UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAIN POINT MEDICAL SYSTEMS, INC.
d/b/a MIBO MEDICAL GROUP, INC.
Petitioner
v.

BLEPHEX, LLC
Patent Owner

Patent No. 9,039,718
Issue Date: May 26, 2015
Title: METHOD AND DEVICE FOR TREATING AN OCULAR DISORDER

Inter Partes Review No. 2016 – 01670

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311 – 319 AND 37 CFR § 42.100 *ET SEQ*.

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TABLE OF EXHIBITS

Exhibit #	Exhibit Description
1001	U.S. Pat. No. 9,039,718 to Rynerson
1002	Declaration of Dr. William Benjamin, OD, PhD
1003	Image file wrapper for U.S. Pat. No. 9,039,718
1004	U.S. Pat. Pub. No. 2007/0060988 to Grenon et al.
1005	Image file wrapper for U.S. Application No. 13/949,365
1006	U.S. Pat. Pub. No. 2014/0052164 by Rynerson (Serial No. 13/949,365)
1007	Merriam-Webster's Collegiate Dictionary, 10th Ed.
1008	Dictionary of Optometry and Visual Science, 7th Ed.
1009	Encyclopedia & Dictionary of Medicine, Nursing, & Allied Health, 7th Ed.
1010	Mosby's Dictionary of Medicine, Nursing & Health Professions, 7th Ed.
1011	Mosby's Medical Dictionary, 9th Ed.
1012	Plaintiff Blephex LLC's Disclosures Pursuant to Paragraphs 4-1 and 4-2 of the Court's Amended Miscellaneous Order No. 62
1013	Product Info - Alger Company Algerbrush II (http://www.algercompany.com/brush/product-info/)
1014	AlgerBrush II Product Spec Sheet
1015	AlgerBrush II Operating Instructions
1016	U.S. Pat. Pub. No. 2007/0049860 by Seminara
1017	Sue Stevens, "How to Clean Eyelids," *Community Eye Health Journal*, 2011 Sep; 24(75): 20 (republished at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/)
1018	U.S. Pat. No. 4,883,454 to Hamburg
1019	Japanese Publication JPH10108801 by Yamaura
1020	Declaration of Christopher O'Hagan in support of printed publications

I. INTRODUCTION

Pain Point Medical Systems, Inc. ("Petitioner") requests that the Patent Trial and Appeal Board (the "Board") institute *Inter Partes* review of U.S. Patent No. 9,039,718 to Rynerson ("the '718 patent") (Ex. 1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 et seq.

The claims of the '718 patent are directed to a method of removing debris from eyelids using a swab that is powered by an electromechanical device. This motorized swab is brought into contact with the eyelid margin to remove accumulated debris such as cellular and sebaceous buildup.

Well before the filing date of the '718 patent, the removal of accumulated debris from the eyelid margins was a well-known treatment for ocular disorders such as blepharitis that produce chronic inflammation and dry eye. This was accomplished by applying a swab or scrub pad against the eyelid margin to mechanically remove the debris, as the Patent Owner admits in its own patent. The '718 patent uses the same method. The only distinction in the '718 patent is the use of a simple electromechanical device to power movement of the swab.

Similar electromechanical devices have been used for decades to clean and debride tissue. The most obvious examples are electric toothbrushes, but similar devices have been used to clean and/or debride the insides of ears, piercing holes, and more relevantly, corneal tissue. Typically these devices are very similar in design with regard to electromechanical motorization, the primary difference between them being the specific contact element (e.g. brush, burr, swab, etc.) appropriate for the tissue in question.

During prosecution, the '718 patent was subject to restriction between the method and apparatus claims. Claims covering the apparatus were subsequently filed in a Continuation-in-Part application, serial no. 13/949,365. It is worth noting that the apparatus claims of the CIP application received a final rejection from the USPTO in light of prior art brought to the attention of the (same) examiner by a third party submission after issuance of the '718 patent. The method claims in the '718 patent are heavily dependent upon the structural limitations of the apparatus. In fact, those structural limitations are the only thing that distinguishes the method of the '718 patent from the prior art method of cleaning eyelid margins.

It is clearly evident that the challenged claims would have been obvious to a person of ordinary skill in the art and rejected by the examiner had he been aware of the prior art references during prosecution of the '718 patent.

In view of the showings of obviousness set forth below, the Petitioner is likely to prevail in establishing that claims 1-11 and 14-17 are unpatentable.

II. MANDATORY NOTICES

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that the real parties-in-interest are Pain Point Medical Systems, Inc., doing business as MiBo Medical Group, Inc.

The following persons are shareholders in Pain Point Medical Systems, Inc.: Michael Whitehurst, Glinda Whitehurst, Michael Lutz, Thomas Kislan, OD, and James Lewis, MD.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

U.S. Patent No. 9,039,718 ("the '718 patent") is the subject of co-pending litigation: *Blephex LLC v. Pain Point Medical Systems, Inc.*, Case No. 3:16-cv-00410-N (N.D. Tex.), the complaint in which was filed February 12, 2016. U.S. Patent Applications 13/949,365 and 14/229,275, pending in the Office, both claim priority to the '718 patent.

C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3))

Lead Counsel: Steven E. Ross (Reg. No. 35,996); Tel. 214.382.0901

Backup Counsel: Michael A. Rahman (Reg. No. 43,872); Tel. 214.382.0895

Backup Counsel: Christopher P. O'Hagan (Reg. No. 46, 966); Tel. 214.445.6073

D. Service Information (37 C.F.R. § 42.8(b)(4))

Please send all correspondence to Lead Counsel at:

Address: Ross IP Group PLLC

1700 Pacific Ave., Suite 3750

Dallas, TX 75201

Petitioner consents to email service at: sross@rossipg.com

III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '718 patent for which review is sought is available for *inter partes* review, and that the Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the Grounds identified in the petition.

IV. STATEMENT OF PRECISE RELIEF REQUESTED (37 C.F.R. § 42.22(a))

Petitioner requests *inter partes* review and requests cancellation of claims 1-11 and 14-17 of U.S. Patent No. 9,039,718. A detailed statement of the reasons for the relief

requested is set forth in Section XIII of this Petition.

V. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW

A petition for *inter partes* review must demonstrate "a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). The Petition meets this threshold. Each of the elements of claims 1-11 and 14-17 of the '718 patent are taught in the prior art as explained below in the proposed Grounds of unpatentability under 35 U.S.C. § 103(a). Also provided are motivations to combine those elements and an explanation of why a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the benefits of the claimed compositions.

VI. TECHNICAL BACKGROUND

The following technical introduction is supported by the Declaration of Dr. William Benjamin, OD, PhD (Ex. 1002).

The meibomian glands are special sebaceous glands at the rim of the eye that produce meibum, an oily substance that prevents evaporation of the eye's tear film. Inflammation of the meibomian glands may cause the glands to become obstructed by thick waxy secretions. Dysfunctional meibomian glands in turn can cause dry eyes and contribute to blepharitis, a condition characterized by chronic inflammation of the eyelid. Symptoms include redness, flaking of skin, and/or crusting at the eyelid margins, producing discomfort and vision impairment. Frequently, cellular and sebaceous debris builds up along the anterior or posterior eyelid margin and lashes.

Treatment of meibomian gland dysfunction focuses on clearing blockage of the glands. Typically heat is applied to the eyelid to melt the hardened secretions, allowing

drainage of the meibomian glands. In some cases antibiotics or steroids are prescribed to address infection and inflammation.

In addition to expressing the blocked meibomian glands, treatment usually includes removing accumulated debris from the eyelid margins. Often a baby shampoo or other non-irritating solution is used to soften and loosen the debris. A mechanical action is then used to remove the debris by direct contact with the lid margin using a swab, scrub pad or similar item. The cleansing action has to be delicate enough to avoid aggravating the preexisting condition.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art at the time of filing of the '718 Patent would be a licensed eye care specialist such as an ophthalmologist (MD or DO) or a doctor of optometry (OD) and three to five years of training and practical experience in the field of eye care.

VIII. THE '718 PATENT

The '718 Patent, entitled "Method and Device for Treating an Ocular Disorder," is directed to a method and device for removing debris from the eye. The device includes a swab connected to an electromechanical device which moves the swab to remove debris from the eye. (Ex. 1001, Col. 2, lines 28-35). The device is described in column 3 of the '718 Patent:

> With reference to FIG. 1, an embodiment of the device 10 for treating an ocular disorder, particularly with respect to eyelid margin diseases, includes a mechanical drive unit 12 which operably moves a swab 14 to facilitate removal of debris from an eye 15 (see FIGS. 2A-2B). The swab 14 is connected to a rigid member 16 having both a distal end portion and a proximal end portion 20. The swab 14 is affixed to the distal end portion 18 of the rigid member 16 to create an instrument 22, which may be secured to the mechanical drive unit 12. As shown in FIG. 1, the proximal

> end portion 20 is removably secured to the mechanical drive unit 12, through the rigid member 16, and the swab 14…. (Ex. 1001, Col. 3, lines 35-47)

According to the '718 Patent the swab 14, which is made from a medical grade sponge, has a base portion and a tip portion sized to access and remove debris from the eye.

> In one aspect of the instrument 22, the swab 14 includes a tip portion and a base portion 26. While the swab 14 may be of a size sufficient to access debris on the eye 15 as shown in FIGS. 1-2B, at least the tip portion 24 is of a size sufficient to access debris on the eye. For instance, the swab 14 has an approximate length between 1.0-3.0 millimeters and an approximate width of 1 millimeter. It will be appreciated that the swab 14 may be manufactured of any material suitable for contacting the eye 15 without harming the eye 15. However, as shown in the embodiment of FIG. 1, the swab 14 is a sponge. As described herein, "sponge" broadly refers to any material that is soft, porous, and resilient. Particularly, the swab 14 is a medical grade sponge or a surgical grade sponge capable of removing debris from the eye 15 without harming the eye 15. As shown in the exemplary embodiment of FIGS. 1-2B, the swab 14 is a methyl cellulose sponge. It will be appreciated, however, that similar materials capable of removing debris from the eye 15 without harming the eye 15 are readily apparent and may also be used. (Ex. 1001, Col. 3, line 56-Column 4, line 11).

The '718 Patent explains how an operator targets the debris with the swab by inspecting the eye and removes the debris from the eye.

> In an exemplary embodiment, the operator preferably targets the debris present on the eye 15 with the swab 14 of the electromechanical device 10. The debris may be targeted by visually inspecting the eye 15 with or without the aid of a magnification device. Once the debris is targeted, the swab 14 contacts the portion of the eye 15 that includes the debris. For purposes of treating the ocular disorder, the debris may be removably attached on either the upper and lower eyelid margins 60, 62 the plurality of eyelashes 64 and the inner edge of the eyelid margins, 60, 62. Thereby, upon contacting the portion of the eye 15 with the debris, the swab impacts the debris to remove the debris from the eye 15. Furthermore, a liquid solution configured to loosen the debris may be absorbed within the swab 14 to further aid in removing the debris from the eye 15 and/or minimizing irritation to the eye 15. It will be appreciated

> that any liquid solution sufficiently capable of loosening the debris for further aid in removing the debris may be so used. (Ex. 1001, Col. 5, line 54-Column 6, line 2).

IX. SUMMARY OF PROSECUTION HISTORY

The '718 Patent issued from U.S. Patent Application No. 13/556,729, which was originally filed on July 24, 2012, with claims 1-23. A copy of the file history of the application which issued into the '718 Patent is attached to this Petition as Exhibit 1003.

Independent claims 1 and 17 of the '718 patent are reproduced below.

> 1. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:
> effecting movement of the swab relative to the electromechanical device, the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin;
> while the swab is being moved by the electromechanical device, contacting a portion of the eye between the eye-lashes and the inner edge of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.

> 17. A method of treating an eye for an ocular disorder with a swab operably connected an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:
> effecting movement of the swab relative to the electromechanical device,
> while the swab is being moved by the electromechanical device, contacting at least an inner edge portion of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.

In a non-final Office Action dated September 19, 2014, the Examiner issued a restriction which required the applicant to elect between one of the following inventions: (1) Claims 1-18 and 21-22, drawn to a method of treating an eye for an ocular disorder; and (2) Claims 9-20 and 23 drawn to a device for the removal of debris from an eye. The

Applicant elected to prosecute Claims 1-18 and 21-22. (Ex. 1003, pp. 151-152) Also, in the Office Action Claims 1-18 and 21-22 were rejected under 35 U.S.C § 102(b) as being anticipated by U.S. Patent Application Publication No.: 2007/0060988 to Grenon et al. ("Grenon"). (Ex. 1003, p. 154)

On November 18, 2014, Applicant's representatives conducted a telephonic interview with the Examiner during which an agreement was reached regarding the cited prior art reference (Grenon). (Ex. 1003, p. 178) On December 19, 2014, Applicant filed an Amendment amending claims 1-4 and 7, canceling claims 9-20 and 23, and adding claims 24-30. (Ex. 1003, pp. 181-184)

In the December 19, 2014 Amendment, Applicant amended claim 1 to specifically recite that the swab has "at least a portion thereof configured to access an inner edge portion of the eyelid margin." Applicant stated:

> …To this end, Grenon fails to describe any portion of the heat sink 46 capable of accessing an inner edge portion of the eyelid margin. Furthermore, as agreed during the interview, the apparatus of Grenon is not capable of contacting an inner edge portion of an eyelid margin. Consequently, Grenon fails to disclose a swab having a portion configured to access an inner edge portion of the eyelid margin of the eye.
> (Ex. 1003, p. 188)

On January 23, 2015, a second telephonic interview was held between the Examiner and Applicant's representative. During the interview, the Examiner proposed amending claim 1 by adding "contacting at least an inner edge portion of the eyelid margin" and canceling claim 30. (Ex. 1003, p. 195). On February 6, 2015, during a third telephonic interview, Applicant's representative authorized the Examiner proposed amendment. (Ex. 1003, p. 251).

A Notice of Allowance was mailed March 11, 2015, allowing claims 1-8, 21, 22 and 24-29. (Ex. 1003, p. 243) On May 26, 2015, the '718 Patent issued with claims 1-17. Independent claims 1 and 17 both include the limitation "the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin."

Since Applicant overcame a 35 U.S.C § 102(b) rejection under Grenon by amending claim 1 to recite "the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin" and by arguing that Grenon fails to disclose a swab having a portion configured to access an inner edge portion of the eyelid margin of the eye, infringement of claim 1 (and claim 17) at least requires a swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin.

U.S. Patent Application No.: 13/949,365

On July 24, 2013, Applicant James M. Rynerson filed a U.S. Patent Application No.: 13/949,365, entitled "Instrument for Treating an Ocular Disorder" ("the '365 Application"), which is a continuation-in-part of the application for the '718 Patent. (Ex. 1006) All pending claims in the '365 Application recite a "swab." Dr. Timothy Ardizone, who prosecuted the '718 Patent before the USPTO, is also prosecuting the '365 Application. The continuation-in-part is the result of the restriction noted above during prosecution of parent application.

During prosecution of the '365 Application, on January 16, 2015, a third-party submission under 37 CFR 1.290 was filed, which included the following prior art references: (1) Alger Brush document (retrieved from the Internet: www.algercompany.com/brush/pdf-file); and (2) Patent Application Publication No.: WO/2009/066077 to Colin Parsloe. A Concise Description of Relevance was included in

the third-party submission, which explained that all elements recited in independent claims 1 and 4 and dependent claims 2-3 and 5-11 of the '365 Application were disclosed in the references submitted in the third-party submission. (Ex.1005, pp. 152-164)

In an Office Action dated June 5, 2015, the patent examiner rejected all claims pending in the '365 Application as being obvious over the following three prior art references: (a) Algerbrush II Quick Reference Catalog ("Catalog"); (b) U.S. Patent No. 3,029,672 to Lowenborg ("Lowenborg"); and (c) U.S. Patent Publication No. 2011/0160635 by Baschnagel ("Baschnagel"). (Ex. 1005, p. 210)

On or about November 2, 2015, Applicant submitted a Response to Non-final Office Action in the prosecution of the '365 Application, which included a narrowing amendment of all claims pending in the '365 Application. More specifically, all pending claims were amended to expressly recite the following new limitation: "wherein said swab is defined by a medical grade sponge." (Ex. 1005, pp. 243-245)

Applicant's November 2, 2015, Response to Non-final Office Action additionally included the following argument in support of the patentability of the claims pending in the '365 Application:

> Applicant further submits that claim 1, and the claims depending therefrom, are allowable for additional grounds independent of the grounds set forth above. In particular, the Office Action relies on Baschnagel as disclosing a swab. Baschnagel discloses the use of a cotton swab. Baschnagel does not disclose or suggest that its cotton swab can be any material other than cotton. In contrast, Applicant has also amended claim 1 to recite that the swab is defined by a medical grade sponge. A medical grade sponge is not a cotton swab. For at least this independent reason, the combination of Catalog, Lowenborg, and Baschnagel fails to disclose or suggest all elements of Applicant's claimed instrument. (Ex. 1005, pp. 248-249)

A review of the prosecution history of the '718 Patent indicates that the Alger Brush document was cited as a reference in an Information Disclosure Statement but was not considered by the Examiner during prosecution of the '718 Patent. It appears that the Examiner did not recognize the relevance of the Alger Brush until it was brought to his attention by the third-party submission during prosecution of the '365 Application, after the '718 Patent had issued. Thus, the Examiner may have simply overlooked the relevance of the Alger Brush document during prosecution of the '718 Patent.

X. CLAIM CONSTRUCTION (37 C.F.R. § 42.100(b))

Claim terms in *inter partes* review are given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). Any claim term that lacks a definition in the specification is therefore given a broad interpretation. For the purposes of this proceeding, claim terms are presumed to take on their plain and ordinary meaning as understood by one of ordinary skill in the art in view of the specification.

Independent claims 1 and 17 and several of the dependent claims recite anatomical structures of the eye in such a way as to appear to be structural limitations of the invention. Such language should be accorded no patentable weight since these anatomical structures were clearly not invented by the Patent Owner.

All claim terms have been accorded their broadest reasonable interpretation in light of the patent specification including their plain and ordinary meaning to the extent such a meaning could be determined by person skilled in the art.

With regard to specific claim terms, Petitioner asserts that the term "swab" be given its ordinary meaning, specifically: a piece of absorbent material capable of removing debris from the eye without harming the eye. This construction is consistent

with ordinary use as well as most medical dictionaries. (Ex. 1007, Ex. 1008, Ex. 1009, Ex. 1010, Ex. 1011). It is also consistent with the specification of the '718 patent itself. (Ex. 1001, Col. 4, lines 1-10)

In its proposed claim term construction in Case No. 3:16-cv-00410-N (N.D. Tex.) Patent Owner Blephex proposed to construct the term "swab" as:

> [A] debris removal component made of a material suitable to contact the eyelid margin when moved by an electromechanical device. (Ex 1012, p. 2)

Petitioner strongly disagrees with such a construction as being inconsistent with the ordinary meaning of "swab" both within and outside the healthcare field. Patent Owner's proposed construction is also inconsistent with the specification of the '718 patent, as well as Patent Owner's amendment noted above in the prosecution history of the '365 CIP Application, which specifically defines the swab as a medical grade sponge.

However, even if one accepts the Patent Owner's proposed construction of "swab" *arguendo*, it does not change the analysis herein with regard to the cited prior art and in fact potentially strengthens the case for invalidity by causing the '718 patent to read on additional prior art.

XI. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B))

Claims 1-11 and 14-17 are unpatentable as shown in the detailed grounds for unpatentability below.

A. Ground 1: Claims 1-11 and 14-17 are unpatentable under 35 U.S.C. § 103(a) over Alger Brush II in view of Seminara and Stevens.

The Alger Brush was invented in 1970. It is an electromechanical motor that rotates a specialized burr. The burr is used to brush away rust rings from the eye. Such rust rings form when the eye is struck by a metallic object such as a spark,

thereby damaging the tissue. Removal of the rust ring leaves a smoother surface, which facilitates faster healing. (Ex. 1013)

The obviousness of adapting the Alger Brush to clean eyelid margins is explicitly admitted by the Patent Owner. In regard to the choice of electromechanical device, the '718 patent discloses:

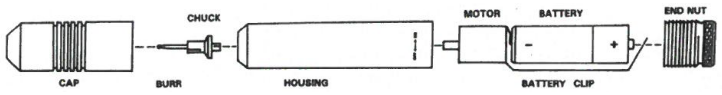
> For instance, operators within the professional clinic setting may desire a durable, reusable mechanical drive unit 12 and single-use instruments 22. Some examples of such a professional mechanical drive unit 12 is an Algerbrush I, an Algerbrush II, or similar medical device. (Ex. 1001, Col. 5, lines 14-20)

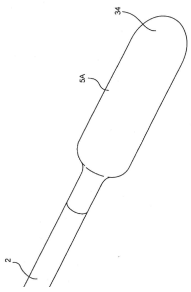
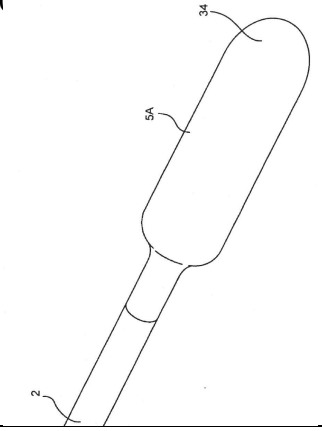
The burr used with the Alger Brush is either carbide or fine grit diamond depending on the specific application. (Ex. 1014, Ex. 1015) While such materials are appropriate for debriding rust rings from damaged tissue, they may too abrasive for removing cellular debris and hardened sebaceous secretions from an eyelid margin. Any eye care specialist would recognize that a softer material can be used to remove such debris from the eyelid margin.

Seminara discloses a medical grade sponge for clearing tissue from anatomical structures. It is specifically designed for contact with fragile structures while minimizing the potential for injury to them. (Ex. 1016, ¶ ¶ 0012, 0042) One of the embodiments of the sponge is bullet shaped with a taper at the distal end. (Ex. 1016, ¶ 0081, Fig. 20)

Motivation to combine the Alger Brush with Seminara is provided by Sue Stevens in the article "How to clean eyelids" published by the *Community Eye Health Journal* and republished by the National Institute of Health. Stevens explains and illustrates how to remove crusting on the eyelid margins in cases of blepharitis using a swab soaked in a solution. (Ex. 1017, Figs. 8 and 10) The '718 patent uses the same method, the only

difference being the use of an electromechanical device to move the swab. The '718 patent admits that the Alger Brush is an obvious device to use for this purpose. The only necessary modification is the substitution of the Alger Brush's carbide burr with a swab made of the medical grade sponge such as that disclosed in Seminara.

'718 Patent Claims	**Alger Brush, Seminara, and Stevens**
1. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II is used by ophthalmologists, ER physicians and, in many states, optometrists who are trained and licensed to remove foreign bodies from the eye of a patient. Foreign bodies in the eye can leave rust rings when removed. These rust rings are normally caused by a ferrous foreign body accidentally striking the cornea or sclera of the patient. When the foreign body (usually from a spark produced by a grinding wheel or welding torch) strikes the eye it sticks to the eye and eventually produces rust when combined with the moisture in the eye. The ALGERBRUSH II is used for the expressed purpose of removing these rust rings from the eye of a patient." "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose. The ALGERBRUSH II has been CE marked since 1998." The fact that the AlgerBrush can be used on both the cornea and sclera shows that it is intended to be used on different types of tissues of the eye. Algerbrush-II-Operating-Instruction-Rev-3_2012:  2007/0049860: "[0081] FIG. 20 shows an embodiment of the invention

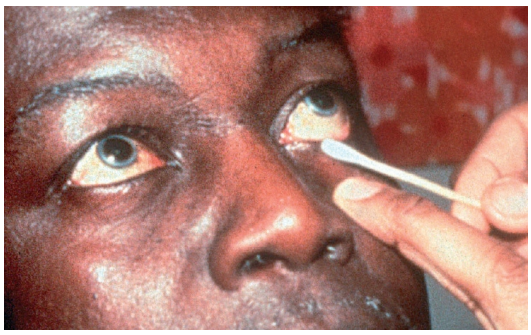
	wherein the expandable sponge 5A has a taper 34 at the distal portion and is attached to handle 2. This is essentially a bullet-shaped sponge."  Every normal eye has an eyelid margin.
effecting movement of the swab relative to the electromechanical device, the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin;	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose." http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/:  Fig. 8 20  "[0012] It is an object of this invention to provide a surgical instrument configured to more effectively remove tissue from anatomical structures, including, without limitations, those that are fragile."

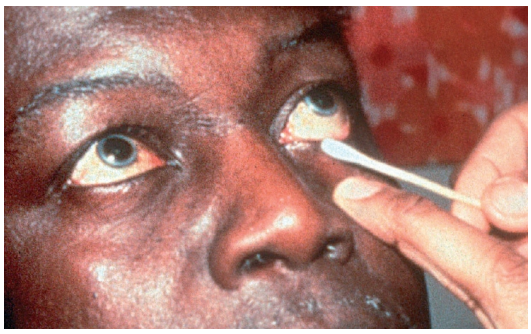
	The shape of the sponge disclosed in Seminara is essentially the same as the swab shown above in Fig. 8 of Stevens for cleaning eyelid margins. It need only be reduced in size in order to access the inner eyelid margin, which would be obvious to any eye care specialist.
while the swab is being moved by the electromechanical device, contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose." http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"Reasons for cleaning eyelids** • **Basic eye hygiene**: to remove any discharge before instillation of eye drops or applying eye ointment, or before applying post-operative eye dressings. • **Blepharitis**: to remove crusting on the eyelid margins." (p. 1) **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just

	below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)

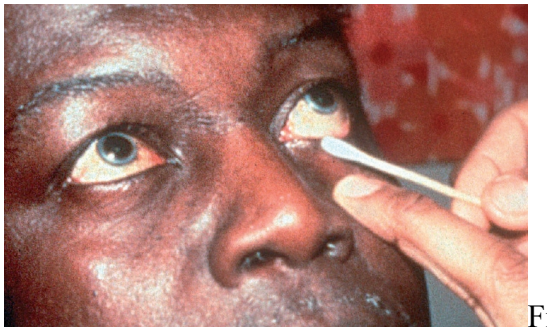
2. The method of claim 1 wherein the eye has a meibomian gland and removing debris further includes at least one of:	All normal eyelids have meibomian glands.
scrubbing the eyelid margin;	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)
exfoliating the eyelid margin;	See above.
buffing the eyelid margin;	See above.

un-roofing the meibomian gland; or	See above.
breaking the debris free of the eyelid margin.	See above.

3. The method of claim 1 wherein the eye has an eyeball and further includes accessing the eyelid margin for contacting the swab to the debris without lifting the eyelid margin from the eye.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/:  Fig. 8 As shown, the eyelids are not lifted from the eye during application of the swab.

4. The method of claim 1 wherein the eye has an eyeball and further includes:	Every normal eye has an eyeball.
positioning the swab near the eyeball along the eyelid margin; and	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: 
targeting the debris with the swab.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"Reasons for cleaning eyelids** • **Basic eye hygiene**: to remove any discharge before instillation of eye drops or applying eye ointment, or before applying post-operative eye dressings. • **Blepharitis**: to remove crusting on the eyelid margins." (p. 1) **"2 The lower eyelid**

	• Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)

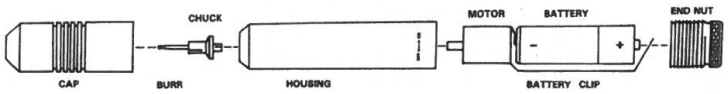
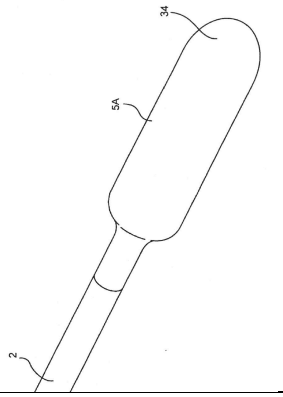
5. The method of claim 1 further including viewing the eye and the debris without the aid of a magnification device.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: The method described and shown in the article by Sue Stevens does not require the use of a magnifying device as shown below.  Fig. 8

6. The method of claim 1 wherein the movement of the swab is at least one of rotating the swab, vibrating	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary

the swab, or reciprocating the swab.	instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose."

7. The method of claim 1 wherein effecting movement of the swab further includes setting the movement of the swab to a desirable speed sufficient to remove the debris from the eye.	Obvious. If the speed is not sufficient to remove debris, why build and use the device at all?

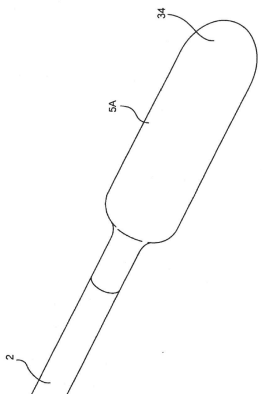
8. The method of claim 1 further including repeating the effecting movement, the contacting the portion of the eye, and impacting the debris with the swab to remove the debris process of claim 1 after periodic intervals until the ocular disorder is sufficiently remedied.	Obvious. Recurring treatment of a medical condition until its resolution has been basic to medical practice for millennia. (See Hippocrates of Kos, *On Regimen in Acute Diseases*, c. 400 BC) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: "If the eyelids are very sticky or encrusted, it will be necessary to repeat any part of the above procedure until all debris or discharge is removed." (p. 8)

9. The method of claim 1 wherein the swab is connected to a rigid member having a proximal end portion, the method further comprising:	Algerbrush-II-Operating-Instruction-Rev-3_2012:  2007/0049860:  "[0081] FIG. 20 shows an embodiment of the invention wherein the expandable sponge 5A has a taper 34 at the distal portion and is attached to handle 2. This is essentially a bullet-shaped sponge."

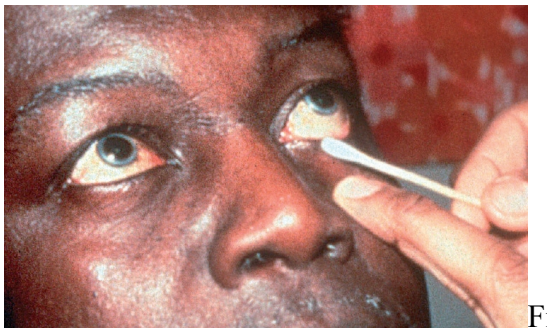
securing the proximal end portion of the rigid member to the electromechanical device; and	Algerbrush-II-Operating-Instruction-Rev-3_2012: "Installation of Chuck and Burr Assembly: *** Note: Motor must be spinning when installing chuck and burr assembly to ensure motor seated properly • To install, ensure motor is spinning, i.e., ALGERBRUSH II is "ON" 1) Gently push chuck and burr assembly onto motor shaft 2) Base of chuck should be close to, but not touching, top of housing 3) Turn "OFF" ALGERBRUSH II until ready to use" (p. 1)
removing the proximal end portion of the rigid member from the electromechanical device.	Algerbrush-II-Operating-Instruction-Rev-3_2012: "To remove, 1) Grasp base of chuck with fingers and pull away from motor shaft - or - 2) Gently pry chuck off motor shaft with suitable instrument 3) Turn "OFF" ALGERBRUSH II until ready to use" (p. 1)

10. The method of claim 9 further comprising:	
removing the proximal end portion of the rigid member after a single use of the swab; and	Obvious. Single use swabs have been used in medicine for decades. In fact, reusable swabs are virtually unheard of. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • ***Discard the swab or bud after use.*** **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud.

	• Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • ***Discard the swab or bud after use.***" (pp. 7-8) [Emphasis added]
repeating the securing and removing of another proximal end portion of another rigid member.	See above.

11. The method of claim 1 wherein the swab is a medical grade sponge for accessing the eyelid margin.	2007/0049860:  "[0081] FIG. 20 shows an embodiment of the invention wherein the expandable sponge 5A has a taper 34 at the distal portion and is attached to handle 2. This is essentially a bullet-shaped sponge." The Seminara invention is a surgical instrument that includes a sponge.

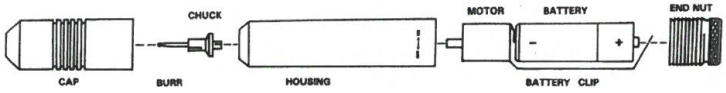
14. The method of claim 1 further comprising:	
accessing at least an inner edge portion of the eyelid margin with the swab.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold

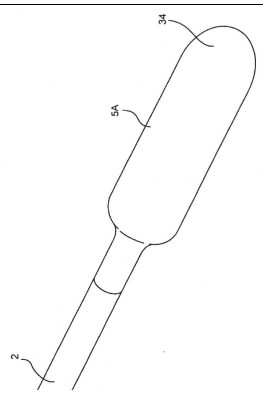
	down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use." (p. 7)  Fig. 8

15. The method of claim 14 further comprising:	
contacting the inner edge portion of the eyelid margin with the swab.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use." (p. 7)  Fig. 8

16. The method of claim 1 wherein the movement of the swab is rotating the swab.	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the

	rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose."

17. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II is used by ophthalmologists, ER physicians and, in many states, optometrists who are trained and licensed to remove foreign bodies from the eye of a patient. Foreign bodies in the eye can leave rust rings when removed. These rust rings are normally caused by a ferrous foreign body accidentally striking the cornea or sclera of the patient. When the foreign body (usually from a spark produced by a grinding wheel or welding torch) strikes the eye it sticks to the eye and eventually produces rust when combined with the moisture in the eye. The ALGERBRUSH II is used for the expressed purpose of removing these rust rings from the eye of a patient." "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose. The ALGERBRUSH II has been CE marked since 1998." The fact that the AlgerBrush can be used on both the cornea and sclera shows that it is intended to be used on different types of tissues of the eye. Algerbrush-II-Operating-Instruction-Rev-3_2012:  2007/0049860: "[0081] FIG. 20 shows an embodiment of the invention wherein the expandable sponge 5A has a taper 34 at the distal portion and is attached to handle 2. This is essentially a bullet-shaped sponge."

	 Every normal eye has an eyelid margin.
effecting movement of the swab relative to the electromechanical device;	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose."
while the swab is being moved by the electromechanical device, contacting at least an inner edge portion of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose." http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"Reasons for cleaning eyelids** • **Basic eye hygiene**: to remove any discharge before instillation of eye drops or applying eye ointment, or before applying post-operative eye dressings. • **Blepharitis**: to remove crusting on the eyelid margins." (p. 1) **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution.

	• With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)

B. Ground 2: Claims 1-11 and 14-17 are unpatentable under 35 U.S.C. § 103(a) over Alger Brush II in view of Hamburg.

The Alger Brush was invented in 1970. It is an electromechanical motor that rotates a specialized burr. The burr is used to brush away rust rings from the eye. Such rust rings form when the eye is struck by a metallic object such as a spark, thereby damaging the tissue. Removal of the rust ring leaves a smoother surface, which facilitates faster healing. (Ex. 1013)

The obviousness of adapting the Alger Brush to clean eyelid margins is explicitly admitted by the Patent Owner. In regard to the choice of electromechanical device, the '718 patent discloses:

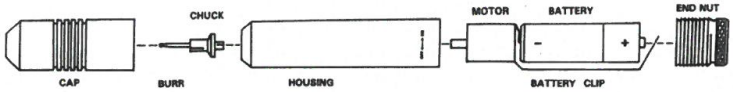
> For instance, operators within the professional clinic setting may desire a durable, reusable mechanical drive unit 12 and single-use instruments 22. Some examples of such a professional mechanical drive unit 12 is an

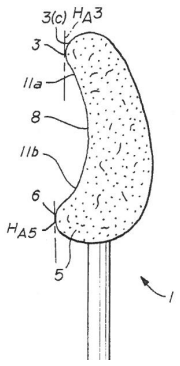
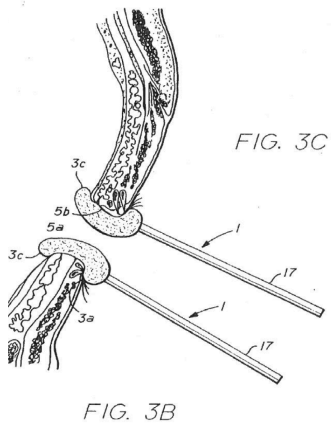
> Algerbrush I, an Algerbrush II, or similar medical device. (Ex. 1001, Col. 5, lines 14-20)

The burr used with the Alger Brush is either carbide or fine grit diamond depending on the specific application. (Ex. 1014, Ex. 1015) While such materials are appropriate for debriding rust rings from damaged tissue, they may too abrasive for removing cellular debris and hardened sebaceous secretions from an eyelid margin. Any eye care specialist would recognize that a softer material can be used to remove such debris from the eyelid margin.

Hamburg (U.S. Pat. No. 4,883,454) discloses a swab specifically designed to clean the eyelid margin, including the meibomian orifices. (Ex. 1011, Col. 1, lines 9-12) The swab is constructed from a porous, sponge-like material that has its own memory of configuration and can retain its shape even when saturated with liquid or medicant. (Ex. 1018, Col. 2, lines 54-65) The swab is applied to the interior surface of the eyelid margin to remove meibomian secretions and other cellular debris. (Ex. 1018, Col. 3, lines 4-11)

The motivation to combine the Alger Brush with Hamburg to treat a condition such as blepharitis is so obvious that it almost does not require explicit statement. The '718 patent admits that the Alger Brush is an obvious device to adapt for cleaning eyelid margins. All that is needed is to replace the burr with an appropriate contact element better suited to cleaning debris from the eyelid margin without irritating the tissue. The Hamburg swab is specifically designed for that purpose.

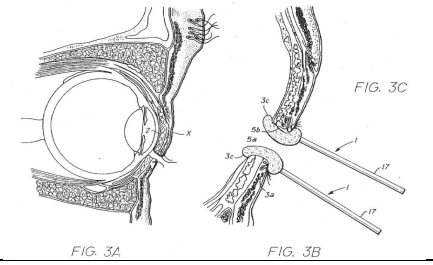
'718 Patent Claims	**Alger Brush II and Hamburg**
1. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II is used by ophthalmologists, ER physicians and, in many states, optometrists who are trained and licensed to remove foreign bodies from the eye of a patient. Foreign bodies in the eye can leave rust rings when removed. These rust rings are normally caused by a ferrous foreign body accidentally striking the cornea or sclera of the patient. When the foreign body (usually from a spark produced by a grinding wheel or welding torch) strikes the eye it sticks to the eye and eventually produces rust when combined with the moisture in the eye. The ALGERBRUSH II is used for the expressed purpose of removing these rust rings from the eye of a patient." "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose. The ALGERBRUSH II has been CE marked since 1998." The fact that the AlgerBrush can be used on both the cornea and sclera shows that it is intended to be used on different types of tissues of the eye. Algerbrush-II-Operating-Instruction-Rev-3_2012:  Pat. No. 4,883,454: "More particularly, the invention is directed to a pre-prepared medicinal swab specifically devised for ophthalmic use by application of the operative surface of the swab simultaneously to the anterior and posterior lid margin surface, including the meibomian orifices." (Col. 1, lines 8-12)

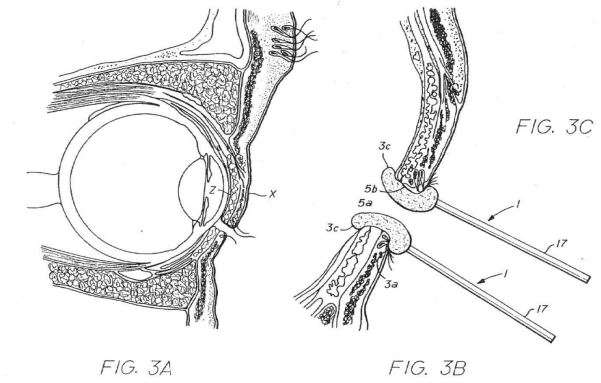
	Every normal eye has an eyelid margin.
effecting movement of the swab relative to the electromechanical device, the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin;	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose." Pat. No. 4,883,454:  "The peak 3c is intended for contact with the upper or lower interior surface of the eyelid margin and is comparatively wide throughout its lateral dimension 7 so that such interior surface of the eyelid can be gently contacted therewith in minimum sequential dabs across the lateral dimension of the muscle so as to remove the lipid meibomian secretions or other cellular debris." (Col. 3, lines 4-11)
while the swab is being moved by the electromechanical device, contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.	Pat. No. 4,883,454:  FIG. 3B "Frequently, however, cellular and sebaceous debris builds up along either the anterior or posterior lid margin and adjacent lashes. It has been shown that a mechanical action to remove the debris from the affected is an effective treatment for this condition. In such a case it is necessary to initiate direct contact with the lid margin to accomplish cleansing thereof. In that event, the special swab of the invention becomes a necessity, and, due to the construction and configuration thereof, there is provided a marked improvement over presently known swabs in the ability to efficiently cleanse the eyelid margin. The three-dimensional configuration, as well as flexible material used, assures adequate treatment of all affected areas and structures of the lid margin." (Col. 2, lines 3-17)

	"The configuration of the swab facilitates the dabbing application of the swab on the eyelid margin as it is sequentially moved laterally across the exterior and lower surfaces thereof." (Col. 3, lines 49-52)

2. The method of claim 1 wherein the eye has a meibomian gland and removing debris further includes at least one of:	Pat. No. 4,883,454: "More particularly, the invention is directed to a pre-prepared medicinal swab specifically devised for ophthalmic use by application of the operative surface of the swab simultaneously to the anterior and posterior lid margin surface, including the meibomian orifices." (Col. 1, lines 8-12)
scrubbing the eyelid margin;	Pat. No. 4,883,454: "Frequently, however, cellular and sebaceous debris builds up along either the anterior or posterior lid margin and adjacent lashes. It has been shown that a mechanical action to remove the debris from the affected is an effective treatment for this condition. In such a case it is necessary to initiate direct contact with the lid margin to accomplish cleansing thereof. In that event, the special swab of the invention becomes a necessity, and, due to the construction and configuration thereof, there is provided a marked improvement over presently known swabs in the ability to efficiently cleanse the eyelid margin." (Col. 2, lines 3-14) "The peak 3c is intended for contact with the upper or lower interior surface of the eyelid margin and is comparatively wide throughout its lateral dimension 7 so that such interior surface of the eyelid can be gently contacted therewith in minimum sequential dabs across the lateral dimension of the muscle so as to remove the lipid meibomian secretions or other cellular debris." (Col. 3, lines 4-11) "The configuration of the swab facilitates the dabbing application of the swab on the eyelid margin as it is sequentially moved laterally across the exterior and lower surfaces thereof." (Col. 3, lines 49-52) "7. An improved swab for use on the eyelid margin for treatment of disease and/or irritation thereto by facilitating removal of cellular and sebaceous debris buildup along either the anterior or exterior lid margin and adjacent lashes with a mechanical action while minimizing contact

	to and irritation of the treated area comprising:" (Col. 5, lines 25-30)
exfoliating the eyelid margin;	See above.
buffing the eyelid margin;	See above.
un-roofing the meibomian gland; or	See above.
breaking the debris free of the eyelid margin.	See above.

3. The method of claim 1 wherein the eye has an eyeball and further includes accessing the eyelid margin for contacting the swab to the debris without lifting the eyelid margin from the eye.	Pat. No. 4,883,454:  As shown, the eyelids are not lifted during application of the swab.

4. The method of claim 1 wherein the eye has an eyeball and further includes:	Every normal eye has an eyeball.
positioning the swab near the eyeball along the eyelid margin; and	Pat. No. 4,883,454: 
targeting the debris with the swab.	Pat. No. 4,883,454: "The peak 3c is intended for contact with the upper or lower interior surface of the eyelid margin and is comparatively wide throughout its lateral dimension 7 so that such interior surface of the eyelid can be gently

	contacted therewith in minimum sequential dabs across the lateral dimension of the muscle so as to remove the lipid meibomian secretions or other cellular debris." (Col. 3, lines 4-11)

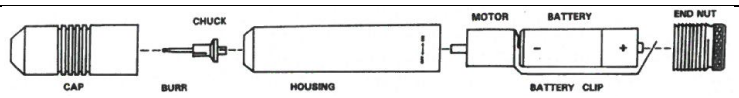
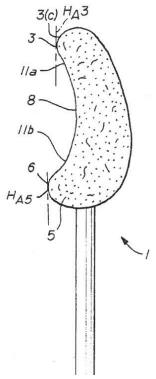
5. The method of claim 1 further including viewing the eye and the debris without the aid of a magnification device.	The swab disclosed in Hamburg does not require the use of a magnification device.

6. The method of claim 1 wherein the movement of the swab is at least one of rotating the swab, vibrating the swab, or reciprocating the swab.	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose."

7. The method of claim 1 wherein effecting movement of the swab further includes setting the movement of the swab to a desirable speed sufficient to remove the debris from the eye.	Obvious. If the speed is not sufficient to remove debris, why build and use the device at all?

8. The method of claim 1 further including repeating the effecting movement, the contacting the portion of the eye, and impacting the debris with the swab to remove the debris process of claim 1 after periodic intervals until the ocular disorder is sufficiently remedied.	Obvious. Recurring treatment of a medical condition until its resolution has been basic to medical practice for millennia. (See Hippocrates of Kos, *On Regimen in Acute Diseases*, c. 400 BC)

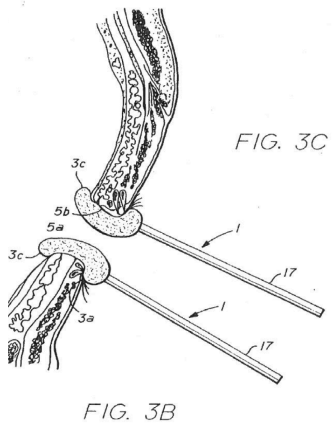
9. The method of claim 1	Algerbrush-II-Operating-Instruction-Rev-3_2012:

wherein the swab is connected to a rigid member having a proximal end portion, the method further comprising:	 Pat. No. 4,883,454: 
securing the proximal end portion of the rigid member to the electromechanical device; and	Algerbrush-II-Operating-Instruction-Rev-3_2012: "Installation of Chuck and Burr Assembly: *** Note: Motor must be spinning when installing chuck and burr assembly to ensure motor seated properly • To install, ensure motor is spinning, i.e., ALGERBRUSH II is "ON" 1) Gently push chuck and burr assembly onto motor shaft 2) Base of chuck should be close to, but not touching, top of housing 3) Turn "OFF" ALGERBRUSH II until ready to use" (p. 1)
removing the proximal end portion of the rigid member from the electromechanical device.	Algerbrush-II-Operating-Instruction-Rev-3_2012: "To remove, 1) Grasp base of chuck with fingers and pull away from motor shaft - or - 2) Gently pry chuck off motor shaft with suitable instrument 3) Turn "OFF" ALGERBRUSH II until ready to use" (p. 1)

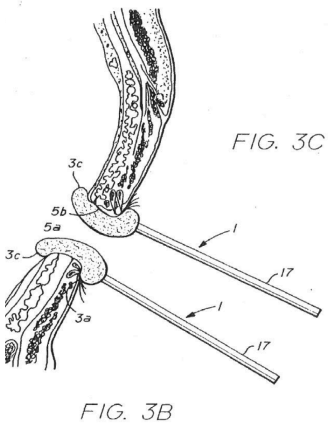
10. The method of claim 9 further comprising:	
removing the proximal end portion of the rigid member after a single use	Obvious. Single use swabs have been used in medicine for decades. In fact, reusable swabs are virtually unheard of.

of the swab; and	
repeating the securing and removing of another proximal end portion of another rigid member.	See above.

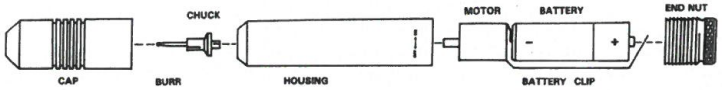
11. The method of claim 1 wherein the swab is a medical grade sponge for accessing the eyelid margin.	Pat. No. 4,883,454: "The improved swab as shown in FIG. 1 is constructed from a lightweight, porous, soft, sponge-like material which may include genuine sponge, a soft lightweight plastic, or other material which is absorbent in nature and capable of retaining a liquid or ointment content therein and of retaining its configuration while so doing. The material of the swab should have its own memory of configuration. It is essential to the invention that the character of the material of the swab be capable of retaining its specific shape when moist and even when saturated with an antibiotic, steroid, or other medicant, as described hereinafter." (Col. 2, lines 54-65)

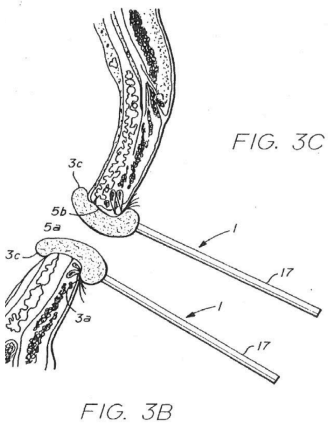
14. The method of claim 1 further comprising:	
accessing at least an inner edge portion of the eyelid margin with the swab.	Pat. No. 4,883,454:  FIG. 3C FIG. 3B "Frequently, however, cellular and sebaceous debris builds up along either the anterior or posterior lid margin and adjacent lashes. It has been shown that a mechanical action to remove the debris from the affected is an effective treatment for this condition. In such a case it is necessary to initiate direct contact with the lid margin to accomplish cleansing thereof. In that event, the special swab of the invention becomes a necessity, and, due to the construction and configuration thereof, there is provided a marked improvement over presently known swabs in the ability to efficiently cleanse the eyelid margin. The three-dimensional configuration, as well as flexible material used, assures adequate treatment of all affected areas and

	structures of the lid margin." (Col. 2, lines 3-17) "The configuration of the swab facilitates the dabbing application of the swab on the eyelid margin as it is sequentially moved laterally across the exterior and lower surfaces thereof." (Col. 3, lines 49-52)

15. The method of claim 14 further comprising:	
contacting the inner edge portion of the eyelid margin with the swab.	Pat. No. 4,883,454:  FIG. 3C FIG. 3B "Frequently, however, cellular and sebaceous debris builds up along either the anterior or posterior lid margin and adjacent lashes. It has been shown that a mechanical action to remove the debris from the affected is an effective treatment for this condition. In such a case it is necessary to initiate direct contact with the lid margin to accomplish cleansing thereof. In that event, the special swab of the invention becomes a necessity, and, due to the construction and configuration thereof, there is provided a marked improvement over presently known swabs in the ability to efficiently cleanse the eyelid margin. The three-dimensional configuration, as well as flexible material used, assures adequate treatment of all affected areas and structures of the lid margin." (Col. 2, lines 3-17) "The configuration of the swab facilitates the dabbing application of the swab on the eyelid margin as it is sequentially moved laterally across the exterior and lower surfaces thereof." (Col. 3, lines 49-52)

16. The method of claim 1 wherein the movement of the swab is rotating the swab.	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose."

17. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II is used by ophthalmologists, ER physicians and, in many states, optometrists who are trained and licensed to remove foreign bodies from the eye of a patient. Foreign bodies in the eye can leave rust rings when removed. These rust rings are normally caused by a ferrous foreign body accidentally striking the cornea or sclera of the patient. When the foreign body (usually from a spark produced by a grinding wheel or welding torch) strikes the eye it sticks to the eye and eventually produces rust when combined with the moisture in the eye. The ALGERBRUSH II is used for the expressed purpose of removing these rust rings from the eye of a patient." "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose. The ALGERBRUSH II has been CE marked since 1998." The fact that the AlgerBrush can be used on both the cornea and sclera shows that it is intended to be used on different types of tissues of the eye. Algerbrush-II-Operating-Instruction-Rev-3_2012:  Pat. No. 4,883,454: "More particularly, the invention is directed to a pre-prepared medicinal swab specifically devised for ophthalmic use by application of the operative surface of the swab simultaneously to the anterior and posterior lid margin surface, including the meibomian orifices." (Col. 1, lines 8-12) Every normal eye has an eyelid margin.

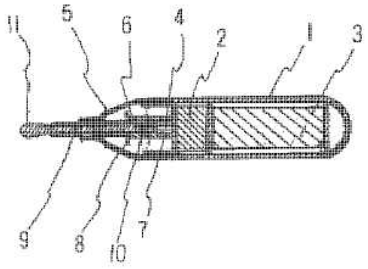
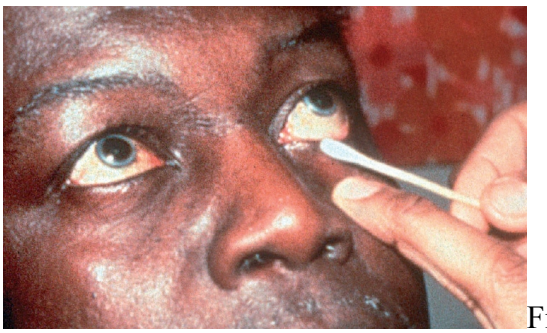
effecting movement of the swab relative to the electromechanical device;	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose."
while the swab is being moved by the electromechanical device, contacting at least an inner edge portion of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.	http://www.algercompany.com/brush/product-info/: "The ALGERBRUSH II has a very low torque motor powered by a single AA battery. The burr in this rotary instrument is used as a "brush" rather than a drill and the rust ring is thus "brushed" from the cornea or sclera leaving a smooth surface which in turn heals much faster than with other instruments which may be used for this purpose." Pat. No. 4,883,454:  FIG. 3C FIG. 3B "Frequently, however, cellular and sebaceous debris builds up along either the anterior or posterior lid margin and adjacent lashes. It has been shown that a mechanical action to remove the debris from the affected is an effective treatment for this condition. In such a case it is necessary to initiate direct contact with the lid margin to accomplish cleansing thereof. In that event, the special swab of the invention becomes a necessity, and, due to the construction and configuration thereof, there is provided a marked improvement over presently known swabs in the ability to efficiently cleanse the eyelid margin. The three-dimensional configuration, as well as flexible material used, assures adequate treatment of all affected areas and structures of the lid margin." (Col. 2, lines 3-17) "The configuration of the swab facilitates the dabbing application of the swab on the eyelid margin as it is sequentially moved laterally across the exterior and lower surfaces thereof." (Col. 3, lines 49-52)

C. Ground 3: Claims 1-10 and 14-17 are unpatentable under 35 U.S.C. § 103(a) over Yamaura in view of Stevens.

Yamaura (JPH10108801) discloses a handheld electromechanical device for cleaning earwax from ear canals. The device comprises a swab (11) inserted into a pipe (9) that is attached to a rotary shaft (4) coupled to a motor (2). (Ex. 1019, Solution to Problem, Claim 1, Images 1 and 2) It is worth noting that ear canals and eyelids both have sebaceous glands, a fact that would be well known by any health care specialist of skill in the art. The Yamaura device could be used to clean the margins of the eyelid according to the method of the '718 patent with no modification.

Motivation to use the Yamaura device to clean eyelid margins is provided by Sue Stevens in the article "How to clean eyelids" published by the *Community Eye Health Journal* and republished by the National Institute of Health. Stevens explains and illustrates how to remove crusting on the eyelid margins in cases of blepharitis using a swab soaked in a solution. (Ex. 1017, Figs. 8 and 10) The '718 patent uses the same method, the only difference being the use of an electromechanical device to move the swab. Though not designed specifically to clean the eyelid margin, the Yamaura device is designed to remove sebaceous secretions and uses a motorized swab for this purpose. Using Yamaura to clean eyelid margins requires little if any modification.

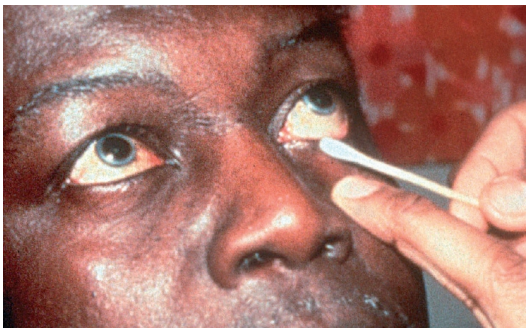
'718 Patent Claims	**Yamaura and Stevens**
1. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device,	JPH10108801: "[Claim 1] The attachment (6) is mounted to the rotating shaft at the tip (4) of the body (1) with a built-in electric motor (2) and a battery (3), and fixated to the body (1) using a cap (5). The attachment (6) is comprised of an

wherein the eye has an eyelid margin and includes a removable debris, the method comprising:	engagement hole (7) which engages with the rotating shaft at the tip (4), a flange (8) and a cotton swab holder pipe (9). The flange (8) provides cotton swab idle-spin prevention (10) at its foot. This invention is characterized by electric ear-cleaning with a cotton swab (11) being inserted into the tip of the cotton swab holder pipe (9)." (p. 2)  Every normal eye has an eyelid margin.
effecting movement of the swab relative to the electromechanical device, the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin;	JPH10108801: "The body (1) has a rotating shaft protruding from the electric motor (2), which has a rectangular plastic component fixated to form the rotating shaft at the tip (4). The rotating shaft at the tip (4) is inserted into the engagement hole (7) of the attachment (6) to spin." (¶ 0009, p. 3) A swab small enough to be inserted into the ear canal (as taught in Yamaura) is small enough to access the inner edge of the eyelid margin as illustrated below in Fig. 8 from Stevens. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/:  Fig. 8

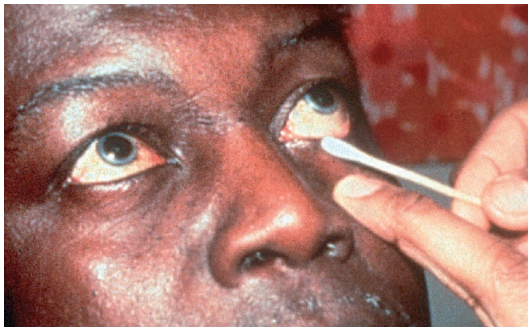
while the swab is being moved by the electromechanical device, contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"Reasons for cleaning eyelids** • **Basic eye hygiene**: to remove any discharge before instillation of eye drops or applying eye ointment, or before applying post-operative eye dressings. • **Blepharitis**: to remove crusting on the eyelid margins." (p. 1) **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)

2. The method of claim 1 wherein the eye has a meibomian gland and removing debris further includes at least one of:	All normal eyelids have a meibomian gland.
scrubbing the eyelid margin;	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up.

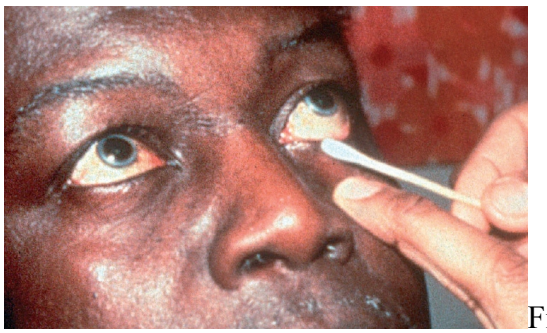
	• With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)
exfoliating the eyelid margin;	See above.
buffing the eyelid margin;	See above.
un-roofing the meibomian gland; or	See above.
breaking the debris free of the eyelid margin.	See above.

3. The method of claim 1 wherein the eye has an eyeball and further includes accessing the eyelid margin for contacting the swab to the debris without lifting the eyelid margin from the eye.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/:  Fig. 8

	As shown, the eyelids are not lifted from the eye during application of the swab.

4. The method of claim 1 wherein the eye has an eyeball and further includes:	Every normal eye has an eyeball.
positioning the swab near the eyeball along the eyelid margin; and	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: 
targeting the debris with the swab.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"Reasons for cleaning eyelids** • **Basic eye hygiene**: to remove any discharge before instillation of eye drops or applying eye ointment, or before applying post-operative eye dressings. • **Blepharitis**: to remove crusting on the eyelid margins." (p. 1) **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease

	the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)

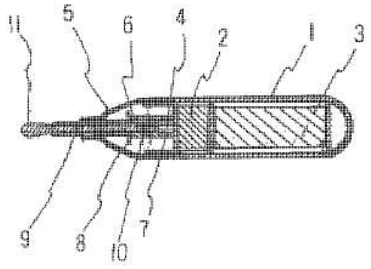
5. The method of claim 1 further including viewing the eye and the debris without the aid of a magnification device.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: The method described and shown in the article by Sue Stevens does not require the use of a magnifying device as shown below.  Fig. 8

6. The method of claim 1 wherein the movement of the swab is at least one of rotating the swab, vibrating the swab, or reciprocating the swab.	JPH10108801: "The body (1) has a rotating shaft protruding from the electric motor (2), which has a rectangular plastic component fixated to form the rotating shaft at the tip (4). The rotating shaft at the tip (4) is inserted into the engagement hole (7) of the attachment (6) to spin." (¶ 0009, p. 3)

7. The method of claim 1 wherein effecting movement of the swab further includes setting the movement of the swab to a desirable speed sufficient to remove the debris from the eye.	Obvious. If the speed is not sufficient to remove debris, why build and use the device at all?

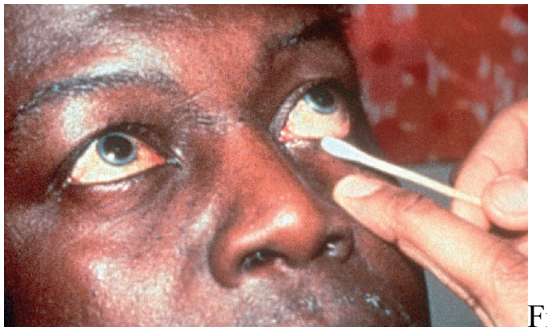
8. The method of claim 1 further including repeating the effecting movement, the	Obvious. Recurring treatment of a medical condition until its resolution has been basic to medical practice for millennia. (See Hippocrates of Kos, *On Regimen in Acute*

contacting the portion of the eye, and impacting the debris with the swab to remove the debris process of claim 1 after periodic intervals until the ocular disorder is sufficiently remedied.	*Diseases*, c. 400 BC)

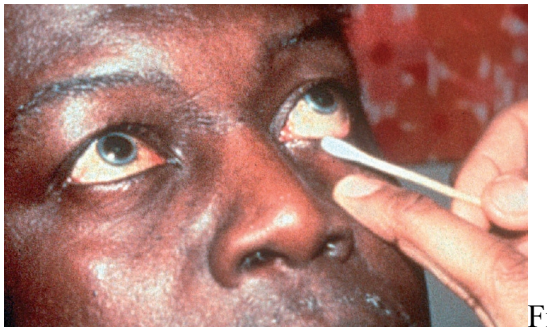
9. The method of claim 1 wherein the swab is connected to a rigid member having a proximal end portion, the method further comprising:	JPH10108801: "This invention is characterized by electric ear-cleaning with a cotton swab (11) being inserted into the tip of the cotton swab holder pipe (9)." (Claim 1, p. 2) 
securing the proximal end portion of the rigid member to the electromechanical device; and	JPH10108801: "[0005] The attachment (6) is comprised of an engagement hole (7) to engage with the rotating shaft at the tip (4), a flange (8) and a cotton swab holder pipe (9). Cotton swab idle-spin prevention (10) is provided at the foot of the flange (8), and the attachment (6) is fixated to the body (1) with a cap (5). A cotton swab (11) is inserted into the cotton swab holder pipe (9) or removed from the tip after the attachment (6) is fixated to the body (1), so the cap (5) does not need to be detached from the body (1) every time the appliance is used." (p. 3)
removing the proximal end portion of the rigid member from the electromechanical device.	See above.

10. The method of claim 9 further comprising:	
removing the proximal end portion of the rigid	JPH10108801: "The cotton swab (11) must be disposable, meaning that it

member after a single use of the swab; and	cannot be permanently fixated to the body (1) and must be replaceable." (p. 3) Single use swabs have been used in medicine for decades. In fact, reusable swabs are virtually unheard of.
repeating the securing and removing of another proximal end portion of another rigid member.	See above.

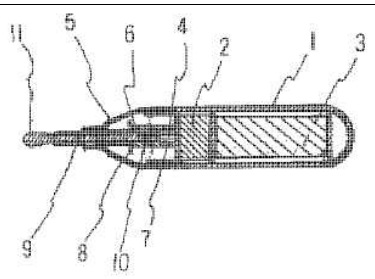
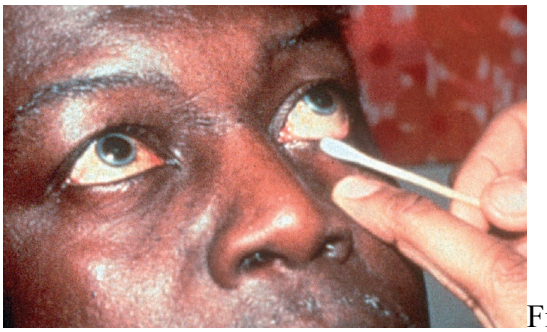
14. The method of claim 1 further comprising:	
accessing at least an inner edge portion of the eyelid margin with the swab.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use." (p. 7)  Fig. 8

15. The method of claim 14 further comprising:	
contacting the inner edge portion of the eyelid margin with the swab.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"2 The lower eyelid** • Ask the patient to look up. • With one hand, take a new swab or bud and moisten it

	in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use." (p. 7)  Fig. 8

16. The method of claim 1 wherein the movement of the swab is rotating the swab.	JPH10108801: "The body (1) has a rotating shaft protruding from the electric motor (2), which has a rectangular plastic component fixated to form the rotating shaft at the tip (4). The rotating shaft at the tip (4) is inserted into the engagement hole (7) of the attachment (6) to spin." (¶ 0009, p. 3)

17. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising:	JPH10108801: "[Claim 1] The attachment (6) is mounted to the rotating shaft at the tip (4) of the body (1) with a built-in electric motor (2) and a battery (3), and fixated to the body (1) using a cap (5). The attachment (6) is comprised of an engagement hole (7) which engages with the rotating shaft at the tip (4), a flange (8) and a cotton swab holder pipe (9). The flange (8) provides cotton swab idle-spin prevention (10) at its foot. This invention is characterized by electric ear-cleaning with a cotton swab (11) being inserted into the tip of the cotton swab holder pipe (9)." (p. 2)

	 Every normal eye has an eyelid margin.
effecting movement of the swab relative to the electromechanical device;	JPH10108801: "The body (1) has a rotating shaft protruding from the electric motor (2), which has a rectangular plastic component fixated to form the rotating shaft at the tip (4). The rotating shaft at the tip (4) is inserted into the engagement hole (7) of the attachment (6) to spin." (¶ 0009, p. 3) A swab small enough to be inserted into the ear canal (as taught in Yamaura) is small enough to access the inner edge of the eyelid margin as illustrated below in Fig. 8 from Stevens. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/:  Fig. 8
while the swab is being moved by the electromechanical device, contacting at least an inner edge portion of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3218399/: **"Reasons for cleaning eyelids** • **Basic eye hygiene**: to remove any discharge before instillation of eye drops or applying eye ointment, or before applying post-operative eye dressings. • **Blepharitis**: to remove crusting on the eyelid margins." (p. 1) **"2 The lower eyelid** • Ask the patient to look up.

eye.	• With one hand, take a new swab or bud and moisten it in the solution. • With the index finger of the other hand, gently hold down the lower eyelid. • With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8). • Discard the swab or bud after use. **3 The upper eyelid** **Note**: extra care is needed when cleaning the upper eyelid margin. Try to keep the cornea in view throughout and avoid touching it with the swab or bud. • Ask the patient to look down. • With one hand, take a new swab or bud and moisten it in the solution. • With a thumb or finger of the other hand, gently ease the upper eyelid up against the orbital rim (just below the eyebrow), taking care not to put any pressure on the eyeball. • With the swab or bud, clean gently along the upper eyelid margin in one movement from inner to outer canthus (Figures 9 and 10). • Discard the swab or bud after use." (pp. 7-8)

D. Ground 4: Claims 1-11 and 14-17 are unpatentable in view of the prosecution history of U.S. Patent Application No.: 13/949,365.

As noted above, the '365 Application is a continuation-in-part of the '718 Patent, covering apparatus claims corresponding to the method claims of the '718 Patent. During prosecution of the '365 Application, Patent Owner specifically amended the claims to more narrowly define the swab as a medical grade sponge in an attempt to distinguish it from the prior art. (Ex. 1005, pp. 248-249) Yet despite the amendments, the examiner still rejected the claims over the prior art references, some of which are cited above.

It stands to reason that if the more narrowly defined claim limitations of the '365 Application are unable to overcome the prior art, then the broader claims of the '718

Patent are invalid in view of the same references, which were not brought to the examiner's attention until after the '718 Patent issued.

XII. CONCLUSION

For the reasons set forth above, and as supported by the technical expert testimony of Dr. Benjamin, claims 1-11 and 14-17 of the '718 patent are rendered obvious by the prior art cited in this Petition. Petitioner has established a reasonable likelihood of prevailing on each ground. Accordingly, prompt and favorable consideration of this Petition and institution of an *Inter Partes* Review is respectfully requested.

Dated: August 24, 2016

Respectfully Submitted,

By /Steven E. Ross/
Steven E. Ross
Reg. No. 35,996
Ross IP Group PLLC
1700 Pacific Ave., Suite 3750
Dallas, TX 75201
(214) 382-0901

By /Michael A. Rahman/
Michael A. Rahman
Reg. No. 43,872
Ross IP Group PLLC
1700 Pacific Ave., Suite 3750
Dallas, TX 75201
(214) 382-0895

By /Christopher P. O'Hagan/
Christopher P. O'Hagan
Reg. No. 46,966
Ross IP Group PLLC
1700 Pacific Ave., Suite 3750
Dallas, TX 75201
(214) 445-6073

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by U.S. Express Mail directed to the attorneys of record for the '718 Patent at the following address:

Paul J. Linden
WOOD HERRON & EVANS, LLP
441 Vine Street
2700 Carew Tower
Cincinnati, Ohio 45202

Dated: August 24, 2016

____/Steven E. Ross/____
Steven E. Ross