyl)borate) has been characterized by a high quality X-ray crystal structure and was found to contain a H_3O_2 bridge. The bridging of the H_3O_2 unit may describe the nucleophile in hydrolytic zinc enzymes that utilize hydrogen-bond stabilized water molecules to perform polypeptide hydrolysis.

51. Zinc borate in engineering polymers
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E. E. Abd El Aal
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Jennifer L. Kisko, Tauqir Fillebeen, Tony Hascall, Gerard Parkin
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Giancarlo Gioia Lobbia, Bruna Bovio, Carlo Santini, Claudio Pettinari, Fabio Marchetti
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57. Mechanical, physical, and biological properties of borate-modified oriented strandboard
Advances in Building Technology, 2002, Pages 137-144
Qinglin Wu, Sunyoung Lee, Jong N. Lee
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Journal of Organometallic Chemistry, *Volume 690, Issue 8, 15 April 2005, Pages 1935-1946*
Susanne Bieller, Michael Bolte, Hans-Wolfram Lerner, Matthias Wagner
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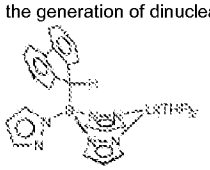
Graphical abstract

Fluorenyl/tris(pyrazol-1-yl)borate hybrid ligands have been prepared, which are of potential use for the generation of dinuclear aggregates as well as mononuclear constrained-geometry complexes.



59. **Human myeloid zinc finger gene *MZF* produces multiple transcripts and encodes a SCAN box protein**
Gene, *Volume 254, Issues 1-2, 22 August 2000, Pages 105-118*
Michael J. Peterson, Jennifer F. Morris
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Abstract

The myeloid zinc finger gene 1 (*MZF1*) encodes a C_2H_2 zinc finger transcription factor that regulates granulopoiesis and may have a regulatory role in cellular proliferation and oncogenesis. The *MZF1* gene has been previously reported to be 3 kb and without introns. However, at least three transcripts of approximately 3, 7.5, and 9 kb are detected by *MZF1*-specific probes in northern blot analysis and the identity of the transcripts has not been addressed. We screened a K562 cDNA library and identified novel transcripts, *MZF1B* and *MZF1C*. The 2.9 kb *MZF1B* cDNA encodes a putative 734 aa protein and *MZF1C* maintains an identical open reading frame with 320 nucleotides deleted in the 5′-untranslated region. The MZF1B/1C protein contains all but the first eight amino acids of MZF1. Thus, MZF protein isoforms share 100 aa, as well as the bipartite 13 zinc finger DNA binding domain. In addition, *MZF1B/1C* encodes a unique 257 aa MZF1B/C amino terminus containing a SCAN box, or leucine-rich domain, which has recently been demonstrated to facilitate protein interactions. Sequence analysis reveals that the *MZF* gene contains six exons and spans 11 kb and may be the most telomeric gene on chromosome 19q13. Exons 1–6 produce *MZF1B/C* cDNA, whereas *MZF1* cDNA initiates within intron 5 and continues through exon 6. The 7.5 and 9 kb transcripts are incompletely processed and contain intron sequences. These studies are the first description of the complete human *MZF* gene and of the composition of the multiple transcripts that are detected by northern blot analysis.

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Advances in Building Technology, 2002, Pages 129-136
Qinglin Wu, Jong N. Lee
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61. **Syntheses, structures and electrochemistry of $[Zn(L^1)_2](BF_4)_2 \cdot 2H_2O$ and $[Zn(L^1)(Tp^R)]BF_4$ (L^1=1-{pyrid-2-yl}-3-{2′,5′-dimethoxyphenyl}pyrazole; $[Tp^R]^-$=tris-{3-arylpyrazolyl}borate)**
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Li Mei Lindy Chia, Andrew E. H. Wheatley, Neil Feeder, John E. Davies, Malcolm A. Halcrow
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Yasushi Mizobe, Masayuki Hosomizu, Masanobu Hidai
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Journal of Alloys and Compounds, Volume 425, Issues 1-2, 30 November 2006, Pages 96-100
Xuean Chen, Haiping Xue, Xinan Chang, Li Zhang, Yinghua Zhao, Jianlong Zuo, Hegui Zang, Weiqiang Xiao
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64. **Tribochemical interactions between micellar calcium borate and ZDDP: Evidence for borophosphate tribofilm by EELS**
Tribology Series, Volume 36, 1999, Pages 433-438
K. Varlof, J.M. Martin, B. Vacher, K. Inoue
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Gene, Volume 148, Issue 2, 21 October 1994, Pages 347-350
Garry B Udy
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66. **Environment of Ni, Co and Zn in low alkali borate glasses: information from EXAFS and XANES spectra**
Journal of Non-Crystalline Solids, Volumes 293-295, November 2001, Pages 105-111
Laurence Galoisy, Laurent Cormier, Georges Calas, Valérie Briois
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Abstract

XANES spectroscopy confirms that transition elements such as nickel, cobalt and zinc are octahedrally co-ordinated in low-alkali borate glasses, a co-ordination state which is unusual in most oxide glasses. EXAFS spectroscopy indicates that, despite their diluted character, transition elements are inhomogeneously distributed, with a medium range order extending up to 6 Å with multiple scattering features characteristic of the presence of collinear cations. This peculiar structure is attributed to the presence of rigid units in these low-alkali borate glasses. The presence of these ordered domains in $0.1Li_2O–0.9B_2O_3$ glasses with NiO contents ranging from 0.5 to 2 wt% shows their independence relative to the concentration of the transition element.

67. **Synthesis and characterization of divalent metal complexes containing the heteroscorpionate ligand dihydrobis(3-carboxyethyl-5-methylpyrazolyl)borate**
Inorganica Chimica Acta, Volume 359, Issue 12, 1 September 2006, Pages 4036-4042
G. Bandoli, A. Dolmella, G. Gioia Lobbia, G. Papini, M. Pellei, C. Santini
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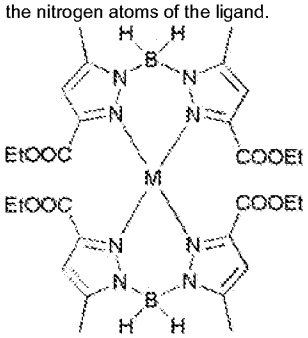
Graphical abstract

The dihydrobis(3-carboxyethyl-5-methylpyrazolyl)borate ligand, $Bp^{COOET,Me}$, reacts with divalent metals to yield complexes of general type $[(Bp^{COOET,Me})_2M]$, where M = Mn(II), Fe(II), Co(II), Ni(II), Zn(II), Cu(II), Pb(II) and Cd(II). A single crystal structural characterization is reported for $[Cu(Bp^{COOET,Me})_2]$ and $[Zn(Bp^{COOET,Me})_2]$, where the metals are four-coordinated and only bound to the nitrogen atoms of the ligand.



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L.D. Bogomolova, V.A. Jachkin
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J. Morales, G. T. Fernandez, S. Gonzalez, P. Esparza, R. C. Salvarezza, A. J. Arvia
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Yasumasa Kanekiyo, Sen-ichi Aizawa, Nobuyoshi Koshino, Shigenobu Funahashi
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Surface Technology, Volume 17, Issue 2, October 1982, Pages 157-164
R.K. Shukla, S.K. Jha, S.C. Srivastava
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72. **The effect of Cu-rich sub-layer on the increased corrosion resistance of Cu–xZn alloys in chloride containing borate buffer**
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Ingrid Milošev, Tadeja Kosec Mikić, Miran Gaberšček
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Materials Letters, Volume 46, Issues 2-3, November 2000, Pages 160-168
Catherine Henrist, André Rulmont, Rudi Cloots, Bernard Gilbert, Alain Bernard, Guenter Beyer
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74. **Iron compounds in non-halogen flame-retardant polyamide systems**
Polymer Degradation and Stability, Volume 82, Issue 2, 2003, Pages 291-296
Edward D. Weil, Navin G. Patel
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Bioresource Technology, Volume 97, Issue 15, October 2006, Pages 1959-1963
J.W. Kirkpatrick, H.M. Barnes
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76. **Syntheses and crystal structures of two new pentaborates**
Journal of Solid State Chemistry, Volume 178, Issue 3, March 2005, Pages 729-735
Guo-Ming Wang, Yan-Qiong Sun, Guo-Yu Yang
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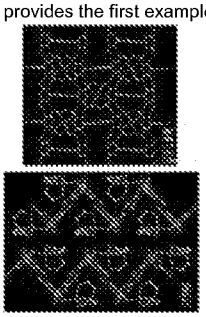
Graphical abstract

Two new zinc pentaborates, $[Zn(DIEN)_2][B_5O_6(OH)_4]_2$ (**I**) and $[B_5O_7(OH)_3Zn(TREN)]$ (**II**), have been synthesized under hydrothermal conditions. Compound **I** is a new pentaborate templated by a transition-metal complex, while **II** is a novel transition-metal complex supported pentaborate, which provides the first example of the combination of B–O cluster with transition-metal complex.



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S. Wallström, E. Strömberg, S. Karlsson
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D. Price, G.J. Milnes, C. Lukas, A.M. Phillips
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A borate fusion method for the determination of fluorine in coal

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Rosemary A. Wood, Leslie S. Dale, Kenneth W. Riley
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81. **Modelling transition state analogues and enzyme-inhibitor complexes of zinc-containing class II aldolases and metalloproteases**
Inorganica Chimica Acta, *Volume 250, Issues 1-2*, *September 1996*, *Pages 271-281*
M. Ruf, K. Weis, I. Brasack, H. Vahrenkamp
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82. **Molecular biology of vertebrate transcription factor IIIA: cloning and characterization of TFIIIA from channel catfish oocytes**
Gene, *Volume 203, Issue 2*, *12 December 1997*, *Pages 103-112*
Martha K. Ogilvie, Jay S. Hanas
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83. **Highly selective extraction of Cu(II) and Zn(II) using $[B(3\text{-}iPrpz)_4]^-$ (iPrpz=isopropylpyrazolyl)**
Polyhedron, *Volume 23, Issues 2-3*, *22 January 2004*, *Pages 283-289*
Tsuyoshi Kitano, Yoshiki Sohrin, Yasuo Hata, Hiroshi Mukai, Hiroki Wada, Kazumasa Ueda
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Graphical Abstract

Solvent extraction of first-series transition metal ions with $[B(3\text{-}iPrpz)_4]^-$ is reported. This ligand quantitatively extracts only Cu(II) and Zn(II). The structures of the extracted species were determined by single-crystal X-ray diffraction. Because the bulky isopropyl groups prevent octahedral geometry, the other metal ions cannot form stable and extractable complexes with $[B(3\text{-}iPrpz)_4]^-$.

84. **Binding of the C6-zinc cluster protein, AFLR, to the promoters of aflatoxin pathway biosynthesis genes in *Aspergillus parasiticus***
Gene, *Volume 230, Issue 2*, *16 April 1999*, *Pages 249-257*
K. C. Ehrlich, B. G. Montalbano, J. W. Cary
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Abstract

AFLR is a Zn_2Cys_6-type sequence-specific DNA-binding protein that is thought to be necessary for expression of most of the genes in the aflatoxin pathway gene cluster in *Aspergillus parasiticus* and *A. flavus*, and the sterigmatocystin gene cluster in *A. nidulans*. However, it was not known whether AFLR bound to the promoter regions of each of the genes in the cluster. Recently, *A. nidulans* AFLR was shown to bind to the motif 5′-$TCGN_5CGA$-3′. In the present study, we examined the binding of AFLR to promoter regions of 11 genes in the *A. parasiticus* cluster. Based on electrophoretic mobility shift assays, the genes *nor1*, *pksA*, *adhA*, *norA*, *ver1*, *omtA*, *ordA*, and, *vbs*, had at least one 5′-$TCGN_5CGA$-3′ binding site within 200 bp of the translation start site, and *pksA* and *ver1* had an additional binding site further upstream. Although the promoter region of *avnA* lacked this motif, AFLR bound weakly to the sequence 5′-TCGCAGCCCGG-3′ at −110 bp. One region in the promoter of the divergently transcribed genes *aflR*/*aflJ* bound weakly to AFLR even though it contained a site with at most only 7 bp of the 5′-$TCGN_5CGA$-3′ motif. This partial site may be recognized by a monomeric form of AFLR. Based on a comparison of 16 possible sites, the preferred binding sequence was 5′-TCGSWNNSCGR-3′.

85. **Syntheses, band structures and optical properties of $Zn_3B_2O_6$ and $KZn_4B_3O_9$**
Solid State Sciences, *Volume 7, Issue 2*, *February 2005*, *Pages 179-188*
D.-G. Chen, W.-D. Cheng, D.-S. Wu, H. Zhang, Y.-C. Zhang, Y.-J. Gong, Z.-G. Kan
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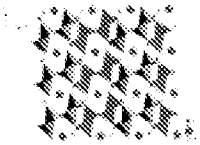
Graphical abstract



86. **A new noncentrosymmetric orthoborate $[Ba_2Zn(BO_3)_2]$**
Materials Research Bulletin, Volume 29, Issue 11, November 1994, Pages 1203-1210
Robert W. Smith, Lenore J. Koliha
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87. **A zinc-selective electrode based on *N,N'*-bis(acetylacetone)ethylenediimine**
Sensors and Actuators B: Chemical, Volume 114, Issue 2, 26 April 2006, Pages 812-818
V.K. Gupta, S. Agarwal, A. Jakob, H. Lang
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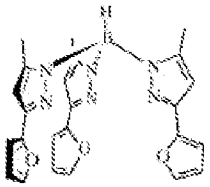
The new ligand hydrotris(3-(2′-furyl)-5-methylpyrazolyl)borate ($Tp^{Fu,Me}$) has been prepared and converted to simple zinc complexes. The "enzyme model" $Tp^{Fu,Me}Zn–OH$ inserts CO_2 and CS_2 and effects hydrolysis of tris(*p*-nitrophenyl)phosphate and γ-thiobutyrolactone. It does not hydrolyse trifluoroacetamide, but instead deprotonates it.



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11/858,781	09/20/2007	424	1616	3205US

APPLICANTS

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Masood A. Chowhan, Arlington, TX;
L. Wayne Schneider, Crowley, TX;
Wesley Wehsin Han, Arlington, TX;

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

This appln claims benefit of 60/827,411 09/28/2006
and claims benefit of 60/826,529 09/21/2006

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Polycarbonate-**polyol** composition and polycarbonate(meth) acrylate ...
A polycarbonate **polyol** composition which can be used to prepare polycarbonate(meth)acrylate and ... **zinc borate**, zinc oxide, lead silicate, lead arsenate, lead carbonate, ... tin compounds, and or metal acetylacetonate **complexes**, etc., ...
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Firestop Material - Patent application - consisting of a polymer ...
These **polyols** involve a certain number of drawbacks notably linked with ... with a high viscosity that makes the use of such a **polyol** particularly **complex**. .... a **zinc borate**, an aluminium oxide, a magnesium oxide or a similar oxide. ...
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(WO/2002/072713) AQUEOUS INTUMESCENT FIRE BARRIER COMPOSITION
by DW ERISMANN - 2002
The composition of claim 1, wherein said **polyol** is selected from the group consisting of **...** of aluminum oxide trihydrate, **zinc borate** and mixtures thereof. **...**
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Cathodic corrosion protection powder coating composition and ...
Jul 27, 2006 **...** Examples of the **polyol** resin are **polyol** resins obtained by **...** The **zinc borate** compound promotes disbondment resistance by reducing **...**
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Borates in Industrial Use
by D Schubert - 2003 - Cited by 8 - Related articles
Borates can be viewed as **complex** salts in which the Lewis basicity of the **....** In the **zinc borate** Zn[B3O4 (OH)3], on the other hand, zinc **.....** of a number of borate **polyol** compounds from various plants [63–65]. These **...**
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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11858781	KABRA ET AL.
	Examiner	**Art Unit**
	ERNST V ARNOLD	1616

ORIGINAL		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
424	78.04	A	6	1	K	31 / 74 (2006.01.01)	A	0	1	N	25 / 00 (2006.01.01)
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CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
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514	912				

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(Assistant Examiner)	(Date)	14	
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1. **A study of the anti-wear and friction-reducing properties of the lubricant additive, nanometer zinc borate**

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(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
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Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2010-11-22
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Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

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Extension-of-Time:				
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Request for continued examination	1801	1	810	810
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EFS ID:	8890335
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
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Attorney Docket Number:	3205US
Receipt Date:	22-NOV-2010
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3205_US_Amend-w-RCE_112210.pdf	519874 1d51bbb638a7f7c577c35e2dcab10d5d6cdfa30e	yes	14

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Drawings-only black and white line drawings	2	2
Claims	3	7
Applicant Arguments/Remarks Made in an Amendment	8	11
Drawings-only black and white line drawings	12	14

Warnings:

Information:

2	Request for Continued Examination (RCE)	3205_US_RCE_112210.pdf	697866 d766898612a96f336afdfbf8badc7288858fcf10	no	3

Warnings:

Information:

3	Transmittal Letter	3205_US_IDS-S2_112210.pdf	558258 20289f8ec4351109a13a8360cc18de5ac12325c1	no	11

Warnings:

Information:

4	Information Disclosure Statement (IDS) Filed (SB/08)	3205_US_IDS-S2_08a_112210.pdf	612409 555cf6fd5735047887c81024d4ed52a5ff2a9360	no	4

Warnings:

Information:

5	Foreign Reference	WO_95_013050_A1.pdf	899311 6ed3c2abcd69afb554163949e690c09f31e35340	no	23

Warnings:

Information:

6	Fee Worksheet (PTO-875)	fee-info.pdf	37403 d0d3d43402b0e617fa68439761d1c940c88269fd	no	2

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Total Files Size (in bytes):	3325121

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra et al.

U.S. Serial No.: 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop RCE; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date: November 22, 2010.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

AMENDMENT FILED WITH A REQUEST FOR CONTINUED EXAMINATION

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

Dear Sir:

This paper is submitted in response to the Notice of Allowance dated August 27, 2010, for which a response is due November 29, 2010.

Applicants believe that no extension of time is required. However, if the U.S. Patent Office deems any fees to be deficient or absent, consider this paragraph such a request and authorization to deduct said fees from Alcon Research, Ltd. Deposit Account No. **010682.**

Applicants respectfully request the Examiner to please enter the following amendments and consider the following remarks relative to the above-identified application.

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

Amendments to the Claims are in the listing of claims that begins on page 3 hereof.

Remarks begin on page 8 of this paper.

AMENDMENTS TO THE DRAWINGS

Applicants provide herewith a set of replacement drawings that address the issue raised in the Notice of Allowance.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1 (currently amended): A multi-dose, self-preserved ophthalmic composition, comprising:

zinc ions at a concentration of 0.04 to 0.4 mM; and

~~a borate and a polyol for forming~~ a borate/polyol complex formed from a borate and a polyol, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v;

wherein: (i) the composition has a ~~the~~ concentration of anionic species ~~present in the composition is~~ less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition ~~compositions~~ to satisfy ~~the~~ USP 27 preservative efficacy requirements.

Claim 2 (previously presented): A composition according to Claim 1, wherein the polyol utilized in the borate/polyol complex is propylene glycol and/or sorbitol.

Claim 3 (currently amended): A composition according to Claim 2, wherein the composition has a concentration of multivalent buffering anions that is less than 5 mM.

Claim 4 (currently amended): A composition according to Claim 1 ~~Claim 3~~, wherein: (i) the composition has a concentration of multivalent buffering anions that is less than 5 mM; and (ii) the composition has a concentration of multivalent metal cations other than zinc that is less than 5 mM.

Claim 5 (currently amended): A composition according to Claim 1 further comprising an effective amount of a therapeutic agent.

Claim 6 (currently amended): A composition according to Claim 1 further comprising a therapeutic agent selected from the group consisting of bimatoprost, latanoprost, travoprost and unoprostone ~~unprostone~~.

Claim 7 (currently amended) A composition according to Claim 6 wherein the therapeutic agent comprises travoprost ~~the composition includes the travoprost~~.

Claim 8 (previously presented): A composition according to Claim 1 wherein the composition has a pH from 5.5 to 5.9.

Claim 9 (previously presented): A composition according to Claim 1 further comprising a non-ionic surfactant.

Claim 10 (currently amended): A composition according to Claim 1 further comprising:

an effective amount of a therapeutic agent; ~~and~~

~~a non-ionic surfactant;~~

wherein:

i. the composition has a pH from 5.5 to 5.9;

ii. the composition has a concentration of multivalent buffering anions that is less than 5 mM;

iii. the composition has a concentration of multivalent metal cations other than zinc that is less than 5 mM;

iv. the borate is present in the composition at a concentration of 0.5 to 1.2% w/v; and

v. the polyol includes propylene glycol and the propylene glycol is present in the composition at a concentration of 0.25 to 1.25% w/v.

Claim 11 (currently amended): A composition according to Claim 10 wherein the therapeutic agent is selected from the group consisting of bimatoprost, latanoprost, travoprost and unoprostone ~~unprostone~~.

Claim 12 (previously presented): A composition according to Claim 10 wherein the therapeutic agent is travoprost.

Claim 13 (currently amended): A composition according to Claim 12 further comprising a ~~wherein the~~ non-ionic surfactant ~~is polyoxyl 40 hydrogenated castor oil~~.

Claim 14 (currently amended): A composition according to Claim 10 wherein the zinc ions are provided by zinc chloride at a concentration of 0.001 to 0.005 w/v%.

Claim 15 (new): A composition according to Claim 10 wherein the propylene glycol is present in the composition at a concentration of 0.75 w/v%, the borate is boric acid and is present in the composition at a concentration of 1.0 w/v% and the zinc ions are provided by zinc chloride at a concentration of 0.0025 w/v%.

Claim 16 (new): A composition according to Claim 1 or Claim 10 wherein the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 17 (new): A composition according to Claim 1 wherein the concentration of anionic species in the composition is less than 10 mM.

Claim 18 (new): A composition according to Claim 1 wherein the concentration of anionic species in the composition is less than 5 mM.

Claim 19 (new): A composition according to Claim 10 wherein the concentration of anionic species in the composition is less than 10 mM.

Claim 20 (new): A composition according to Claim 10 wherein the concentration of anionic species in the composition is less than 5 mM.

Claim 21 (new): A composition according to Claim 1 wherein the composition comprises zinc ions at a concentration of 0.1 to 0.4 mM.

Claim 22 (new): A composition according to Claim 10 wherein the composition comprises zinc ions at a concentration of 0.1 to 0.4 mM.

Claim 23 (new): A multi-dose, self-preserved ophthalmic composition, comprising:

an effective amount of travoprost;

zinc ions at a concentration of 0.1 to 0.4 mM wherein the zinc ions are provided by zinc chloride;

a borate/polyol complex formed from borate and polyol, the borate being present as boric acid in the composition at a concentration of 0.5 to 1.2% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.25 to 1.25% w/v and the sorbitol being present in the composition at a concentration of 0.05 to 0.5% w/v; and

water;

wherein: (i) the composition has a concentration of anionic species less than 10 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv) the composition has a pH from 5.5 to 5.9.

Claim 24 (new): A composition according to Claim 23 further comprising a non-ionic surfactant.

Claim 25 (new): A composition according to Claim 24 wherein the concentration of travoprost in the composition is 0.004 % w/v, the concentration of zinc chloride in the composition is 0.0025 % w/v, the concentration of boric acid is 1.0 % w/v, the concentration of propylene glycol in the composition is 0.75 % w/v, the concentration of sorbitol in the composition is 0.25 w/v % and the concentration of non-ionic surfactant in the composition is 0.5 w/v%.

Claim 26 (new): A composition according to Claim 23 wherein the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 27 (new): A multi-dose, self-preserved ophthalmic composition, consisting of:

an effective amount of travoprost;

zinc ions at a concentration of 0.1 to 0.4 mM wherein the zinc ions are provided by zinc chloride;

a non-ionic surfactant;

a borate/polyol complex formed from borate and polyol, the borate being present as boric acid in the composition at a concentration of 0.5 to 1.2% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.25 to 1.25% w/v and the sorbitol being present in the composition at a concentration of 0.05 to 0.5% w/v;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 10 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv)

the composition has a pH from 5.5 to 5.9.

Claim 28 (new): A multi-dose, self-preserved ophthalmic composition, consisting of:

travoprost at a concentration of 0.004% w/v;

zinc chloride at a concentration of 0.0025% w/v;

polyoxyl 40 hydrogenated castor oil at a concentration of 0.5% w/v;

a borate/polyol complex formed from borate and polyol, the borate being present as boric acid in the composition at a concentration of 1.0% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.75% w/v and the sorbitol being present in the composition at a concentration of 0.25 w/v%;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 5 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv) the composition has a pH from 5.5 to 5.9.

REMARKS

By this amendment, Applicants have made formality changes to the claims and have added three independent claims and 10 new dependent claims. Applicants request that Examiner Arnold enter these changes and additions and issue a new Notice of Allowance for the present application. To aid in Examiner Arnold's review of these changes and additions, Applicants explain each change or addition below:

I) In claim 1, the phrase "a borate and a polyol for forming a borate/polyol complex" has been amended to read "a borate/polyol complex formed from a borate and a polyol". Applicants assert that claim 1, as amended, more clearly recites that at least a portion of the borate and polyol of the claim actually forms a borate/polyol complex.

II) Also in claim 1, the phrase "the concentration of anionic species present in the composition is less than 15 mM" has been amended to read "the composition has a concentration of anionic species less than 15 mM". This amendment merely corrects a potential lack of antecedent basis.

III) Also in claim 1, the term "compositions" has been amended to read "composition" in order to correct a typographical error and the word "the" has been removed prior to the phrase "USP 27 preservative efficacy requirements" in order to avoid any potential lack of antecedent basis.

IV) In claim 3, the term "multivalent" has been added prior to the phrase "buffering anions" in order to improve the form of the claim.

V) Claim 4 has been amended to depend upon claim 1 as opposed to claim 3. This amendment avoids a potentially repetitive limitation that occurs in both claim 3 and claim 4. Claim 4 is a dependent claim that further narrows the already allowed subject matter of claim 1.

VI) In claim 4, the phrase "multivalent metal cations" has been replaced with the phrase "multivalent metal cations other than zinc". The specification, at page 8, lines 16-18, refers to "multivalent metal cations other than zinc" and it is clear from the discussion starting at page 7, line 35 of the specification that multivalent metal cations that are

competitive with zinc are to be kept to a minimum.

VII) In claim 5, the phrase "an effective amount of" has been added before the phrase "therapeutic agent".

VIII) In claim 6, the misspelled term "unprostone" has been replaced with the proper spelling "unoprostone".

IX) In claim 7, the phrase "the composition includes the travoprost" has been amended to read "the therapeutic agent comprises travoprost" so as to improve the form of the claim.

X) In claim 10, the phrase "multivalent metal cations" has been replaced with the phrase "multivalent metal cations other than zinc". This change is the same as the change made in claim 4. Applicants have also removed the element "a non-ionic surfactant" from dependent claim 10.

XI) In claim 11, the misspelled term "unprostone" has been replaced with the proper spelling "unoprostone".

XII) In claim 13, Applicants have replaced the phrase "wherein the non-ionic surfactant is poloxyl 40 hydrogenated castor oil" with the phrase "further comprising a non-ionic surfactant."

XIII) Claim 14 has been amended to specify the concentration of zinc chloride that provides the zinc ions in claim 10. The recited concentration range is supported in the specification at page 6, lines 31-33.

XIV) Claim 15 has been added to recite concentrations of a desirable embodiment of the composition of claim 10. The subject matter of claim 15 is at least supported by Table Y-1 on page 35 of the specification.

XV) Claim 16 has been added to more specifically claim a particular embodiment of the invention claimed in claim 10, wherein the composition does not contain any multivalent buffering anions and does not contain any multivalent metal cations other

than zinc. The subject matter of claims 16 is supported at page 7, lines 22-25 and at page 8, lines 10-13.

XVI) Claim 17 has been added to recite that the concentration of anionic species is less than 10 mM. Claim 17 finds support at page 7, lines 9-11.

XVII) Claim 18 has been added to recite that the concentration of anionic species is less than 5 mM. Claim 18 finds support at page 7, lines 9-11.

XVIII) Claims 19 and 20 are the same as claims 17 and 18 with the exception that claims 19 and 20 are dependent upon claim 10 rather than claim 1.

XIX) Claims 21 and 22 have been added to narrow the range of zinc ions present in the composition. Claims 21 and 22 find support at page 6, lines 25-28 of the application.

XX) Claims 23-28 have been added to provide narrow claims to highly preferred embodiments of the invention. The breadth of claims 23 through 28 is completely narrowed in scope relative to claim 1. The additional limitations of those claims find support at page 9, lines 1-5; page 2, lines 26-31; page 14, lines 20-25.

In the event that any of the above discussed amendments are considered to be objectionable, Applicants respectfully request that Examiner Arnold phone the undersigned to provide an opportunity to cancel such amendment[s] or arrange to make the amendment[s] in a different manner.

CONCLUSION

Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

Alcon Research, Ltd.

November 22, 2010

Scott A. Chapple
Reg. No. 46,287

Attachment: Replacement Drawings

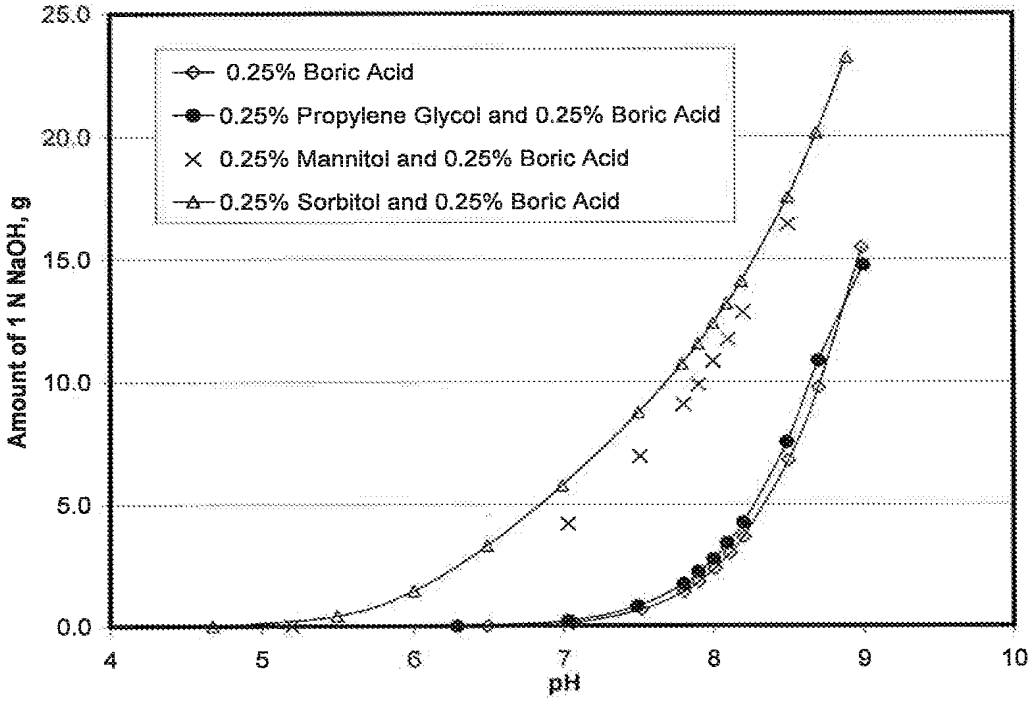
Address for Correspondence:
Scott A. Chapple, IP Legal
Alcon Research, Ltd.
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Attorney Docket: 3205US

REPLACEMENT SHEET

1 / 3

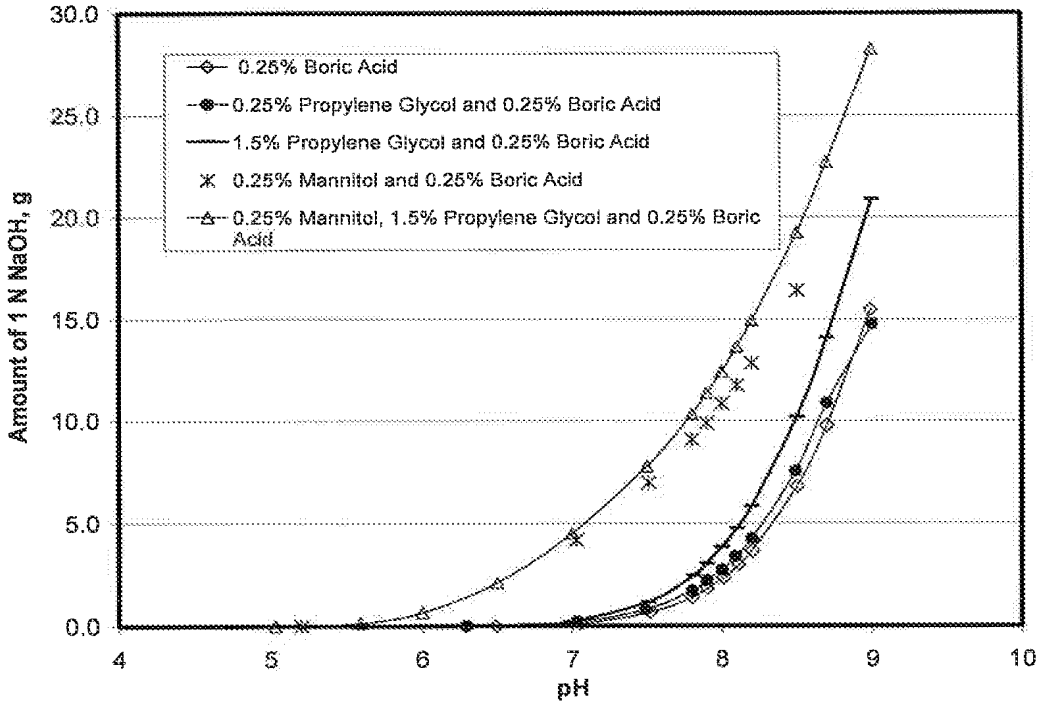
FIG. 1



REPLACEMENT SHEET

2 / 3

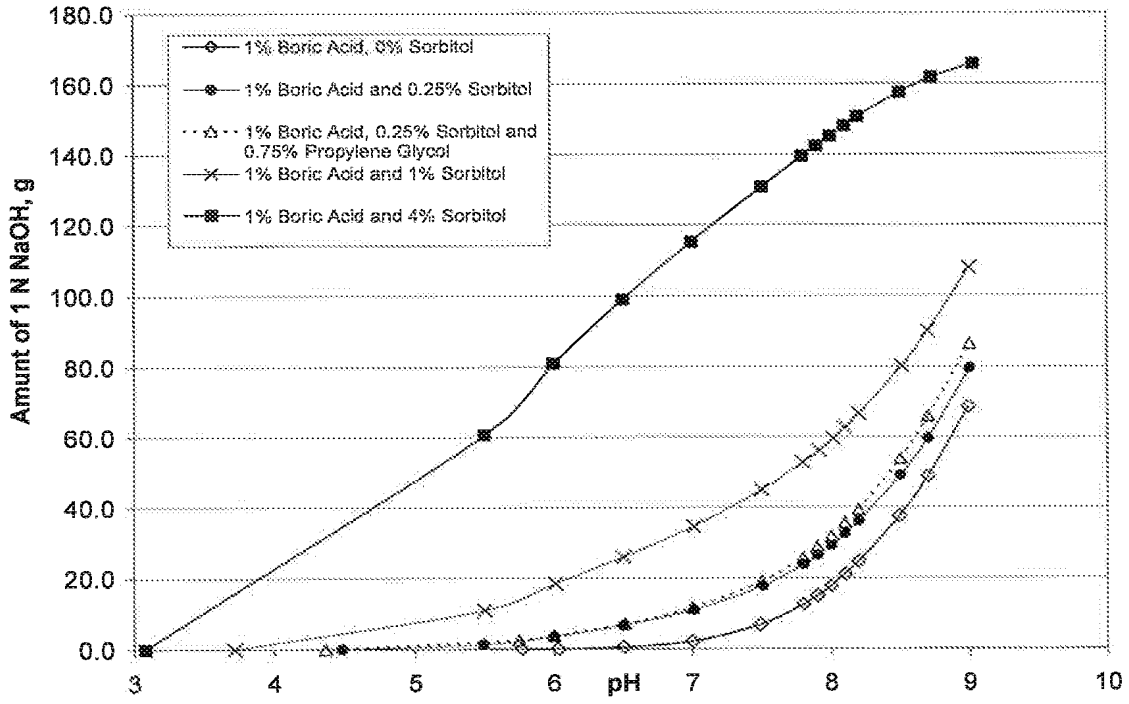
FIG. 2



REPLACEMENT SHEET

3 / 3

FIG. 3



PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11858781	Filing Date	2007-09-20	Docket Number (if applicable)	3205US	Art Unit	1613
First Named Inventor	Bhagwati P. Kabra			Examiner Name	Arnold, Ernst V.		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 010682

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2010-11-22
Name	Scott A. Chapple	Registration Number	46287

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra, et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop RCE; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

November 22 2010.

By: /Barbara McKenzie/
Barbara McKenzie

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and FEE PURSUANT TO 37 C.F.R. § 1.17 (p)

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

Sir:

In accordance with Rules 56, 97 and 98 of the Rules of Practice in Patent Cases 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and fee pursuant to 37 C.F.R. § 1.17 (p), enclosed is Form PTO/SB/08a Information Disclosure Statement by Applicant.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

The requisite fee under 37 C.F.R. §1.17(p) has been charged to Deposit Account No. **010682** via EFS Web.

Applicants provide herewith a copy of an Office Action issued relative to USSN 12/441,995 dated June 24, 2010. This application was mentioned in the Notice of Allowance issued for the present application. Applicants provide a copy of the Office Action to assure that the Patent Office is aware that it issued.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

ALCON RESEARCH, LTD.

November 22, 2010

Scott A. Chapple
Reg. No. 46,287

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Docket No. 3205US

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/858,781	09/20/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 11/22/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $ =		OR	X $220=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

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

Legal Instrument Examiner:
/Kim Downing/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 12/17/2010

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
12/17/2010	PAPER

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

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1613	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ERNST V. ARNOLD*. (3)_____.

(2) *Scott Chapple*. (4)_____.

Date of Interview: *09 December 2010*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *1*.

Identification of prior art discussed: *US 7445771*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Ernst V Arnold/ Primary Examiner, Art Unit 1613	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant filed an RCE with claim amendments and new claims after a NOA and included an information disclosure statement. Applicant discussed the claim amendments and new claims and directed the Examiner to Table 3 of US 7445771. Table 3 contains an artificial tear composition with 0.00015% (w/v) of ZnCl2 and very low amounts of anions which is close to the instantly claimed "less than 15mM" value. The tears also contain boric acid 0.8% (w/v) and propylene glycol 0.3% (w/v) and sorbitol 1.4% (w/v). The Examiner said he would take these points into consideration once the application was picked up for examination.

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

26356 7590 02/23/2011

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER
ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
1613	

DATE MAILED: 02/23/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	05/23/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26356 7590 02/23/2011

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IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	05/23/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
ARNOLD, ERNST V	1613	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

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FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1613	

DATE MAILED: 02/23/2011

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 510 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 510 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1613	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/22/10*.

2. ☒ The allowed claim(s) is/are *1-28*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 11/22/10
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/10 has been entered.

Claims 15-28 are new. Claims 1-28 are pending and under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/22/10 was filed after the mailing date of the notice of allowance on 8/27/10. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: after careful consideration of the information disclosure statement filed on 11/22/10, there is no art,

alone or in combination, that anticipates or renders obvious the instantly claimed self-preserved ophthalmic composition. The instant composition is therefore free of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1-28 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
11858781	11858781	KABRA ET AL.
	Examiner	**Art Unit**
	ERNST V ARNOLD	1616

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
EAST 424/642, 660; 514/912 text limited all databases	4/12/10	eva
inventor name PALM	4/12/10	eva
EAST 424/78.04, 405, 641, 657, 659, 660 text limited all databases	8/16/10	eva
google	8/15/10	eva
pubmed	8/15/10	eva
science direct	8/15/10	eva
inventor name PALM/EAST	8/16/10	eva
search update EAST	2/8/11	eva

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**
USPGPUB TEXT SEARCH	EAST	8/16/10	eva

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 3372

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/858,781	09/20/2007	424	1613	3205US

APPLICANTS

Bhagwati P. Kabra, Euless, TX;
Masood A. Chowhan, Arlington, TX;
L. Wayne Schneider, Crowley, TX;
Wesley Wehsin Han, Arlington, TX;

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

This appln claims benefit of 60/827,411 09/28/2006
and claims benefit of 60/826,529 09/21/2006

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

12/08/2007

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ERNST V ARNOLD/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		TX	3	28 ~~18~~	4 ~~2~~

ADDRESS

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134
UNITED STATES

TITLE

SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

FILING FEE RECEIVED		
3234	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
11858781	11858781	KABRA ET AL.
	Examiner	**Art Unit**
	ERNST V ARNOLD	1616

ORIGINAL		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
424	78.04	A	6	1	K	31 / 74 (2006.01.01)	A	0	1	N	25 / 00 (2006.01.01)
CROSS REFERENCE(S)		A	6	1	K	33 / 32 (2006.01.01)	A	0	1	N	59 / 16 (2006.01.01)
		A	6	1	K	33 / 22 (2006.01.01)	A	0	1	N	59 / 14 (2006.01.01)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
424	405	641	657	659	660
514	912				

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 28	
/ERNST V ARNOLD/ Primary Examiner.Art Unit 1616 (Primary Examiner)	2/8/11 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure none

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	0	"4648906".pn. and (zinc and polyol and (propylene or sorbitol))	USPAT	OR	ON	2010/08/15 14:20
S2	1	"4648906".pn. and (zinc and (propylene or sorbitol))	USPAT	OR	ON	2010/08/15 14:21
S3	0	sofzia	USPAT	OR	ON	2010/08/15 14:42
S4	0	sofzia	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/08/15 14:43
S5	5327	((ophthalmic or eye) and zinc and borate and ((propylene adj glycol) or sorbitol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/08/15 14:43
S6	3645	S5 and @ad<"20060921"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/08/15 14:44
S7	1093	S6 and (zinc with (polyol or glycol or sorbitol or borate))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/08/15 14:45
S8	40	S7 and (zinc and borate).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/08/15 14:45
S9	7	S8 and (ophthalmic or eye).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/08/15 14:46
S10	1	"20020123482".pn. and (zinc and polyol and (propylene or sorbitol))	US-PGPUB; USPAT	OR	ON	2010/08/16 06:01

S11	0	"6503497".pn. and (zinc and polyol and (propylene or sorbitol))	US-PGPUB; USPAT	OR	ON	2010/08/16 06:03
S12	1	"6503497".pn.	US-PGPUB; USPAT	OR	ON	2010/08/16 06:03
S13	6	chowhan.in. and zinc and borate and polyol	US-PGPUB; USPAT	OR	ON	2010/08/16 06:33
S14	0	"20080075790".pn. and ((zinc adj chloride) and (polyoxyl with castor) and travopost and unprostone and pH and surfactant)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:44
S15	0	"20080075790".pn. and ((zinc adj chloride) and (polyoxyl with castor) and travopost and unprostone)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:44
S16	0	"20080075790".pn. and ((zinc adj chloride) and travopost and unprostone)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
S17	0	"20080075790".pn. and ((zinc adj chloride) and travopost)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
S18	0	"20080075790".pn. and (zinc and travopost)	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
S19	1	"20080075790".pn.	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
S20	1	"20080075790".pn. and zinc	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
S21	1	"20080075790".pn. and zinc and chloride	US-PGPUB; USPAT	OR	ON	2010/08/16 07:45
S22	1	"20080075790".pn. and zinc and chloride and travoprost	US-PGPUB; USPAT	OR	ON	2010/08/16 07:46
S23	1	"20080075790".pn. and zinc and chloride and travoprost and castor	US-PGPUB; USPAT	OR	ON	2010/08/16 07:46
S24	17	424/78.04.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
S25	52	424/405.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
S26	54	424/641.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54

S27	15	424/657.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
S28	17	424/659.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
S29	22	424/660.ccls. and (zinc and borate and (sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT	OR	ON	2010/08/16 07:54
S30	0	"6143799".pn. and (zinc and polyol and (propylene or sorbitol))	USPAT	OR	ON	2011/02/01 13:48
S31	0	"6143799".pn. and (zinc and polyol)	USPAT	OR	ON	2011/02/01 13:48
S32	1	"6143799".pn.	USPAT	OR	ON	2011/02/01 13:48
S33	0	"6143799".pn. and zinc	USPAT	OR	ON	2011/02/01 13:50
S34	1	"7445771".pn. and zinc and mannitol	USPAT	OR	ON	2011/02/01 13:50
S35	1	"20050129771".pn. and zinc and mannitol	US-PGPUB; USPAT	OR	ON	2011/02/01 13:51
S36	0	"20050154065".pn. and zinc and mannitol	USPAT	OR	ON	2011/02/01 13:52
S37	1	"20050154065".pn. and zinc and mannitol	US-PGPUB; USPAT	OR	ON	2011/02/01 13:52
S38	1	"20080075790".pn.	US-PGPUB; USPAT	OR	ON	2011/02/01 15:12

2/8/2011 10:35:01 AM
C:\Documents and Settings\earnold\My Documents\EAST\Workspaces\11858781a.wsp

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/E.A./	1	6143799		2000-11-07	Chowhan et al.	
/E.A./	2	7445771		2008-11-04	Dassanayake et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/E.A./	1	20050129771		2005-06-16	Asgharian	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
/E.A./	1	95/13050	WO		1995-05-18	Ciba-Geigy AG		☐

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/Ernst Arnold/ 02/01/2011

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Ernst Arnold/	Date Considered	02/01/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26356 7590 02/23/2011

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6201 SOUTH FREEWAY
FORT WORTH, TX 76134

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of [redacted] EFS-Web

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Barbara McKenzie (Depositor's name)
[redacted] (Signature)
April 15, 2011 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	05/23/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
ARNOLD, ERNST V	1613	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Scott A. Chapple
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Alcon Research, Ltd.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Fort Worth, Texas

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 010682 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature [signature] Date 4-15-11

Typed or printed name Scott A. Chapple Registration No. 46,287

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1510	1510
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1810**

Electronic Acknowledgement Receipt

EFS ID:	9891123
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	15-APR-2011
Filing Date:	20-SEP-2007
Time Stamp:	15:09:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1810
RAM confirmation Number	1524
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	3205_US_FeeTransmittal_041511.pdf	146782 360484192f49d1a88e5f495645895497d73291b5	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	32069 72c47f85e02ea74855803af0c358bfa472061379	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	178851		

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11858781	Filing Date	2007-09-20	Docket Number (if applicable)	3205US	Art Unit	1613
First Named Inventor	Bhagwati P. Kabra			Examiner Name	Arnold, Ernst V.		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 010682

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2010-04-29
Name	Scott A. Chapple	Registration Number	46287

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra, et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop RCE; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

April 29, 2011.

By: /Barbara McKenzie/
Barbara McKenzie

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and FEE PURSUANT TO 37 C.F.R. § 1.17 (p)

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

Sir:

In accordance with Rules 56, 97 and 98 of the Rules of Practice in Patent Cases 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and fee pursuant to 37 C.F.R. § 1.17 (p), enclosed is Form PTO/SB/08a Information Disclosure Statement by Applicant.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

The requisite fee under 37 C.F.R. §1.17(p) has been charged to Deposit Account No. **010682** via EFS Web.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

ALCON RESEARCH, LTD.

April 29, 2011

Scott A. Chapple
Reg. No. 46,287

ADDRESS FOR CORRESPONDENCE:
Alcon Research, Ltd.
Scott A. Chapple, IP Legal
6201 South Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Docket No. 3205US

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050214382		2005-09-29	Xia et al.	
	2	20070212420		2007-09-13	Xia et al.	
	3	20070297990		2007-12-27	Shah et al.	
	4	20100227003		2010-09-09	Shah et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-04-29
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Petition fee- 37 CFR 1.17(h) (Group III)	1464	1	130	130
Request for continued examination	1801	1	810	810
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**940**

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Decision Date : April 29,2011

In re Application of :

Bhagwati Kabra

DECISION ON PETITION

UNDER CFR 1.313(c)(2)

Application No : 11858781

Filed : 20-Sep-2007

Attorney Docket No : 3205US

This is an electronic decision on the petition under 37 CFR 1.313(c)(2), filed April 29,2011 , to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED.**

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid in this application cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.

Telephone inquiries concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

This application file is being referred to Technology Center AU 1613 for processing of the request for continuing examination under 37 CFR 1.114 .

Office of Petitions

Electronic Acknowledgement Receipt

EFS ID:	9983828
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	29-APR-2011
Filing Date:	20-SEP-2007
Time Stamp:	10:38:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$940
RAM confirmation Number	11753
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Petition automatically granted by EFS	petition-request.pdf	31911 42c73f4fa5a7de1706025507b53136d4d7cba20f	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	3205_US_RCE_042911.pdf	798002 45e378e671904b97c70bc1b5e7ca107a5b087234	no	3
Warnings:					
Information:					
3	Transmittal Letter	3205_US_IDS-S3_042911.pdf	65516 90ee744984799e03bd46914f5e888df46c567b4f	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Filed (SB/08)	3205_US_IDS-S3_08a_042911.pdf	612460 4bf6f31fe20ffba3f96d3d19ea8d34252ed63d84	no	4
Warnings:					
Information:					
5	Fee Worksheet (PTO-875)	fee-info.pdf	32551 4fdd52d04dbeed14c62d77633291b40275755f6e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1540440		

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: PET.AUTO Document Description: Petition automatically granted by EFS-Web	PTO/SB/140 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**PETITION TO WITHDRAW AN APPLICATION FROM ISSUE AFTER PAYMENT OF THE ISSUE FEE UNDER 37 CFR 1.313(c)**
Application Number	11858781
Filing Date	20-Sep-2007
First Named Inventor	Bhagwati Kabra
Art Unit	1613
Examiner Name	ERNST ARNOLD
Attorney Docket Number	3205US
Title	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17(h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary.

APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c).

A grantable petition requires the following items:
(1) Petition fee; and
(2) One of the following reasons:
(a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;
(b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or
(c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).

Petition Fee

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

☐ Applicant(s) status remains as SMALL ENTITY.

☒ Applicant(s) status remains as other than SMALL ENTITY

Reason for withdrawal from issue

◯ One or more claims are unpatentable ◉ Consideration of a request for continued examination (RCE) (List of Required Documents and Fees) ◯ Applicant hereby expressly abandons the instant application (any attorney/agent signing for this reason must have power of attorney pursuant to 37 CFR 1.32(b)).
RCE request,submission, and fee. ☐ I certify, in accordance with 37 CFR 1.4(d)(4) that : The RCE request ,submission, and fee have already been filed in the above-identified application on ☒ Are attached.
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who has been given power of attorney in this application. ◯ An attorney or agent registered to practice before the Patent and Trademark Office, acting in a representative capacity. ◯ A sole inventor ◯ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors ◯ A joint inventor; all of whom are signing this e-petition ◯ The assignee of record of the entire interest that has properly made itself of record pursuant to 37 CFR 3.71

Signature	/Scott A. Chapple, Reg. #46,287/
Name	Scott A. Chapple
Registration Number	46287

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold. Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold. Ernst V.
	Attorney Docket Number	3205US

	1	Guttman, "Liquid gel therapy broadens role of dry eye product line", Ophthalmologytimes.com, 2006, pgs 33-34 and copyright notice	☐
	2	Illustration of packaging for Systane® Free marketed by Alcon	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Application Number	11858781
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	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold. Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-07-08
Name/Print	Scott A. Chapple	Registration Number	46287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	1	52	52
Independent claims in excess of 3	1201	1	220	220
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**452**

Electronic Acknowledgement Receipt

EFS ID:	10481373
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	08-JUL-2011
Filing Date:	20-SEP-2007
Time Stamp:	16:18:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$452
RAM confirmation Number	12306
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3205_US_Amend-after-RCE_070811.pdf	362776 c1d4add22fa8135e3517f6b46bda01dda2456eed	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	7
Applicant Arguments/Remarks Made in an Amendment	8	9

Warnings:

Information:

2	Transmittal Letter	3205_US_IDS-S4_070811.pdf	96044 4da402498f3b6002076dee2ecb7a8ec743289fe5	no	3

Warnings:

Information:

3	Information Disclosure Statement (IDS) Form (SB08)	3205_US_IDS-S4_08a_070811.pdf	612543 9e1c427851d3534fbf04d5f451d0be7e1633ffae	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

4	Non Patent Literature	GUTTMAN_2006_OphthalmologyTimes.pdf	317495 fbd8f87e6f130a7d13891e754fe1214a2957fc62	no	3

Warnings:

Information:

5	Non Patent Literature	Systane_Free_Packaging.pdf	117195 904505e9423f466bbc071a7252b4a37b737d34f5	no	1

Warnings:

Information:

6	Fee Worksheet (SB06)	fee-info.pdf	33634 bbef560f45491bc0333c62879ddd7e2f5f74d08f	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	1539687

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra et al.

U.S. Serial No.: 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

July 8, 2011.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

AMENDMENT FILED AFTER A REQUEST FOR CONTINUED EXAMINATION

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

Dear Sir:

This paper is submitted in response to the Notice of Allowance dated February 23, 2011 and after filing of a second Request for Continued Examination dated April 29, 2011.

Applicants believe that no extension of time is required. However, if the U.S. Patent Office deems any fees to be deficient or absent, consider this paragraph such a request and authorization to deduct said fees from Alcon Research, Ltd. Deposit Account No. **010682.**

Applicants respectfully request the Examiner to please enter the following amendments and consider the following remarks relative to the above-identified application.

Amendments to the Claims are in the listing of claims that begins on page 2 hereof.

Remarks begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1 (currently amended): A multi-dose, self-preserved ophthalmic composition, comprising:

zinc ions at a concentration of 0.04 to 0.4 mM; and

borate and polyol ~~a borate/polyol complex formed from a borate and a polyol~~, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v, the polyol comprising propylene glycol and sorbitol;

wherein: (i) the composition has a concentration of anionic species less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements.

Claim 2 (currently amended): A composition according to Claim 1, wherein the propylene glycol is present in the composition at a concentration of 0.25 to 1.25% w/v and the sorbitol is present in the composition at a concentration of 0.05 to 0.5% w/v ~~wherein the polyol utilized in the borate/polyol complex is propylene glycol and/or sorbitol~~.

Claim 3 (previously presented): A composition according to Claim 2, wherein the composition has a concentration of multivalent buffering anions that is less than 5 mM.

Claim 4 (previously presented): A composition according to Claim 1, wherein: (i) the composition has a concentration of multivalent buffering anions that is less than 5 mM; and (ii) the composition has a concentration of multivalent metal cations other than zinc that is less than 5 mM.

Claim 5 (previously presented): A composition according to Claim 1 further comprising an effective amount of a therapeutic agent.

Claim 6 (previously presented): A composition according to Claim 1 further comprising a therapeutic agent selected from the group consisting of bimatoprost, latanoprost, travoprost and unoprostone.

Claim 7 (previously presented): A composition according to Claim 6 wherein the therapeutic agent comprises travoprost.

Claim 8 (currently amended): A composition according to Claim 1 further comprising polyoxyl 40 hydrogenated castor oil wherein the composition has a pH from 5.5 to 5.9.

Claim 9 (previously presented): A composition according to Claim 1 further comprising a non-ionic surfactant.

Claim 10 (currently amended): A composition according to Claim 1 further comprising:

an effective amount of a therapeutic agent;

wherein:

i. ~~the composition has a pH from 5.5 to 5.9;~~

~~ii~~ the composition has a concentration of multivalent buffering anions that is less than 5 mM;

ii. the composition has a concentration of multivalent metal cations other than zinc that is less than 5 mM;

iii. the borate is present in the composition at a concentration of 0.5 to 1.2% w/v; and

iv. ~~the polyol includes propylene glycol and~~ the propylene glycol is present in the composition at a concentration of 0.25 to 1.25% w/v.

Claim 11 (previously presented): A composition according to Claim 10 wherein the therapeutic agent is selected from the group consisting of bimatoprost, latanoprost, travoprost and unoprostone.

Claim 12 (previously presented): A composition according to Claim 10 wherein the therapeutic agent is travoprost.

Claim 13 (currently amended): A composition according to Claim 12 further comprising ~~a non-ionic surfactant~~ polyoxyl 40 hydrogenated castor oil wherein the composition has a pH from 5.5 to 5.9.

Claim 14 (previously presented): A composition according to Claim 10 wherein the zinc ions are provided by zinc chloride at a concentration of 0.001 to 0.005 w/v%.

Claim 15 (previously presented): A composition according to Claim 10 wherein the propylene glycol is present in the composition at a concentration of 0.75 w/v%, the borate is boric acid and is present in the composition at a concentration of 1.0 w/v% and the zinc ions are provided by zinc chloride at a concentration of 0.0025 w/v%.

Claim 16 (previously presented): A composition according to Claim 1 or Claim 10 wherein the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 17 (previously presented): A composition according to Claim 1 wherein the concentration of anionic species in the composition is less than 10 mM.

Claim 18 (previously presented): A composition according to Claim 1 wherein the concentration of anionic species in the composition is less than 5 mM.

Claim 19 (previously presented): A composition according to Claim 10 wherein the concentration of anionic species in the composition is less than 10 mM.

Claim 20 (previously presented): A composition according to Claim 10 wherein the concentration of anionic species in the composition is less than 5 mM.

Claim 21 (previously presented): A composition according to Claim 1 wherein the composition comprises zinc ions at a concentration of 0.1 to 0.4 mM.

Claim 22 (previously presented): A composition according to Claim 10 wherein the composition comprises zinc ions at a concentration of 0.1 to 0.4 mM.

Claim 23 (currently amended): A multi-dose, self-preserved ophthalmic composition, comprising:

an effective amount of travoprost;

zinc ions at a concentration of 0.1 to 0.4 mM wherein the zinc ions are provided by zinc chloride;

~~a borate/polyol complex formed from~~ borate and polyol, the borate being present as boric acid in the composition at a concentration of 0.5 to 1.2% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a

concentration of 0.25 to 1.25% w/v and the sorbitol being present in the composition at a concentration of 0.05 to 0.5% w/v; and

water;

wherein: (i) the composition has a concentration of anionic species less than 10 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; and (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc~~; and (iv) the composition has a pH from 5.5 to 5.9~~.

Claim 24 (currently amended): A composition according to Claim 23 further comprising ~~a non-ionic surfactant~~ polyoxyl 40 hydrogenated castor oil wherein the composition has a pH from 5.5 to 5.9.

Claim 25 (currently amended): A composition according to Claim 24 wherein the concentration of travoprost in the composition is 0.004 % w/v, the concentration of zinc chloride ionized in the composition is 0.0025 % w/v, the concentration of boric acid is 1.0 % w/v, the concentration of propylene glycol in the composition is 0.75 % w/v, the concentration of sorbitol in the composition is 0.25 w/v % and the concentration of non-ionic surfactant in the composition is 0.5 w/v%.

Claim 26 (previously presented): A composition according to Claim 23 wherein the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 27 (currently amended): A multi-dose, self-preserved ophthalmic composition, consisting of:

an effective amount of travoprost;

zinc ions at a concentration of 0.1 to 0.4 mM wherein the zinc ions are provided by zinc chloride;

polyoxyl 40 hydrogenated castor oil;

~~a borate/polyol complex formed from~~ borate and polyol, the borate being present as boric acid in the composition at a concentration of 0.5 to 1.2% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.25 to 1.25% w/v and the sorbitol being present in the composition at a concentration of 0.05 to 0.5% w/v;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 10 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv) the composition has a pH from 5.5 to 5.9.

Claim 28 (currently amended): A multi-dose, self-preserved ophthalmic composition, consisting of:

travoprost at a concentration of 0.004% w/v;

ionized zinc chloride at a concentration of 0.0025% w/v;

polyoxyl 40 hydrogenated castor oil at a concentration of 0.5% w/v;

~~a borate/polyol complex formed from~~ borate and polyol, the borate being present as boric acid in the composition at a concentration of 1.0% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.75% w/v and the sorbitol being present in the composition at a concentration of 0.25 w/v%;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 5 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv) the composition has a pH from 5.5 to 5.9.

Claim 29 (new): A multi-dose, self-preserved ophthalmic composition, consisting of:

travoprost at a concentration of 0.004% w/v;

zinc chloride ionized in the composition at a concentration of 0.0025% w/v;

polyoxyl 40 hydrogenated castor oil at a concentration of 0.5% w/v; and

borate and polyol, the borate being present in the composition as boric acid at a concentration of 1.0% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.75% w/v and the sorbitol being present in the composition at a concentration of 0.25 w/v%;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 15 mM;

and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements.

REMARKS

By this amendment, Applicants have amended claims 1, 2, 8, 10, 13, 23, 24, 27 and 28 and have added new claim 29. Applicants believe the present claims of the present application are novel and non-obvious relative to the prior art.

CONCLUSION

Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

Alcon Research, Ltd.

July 8, 2011

Scott A. Chapple
Reg. No. 46,287

Address for Correspondence:
Scott A. Chapple, IP Legal
Alcon Research, Ltd.
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Attorney Docket: 3205US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra, et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendments; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:
July 8, 2011.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and FEE PURSUANT TO 37 C.F.R. § 1.17 (p)

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

Sir:

In accordance with Rules 56, 97 and 98 of the Rules of Practice in Patent Cases 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and fee pursuant to 37 C.F.R. § 1.17 (p), enclosed is Form PTO/SB/08a Information Disclosure Statement by Applicant.

This Information Disclosure Statement includes an article and an illustration of packaging for a product named Systane Free Lubricant Eye Drops Liquid Gel, which was previously marketed in the United States for a limited time by Alcon Laboratories, Inc. ("Alcon"). It is believed that Alcon's first commercial sale of this product occurred on or about December 14, 2005. The product is not currently sold; it was withdrawn from the market in or around December 2006. The formulation of the product was as follows:

Component	Concentration	Units
Hydroxypropyl Guar 8a	0.16% to 0.19%	W/V %
Boric Acid	0.7%	W/V %

Sorbitol	1.4%	W/V %
Polyethylene Glycol (400)	0.4%	W/V %
Propylene Glycol	0.3%	W/V %
Potassium Chloride	0.12%	W/V %
Sodium Chloride	0.1%	W/V %
Calcium Chloride (Dihydrate)	0.0053%	W/V %
Magnesium Chloride (Hexahydrate)	0.0064%	W/V %
Zinc Chloride	0.0015%	W/V %
2-Amino-2-Methyl-Propanol (Amp)	0.57%	W/V %
Hydrochloric Acid (1n)	0.15%	W/V %
Sodium Hydroxide	adjust pH to 7.9	W/V %
Purified Water	qs to 100%	W/V %

Formulation Comments:

$ZnCl_2$ may be added in up to 5% xs to compensate for manufacturing losses.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

The requisite fee under 37 C.F.R. §1.17(p) has been charged to Deposit Account No. **010682** via EFS Web.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

ALCON RESEARCH, LTD.

July 8, 2011

Scott A. Chapple
Reg. No. 46,287

ADDRESS FOR CORRESPONDENCE:
Alcon Research, Ltd.
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6201 South Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Docket No. 3205US

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold. Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5460834		1995-10-24	Bhagat	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold. Ernst V.
	Attorney Docket Number	3205US

	1		☐
	2		☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold. Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-07-08
Name/Print	Scott A. Chapple	Registration Number	46287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	10481648
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	08-JUL-2011
Filing Date:	20-SEP-2007
Time Stamp:	16:34:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	3205_US_IDS-S4a_08a_070811.pdf	612435 b88c48387e37eb92880ec496234b3047916f461f	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	612435

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

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

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

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/858,781	09/20/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	07/08/2011									
	Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 5	Minus	***4	= 1	X $ =		OR	X $220=	220
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	220

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

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

Legal Instrument Examiner:
/MARY HOLMES/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1	USSN 12/441,995 Office Action dated September 16, 2011	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

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☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-10-03
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	11098817
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	03-OCT-2011
Filing Date:	20-SEP-2007
Time Stamp:	14:51:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	3205_US_IDS-S5_100311.pdf	67661 fee94960a77a6d73a41c4ab5f0762ee3519a2bbf	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	3205_US_IDS-S5_08a_100311.pdf	612398 c9018e03ff84ac22b07c0a82f1309ffa69632fae	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

3	Non Patent Literature	USSN_12-441995_091611_OA.pdf	364277 a68473c4821dc4e6b5fc33037501582bd88b4310	no	10

Warnings:

Information:

Total Files Size (in bytes):	1044336

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra, et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendments; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:
October 3, 2011.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and FEE PURSUANT TO 37 C.F.R. § 1.17 (p)

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

Sir:

In accordance with Rules 56, 97 and 98 of the Rules of Practice in Patent Cases 37 C.F.R. §§ 1.56, 1.97(b)(4), 1.98 and fee pursuant to 37 C.F.R. § 1.17 (p), enclosed is Form PTO/SB/08a Information Disclosure Statement by Applicant.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

ALCON RESEARCH, LTD.

October 3, 2011

Scott A. Chapple
Reg. No. 46,287

ADDRESS FOR CORRESPONDENCE:
Alcon Research, Ltd.
Scott A. Chapple, IP Legal
6201 South Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Docket No. 3205US

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1	USSN 12/441,742 Office Action dated July 28, 2011	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-10-17
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	11200649
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	17-OCT-2011
Filing Date:	20-SEP-2007
Time Stamp:	15:28:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	3205_US_IDS-S6_101711.pdf	74623 d3a34a6bfa3eaba7beb90e3d14e3fe781ae93a17	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	3205_US_IDS-S6_08a_101711.pdf	612392 32d207f550bb812220763d8c25d2956ab7612668	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

3	Non Patent Literature	USSN_12-441742_OA_7-28-2011.pdf	568356 f0e50ff2035c1644399f95a7da3845746 5f29ea2	no	16

Warnings:

Information:

Total Files Size (in bytes):	1255371

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra, et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendments; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:
October 17, 2011.

By: /Barbara McKenzie/
Barbara McKenzie

SIXTH INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. 1.56, 1.97(b)(3), AND 1.98

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

Sir:

In accordance with Rules 56, 97 and 98 of the Rules of Practice in Patent Cases (37 C.F.R. § 1.56, 1.97(b)(3) and 1.98), enclosed is Form PTO/SB/08a Information Disclosure Statement by Applicant.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed. Applicants do not concede that these materials constitute prior art within the meaning of the United States patent statutes.

Applicants requests that the listed references be considered during prosecution of this application and that the references appear among the "References Cited" on any patent issuing from the application.

This statement is filed before the mailing of a first Office Action on the merits pursuant to 37 C.F.R. § 1.97(b), and therefore no fee for the consideration of this statement is enclosed herewith. However, the Commissioner is hereby authorized to charge any amount required for the consideration of this statement to Deposit Account No. 010682 of Alcon Research, Ltd.

Respectfully submitted,

ALCON RESEARCH, LTD.

October 17, 2011

Scott A. Chapple
Reg. No. 46,287

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Docket No. 3205US

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 02/27/2012

ALCON
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FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
02/27/2012	PAPER

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

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST ARNOLD	1613	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2011*.

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

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

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

Disposition of Claims

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

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-29* is/are rejected.

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

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

Application Papers

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

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/11(2), 10/3/11, 10/17/11, 4/29/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/11 has been entered.

Claims 1-29 are pending and under examination.

Information Disclosure Statement

References without a date have not been considered and a line has been drawn through the reference.

Withdrawn rejections:

Applicant's amendments and arguments filed 7/8/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

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

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

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

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

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 2005/0214382: IDS reference 1 filed on 4/29/11) and Asgharian (US 6319464: IDS reference 19 filed on 6/24/08) and Chowhan et al. (US 6503497: IDS reference 23 filed on 6/24/08) and Deaciuc et al. (US 20060270735) as evidenced by Sherman (US 5843891).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims, for example:

> Claim 1 (currently amended): A multi-dose, self-preserved ophthalmic composition, comprising:
>
> zinc ions at a concentration of 0.04 to 0.4 mM; and
>
> borate and polyol a borate/polyol complex formed from a borate and a polyol, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v, the polyol comprising propylene glycol and sorbitol;
>
> wherein: (i) the composition has a concentration of anionic species less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Xia et al. teach ophthalmic compositions with a preservative effective amount of a zinc compound comprising **water** (Abstract and claims 14 and 29). Xia et al. teach compositions with a minimum of about 0.001 wt% to a maximum of about 1 wt% of a zinc compound such as **zinc chloride** in the composition (claims 14-17, 29-43 and 55-66 and [0021]). Zinc is intrinsically ionized in aqueous solution. Please note that no other anions or multivalent cations are required in the composition and therefore their concentrations are less than 15 mM and 5 mM respectively. Also note that while Xia et al. report amounts in terms of wt% and Applicant claims w/v% and the solute is dissolved in water where 100 ml is equal to approximately 100 g then w/v% is no different from w/w%. In other words, a solution with 1 g of solute dissolved in a final volume of 100 ml aqueous solution may also be considered 1% w/w. By extension, since zinc chloride is $ZnCl_2$ then the amount in 100 ml of aqueous solution where 1 ml is about 1g: 0.001 g $ZnCl_2$/136.3 g/mol $ZnCl_2$ = 7.33 X 10^{-6} mol $ZnCl_2$/0.1 L = 0.0733 mM $ZnCl_2$

1.0 g $ZnCl_2$/136.3 g/mol $ZnCl_2$ = 0.00733 mol $ZnCl_2$/0.1 L = 73.3 mM $ZnCl_2$

Since the term "about" was used by Xia et al., those numbers have 'wiggle room' above and below the calculated values. Thus, Xia et al. provide a teaching with sufficient specificity to select a composition with zinc chloride with "about 0.001 wt%" which reads on the instantly claimed lower value of 0.1 mM.

Indeed, Xia et al. teach using various zinc concentrations ranging from 0.05 to 0.025 to 0.0125 and 0.0065 in Tables 9-11 on pages 8 and 9.

0.0065 g $ZnCl_2$/136.3 g/mol $ZnCl_2$ = 4.76 X 10^{-5} mol $ZnCl_2$/0.1 L = 0.476 mM $ZnCl_2$

Consequently, the instantly claimed range for the zinc ions is bracketed with sufficient specificity by the reference. Single or multi-dose is irrelevant because it is at the discretion of the practitioner as to what constitutes a dose. Thus, a 100 ml sample could be a large single dose or 100 smaller 1 ml doses.

Xia et al. teach the addition of other agents such as therapeutic agents including **prostaglandins** (claims 28, 43 and [0051]) as well as tonicity adjusting agents, buffering agents, **pH adjusting agents** and viscosity adjusting agents.

Borate and boric acid are present at 0.090 and 0.85 wt% respectively (Tables 9-11 pages 8-9) and borate buffers are preferred and can be present from about 0.05 wt% to a maximum of about 2.5 wt% [0050]. Please note that in aqueous solution, boric acid will exist in equilibrium with borate.

Glycerin, a polyol, can be included with **non-ionic surfactants** [0054] as well as **propylene glycol** [0056].

The **pH of the composition** has a minimum of about 5 and about 6 [0050] thus embracing the instantly claimed ranges of pH.

Xia et al. teach that the basic ophthalmic composition can be the therapeutic agent and a preservative effective and soluble amount of a zinc compound thus reading on only two components besides the solvent in the composition (claim 29).

Asgharian teaches multi-dose ophthalmic compositions that contain borate/polyol buffer system (Abstract and claims 5-12) where: "The compositions of the present invention preferably contain one or more borates in an amount of from about 0.01 to about 2.0% w/v, more preferably from about 0.3 to 1.2% w/v, and one or more polyols in an amount of from about 0.01 to 5.0% w/v," (column 5, lines 22-26). Asgharian teaches the polyol as mannitol, glycerin, xylitol and sorbitol with **sorbitol being preferred** (column 5, lines 12-17). Asgharian teaches that the addition of one or more polyols to a borate buffer enhances the anti-microbial activity of the composition (column 2, lines 42-48). Asgharian teaches NaOH and HCl as a pH adjusting agents (Examples 5-7 and claim 12, for example).

Chowhan et al. teach in the Abstract: "Water-soluble borate-polyol complexes are useful as buffers and/or antimicrobials in aqueous ophthalmic compositions, including those containing polyvinyl alcohol. These compositions have greater antimicrobial activity than comparable compositions containing typical borate buffers and unexpectedly increase the antimicrobial efficacy of other antimicrobial agents when used in combination."

Chowhan et al. teach that ophthalmic compositions are generally formulated to have a pH between about 4.0 and 8.0 (column 1, lines 28-30) and Chowhan et al. teach using NaOH/HCl to adjust the pH (Example 1 and 5-7).

Chowhan et al. teach polyols such as mannitol, glycerin and propylene glycol to be mixed with boric acid (column 2, lines 20-23 and Example 1, Formulations A-H; Examples 2 and 3, Formulations 1-19) with the aqueous ophthalmic compositions comprising 0.05 to 6.0 wt% of a water soluble borate-polyol complex in a molar ratio of borate and polyol of 1:0.1 to 1:10, for example (claims 1-38).

Deaciuc et al. teach ophthalmic compositions comprising **0.004% w/v** of **travoprost**, boric acid and the polyol mannitol where the pH is in the range of 5.0 to 7.5 (claims 1-21). Diaciuc et al. direct the artisan to using the surfactant cremaphor RH40 in **0.5% w/v** [0070 and Table 1, F4-F6] which is **polyoxyl 40 hydrogentated castor oil** as evidenced by Sherman (column 4, lines 34-36).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Xia et al. is that Xia et al. do not expressly teach an embodiment with the instantly claimed amounts of sorbitol and propylene glycol in the composition that satisfies USP 27 preservative efficacy requirements or the use of NaOH and/or HCl to adjust the pH. This deficiency in Xia et al. is cured by the teachings of Asgharian and Chowhan et al.

2. The difference between the instant application and Xia et al. is that Xia et al. do not expressly teach an embodiment with the instantly claimed amounts of travoprost and polyoxyl 40 hydrogentated castor oil. This deficiency in Xia et al. is cured by the teachings of Deaciuc et al. as evidenced by Sherman.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the instantly claimed amounts of sorbitol and propylene glycol in the composition that satisfies USP 27 preservative efficacy requirements or the add NaOH and/or HCl to adjust the pH**,** as suggested by Asgharian and Chowhan et al., to the composition of Xia et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is well known in the art that the addition of polyols to borate buffer preservative systems enhances the antimicrobial activity of the composition. The ordinary artisan recognizing that Xia already teach adding polyols such as proplylene glycol and glycerine with the further knowledge of the beneficial enhancement by the addition of the polyols to the composition as taught by Asgharian and Chowhan et al., would desire the best preservative composition and add the instantly claimed polyols to the composition. It is simply routine optimization to determine the amount of each polyol in order to satisfy USP 27 preservative efficacy requirements which is intrinsically met by the combination of the antimicrobial properties of any of the components that have antimicrobial properties and the pH. Furthermore, Xia et al. already suggest adding pH adjusting agents and both Chowhan et al. and Asgharian suggests adding NaOH or HCl to provide pH adjustment and therefore it is just optimization to the desired pH of between 5.5 and 5.9.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the instantly claimed amounts of travoprost and polyoxyl 40 hydrogentated castor oil**,** as suggested by Deaciuc et al. as evidenced by Sherman, to the composition of Xia et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Xia et al. already suggest adding prostaglandins and surfactants and the art of Deaciuc et al. provides sufficient specificity to the type of prostaglandin and surfactant in the same amounts as instantly claimed to add to ophthalmic compositions. It is the Examiner's position that travoprost renders obvious other prostaglandins such as bimatoprost, latanoprost and unoprostone to the artisan in the ophthalmic arts.

Thus, it is reasonable to add the ingredients as taught by the secondary references to the composition of Xia et al. to produce a composition ***consisting of*** only those ingredients especially when Xia et al. teach that the basic ophthalmic composition can be the therapeutic agent and a preservative effective and soluble amount of a zinc compound (claim 29). Therefore it is merely judicious selection and routine optimization of travoprost; zinc chloride, polyoxyl 40 hydrogenated castor oil, borate, propylene glycol, sorbitol, the pH adjusting agents NaOH and/or HCl and water which the art suggests adding to these ophthalmic compositions with sufficient specificity in the first place. The predictable result is a travoprost ophthalmic composition.

This rejection is based on the well-established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. From MPEP 2143 A: "…all the claimed elements were known in the prior art and one skilled in the art could

have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson 's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950)."

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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

1. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 14, 15, 17, 21 and 23-26 of copending Application No. 12/441995. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to borate/polyol multi-dose self preserved ophthalmic compositions comprising zinc, borate and polyol such as sorbitol and propylene glycol, and travoprost.

The copending does not expressly teach satisfying USP 27 preservative efficacy requirements or the exact amounts of the polyols and travoprost in the composition.

However, the same ingredients making both compositions and therefore the copending application will satisfy not only USP 26 but also USP 27 preservative efficacy requirements. The

amount of each ingredient is merely routine optimization to achieve the desired effect. Consequently, the ordinary artisan would have recognized the obvious variation of the instant subject matter over the copending subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-32 of copending Application No. 13/086950. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to borate/polyol multi-dose self preserved ophthalmic compositions comprising zinc, borate and polyol such as sorbitol and propylene glycol, polyoxyl 40 hydrogenated castor oil and travoprost at the same pH of 5.5 to 5.9.

Consequently, the ordinary artisan would have recognized the obvious variation of the instant subject matter over the copending subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Primary Examiner, Art Unit 1613

Notice of References Cited	Application/Control No. 11/858,781	Applicant(s)/Patent Under Reexamination KABRA ET AL.	
	Examiner ERNST ARNOLD	Art Unit 1613	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
*	B	US-2006/0270735	11-2006	Deaciuc et al.	514/530
*	C	US-5,843,891	12-1998	Sherman, Bernard C.	424/456
	D	US-			
	E	US-			
	F	US-			
	G	US-			
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	I	US-			
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	K	US-			
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FOREIGN PATENT DOCUMENTS

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold. Ernst V.
Attorney Docket Number	3205US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5460834		1995-10-24	Bhagat	

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	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold. Ernst V.
	Attorney Docket Number	3205US

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Examiner Signature	/Ernst Arnold/	Date Considered	02/24/2012

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	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1	USSN 12/441,995 Office Action dated September 16, 2011	☐

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	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-10-03
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11858781	KABRA ET AL.
	Examiner	Art Unit
	ERNST V ARNOLD	1616

SEARCHED

Class	Subclass	Date	Examiner

SEARCH NOTES

Search Notes	Date	Examiner
EAST 424/642, 660; 514/912 text limited all databases	4/12/10	eva
inventor name PALM	4/12/10	eva
EAST 424/78.04, 405, 641, 657, 659, 660 text limited all databases	8/16/10	eva
google	8/15/10	eva
pubmed	8/15/10	eva
science direct	8/15/10	eva
inventor name PALM/EAST	8/16/10	eva
search update EAST	2/8/11	eva
search update EAST all databases	2/24/12	eva

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
USPGPUB TEXT SEARCH	EAST	8/16/10	eva

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20050214382".pn. and (surfactant or nonionic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:12
L2	2	"20050214382".pn. and (USP or efficacy)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:14
L3	1	"20050214382".pn. and (sodium adj chloride)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:30
L7	2	"6319464".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:36
L8	2	"6319464".pn. and (sorbitol or polyol or zinc or borate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:37
L9	53	(travoprost and ophthalmic).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:58
L10	15	l9 and (borate or boric).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:59
L11	11	l10 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 07:59
L12	42	((hydrogenated with castor) and ophthalmic).clm.	US-PGPUB; USPAT;	OR	ON	2012/02/24 08:49

			USOCR; FPRS; EPO; JPO; DERWENT			
L13	33	l12 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 08:50
L14	13	l13 and (polyoxy or polyoxyl)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 08:50
L15	1	l14 and travoprost	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 08:52
L16	4	((Cremaphor adj RH40) and (tear or eye or ophthalmic).clm.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 08:56
L17	4	l16 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 08:56
L18	2	"20050214382".pn. and (NaOH or HCl or pH)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 09:35
L19	1	"6319464".pn. and (NaOH or HCl or pH)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 09:37
L20	2	"6503497".pn. and (NaOH or HCl or pH)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 09:45
L21	2	"20050214382".pn. and (water or aqueous)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/24 10:03
L22	2	"20060270735".pn.	US-PGPUB; USPAT;	OR	ON	2012/02/24 10:17

			USOCR; FPRS; EPO; JPO; DERWENT			
S1	0	"6211238".pn. and zinc	USPAT	OR	OFF	2012/02/23 13:42
S2	1	"6211238".pn.	USPAT	OR	ON	2012/02/23 13:42
S3	634	(((kabra or chowhan or schneider or han).in. or "alcon.as.") and (zinc and (borate or boric) and (polyol or mannitol or glycerin or glycerol or xylitol or sorbitol or (propylene adj glycol))))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 13:50
S4	8	(((kabra or chowhan or schneider or han).in. or "alcon.as.") and (zinc and (borate or boric) and (polyol or mannitol or glycerin or glycerol or xylitol or sorbitol or (propylene adj glycol))).clm.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 13:51
S5	1	"20020123482".pn. and (zinc and polyol and (borate or borax or boric))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 14:12
S6	3903	(zinc and (borate or boric) and (polyol or mannitol or glycerin or glycerol or xylitol or sorbitol or (propylene adj glycol)).clm.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 14:16
S7	1	"20080075790".pn. and (amount with anions)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 14:49
S8	1	"20080075790".pn. and ((amount with anion) and (multivalent with cation))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 14:58
S9	0	"6503497".pn. and zinc and borate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 15:07
S10	0	"6503497".pn. and zinc	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 15:07
S11	3	"6503497".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2012/02/23 15:07

			JPO; DERWENT			
S12	2	"7445771".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 15:16
S13	2	"5460834".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 15:18
S14	2	"20110195132".pn. and ("0.001" or "0.005" or "0.005%" or "0.5" or "1.2%" or "0.25" or "1.25%")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 15:50
S15	1	"5597559".pn. and zinc	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 15:53
S16	78	((tear or (artificial with tear) or ophthalmic).clm. and (zinc with (amount or concentration)) and zinc.clm.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 17:12
S17	62	S16 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 17:12
S18	87	(bion with tear)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:18
S19	16	S18 and (ZnCl2 or (zinc with chloride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:19
S20	5	S19 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:19
S21	2	(zinc and (boric or borate) and (polyol or mannitol or glycerol or glycerin or xylitol or sorbitol or glycol) and (artificial with tear)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2012/02/23 18:30

			JPO; DERWENT			
S22	2	S21 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:30
S23	777	((zinc with preservative) and (zinc with (amount or concentration)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:33
S24	519	S23 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:33
S25	37	S24 and ((zinc with preservative) and (zinc with (amount or concentration))).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 18:33
S26	1	"20050214382".pn. and ((borate or boric) and (polyol or mannitol or glycerin or glycerol or xylitol or sorbitol or (propylene adj glycol)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 19:15
S27	0	S26 and sorbitol	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 19:15
S28	2	"20050214382".pn. and (prostaglandin or travoprost)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 19:16
S29	87	((sorbitol or glucitol or sorbogem or sorbo) and (propanediol or (propylene adj glycol) or ((methyl adj ethyl) adj glycol)) and (tear or ophthalmic)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 19:20
S30	60	S29 and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/02/23 19:20
S31	60	S30 and ((sorbitol or glucitol or sorbogem or sorbo) and (propanediol or (propylene adj glycol) or ((methyl adj ethyl) adj glycol)) and (tear or	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2012/02/23 19:21

		ophthalmic))	JPO; DERWENT				

2/ 24/ 2012 10:36:25 AM
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

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	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.A./

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	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

	1	USSN 12/441,742 Office Action dated July 28, 2011	☐

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EXAMINER SIGNATURE

Examiner Signature	/Ernst Arnold/	Date Considered	02/24/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2011-10-17
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Art Unit	1613
Examiner Name	Arnold. Ernst V.
Attorney Docket Number	3205US

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	Art Unit	1613
	Examiner Name	Arnold. Ernst V.
	Attorney Docket Number	3205US

	1	Guttman, "Liquid gel therapy broadens role of dry eye product line", Ophthalmologytimes.com, 2006, pgs 33-34 and copyright notice	☐
	2	Illustration of packaging for Systane® Free marketed by Alcon	☐

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Examiner Signature	/Ernst Arnold/	Date Considered	02/24/2012

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	1	20050214382		2005-09-29	Xia et al.	
	2	20070212420		2007-09-13	Xia et al.	
	3	20070297990		2007-12-27	Shah et al.	
	4	20100227003		2010-09-09	Shah et al.	

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	1		☐

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Examiner Signature	/Ernst Arnold/	Date Considered	02/24/2012

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 05/17/2012

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
05/17/2012	PAPER

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

The time period for reply, if any, is set in the attached communication.

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST ARNOLD	1613	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ERNST ARNOLD*. (3)_____.

(2) *Scott Chappel*. (4)_____.

Date of Interview: *16 May 2012*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *xia 20050214382*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Discussed the examples of Xia with respect to the presence of the tonicity agent NaCl. It was applicant's position that the artisan following the guidelines set forth by Xia would add NaCl as a tonicity agent to the compositions. The Examiner noted that claims 14 and 29 of Xia did not require a tonicity agent and while the examples did disclose NaCl, the claims are not limited by the examples. Indeed, [0045] cited by Applicant recites that the solutoins are typically adjusted with tonicity agents. The Examiner interprets this to mean that other embodiments exist without tonicity agents which would also be within the context of the claim language. The Examiner suggested amendments and arguments concerning the specific amounts of propylene glycol and sorbitol which are not expressly taught by Xia. Applicant will consider filing claim amendments and arguments for the Examiners consideration. .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Ernst V Arnold/ Primary Examiner, Art Unit 1613	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

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	Attorney Docket Number	3205US

	1	HOFFMAN H.M. et al., "Pre-clinical in vitro Testing of an Artificial Tear Formulation with a Novel Preservation System", poster presentation at the annual meeting of the Association for Research In Vision And Ophthalmology (ARVO), Ft. Lauderdale, FL., April 30, 2006	☐
	2	Illustration of packaging for Systane® Free, March 7, 2006	☐
	3	SYSTANE® FREE promotional document (minimal-blur) published on or about January 1, 2006	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, Reg. #46,287/	Date (YYYY-MM-DD)	2012-05-17
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	12808092
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	17-MAY-2012
Filing Date:	20-SEP-2007
Time Stamp:	17:52:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	4870
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3205_US_Amend_051712.pdf	676597 d040a718aea421dbbf8d4296239daa81090dabde	yes	13

Multipart Description/PDF files in .zip description

Document Description	Start	End
Applicant Arguments/Remarks Made in an Amendment	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	13

Warnings:

Information:

2	Transmittal Letter	3205_US_IDS-S7_051712.pdf	72016 7861e1ca6ffd92c9ed0565809982e5238e80d7ff	no	2

Warnings:

Information:

3	Information Disclosure Statement (IDS) Form (SB08)	3205_US_IDS-S7_08a_051712.pdf	612634 b2695405545a19db10ea34f0453c25467cbea02b	no	4

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4	Non Patent Literature	Hoffman_et_al_2006-04-30.pdf	263962 70f7c59d27cbba45054ea327b8586fc267d03d65	no	1

Warnings:

Information:

5	Non Patent Literature	Systane_Free_Packaging.pdf	117195 904505e9423f466bbc071a7252b4a37b737d34f5	no	1

Warnings:

Information:

6	Non Patent Literature	Systane_Free_promotional_2006.pdf	202005 b426e99c7ccce7f1fa31f7e6c15f88e3164e09e2	no	2
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	30565 e867263652c13599af459576f647303e86e0f0b1	no	2
Warnings:					
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			Total Files Size (in bytes):	1974974	

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

New International Application Filed with the USPTO as a Receiving Office
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra et al.

U.S. Serial No.: 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendment; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

May 17, 2012

By: /Barbara McKenzie/
Barbara McKenzie

AMENDMENT AND RESPONSE

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

Dear Sir:

This paper is submitted in response to the Office Action dated February 27, 2012 for which the three month deadline for filing a response is May 27, 2012.

Applicants believe that no extension of time is required. However, if the U.S. Patent Office deems any fees to be deficient or absent, this paragraph is a request and authorization to deduct such fees from Alcon Research, Ltd. Deposit Account No. **010682.**

Applicants respectfully request the Examiner to consider the following remarks relative to the above-identified application.

A listing of claims begins on page 2 hereof.

Remarks begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1 (currently amended): A multi-dose, self-preserved ophthalmic composition, comprising:

zinc ions at a concentration of 0.04 to 0.4 mM; and

borate and polyol, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v, the polyol comprising propylene glycol in the composition at a concentration of 0.25 to 1.25% w/v and sorbitol in the composition at a concentration of 0.05 to 0.5% w/v;

wherein: (i) the composition has a concentration of anionic species less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements.

Claim 2 (canceled)

Claim 3 (currently amended): A composition according to Claim 1 ~~Claim 2~~, wherein the composition has a concentration of multivalent buffering anions that is less than 5 mM.

Claim 4 (previously presented): A composition according to Claim 1, wherein: (i) the composition has a concentration of multivalent buffering anions that is less than 5 mM; and (ii) the composition has a concentration of multivalent metal cations other than zinc that is less than 5 mM.

Claim 5 (previously presented): A composition according to Claim 1 further comprising an effective amount of a therapeutic agent.

Claim 6 (previously presented): A composition according to Claim 1 further comprising a therapeutic agent selected from the group consisting of bimatoprost, latanoprost, travoprost and unoprostone.

Claim 7 (previously presented): A composition according to Claim 6 wherein the therapeutic agent comprises travoprost.

Claim 8 (previously presented): A composition according to Claim 1 further comprising polyoxyl 40 hydrogenated castor oil wherein the composition has a pH from 5.5 to 5.9.

Claim 9 (previously presented): A composition according to Claim 1 further comprising a non-ionic surfactant.

Claim 10 (currently amended): A composition according to Claim 1 further comprising:

an effective amount of a therapeutic agent;

wherein:

i. the composition has a concentration of multivalent buffering anions that is less than 5 mM;

ii. the composition has a concentration of multivalent metal cations other than zinc that is less than 5 mM; and

iii. the borate is present in the composition at a concentration of 0.5 to 1.2% w/v; ~~and~~

~~iv. the propylene glycol is present in the composition at a concentration of 0.25 to 1.25% w/v.~~

Claim 11 (previously presented): A composition according to Claim 10 wherein the therapeutic agent is selected from the group consisting of bimatoprost, latanoprost, travoprost and unoprostone.

Claim 12 (previously presented): A composition according to Claim 10 wherein the therapeutic agent is travoprost.

Claim 13 (previously presented): A composition according to Claim 12 further comprising polyoxyl 40 hydrogenated castor oil wherein the composition has a pH from 5.5 to 5.9.

Claim 14 (previously presented): A composition according to Claim 10 wherein the zinc ions are provided by zinc chloride at a concentration of 0.001 to 0.005 w/v%.

Claim 15 (previously presented): A composition according to Claim 10 wherein the propylene glycol is present in the composition at a concentration of 0.75 w/v%, the borate is boric acid and is present in the composition at a concentration of 1.0 w/v% and the zinc ions are provided by zinc chloride at a concentration of 0.0025 w/v%.

Claim 16 (previously presented): A composition according to Claim 1 or Claim 10 wherein the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 17 (previously presented): A composition according to Claim 1 wherein the concentration of anionic species in the composition is less than 10 mM.

Claim 18 (previously presented): A composition according to Claim 1 wherein the concentration of anionic species in the composition is less than 5 mM.

Claim 19 (previously presented): A composition according to Claim 10 wherein the concentration of anionic species in the composition is less than 10 mM.

Claim 20 (previously presented): A composition according to Claim 10 wherein the concentration of anionic species in the composition is less than 5 mM.

Claim 21 (previously presented): A composition according to Claim 1 wherein the composition comprises zinc ions at a concentration of 0.1 to 0.4 mM.

Claim 22 (previously presented): A composition according to Claim 10 wherein the composition comprises zinc ions at a concentration of 0.1 to 0.4 mM.

Claim 23 (previously presented): A multi-dose, self-preserved ophthalmic composition, comprising:

an effective amount of travoprost;

zinc ions at a concentration of 0.1 to 0.4 mM wherein the zinc ions are provided by zinc chloride;

borate and polyol, the borate being present as boric acid in the composition at a concentration of 0.5 to 1.2% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.25 to 1.25% w/v

and the sorbitol being present in the composition at a concentration of 0.05 to 0.5% w/v; and

water;

wherein: (i) the composition has a concentration of anionic species less than 10 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; and (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 24 (previously presented): A composition according to Claim 23 further comprising polyoxyl 40 hydrogenated castor oil wherein the composition has a pH from 5.5 to 5.9.

Claim 25 (previously presented): A composition according to Claim 24 wherein the concentration of travoprost in the composition is 0.004 % w/v, the concentration of zinc chloride ionized in the composition is 0.0025 % w/v, the concentration of boric acid is 1.0 % w/v, the concentration of propylene glycol in the composition is 0.75 % w/v, the concentration of sorbitol in the composition is 0.25 w/v % and the concentration of non-ionic surfactant in the composition is 0.5 w/v%.

Claim 26 (previously presented): A composition according to Claim 23 wherein the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc.

Claim 27 (previously presented): A multi-dose, self-preserved ophthalmic composition, consisting of:

an effective amount of travoprost;

zinc ions at a concentration of 0.1 to 0.4 mM wherein the zinc ions are provided by zinc chloride;

polyoxyl 40 hydrogenated castor oil;

borate and polyol, the borate being present as boric acid in the composition at a concentration of 0.5 to 1.2% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.25 to 1.25% w/v and the sorbitol being present in the composition at a concentration of 0.05 to 0.5% w/v;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 10 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to

satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv) the composition has a pH from 5.5 to 5.9.

Claim 28 (previously presented): A multi-dose, self-preserved ophthalmic composition, consisting of:

travoprost at a concentration of 0.004% w/v;

ionized zinc chloride at a concentration of 0.0025% w/v;

polyoxyl 40 hydrogenated castor oil at a concentration of 0.5% w/v;

borate and polyol, the borate being present as boric acid in the composition at a concentration of 1.0% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.75% w/v and the sorbitol being present in the composition at a concentration of 0.25 w/v%;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 5 mM; (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements; (iii) the composition does not contain multivalent buffering anions and does not contain multivalent cations other than zinc; and (iv) the composition has a pH from 5.5 to 5.9.

Claim 29 (previously presented): A multi-dose, self-preserved ophthalmic composition, consisting of:

travoprost at a concentration of 0.004% w/v;

zinc chloride ionized in the composition at a concentration of 0.0025% w/v;

polyoxyl 40 hydrogenated castor oil at a concentration of 0.5% w/v; and

borate and polyol, the borate being present in the composition as boric acid at a concentration of 1.0% w/v and the polyol including propylene glycol and sorbitol, the propylene glycol being present in the composition at a concentration of 0.75% w/v and the sorbitol being present in the composition at a concentration of 0.25 w/v%;

sodium hydroxide and/or hydrochloric acid to adjust pH; and

water;

wherein: (i) the composition has a concentration of anionic species less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements.

REMARKS

Applicants thank Examiner Arnold for the courtesies extended to the undersigned during a telephonic Interview conducted on May 16, 2012. The Office Action rejected claims 1-29. By this amendment, Applicants have amended claims 1, 3 and 10 and canceled claim 2. Applicants respectfully request reconsideration based upon the discussion provided below. Applicants believe the claims of the present application are novel and non-obvious relative to the prior art.

I. Claim Rejections under 35 USC 103

The Office Action rejected claims 1-29 under 35 USC 103(a) as being obvious over Xia et al. (US 2005/0214382) in view of one or more of the following references: Asgharian (US 6319464); Chowhan et al. (US 6503497); Deaciuc et al. (US 20060270735); and Sherman (US 5843891). Applicants respectfully request reconsideration of these rejections. Below, Applicants briefly review a primary advantage of the subject matter of the claims of the present application and then provide reasoning as to the patentability of the claimed subject matter relative to the cited prior art.

Advantage of the Subject Matter of the Claims

The subject matter of the claims of the present application represents a significant advance in preservation of ophthalmic compositions. The subject matter represents a novel zinc-based preservative system that achieves desired preservation of an ophthalmic composition using a very low concentration of zinc. The preservation system relies upon the maintenance of a low concentration of anionic species in the ophthalmic composition to provide that composition with the ability to pass United States Pharmacopeia preservation standards while using the very low concentration of zinc and no conventional anti-microbial preservative.

Subject Matter of the Claims Relative to the Cited Prior Art

The Office Action specifically defines that which the Examiner believes to be the difference between the claims of the present application and the prior art. As part of that definition, the Office Action, at page 7 thereof, reads:

> The difference between the instant application and Xia et al. is that Xia et al. do not expressly teach an embodiment with the instantly claimed amounts of sorbitol and propylene glycol in the composition that satisfies USP 27

> preservative efficacy requirements or the use of NaOH and/or HCl to adjust the pH. This deficiency in Xia et al. is cured by the teachings of Asgharian and Chowhan et al.

Applicants suggest that this definition of differences is not complete. Applicants respectfully request reconsideration of this definition of the differences between the prior art and the subject matter of the claims of the present application and reconsideration of whether Asgharian and Chowhan et al. actually cure the deficiencies in the disclosure of Xia et al.

In addition to the differences identified by the Examiner in the Office Action, each of the claims of the present application specifically recites a concentration range of zinc ions (i.e., 0.04 mM to 0.4 mM) and recites an upper limit to the concentration of anionic species (e.g., 15mM). These recitations represent important differences between the subject matter of the claims of the present application and the prior art, particularly Xia et al. This is particularly the case when these recitations are considered in conjunction with the other differences recited by the Examiner in the Office Action.

In regard to Xia et al., the Office Action states, at page 4 thereof, that "no other anions or multivalent cations [other than those from zinc chloride] are required in the composition and therefore their concentrations are less than 15 mM and 5mM." The skilled artisan, however, would read Xia et al. much differently and would not come to the same conclusion suggested by the Office Action. Paragraph 45 of Xia et al. reads as follows:

> The aqueous solutions of the present invention are typically adjusted with tonicity agents to approximate the tonicity of normal lacrimal fluids (approximately equivalent to a 0.9 wt. % solution of sodium chloride or 2.8 wt. % glycerol solution). Typically, the solutions are hypotonic or substantially isotonic with physiological saline used alone or in combination with other adjusting agents ...

Xia et al. then go on to provide a total of twenty specific examples of formulations, each having a concentration of 0.220 wt% of sodium chloride (NaCl) or greater. In doing so, Xia et al. express a very clear preference for producing osmolality in their compositions with high concentrations of NaCl and, more particularly, concentrations of NaCl that cause the anionic species of the formulation of Xia et al. to be greater than 15 mM (see calculations below).

0.220 wt% NaCl = 0.00220 mg NaCl per mg of solution, 1 g of solution = almost exactly 1 ml of solution
Thus, 0.220 wt% NaCl = 0.00220 mg NaCl per ml or 2.20 g NaCl per liter, molar mass NaCl = 58.4 g/mol
2.20 g/L ÷ 58.4 g/mol = 0.0377 M NaCl = 37.7 mM NaCl or 37.7 mM of anionic species chloride.

Thus, the concentration of anionic species in the Xia et al. formulations from NaCl alone is approximately 37.7 mM, which is more than twice the upper limit of the total concentration of anionic species recited in the claims of the present application.

Based on the disclosure of Xia et al., the skilled artisan would read Xia et al. to suggest that their compositions should include a substantial amount of NaCl. The skilled artisan would read Xia et al. to suggest that their composition should include an amount of NaCl that would cause those compositions to have a concentration of anionic species substantially higher than the limit recited in the claims of the present application. As such, the skilled artisan would never read Xia et al. as disclosing or suggesting a composition with an upper limit of anionic species of 5 mM or even 15 mM.

In addition to the above, Xia et al. provide no recognition of the deleterious effect of anionic species upon the ability of zinc to provide preservation efficacy and actually encourage the use of anionic species in their composition. Paragraphs 22 and 24 of Xia et al. read:

> ... The compositions of the present invention include a polycationic material. The term "polycation" material denotes a material having multiple cationic moieties, such as quaternary ammonium groups, in the same molecule.
>
> In general, polyquaternium polymers suitable for use in the present invention are a well-known class of polymers of which many variations are commercially available. The polyquaternium polymer preferably includes an ophthalmologically suitable anionic organic or inorganic counterion. A preferred counterion may include, but are not limited to fluoride ions, chloride ions, bromide ions, iodide ions and the like.

Thus, Xia et al. teach toward the inclusion of anions as counterions in their composition. Again, the skilled artisan would never read Xia et al. as disclosing or suggesting a composition with an upper limit of anionic species of 5 mM or even 15 mM.

The Office Action asserts, at page 4 thereof, that Xia et al. teach compositions with a concentration of zinc at a minimum of about 0.001 wt% to a maximum of about 1 wt%. While this range admittedly at least overlaps with the range of zinc ions (i.e., 0.04 mM to 0.4 mM) recited in the claims of the present application, it does not end the inquiry into the scope and content of the prior art or the differences between the prior art and the claimed subject matter. The true difference between the subject matter of the claims of the present application and Xia et al. is that the present application provides a composition that passes U.S. Pharmacopeia preservation standards using a preservative system that combines borate and polyol with very low concentrations of zinc, as recited in the claims of the present application.

Xia et al. provide no teaching of whether it is possible to pass U.S. Pharmacopeia standards with a concentration of zinc ions that is from 0.04 to 0.4 mM, and certainly does not teach how to do so. As suggested by the Office Action, at page 5 thereof, Tables 9-11 of Xia et al. teach zinc wt.% concentration ranges "from 0.05 to 0.025 to 0.0125 and 0.0065" and as calculated in the office action, the lowest concentration of 0.0065 is close to 0.476 mM of zinc ions. However, this concentration of zinc ions does not overlap with the concentration of zinc ions recited in the claims of the present application. Further, Xia et al. do not teach the ability to pass U.S. Pharmacopeia standards at zinc concentrations below 0.0065 wt%. In contrast, the zinc-based preservation system taught in the present application combines low concentrations of zinc with 0.1 – 2.0% of borate and 0.25 – 2.5% of polyol (i.e., propylene glycol and sorbitol) to create compositions that pass U.S. Pharmacopeia preservation efficacy standards at $ZnCl_2$ concentrations of 0.0025 w/v%, which is substantially lower than the 0.0065 wt % disclosed in Xia et al.

The compositions of the present application are able to pass the U.S. Pharmacopeia preservation efficacy standard with substantially lower concentrations of zinc than those exemplified in Xia et al. by limiting the concentration of anionic species to 15 mM or less, as recited in all of Applicants' claims. Moreover, Xia et al. do not disclose or suggest controlling the concentration of multivalent buffering anions less than 5 mM or the

concentration of multivalent metal cations other than zinc less than 5mM, as recited in some of Applicants' dependent claims.

Secondary References

None of the secondary references cited by the Office Action can overcome the above deficiencies of Xia et al. None of the cited secondary references, alone or in combination, teaches the presently claimed preservation system. None of these references discloses or suggests the maintenance of anionic species below a certain concentration significantly improves the ability of a zinc-based preservative system containing borate and polyol to provide preservation efficacy at a very low concentration of zinc ions. Moreover, this information is not part of the ordinary knowledge of the skilled artisan at the time of filing the present application.

There is a long history of attempts to provide zinc-based preservation systems that pass preservation efficacy standards using zinc. Olejnik (US 5597559), which was discussed in the first Notice of Allowance issued for this application, illustrates just how difficult it has been to provide preservation efficacy with zinc-based preservation systems[1]. As discussed above, the subject matter of the claims of the present application represents a significant advance relative to these past efforts.

Moreover, the Office Action suggests that, "it is simply routine optimization to determine the amount of each polyol in order to satisfy USP 27 preservative efficacy requirements which is intrinsically met by the combination of antimicrobial properties and the pH." Applicants suggest that this statement lacks merit. In particular, the references cited by the Office Action do not specifically teach the particular combination of polyols at the ranges now recited in the claims (i.e., propylene glycol in the composition at a concentration of 0.25 to 1.25% w/v and sorbitol in the composition at a concentration of 0.05 to 0.5% w/v) in conjunction with a low concentration of zinc ions and a low concentration of anionic species to achieve the surprising high degree of preservative efficacy shown by the data of the present application. This is particularly the case since the particular combination of polyols recited along with the borate and the zinc achieve this high degree of preservation efficacy without any substantial assistance from any other antimicrobial agents.

---

[1] The first Notice of Allowance reads, "... it is surprising that Applicant can use about half as much zinc as Olejnik et al. (US 5597559) and obtain a much greater duration of preservative effect. In contrast Olejnik et al. teach only 72 hours of efficacy, which clearly does not meet USP 27 standards ..."

Based on the above, Applicants respectfully request reconsideration of the subject matter that is actually taught by Xia et al. and how the differences between the subject matter of Xia et al. and the subject matter of the claims of the present application show that the claims of the present application represent a significant advance over Xia et al. Applicants further respectfully request reconsideration of whether any of the secondary references provide teachings that, even when considered in conjunction with the ordinary knowledge of the skilled artisan, would lead a skilled artisan to the subject matter of the claims of the present application. Finally, Applicants respectfully request that the claims of the present application be given a Notice of Allowance so that Letters Patent may be issued.

CONCLUSION

Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

Alcon Research, Ltd.

May 17, 2012

Scott A. Chapple
Reg. No. 46,287

Address for Correspondence:
Scott A. Chapple, IP Legal
Alcon Research, Ltd.
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Attorney Docket: 3205US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Bhagwati P. Kabra, et al.

U.S. Serial No. 11/858,781

Confirmation No.: 3372

Filed: September 20, 2007

Examiner: Arnold, Ernst V.

Group Art Unit: 1613

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Amendments; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:
May 17, 2012.

By: /Barbara McKenzie/
Barbara McKenzie

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

SEVENTH INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. 1.56, 1.97(b)(3), AND 1.98

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

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. § 1.97(c), Applicants submit the attached PTO Form PTO/SB/08a. Neither a final Office Action under §1.113 nor a notice of allowance under §1.311 have been issued in the above-referenced application.

This Information Disclosure Statement cites three references. Each of the three references relates to Systane® Free, an artificial tear product marketed by the assignee of the present application. The composition of Systane® Free was disclosed in detail in the Information Disclosure Statement that was filed in present application on July 8, 2011.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S.

national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

The requisite fee under 37 C.F.R. §1.17(p) has been charged to Deposit Account No. 010682 via EFS Web.

Respectfully submitted,

ALCON RESEARCH, LTD.

May 17, 2012

Scott A. Chapple
Reg. No. 46,287

ADDRESS FOR CORRESPONDENCE:
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6201 South Freeway, TB4-8
Fort Worth, TX 76134-2099
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Docket No. 3205US

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/858,781	09/20/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 05/17/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 29	Minus	** 29	= 0	X $ =		OR	X $60=	0
Independent (37 CFR 1.16(h))	* 5	Minus	***5	= 0	X $ =		OR	X $250=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

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

Legal Instrument Examiner:
/SONYA HILLIARD/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26356 7590 07/24/2012

ALCON
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6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER
ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
1613	

DATE MAILED: 07/24/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$230	$0	$1510	$230	10/24/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26356 7590 07/24/2012

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$230	$0	$1510	$230	10/24/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
ARNOLD, ERNST V	1613	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

26356 7590 07/24/2012

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1613	

DATE MAILED: 07/24/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 692 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 692 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	11/858,781	KABRA ET AL.	
	Examiner	Art Unit	
	ERNST ARNOLD	1613	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *5/17/12*.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1 and 3-29*.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 5/17/12
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613

DETAILED ACTION

Claim 2 has been cancelled. Claims 1 and 3-29 are pending and under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/17/12 was filed after the mailing date of the office action on 2/27/12. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Withdrawn rejections:

Applicant's amendments and arguments filed 5/17/12 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 1-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 2005/0214382: IDS reference 1 filed on 4/29/11) and Asgharian (US 6319464: IDS reference 19 filed on 6/24/08) and Chowhan et al. (US 6503497: IDS reference 23 filed on 6/24/08) and Deaciuc et al. (US 20060270735) as evidenced by Sherman (US 5843891). Applicant's amendments and arguments are persuasive to overcome this rejection. Accordingly, the rejection is withdrawn by the Examiner.

Double Patenting

The Examiner notes possible double patenting with later filed 12/441995 claims 11, 14, 15, 17, 21 and 23-26 and later filed 13/086950 claims 19-32 drawn to self-preserved pharmaceutical compositions with zinc ions and borate/amino alcohol systems. From MPEP 804: If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. Accordingly, this application is allowed without the need of a terminal disclaimer.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: the closest prior art of Xia et al. (US 2005/0214382: IDS reference 1 filed on 4/29/11) does not teach or suggest, alone or in combination, the instant multi-dose, self-preserved ophthalmic composition with less than 15 mM anionic species and the specific amounts of propylene glycol and sorbitol as instantly claimed. There is no suggestion or motivation in the art to optimize both of these specific components in the amounts instantly claimed in combination with the other components in the multi-dose, self-preserved ophthalmic composition. Therefore, the Examiner deems the instant invention free of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1 and 3-29 [renumbered as 1-28] are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	54	(zinc and (boric or borate) and (sorbitol and (propylene adj glycol))).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2012/07/16 10:13
L2	8	l1 and (eye or ophthalmic).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2012/07/16 10:14

7/16/2012 10:16:19 AM
C:\Users\earnold\Documents\EAST\Workspaces\11858781i.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11858781	KABRA ET AL.
	Examiner	Art Unit
	ERNST V ARNOLD	1616

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

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

CLAIM		DATE								
Final	Original	07/16/2012								
	1	=								
	2	-								
	3	=								
	4	=								
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	25	=								
	26	=								
	27	=								
	28	=								
	29	=								

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11858781	KABRA ET AL.
Examiner	**Art Unit**
ERNST V ARNOLD	1616

ORIGINAL

CLASS	SUBCLASS
424	78.04

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
424	405	641	657	659	660
514	912				

INTERNATIONAL CLASSIFICATION

CLAIMED					NON-CLAIMED				
A	6	1	K	31 / 74 (2006.01.01)	A	0	1	N	25 / 00 (2006.01.01)
A	6	1	K	33 / 32 (2006.01.01)	A	0	1	N	59 / 16 (2006.01.01)
A	6	1	K	33 / 22 (2006.01.01)	A	0	1	N	59 / 14 (2006.01.01)

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE

(Assistant Examiner) (Date)

Total Claims Allowed: 28

/ERNST V ARNOLD/
Primary Examiner.Art Unit 1616 7/16/12

(Primary Examiner) (Date)

O.G. Print Claim(s): 1

O.G. Print Figure: none

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11858781	KABRA ET AL.
	Examiner	Art Unit
	ERNST V ARNOLD	1616

SEARCHED

Class	Subclass	Date	Examiner
424	405, 641, 657, 659, 660, 78.04 text limited	7/16/12	eva

SEARCH NOTES

Search Notes	Date	Examiner
EAST 424/642, 660; 514/912 text limited all databases	4/12/10	eva
inventor name PALM	4/12/10	eva
EAST 424/78.04, 405, 641, 657, 659, 660 text limited all databases	8/16/10	eva
google	8/15/10	eva
pubmed	8/15/10	eva
science direct	8/15/10	eva
inventor name PALM/EAST	8/16/10	eva
search update EAST	2/8/11	eva
search update EAST all databases	2/24/12	eva

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
USPGPUB TEXT SEARCH	EAST	8/16/10	eva
USPGPUB TEXT SEARCH	EAST	7/16/12	EVA

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	44	424/405.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:17
L4	49	424/641.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:17
L5	0	424/657.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:17
L6	15	424/659.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:17
L7	13	424/660.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:18
L8	16	424/78.04.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:18
L11	38	424/405.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol)) and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:19
L12	28	424/641.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol)) and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:19
L13	0	424/657.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol)) and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:19
L14	7	424/659.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol)) and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:20
L15	7	424/660.ccls. and (zinc and (boric or borate) and sorbitol and (propylene adj glycol)) and @ad<"20070920"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:20
L16	26	l11 and (sorbitol with propylene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:21

L17	17	l12 and (sorbitol with propylene)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2012/07/16 10:22

7/ 16/ 2012 10:23:24 AM
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BIB DATA SHEET

CONFIRMATION NO. 3372

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/858,781	09/20/2007	424	1613	3205US

APPLICANTS

Bhagwati P. Kabra, Euless, TX;
Masood A. Chowhan, Arlington, TX;
L. Wayne Schneider, Crowley, TX;
Wesley Wehsin Han, Arlington, TX;

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

This appln claims benefit of 60/827,411 09/28/2006
and claims benefit of 60/826,529 09/21/2006

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

12/08/2007

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ERNST V ARNOLD/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		TX	3	28 ~~18~~	4 ~~2~~

ADDRESS

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IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134
UNITED STATES

TITLE

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BIB (Rev. 05/07).

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11858781
Filing Date	2007-09-20
First Named Inventor	Bhagwati P. Kabra
Art Unit	1613
Examiner Name	Arnold, Ernst V.
Attorney Docket Number	3205US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11858781
	Filing Date	2007-09-20
	First Named Inventor	Bhagwati P. Kabra
	Art Unit	1613
	Examiner Name	Arnold, Ernst V.
	Attorney Docket Number	3205US

/E.A./	1	HOFFMAN H.M. et al., "Pre-clinical in vitro Testing of an Artificial Tear Formulation with a Novel Preservation System", poster presentation at the annual meeting of the Association for Research In Vision And Ophthalmology (ARVO), Ft. Lauderdale, FL., April 30, 2006	☐
/E.A./	2	Illustration of packaging for Systane® Free, March 7, 2006	☐
/E.A./	3	SYSTANE® FREE promotional document (minimal-blur) published on or about January 1, 2006	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Ernst Arnold/	Date Considered	07/16/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Barbara McKenzie	(Depositor's name)
Barbara McKenzie	(Signature)
10 August 2012	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$230	$0	$1510	$230	10/24/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
ARNOLD, ERNST V	1613	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Scott A. Chapple
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Alcon Research, Ltd.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Fort Worth, Texas 76134-2099

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies .....

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☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 010682 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature: Scott A. Chapple Date: 8 August 2012

Typed or printed name: Scott A. Chapple Registration No.: 46,287

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Electronic Acknowledgement Receipt

EFS ID:	13466962
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	10-AUG-2012
Filing Date:	20-SEP-2007
Time Stamp:	12:09:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	3205_US_FeeTransmittal_081012.pdf	151429 12b53e6b3b502fa46080a9e160e6faf38009779d	no	1

Warnings:	
Information:	

Total Files Size (in bytes):	151429

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

TJW

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OPAP IAP23 AUG 10 2012 PATENT & TRADEMARK OFFICE

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Barbara McKenzie	(Depositor's name)
Barbara McKenzie	(Signature)
10 August 2012	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/20/2007	Bhagwati P. Kabra	3205US	3372

TITLE OF INVENTION: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$230	$0	$1510	$230	10/24/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
ARNOLD, ERNST V	1613	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Scott A. Chapple
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Alcon Research, Ltd.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Fort Worth, Texas 76134-2099

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☒ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies .....

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 010682 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

08/13/2012 HVUONG2 00000057 010682 11858781
01 FC:1501 1740.00 DA

Authorized Signature: Scott Chapple Date: 8/10/2012

Typed or printed name: Scott A. Chapple Registration No.: 46,287

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Adjustment date: 08/13/2012 HVUONG2
04/10/2011 INTEFSW 00001524 010682 11858781
01 FC:1501 1510.00 CR

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/858,781	09/18/2012	8268299	3205US	3372

26356 7590 08/29/2012

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 754 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Bhagwati P. Kabra, Euless, TX;
Masood A. Chowhan, Arlington, TX;
L. Wayne Schneider, Crowley, TX;
Wesley Wehsin Han, Arlington, TX;

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:
Bhagwati P. Kabra et al.

Serial No.: 11/858,781 Examiner: Ernst V. Arnold

Filed: September 20, 2007

Patent No.: 8,268,299 Group Art Unit: 1613

Issued: September 18, 2012

For: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

Application and Petition for Patent Term Adjustment
Under 37 CFR 1.705(d)

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

Dear Sir:

This Application for Patent Term Adjustment Under 37 CFR § 1.705(d), and accompanying Fee Under 37 CFR § 1.18(e) is filed in order to request a recalculation of the term of the adjustment granted by the PTO under 35 U.S.C. § 154(b) on the face of U.S. Patent No. 8,268,299, which issued on September 18, 2012. The fee set forth in 37 C.F.R. § 1.18(e) accompanies this paper. The Assistant Commissioner is authorized to withdraw any fees that may be due under 37 C.F.R. §§ 1.16 to 1.21 from Alcon Deposit Account No. 010682.

It is believed that this paper is timely filed within two months of the issue date of the patent pursuant to 37 U.S.C. § 1.705(d) because the issues raised in this paper could not have been raised in an application for patent term adjustment under 37 C.F.R. § 1.705(b).

On January 7, 2010, the Federal Circuit held in *Wyeth v. Kappos* (No. 2009-1120) that the USPTO has been incorrectly calculating patent term adjustment ("PTA") under the Patent Statute. According to the Federal Circuit, a PTA should be calculated as:

PTA = (A-delay) + (B-delay) – (overlap) – (applicant delay)

On November 1, 2012, the Eastern District of Virginia wrote:

> In sum, the plain and unambiguous language of [35 U.S.C. § 154(b)(1)(B)] requires that the time devoted to an RCE tolls the running of the three year clock if the RCE is filed within the three year period. And, put simply, *RCE's have no impact on PTA if filed after the three year deadline has passed.* The PTO's arguments to the contrary are not persuasive and, accordingly, the PTO's interpretation of subparagraph (B) must be set aside as "not in accordance with law" and "in excess of [its] statutory . . . authority."

Exelixis, Inc. v. Kappos, Case No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. November 1, 2012).

When calculated in view of *Exelixis* and using the formula provided by the Federal Circuit in *Wyeth*, the patent term adjustment for the present case should be **1239 days**, rather than the 754 days granted on the face of the patent. The pertinent facts relative to the PTO's miscalculation of the patent term adjustment are as follows:

1. The present application was originally filed under 35 U.S.C. §111(a) as a non-provisional, utility application on September 20, 2007.

A-delay:

2. Applicants are entitled to a first period of A-delay in the present case resulting from the PTO's failure to provide a first action under 35 U.S.C. §132 within fourteen months after the filing date of the application and are entitled to a second period of A-delay from the PTO's failure to respond to a request for continued examination in four months.
3. The A-delay calculation is as follows:
    a. For purposes of 37 C.F.R. §1.703(a)(1), the date that is fourteen months after the date on which the application was filed under 35 U.S.C. §111(a) is **November 20, 2008**.
    b. The date of mailing of an action under 35 U.S.C. §132 was **April 14, 2010**.

c. The number of days between November 20, 2008 and April 14, 2010 is **510 days**.

d. For purposes of 37 C.F.R. §1.703(a)(2), a request for continued examination was filed on **April 29, 2011**.

e. The date of mailing an action under 35 U.S.C. §132 after the filing of the request for continued examination was **February 27, 2012**.

f. The date that is four months after the date on which the request for continued examination was filed under 35 U.S.C. §111(a) is **August 29, 2011**.

g. The number of days between August 29, 2011 and February 27, 2012 is **182 days.**

B-delay:

1. Applicants are entitled to a period of B-delay in the present case resulting from the pendency of the application for a period of time greater than three years.

   a. Considering the exceptions to the guarantee of no more than a 3-year application pendency set forth in 35 U.S.C. § 154(b)(1)(B), it is pointed out that a first request for continued examination was filed on **November 22, 2010**, which is more than three years after the indicated application filing date of **September 20, 2007**. Therefore, the USPTO should not have cut-short any further § 154(b)(1)(B) term adjustments based on the indicated first request for continued examination filed in the application. *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. November 1, 2012).

2. The B-delay calculation is as follows:

   a. For purposes of 37 C.F.R. §1.703(b), the date that is three years after the date on which the application was filed under 35 U.S.C. §111(a) is **September 20, 2010**.

   b. The date on which the patent issued is **September 18, 2012.**

c. The number of days between September 20, 2010 and September 18, 2012 is **729 days**.

Overlap:

3. For purposes of 37 C.F.R. §1.703(f), the periods of A-delay that overlaps with the period of B-delay is the 182 days calculated in part (g) of the section on A-delay above. Therefore, the number of overlapping days between the A-delay and the B-delay is **182 days**.

Applicant delay:

4. There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. §1.704.

Calculation of Patent Term Adjustment:

5. Using the formula prescribed by the Federal Circuit in *Wyeth*, the proper calculation of the Patent Term Adjustment is as follows:

PTA = (510 days + 182 days) + (729 days) – (182 days) – (0 days) = 1239 days

6. As a result of the calculation set forth above, Applicant requests that the Patent Term Adjustment be revised to **1239 days**.

Terminal Disclaimer

7. The patent is not subject to terminal disclaimer.

The United State Patent Office is invited to contact the undersigned attorney at 817 - 615 - 5288 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

ALCON RESEARCH, LTD.

November 15, 2012
Date

Scott A. Chapple
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Attorney Docket: 3205US

Electronic Patent Application Fee Transmittal

Application Number:	11858781
Filing Date:	20-Sep-2007
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3205US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Application for patent term adjustment	1455	1	200	200
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt

EFS ID:	14240666
Application Number:	11858781
International Application Number:	
Confirmation Number:	3372
Title of Invention:	SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS
First Named Inventor/Applicant Name:	Bhagwati P. Kabra
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3205US
Receipt Date:	15-NOV-2012
Filing Date:	20-SEP-2007
Time Stamp:	16:35:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$200
RAM confirmation Number	3844
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Patent Term Adjustment Petition	3205_US_A_PTA_111512.pdf	184775 35f191566915b31ad3326450b0eae9e872d279ee	no	5
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30532 0b5a8bbc3584c2787ab971d3a33d1bd2195f54aa	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	215307		

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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