

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NULIDS, LLC,

Petitioner

v.

BLEPHEX, LLC,

Patent Owner

U.S. Patent No. 11,083,621

Issue Date: August 10, 2021

Title: INSTRUMENT FOR TREATING AN OCULAR DISORDER

CASE: IPR2024-00764

Petition for Inter Partes Review of U.S. Patent No. 11,083,621

**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT
NO. 11,083,621**

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,083,621 (“the ’621 Patent”)
1002	Declaration of Dr. Robert Cykiert
1003	CV of Dr. Robert Cykiert
1004	Court, Deposition & Arbitration Testimony of Dr. Robert Cykiert
1005	U.S. Patent Pub. No. 2007/0060988 (“Grenon I”)
1006	U.S. Patent Pub. No. 2007/0016254 (“Grenon II”)
1007	U.S. Patent Pub. No. 2013/0331768 (“Nichamin”)
1008	PCT Pub. No. WO 2009/066077 (“Colin”)
1009	U.S. Patent No. 4,838,851 (“Shabo”)
1010	Soft Definition & Meaning Britannica Dictionary
1011	Buff Definition & Meaning Britannica Dictionary
1012	Eyelid Margin Diagram

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I. INTRODUCTION

Petitioner NuLids, LLC (“Petitioner”) respectfully requests inter partes review (“IPR”) of Claims 1-6, and 9-18 (the “Challenged Claims”) of U.S. Patent No. 11,083,621 (“the ’621 Patent,” EX1001).

The ’621 Patent describes a method and apparatus for treating an ocular disorder. EX1001, Abstract. The basic outline of this apparatus is taught in the prior art references, which provide methods and apparatuses for treating ocular disorders through the removal of debris from the eyelid margins. This removal was done by contacting the debris with a contact member, such as a swab, to mechanically remove the debris.

It is clearly evident that the ’621 Patent would have been obvious to a person of ordinary skill in the art and would not have been permitted to issue, had the examiner been aware of the prior art references during prosecution. And, as demonstrated in detail below, the ’621 Patent should be found unpatentable.

II. GROUND FOR STANDING PURSUANT TO 37 C.F.R. § 42.104(A) & § 42.102

Petitioner certifies that the ’621 Patent is eligible for IPR and that Petitioner is not barred or estopped from requesting an IPR challenging the claims on the grounds identified herein. For the reasons discussed below, at least one claim of the ’621 Patent has an effective filing date on or after July 24, 2012, such that IPR is

eligible. This Petition is filed more than nine months after the issuance of the ‘621 Patent.

A. Overview Of The '621 Patent

The swab (14), described as a medical grade sponge, has a tip portion and a base portion, wherein the tip portion is capable of removing debris from the eye without harming the eye. EX1001 at 3:51-4:5. The debris is removed by contacting

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the swab (14) to a portion of the eyelid that includes the debris and the mechanical drive unit moving the swab (14) to impact the debris. EX1001 at 4:42-46.

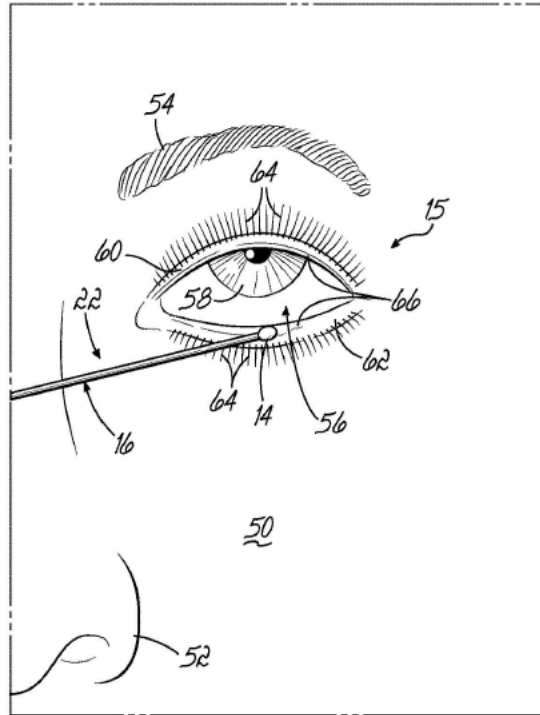


FIG. 5A

EX1001

The '621 Patent describes using a swab (14) connected to the mechanical drive (12) unit to contact a portion of the eye having debris in order to impact and remove the debris according to a claimed method. *See also* EX1002 ¶¶28-32.

B. Prosecution History

During prosecution, the application leading to the '621 Patent was rejected as anticipated by U.S. Patent Pub. No. 2007/0060988 ("Grenon I") and was further

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rejected for double patenting with U.S. Patent No. 9,039,718 (the “’718 Patent”). In response, claims 16-29 were cancelled to overcome Grenon I and a terminal disclaimer to the ’718 Patent was filed. A Notice of Allowance was issued on March 11, 2020. In response to the Notice of Allowance, an RCE and IDS were filed. A subsequent Notice of Allowance was issued on June 24, 2020. In response to the Notice of Allowance, an RCE and amendment to the Claims was filed. The amendment removed the limitation of *unroofing a plurality of meibomian glands along the eyelid margin* from Claim 1 and added the limitation to dependent Claim 2.

A Non-Final Rejection was issued on October 8, 2020, rejecting Claims 1, 2, 4-6, 10-14, and 21-24 as obvious over U.S. Patent Pub. No. 2013/0331768 (“Nichamin”) in view of U.S. Patent Pub. No. 2009/0124985 (“Hasenoehrl”). Claims 7, 8, 9, and 15 were further rejected as obvious over Nichamin in view of Hasenoehrl and further in view of U.S. Patent Pub. No. 2014/0249509 (“Rubinfield”). Claim 3 which included the limitation of *wherein the eye has an eyeball and further includes accessing the eyelid margin for contacting the contact member to the debris without lifting the eyelid margin from the eye*, was objected to for its dependence on a rejected base claim. The Examiner indicated that this limitation would be allowable because Nichamin does not teach *without lifting the eyelid margin from the eye*. But as discussed herein, the prior art references presented

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in this petition that were relied upon for allowance disclose the elements that were relied upon for allowance.

In response, Claim 1 was amended to include the limitation of *without lifting the eyelid margin from the eye*. A Notice of Allowance was issued on March 31, 2021, and the issue fee was paid and the ‘621 Patent was issued.

IV. IDENTIFICATION OF CHALLENGE PURSUANT TO 37 C.F.R. § 42.104(B)

A. 37 C.F.R. § 42.104(b)(1): Claims For Which IPR Is Requested

IPR is requested for Claims 1-6 and 9-18 of the ‘621 Patent.

B. 37 C.F.R. § 42.104(b)(2): The Prior Art And Specific Grounds On Which The Challenge Is Based

1. The Prior Art

All prior art relied on in this Petition was published before the ‘621 Patent’s earliest priority date of July 24, 2012, and is, therefore, prior art to the ‘621 Patent under 35 U.S.C. § 102(a)(1). The following patent literature is prior art to the ‘621 Patent at least under 35 U.S.C. § 102(a)(1):

- **U.S. Patent Pub. No. 2007/0060988** to Grenon *et al.* (“Grenon I”, EX 1005);
- **U.S. Patent Pub. No. 2007/0016254** to Grenon *et al.* (“Grenon II”, EX1006);

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- **U.S. Patent Pub. No.** 2013/0331768 to Nichamin (“Nichamin”, EX1007);
- **PCT Pub. No. WO** 2009/066077 to Colin (“Colin”, EX1008); and
- **U.S. Patent No.** 4,838,851 to Shabo (“Shabo”, EX1009).

2. The Grounds

The specific statutory grounds, claims challenged, and prior art relied upon for each ground are as follows:

Ground #1: Obviousness of Claims 1-3, 5, 9, and 12-15 under 35 U.S.C. § 103 by Grenon I in view of Grenon II and Nichamin;

Ground #2: Obviousness of Claims 1-3, 5, and 12-15 under 35 U.S.C. § 103 by Grenon II in view of Colin;

Ground #3: Obviousness of Claims 1-6 and 9-18 under 35 U.S.C. § 103 by Grenon II in view of Colin and Shabo;

C. 37 C.F.R. § 42.104(b)(3): Claim Construction

For the validity issues raised in this Petition, the claim terms are applicable according to their plain and ordinary means and no claim construction is needed. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1011, 1017 (Fed. Cir. 2017). Petitioner reserves the right to respond to any constructions offered by the Patent Owner.

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D. 37 C.F.R. § 42.104(b)(4): How The Construed Claims Are Unpatentable

An explanation of how the Challenged Claims are unpatentable, including where each claim feature is found in the prior art, is set forth in Section VI.

E. 37 C.F.R. § 42.104(b)(5): Supporting Evidence

A list of exhibits supporting this Petition is at page i. EX1002 is a Declaration of Dr. Robert Cykiert under 37 C.F.R. § 1.68. The relevance of the evidence to the Challenged Claims is included in Section VI.

V. THE CHALLENGED CLAIMS HAVE AN EFFECTIVE FILING DATE OF OCTOBER 1, 2019, AND ARE ELIGIBLE FOR IPR

The '621 Patent was filed on October 1, 2019, and is a continuation of U.S. Application No. 16/352,758 filed March 13, 2019, which is a continuation of 13/949,365 filed July 24, 2013, which is a continuation-in-part of U.S. Application No. 13/556,729 filed July 24, 2012. EX1001. The '621 Patent issued on August 10, 2021, more than nine months before the filing of the Petition. *Id.* Accordingly, the '621 Patent is eligible for IPR.

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**VI. IT IS MORE LIKELY THAN NOT THAT AT LEAST ONE OF THE
CHALLENGED CLAIMS IS UNPATENTABLE**

A. Level of Skill in the Art

A PHOSITA would have a medical degree (M.D. or D.O) or a doctor of optometry degree (O.D.) and three to five years of training and practical experience in the field of eye care. EX1002 ¶¶25-27.

B. Ground 1: Obviousness of Claims 1-5, 9, and 11-15 under 35 U.S.C. § 103 in view of Grenon I, Grenon II, and Nichamin

1. Motivation to Combine

Grenon I and Grenon II are related patents having the same inventors. EX1005 Cover (76), EX1006 Cover (76). Grenon I, which was cited in the prosecution, is directed to the “treatment of mammalian eyes” by relieving obstruction of meibomian glands. EX1005 ¶4. Grenon II is directed to a method “for treating meibomian gland dysfunction wherein the flow of naturally occurring secretions from the meibomian gland is restored.” EX1006 ¶23. Nichamin, which was a prior art reference cited during prosecution, is directed to “a method of treating or preventing an eye condition in eye area tissue.” EX1007 ¶30.

The motivation to combine Grenon I, Grenon II, and Nichamin is inherent in the references. Indeed, the motivation to combine Grenon I and Grenon II is evident in the respective disclosures. Grenon I includes heating and vibration elements that are configured to sit over and contact the outer eyelid. EX1005 ¶128. “[T]he

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application of regulated heating to the eyelids for therapeutic purposes” in Grenon I is provided to assist in the removal of obstructions in the meibomian glands. EX1005

¶4. Other methods that Grenon I’s mechanical device utilize in the removal of obstructions includes the application of “vibration, pulsation, and/or milking action of the eyelid to stimulate secretion from the meibomian glands.” EX1005 ¶34.

Grenon II is a mechanical device similar to Grenon I that includes heating and vibration elements to extract clots and remove debris from the meibomian glands. EX1006 ¶3. The method described in Grenon II “comprises applying a regulated force, regulated energy, regulated heat and/or chemical/pharmacological agent or combinations thereof to the eyelid to remove obstructions.” EX1006 ¶23. Grenon II discloses various embodiments of mechanical devices, including devices configured to contact a portion of the eyelid and eyelid margin to remove the obstructions. One example of such a device is provided in FIG. 5 of Grenon II, which illustrates a probe in contact with a meibomian gland on the eyelid margin to remove the obstructions. EX1006 ¶58.

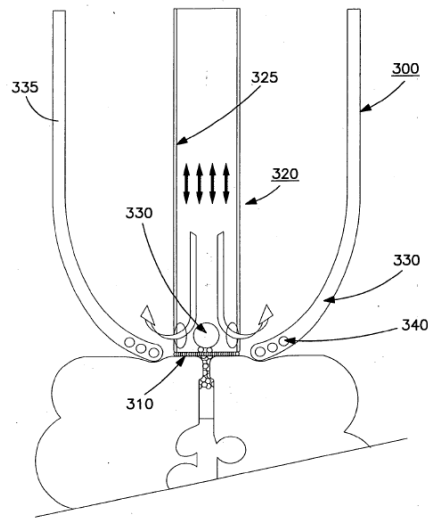


FIG. 5

EX1006

In another embodiment of Grenon II, the mechanical device has an eyelid interface portion that contacts the eyelid and a portion of the eyelid margin to provide heat to the eyelid to dissolve the obstructions and pressure to express the obstruction from the meibomian gland. EX1006 ¶69.

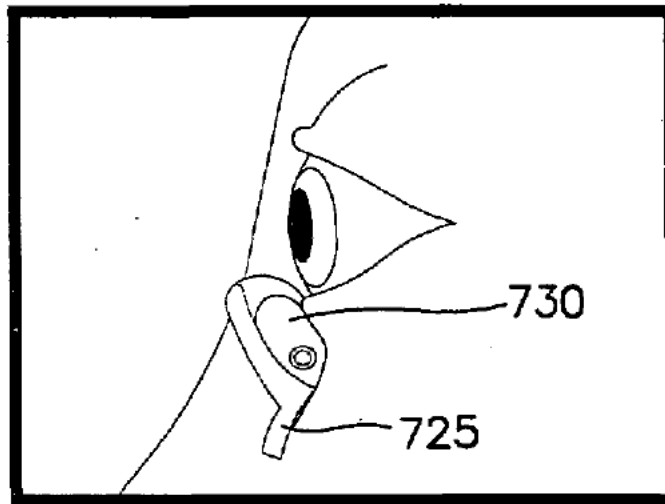


FIG. 11E

EX1006

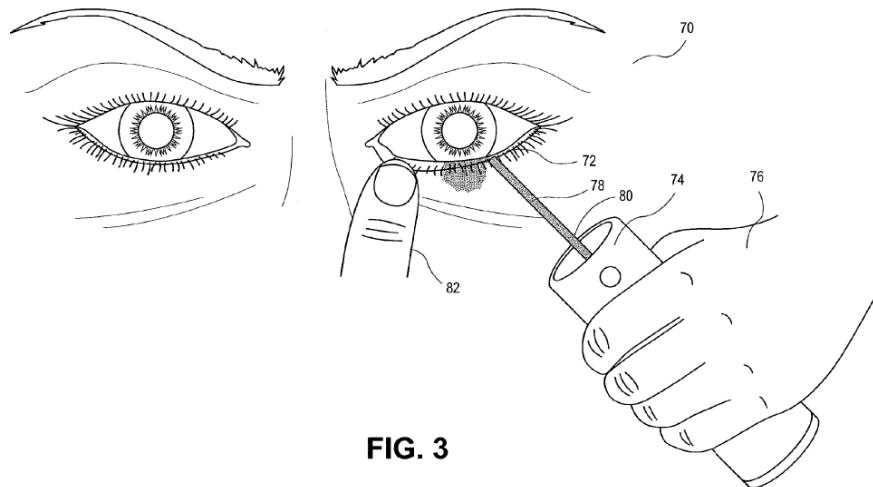
Motivation to combine the mechanical device in FIG. 5 to the device in FIG. 11E is expressly provided in paragraph 70 of Grenon II:

Another embodiment of the invention may employ a chemical agent or compound to clean the glandular margin to remove or exfoliate cells from the gland orifice. A probe similar to that shown in FIG. 5 may be employed, except that the outer drum or roller will deliver the chemical agent and the suction applied by the outer covering will be used to evacuate the used chemical agent and cellular material mixture away from the gland margin. Similarly, the heating and vibrational features discussed above may also be included. EX1006 ¶70.

Therefore, Grenon II expressly provides motivation to combine a probe with an eyelid heater and massager.

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Nichamin is directed to a mechanical device for removing debris from meibomian glands of the eyelid margin. EX1007 ¶48. Nichamin has an applicator extending from an electromechanical device to permit movement of the applicator, such as rotation and vibration, along the eyelid margin. EX1007 ¶54. An ordinary artisan would recognize that the applicator in Nichamin is similar to the probe in Grenon II and would have been motivated to modify the disclosure of Grenon II to include the movement of the applicator described in Nichamin. *Id.*, EX1006 ¶¶23, 69-70.

**EX1007**

A person having ordinary skill in the art (PHOSITA) would be motivated to combine the disclosures in Grenon I, Grenon II, and Nichamin according to the teachings of Grenon II. EX1005 ¶34, EX1007 ¶54, EX1006 ¶¶23, 69-70. Namely,

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the PHOSITA would be motivated to combine the mechanical devices of Grenon I, Grenon II, and Nichamin to provide a mechanical device for the treatment of ocular disorders, such as blepharitis. *See also* EX1002 ¶¶67-68.

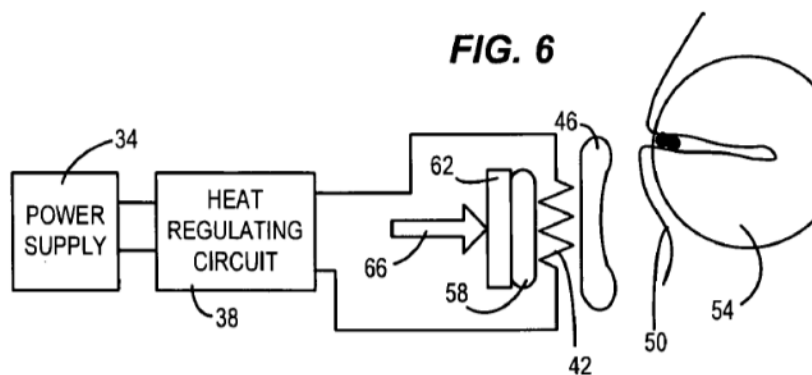
2. Independent Claim 1

a. “A method of treating an eye for an ocular disorder”

To the extent the preamble is limiting, each of Grenon I, Grenon II, and Nichamin disclose this limitation. As discussed above under motivation to combine, Grenon I teaches that its “invention relates generally to treatment of mammalian eyes.” EX1005 ¶4. Likewise, Grenon II and Nichamin each disclose methods for treating eye disorders. EX1006 ¶23, EX1007 ¶30. It is abundantly clear from these references that insofar as the preamble is limiting, Grenon I, Grenon II, and Nichamin each disclose this limitation. *See also* EX1002 ¶69.

b. “with a contact member comprising a soft and resilient material”

The preamble further provides that the treatment occurs “with a contact member comprising a soft and resilient material.” To the extent that this limitation in the preamble is considered limiting, this limitation is taught in Grenon I. Grenon I discloses a heat sink (46) that contacts the eyelid where the heat sink is “a flexible silicon member that flexes (along the heating element in some embodiments) to conform to the shape of the eyelid being treated.” EX1005 ¶87, FIG. 6.



EX1005

The Britannica Dictionary defines soft as “easy to press, bend, cut, etc.: not hard or firm.” EX1010. As Grenon I disclosed that its heat sink is a flexible silicone configured to shape to the eyelid, the ordinary definition of soft is taught. Further, as a PHOSITA will appreciate, flexible silicone is a resilient material, configured to shape to a surface when applied, but able to return to its normal state when removed. EX1002 ¶38.

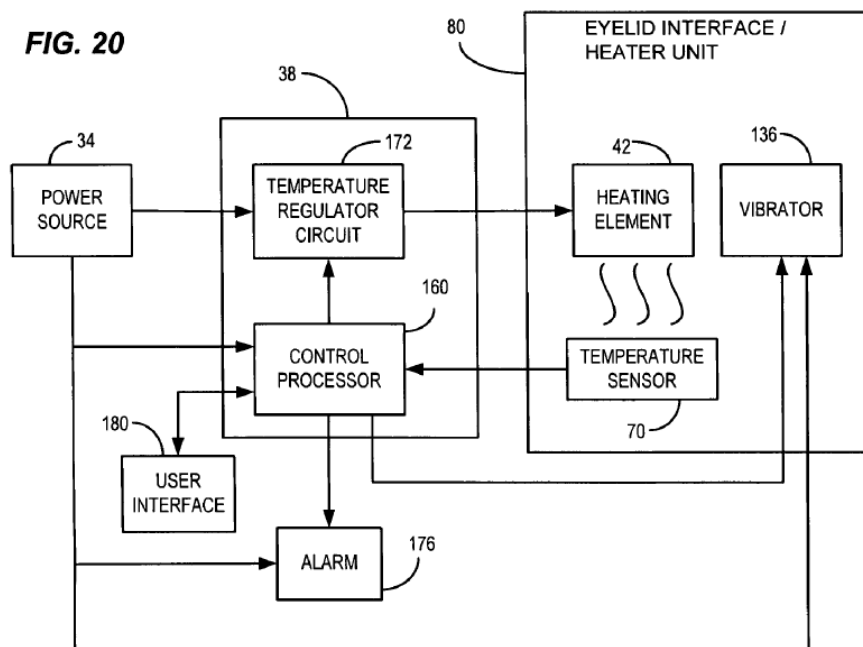
Thus, the heat sink in Grenon I discloses the contact member *comprising a soft and resilient material*. EX1005 ¶87. See also EX1002 ¶70.

c. “operably connected to an electromechanical device,”

Continuing in the preamble of the ‘621 Patent provides that its contact member is “operably connected to an electromechanical device.” Grenon I discloses that a “[p]ower source 34 supplies power both to the heating element and the control

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processor 160, as well as to an alarm 176 and vibrator 136.” EX1005 ¶128. Grenon I shows in FIG. 20 a block diagram of the interaction between components of its device, including the interaction between its eyelid interface, power supply, control processor, and vibrator. EX1005 ¶128.



EX1005

The power source, control processor, and the vibrator in Grenon I are all electromechanical devices that are in communication with the eyelid interface, also referred to as the heat sink. EX1005 ¶115.

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Thus, Grenon I discloses that its contact member is *operatively connected to an electromechanical device. See also* EX1002 ¶71.

d. “wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:”

The limitation of the preamble describing the eye having an eyelid margin, an eyeball, and removable debris is inherent within a human organism. EX1002 ¶¶66, 72. As this limitation appears to positively recite anatomical structures of an eye, which are not a portion of a device or the method and clearly not invented by the Patent Owner, this limitation is not subject to protection and should be given little to no weight in analysis. MPEP § 2105(III), Sect. 33(a) AIA.

As a PHOSITA will recognize, eyes, eyeballs, and eyelid margins are known anatomical structures, and the presence of debris along these anatomical structures is well known in the art. EX1002 ¶¶66, 72. Grenon I further discloses an eye, an eyeball, and an eyelid margin that includes removable debris. EX1005 ¶6. In Grenon I, two types of removable debris are disclosed, including cells on the eyelid margin and obstruction within the meibomian gland. EX1005 ¶¶12-15.

Thus, Grenon I discloses *wherein the eye has an eyelid margin and an eyeball and includes a removable debris.*

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Therefore, Grenon I in view of Grenon II and Nichamin disclose every limitation of the preamble. *See also* EX1002 ¶¶72-73.

e. “effecting movement of the contact member relative to the electromechanical device,”

Grenon I further discloses “effecting movement of the contact relative to the electromechanical device.” Grenon I discloses “a heating unit 80 consistent with certain embodiments is depicted in which again a layered sandwich style assembly is depicted with an insulator 58 providing a rearmost layer, a heating element 42 providing a central layer, and a thermal heat sink 46 providing a front layer which will be placed in contact with the eyelid . . . the thermal heat sink 46 may be flexible or pliable so that when pressed in place it conforms to the shape of the eyelid.” EX1005 ¶115. Additionally, the heating unit comprises a vibrator that “generates vibration, pulsation, and/or milking action” to “impart[] mechanical energy to the eyelid.” EX1005 ¶34.

Mechanical movement of the type discussed in Grenon I is well known in the art. Indeed, Grenon I provides that its vibrator can be of any suitable design, such as a generic vibrator. EX1005 ¶119. An ordinary artisan would have understood that the movement effected by the electromechanical vibrator results in movement of the elements in connection with. EX1002 ¶74. In Grenon I the vibrator and heat sink are

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in communication through the heater unit, and thus movement of the vibrator effects movement of the flexible heat sink. EX1005 ¶115.

Thus, Grenon I in view of Grenon II and Nichamin discloses *movement of the contact member relative to the electromechanical device. See also* EX1002 ¶74.

**f. “the contact member having at least a portion thereof
configured to access a portion of the eyelid margin,”**

Grenon II discloses a probe tip “in contact over the gland orifice creating a seal between the tip and the skin.” EX1006 ¶59. The tip is shown in FIG. 5 in contact with a meibomian gland opening, which occurs at the eyelid margin. *Id.* EX1002 ¶75. Thus, the disclosure in Grenon II provides a contact member that is configured to access a portion of the eyelid margin.

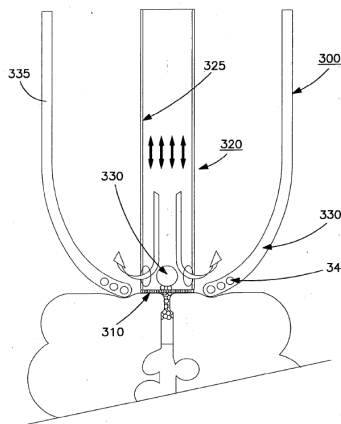


FIG. 5

EX1006

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Another example of contacting the eyelid margin is illustrated in FIG. 4C of Grenon II. In FIG. 4C, a probe illustrated in FIG. 4B is shown in place over the eyelid margin to remove an obstruction from the glands. EX1006 ¶55. As is visible in the embodiment shown in FIG. 4C of Grenon II, the probe is configured to contact a portion of the lower eyelid and a portion configured to extend over the eyelid margin. EX1006 FIG. 4C. Grenon II discloses that that the probe “assists in softening, liqu[e]fying or melting the obstruction P via heat transfer through the tissue when the probe is placed against the tissue.” EX1006 ¶57. A portion of the probe in contact with the eyelid margin is “equipped with aspiration means 260 . . . for introducing aspiration, suction or vacuum into the gland channel C to evacuate the obstruction remnants. Alternatively, heat and aspiration may be employed . . . in addition [to] vibration.” EX1006 ¶56.



FIG. 4B

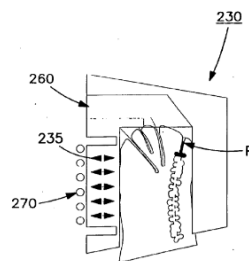


FIG. 4C

EX1006

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Thus, the combination of Grenon I and Grenon II discloses the contact member having at least a portion thereof configured to access a portion of the eyelid margin. An ordinary artisan would have understood that the flexible heat sink in Grenon I could be combined with the probe in Grenon II to combine a flexible heat sink with the probe to access a portion of the eyelid margin and provide heat and vibration as taught in Grenon I. EX1006 ¶¶56, 57, EX1005 ¶115.

Grenon I in view of Grenon II and Nichamin therefore discloses *the contact member having at least a portion thereof configured to access a portion of the eyelid margin. See also* EX1002 ¶75.

g. “wherein the movement comprises electromechanical rotation of the contact member;”

The combination of Grenon I and Grenon II in view of Nichamin discloses “wherein the movement comprises electromechanical rotation of the contact member.” Nichamin discloses a handheld electromechanical device having an applicator portion that contacts the eyelid margin in order to chafe the eyelid margin. EX1007 ¶65. “The device is being used by an individual 76 to chafe eyelid margin tissue 72 with the mixture. The **applicator may rotate, rub, vibrate, or otherwise move** to aid in the chafing process.” EX1007 ¶65. It would have been obvious to a PHOSITA to combine the electromechanical rotation of the applicator disclosed in

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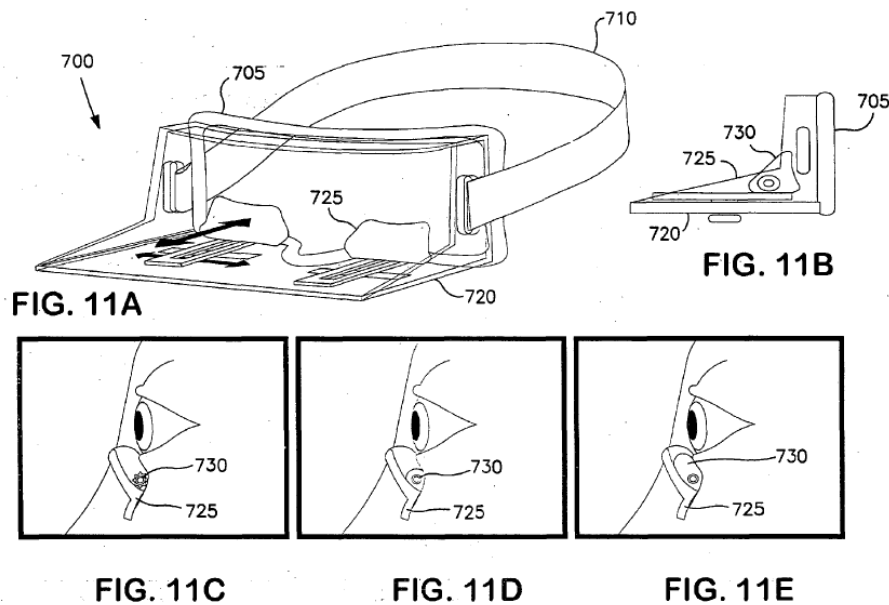
Nichamin with the disclosures of vibration in Grenon I and Grenon II. *Id.*, EX1005 ¶34, EX1006 ¶56, EX1002 ¶76.

Indeed, the disclosure in Nichamin provides a variety of different motions that may be used in order to chafe the eyelid margin, including vibration. EX1007 ¶65. As Grenon I and Grenon II both disclose that their electromechanical devices provide vibrational movement, an ordinary artisan would have understood that other forms of electromechanical movement, such as those disclosed in Nichamin, may be utilized. *Id.*, EX1005 ¶34, EX1006 ¶56.

Grenon I in view of Grenon II and Nichamin therefore disclose *wherein the movement comprises electromechanical rotation of the contact member*. See also EX1002 ¶76.

**h. “while the contact member is being moved by the
electromechanical device, contacting the eyelid margin
with the contact member without lifting the eyelid”**

Grenon II shows in FIGS. 11A-E an embodiment of its electromechanical device “incorporated into a goggle-like device.” EX1006 ¶69. The goggle-like device is designed to position the electromechanical device proximate to the eyelids to apply heat and a massaging force to the meibomian glands. *Id.* It would be clear to an ordinary artisan that Grenon II’s goggle-like device prevents access to, and thus the ability to lift, the eyelid margin during use. EX1002 ¶77.



EX1006

Grenon II's goggle-like device is disclosed as being used in conjunction with "any of the extraction modalities mentioned" described in Grenon II, including the device shown in FIG. 5 where a probe is placed "in contact over the gland orifice creating a seal between the tip and the skin [where m]ovement of the probe 330 would cause the abrasive 310 on the bottom of the tip to separate the cells from the skin and the aspiration, suction or vacuum would extract the cellular material from the vicinity of the gland opening." EX1006 ¶¶58, 59, 70. Still further, the device shown in FIG. 4C expressly depicts a portion configured to contact the eyelid margin and the eyelid margin. EX1006 ¶¶55-57. According to the teaching of Grenon II it

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would have been obvious to combine the probe in FIG. 4C or FIG. 5 with the goggle-like device shown in FIG. 11, which prevents the lifting of the eyelid margin during use. EX1006 ¶70.

Thus, Grenon I in view of Grenon II and Nichamin disclose *while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid margin from the eye. See also* EX1002 ¶77.

**i. “so as to scrub the portion of the eyelid margin that
includes the removable debris with the contact
member”**

Nichamin discloses “so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member.” In FIG. 2 Nichamin illustrates that the “[h]ead 52 of wand 50 is chafing posterior eyelid margin 38 on lower eyelid” to “clean margin surface and eyelash 44.” EX1007 ¶54. As provided in Nichamin, and well known in the art, meibomian glands can become blocked by buildup and chafing the eyelid margin results in “unblocked or opened meibomian glands 42 and allow[s] fluid, debris, oils, sebum or micro-biologic material to escape from meibomian glands 48.” *Id.*

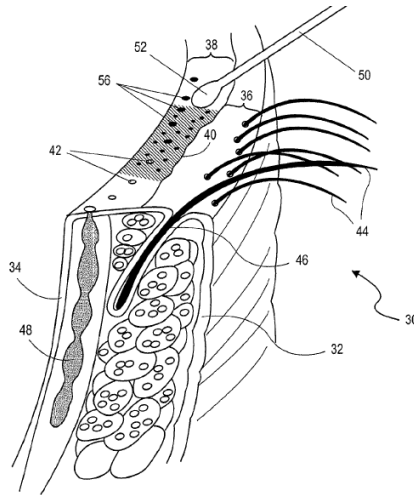


FIG. 2

EX1007

An ordinary artisan would recognize that “scrub” as claimed in the ‘621 Patent is synonymous with “chafing” as disclosed in Nichamin. EX1002 ¶78. Therefore, reviewing the teachings of Nichamin, an ordinary artisan would find that the limitation of scrubbing is obvious.

Thus, Grenon I in view of Grenon II and Nichamin teach the limitation of *so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member*. See also EX1002 ¶78.

j. “thereby impacting the debris with the contact member to remove debris from the eye.”

Nichamin further discloses that an applicator “[r]ubbing, chafing, or otherwise agitating posterior eyelid margin, anterior eyelid margin, eyelid skin, and/or other

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eye area tissue may move eyelash follicle 46 or may move other structures at or below the surface. ” EX1007 ¶54. As a PHOSITA will recognize, debris builds up along the eyelid margin and within the meibomian glands below the eyelid margin surface, and “agitation along with the chafing may improve or allow flow of body oil, sebum or micro-biologic material out of tissue” through the removal of this debris. *Id.*, EX1002 ¶79. Thus, Grenon I, in view of Grenon II and Nichamin discloses *thereby impacting the debris with the contact member to remove debris from the eye.*

Claim 1 of the ‘621 Patent would have been obvious in view of the teachings of Grenon I, Grenon II, and Nichamin in view of the general knowledge of an ordinary artisan. *See also* EX1002 ¶¶79-80.

3. Dependent Claim 2

a. “The method of claim 1, wherein removing debris further comprises at least one of:”

The preamble of Claim 2 provides “wherein removing debris further comprises at least one of.” To the extent this limitation limiting, it is disclosed in Grenon I in view of Grenon II and Nichamin as discussed in Section VI.B.2.j, *supra*. *See also* EX1002 ¶81.

b. “exfoliating the eyelid margin;”

Further, Grenon II discloses the limitation of “exfoliating the eyelid margin.” Grenon II discloses that “[a] second embodiment of the invention (FIG. 5) employs microdermabrasion or exfoliation to remove any cells or cellular material that may have overgrown the gland opening.” EX1006 ¶58. As a PHOSITA will recognize, the gland openings are found on the eyelid margin. EX1002 ¶43. Therefore, the disclosure of exfoliation to remove cells or cellular material that have overgrown the gland opening, disclosing exfoliating the eyelid margin. *Id.*, EX1006 ¶58

Thus, Grenon I in view of Grenon II and Nichamin disclose *exfoliating the eyelid margin*. See also EX1002 ¶82.

c. “unroofing a plurality of meibomian glands along the eyelid margin;”

Grenon II discloses “unroofing a plurality of meibomian glands along the eyelid margin.” As a PHOSITA will recognize unroofing refers getting rid of hardened obstructions at the top of the meibomian glands. EX1002 ¶83. This can be done through a variety of different methods, such as scrubbing the eyelid to remove debris that has built up on the glands, dissolving the obstructions through the application of heat, or applying pressure to the meibomian glands to extract the obstruction. *Id.*

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Grenon II discloses one method of unroofing a plurality of meibomian glands through “rollers applying constant regulated pressure to the meibomian gland to apply a ‘milking’ type force to expel the obstructions.” EX1006 ¶63. As illustrated in FIG. 6B this can be accomplished by contacting the rollers to a portion of the eyelids and applying pressure to the glands to extract the obstruction. EX1006 ¶64. Grenon II’s probe further discloses a suction portion that is in contact with the eyelid margin to remove the extracted obstruction. *Id.*

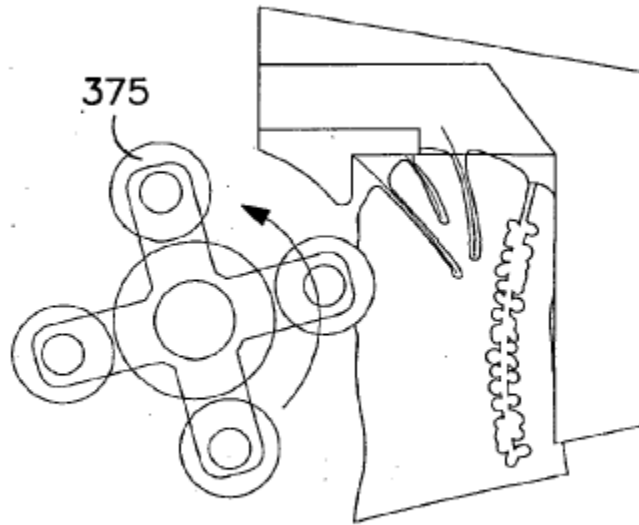


FIG. 6B

EX1006

Grenon II further discloses that the obstructions may be extracted, and thus the meibomian glands unroofed, by the suction alone. EX1006 ¶64.

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Thus, Grenon I in view of Grenon II and Nichamin disclose *unroofing a plurality of meibomian glands along the eyelid margin*. See also EX1002 ¶83.

d. “buffing the eyelid margin; and”

Nichamin discloses “buffing the eyelid margin.” More particularly, Nichamin discloses that “[t]he applicator may rotate, rub, vibrate, or otherwise move to aid in the chafing process.” EX1007 ¶65. As an ordinary artisan will recognize, buffing refers to making a surface smooth by rubbing it. EX1011. Nichamin discloses rubbing the eyelid margin to remove debris on the eyelid margin, resulting in a smooth surface. EX1007 ¶54. Thus, Nichamin’s disclosure of rubbing the eyelid margin discloses the claimed limitation of “buffing.” EX1002 ¶84.

Grenon I in view of Grenon II and Nichamin therefore disclose *buffing the eyelid margin*. See also EX1002 ¶84.

e. “breaking the debris free of the eyelid margin.”

Grenon II further discloses “breaking the debris free of the eyelid margin.” As disclosed in Grenon II, its method of treating eye disorders includes “applying a regulated force, regulated energy, regulated heat and/or chemical/pharmacological agent or combinations thereof to the eyelid to remove obstruction in order to restore the natural flow of secretion from the meibomian gland.” EX1006 ¶23. As is evident

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from Grenon II's disclosure, breaking debris free of the eyelid margin is well known in the art and is not a novel concept. EX1002 ¶85.

Thus, Grenon I in view of Grenon II and Nichamin discloses *breaking the debris free of the eyelid margin*.

Therefore, Grenon I in view of Grenon II and further in view of Nichamin discloses each limitation in Claim 2 of the '621 Patent. *See also* EX1002 ¶¶85-87.

4. Dependent Claim 3

a. "The method of claim 1, wherein the eye has an eyeball and further includes"

The preamble of Claim 3 provides "wherein the eye has an eyeball and further includes." This limitation is disclosed in Grenon I in view of Grenon II and Nichamin as discussed in Section VI.B.2.d, *supra*. *See also* EX1002 ¶88.

b. "positioning the contact member near the eyeball along the eyelid margin; and"

The limitation of "positioning the contact member near the eyeball along the eyelid margin" is inherent in Claim 1's limitation of "contacting the eyelid margin with the contact member" Section VI.B.2.h. As a PHOSITA will recognize, in order for the contact member to contact the eyelid margin, it must be positioned along the eyelid margin near the eyeball. EX1002 ¶90.

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Nevertheless, Grenon II discloses that “the clinician would place the abrasive tip 310 in contact over the gland orifice creating a seal between the tip and the skin.” EX1006 ¶59. As a PHOSITA will recognize, the gland orifice is present on the eyelid margin, in close proximity to the eyeball. EX1002 ¶¶43, 90. Therefore, the disclosure in Grenon II of placing the tip over the gland orifice provides for positioning the contact member on the eyelid margin.

Grenon I in view of Grenon II and Nichamin therefore discloses *positioning the contact member near the eyeball along the eyelid margin*. See also EX1002 ¶89.

c. “targeting the debris with the contact member.”

The limitation of “targeting the debris with the contact member” is disclosed in Grenon II. Grenon II discloses that “[t]reatment to remove the obstruction will involve the application of an external regulated force to the eyelid and/or **directly over** the obstructed orifice to loosen the obstruction within the gland G and the orifice.” EX1006 ¶51. As Grenon II explicitly discloses targeting the obstructed orifice within the meibomian gland, Grenon II discloses targeting the debris with the contact member.

Therefore, Grenon I in view of Grenon II and Nichamin disclose each and every limitation of Claim 3. See also EX1002 ¶89.

5. Dependent Claim 5

- a. “The method of claim 1, further comprising repeating the effecting movement, the contacting the portion of the eye, and the impacting the debris with the contact member to remove the debris process of claim 1”**

Claim 5 of the ‘621 Patent includes repeating the limitations of Claim 1. The limitation of “effecting movement” is discussed in Section VI.B.2.e, *supra*, the limitation of “contacting the portion of the eye” is discussed in Section VI.B.2.h, *supra*, and the limitation of “impacting the debris with the contact member to remove the debris” is discussed in Section VI.B.2.j, *supra*.

Thus, as discussed in Claim 1, Grenon I in view of Grenon II and Nichamin disclose these limitations. *See also* EX1002 ¶90.

- b. “after periodic intervals until the ocular disorder is sufficiently remedied.”**

Claim 5 of the ‘621 Patent further provides repeating Claim 1 at “periodic intervals until the ocular disorder is sufficiently remedied.” This is simply a repetition of the limitations of Claim 1 and is not a novel concept. Indeed, the “duplication of steps . . . is obvious absent a new and unexpected result brought about by the duplication.” *Ex Parte Gruetering*, No. 2017-011346 (P.T.A.B. 2020) (“It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced.”) (*citing In re Harza*, 274 F.2d 669,

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774 (C.C.P.A. 1960)); *See also Ex Parte Ward*, No. 2016-003204 (P.T.A.B. 2016) (“Claim 1 recites the mere duplication of the suspension of a first print job Here, we discern no new or unexpected result from the use of multiple suspensions of the first print job . . . and Appellants do not argue a new or unexpected result. Thus we do not find such duplication of steps to be non-obvious in view of the cited references.”).

As provided in the preamble of Claim 5, repeating the steps of Claim 1 is performed in order to further remedy the ocular disorder. Thus, it is abundantly clear that this limitation is obvious in view of Grenon I, Grenon II, Nichamin, and the knowledge of PHOSITA.

Nevertheless, Grenon I discloses “[t]he treatment technique is simple and easily implemented and may even be utilized by the patient himself or herself to provide an at-home therapy to supplement treatment that may be administered by a medical professional and to assist in keeping the lipids produced in the meibomian glands flowing freely.” EX1005 ¶144. As a PHOSITA will recognize, Grenon I provides periodically treating an ocular disorder to sufficiently remedy the ocular disorder between other treatments. EX1002 ¶90.

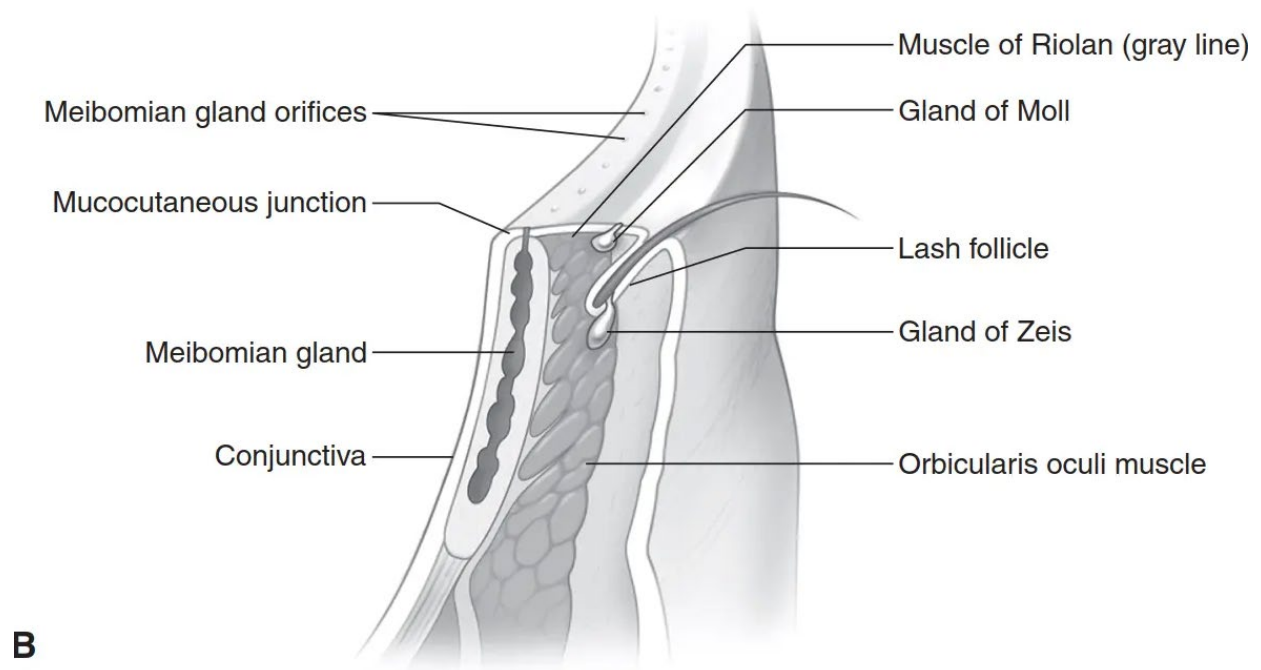
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Therefore, Grenon I in view of Grenon II and Nichamin and further in view of the knowledge of an ordinary artisan render every limitation of Claim 5 obvious. *See also* EX1002 ¶90.

6. Dependent Claim 9

Claim 9 is dependent on Independent Claim 1 and further recites “wherein the portion of the eyelid margin includes eyelashes on the eyelid margin.” As this limitation positively recites the anatomical structures of an eye, which are not a portion of a device or the method and clearly not invented by the Patent Owner, this limitation is not subject to protection and should be given little to no weight in analysis. MPEP § 2105(III), Sect. 33(a) AIA.

As a PHOSITA will recognize, the eyelid margin includes a posterior eyelid margin and an anterior eyelid margin anatomically separated by the gray line. EX1002 ¶66. As illustrated in the cross sectional view, the posterior eyelid margin includes the meibomian gland orifices and the anterior eyelid margin includes the lash follicles. *Id.*



EX1012¹

Therefore, it is obvious, according to the known anatomy of the eyelid margin, that eyelashes are a portion of the eyelid margin. EX1002 ¶91.

Nevertheless, Nichamin teaches chafing an eyelash follicle as a portion eye area tissue to be chafed. EX1007 ¶31.

¹ American Academy of Ophthalmology,

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Thus, Claim 9 is obvious in light of the knowledge of a person of ordinary skill in the art. In the alternative, Claim 9 is obvious over Grenon I in view of Grenon II and further in view of Nichamin. *See also* EX1002 ¶91.

7. Independent Claim 12

a. “A method of treating an eye for an ocular disorder”

As discussed in Section VI.B.2.a, *supra*, the Grenon I, Grenon II, and Nichamin demonstrated “a method of treating an eye for an ocular disorder” of Claim 1. *See also* EX1002 ¶92.

b. “with a contact member comprising a soft and resilient material”

Grenon I includes a disclosure to “a contact member comprising a soft and resilient material.” As discussed in Section VI.B.2.b, *supra*, Grenon I discloses a flexible heat sink that is in contact with the patient during use. EX1005, ¶ 87. As a PHOSITA will recognize, a flexible silicone heat sink, such as the one disclosed in Grenon I, comprises characteristics that are both soft and resilient. *Id.* EX1002 ¶93.

c. “operably connected to an electromechanical device,”

Continuing in the preamble of the ‘621 Patent provides that its contact member is “operably connected to an electromechanical device.” As discussed in Section VI.B.2.c, *supra*, Grenon I discloses that a “[p]ower source 34 supplies power both to the heating element and the control processor 160, as well as to an alarm 176

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and vibrator 136.” EX1005 ¶128. Thus, Grenon I teaches the limitation of *operably connected to an electromechanical device* as demonstrated in Claim 1. *See also* EX1002 ¶94.

d. “wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:”

As discussed in Section VI.B.2.d, *supra*, Grenon I discloses an eye having an eyeball, eyelid margin, and removable debris. EX1005 ¶¶6, 12-15. *See also* EX1002 ¶95.

e. “effecting movement of the contact member relative to the electromechanical device,”

As discussed in Section VI.B.2.e, *supra*, Grenon I discloses “effecting movement of the contact member relative to the electromechanical device.” *See also* EX1002 ¶96.

f. “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid”

As discussed in Section VI.B.2.f, *supra*, Grenon II discloses an electromechanical device “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid.” *See also* EX1002 ¶97.

g. “thereby impacting the debris with the contact member to remove debris from the eye”

As discussed in Section VI.B.2.i and VI.B.2.j, *supra*, Nichamin discloses a “thereby impacting the debris with the contact member to remove debris from the eye.” *See also* EX1002 ¶98.

h. “unroofing a plurality of meibomian glands along the eyelid margin.”

As discussed in Section VI.B.3.c, *supra*, Grenon II discloses “unroofing a plurality of meibomian glands along the eyelid margin.” *See also* EX1002 ¶99.

8. Dependent Claim 13

a. “The method of claim 12, wherein removing debris further comprises at least one of:”

The preamble of Claim 13 provides “wherein removing debris further comprises at least one of.” To the extent this limitation limiting, it is disclosed in Grenon I in view of Grenon II and Nichamin as discussed in Section VI.B.3.g, *supra*. *See also* EX1002 ¶100.

b. “scrubbing the eyelid margin”

As discussed in Section VI.B.2.i, *supra*, Grenon II “scrubbing the eyelid margin.” *See also* EX1002 ¶101.

c. “exfoliating the eyelid margin;”

Grenon II discloses As discussed in Section VI.B.3.b, *supra*, Grenon II discloses the limitation of “exfoliating the eyelid margin.” *See also* EX1002 ¶102.

d. “buffing the eyelid margin”

As discussed in Section VI.C.3.d, *supra*, Nichamin discloses the limitation of “buffing the eyelid margin.” *See also* EX1002 ¶103.

e. “breaking the debris free of the eyelid margin.”

As discussed in Section VI.B.3.e, *supra*, Grenon II “breaking the debris free of the eyelid margin.”

Therefore, Claim 13 is obvious according to the disclosures in Grenon I, Grenon II, and Nichamin. *See also* EX1002 ¶104.

9. Dependent Claim 14

Claim 14 depends on Independent Claim 12 and further recites “wherein the portion of the eyelid margin includes eyelashes of the eyelid margin.” Claim 14 is substantially identical to Claim 9. Thus, for at least the reasons discussed in Section VI.B.6, *supra*, Nichamin discloses the limitation of Claim 14. *Id.* *See also* EX1002 ¶105.

10. Dependent Claim 15

Claim 15 depends on Independent Claim 12 and further recites “wherein the eye has an eyeball and further includes: positioning the contact member near the eyeball along the eyelid margin; and targeting the debris with the contact member.” Claim 15 is substantially identical to Claim 3. EX1006. Thus, for at least the reasons discussed in Section VI.B.4, *supra*, Grenon II discloses the limitations of Claim 15. *Id.* See also EX1002 ¶106.

C. Ground 2: Obviousness of Claims 1-3, 5, and 12-15 under 35 U.S.C. § 103 in view of Grenon II and Colin

1. Motivation to Combine

An ordinary artisan would have found it obvious to combine the electromechanical device described in Grenon II with the eyelid interface and movement of Colin.

Grenon II is directed to a method “for treating meibomian gland dysfunction wherein the flow of naturally occurring secretions from the meibomian gland is restored.” EX1006 ¶23. Likewise, Colin is directed to “devices and methods for using such a device for therapeutic or prophylactic massage of mammalian eyelids.” EX1008 1:7-9.

The method described in Grenon II “comprises applying a regulated force, regulated energy, regulated heat and/or chemical/pharmacological agent or

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combinations thereof to the eyelid to remove obstructions.” EX1006 ¶23. Grenon II discloses various embodiments of mechanical devices that could be used including a device configured to contact a portion of the eyelid and eyelid margin to remove the obstructions.

Like Grenon II, Colin discloses “a device for heating and massaging the eyelid.” EX1008 5:17-18. According to the teachings of Colin:

*It would be useful if there were **a device available to carefully control heat applied to the eyelid** and additionally reduce the likelihood of contamination of the eye by foreign bacteria. Indeed it would be useful if a device were available that could address some of the shortcomings of the art known treatment methods.*

*It is an object of the present invention to provide **a device for heating and massaging the eyelid** with concomitant scrubbing of the lash bases or to at least provide the public or medical community with a useful alternative to prior art devices. EX1008 5:10-21.*

An ordinary artisan would have found it obvious to combine the electromechanical device for heating and massaging the eyelid in Grenon II components of the electromechanical device for heating and massaging the eyelid in Colin. “When a work is available in one field of endeavor, design incentives and other market forces can prompt variation of it, either in the same field or a different one.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

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Therefore, it would have been obvious to a PHOSITA to combine the device in Grenon II with the teachings in Colin. *See also* EX1002 ¶107-08.

2. Independent Claim 1

a. “A method of treating an eye for an ocular disorder”

To the extent the preamble is limiting, each of Grenon II and Shabo disclose this limitation. As discussed above under motivation to combine, Grenon II discloses that it is directed to “a method and apparatus for treating meibomian gland dysfunction wherein the flow of naturally occurring secretions from the meibomian gland is restored.” EX1006 ¶23. Likewise, Colin is directed to “an apparatus for melting and expressing material from blocked glands in a mammalian eyelid.” EX1008 5:30-32. As a person of ordinary skill will recognize, the blocked glands disclosed in Colin are symptoms of ocular disorders, such as blepharitis. EX1008 2:1-3:13, EX1002 ¶66.

Thus, Grenon II in view of Colin teaches *a method of treating an eye for an ocular disorder*. *See also* EX1002 ¶109.

b. “with a contact member comprising a soft and resilient material”

The preamble further provides that the treatment occurs “with a contact member comprising a soft and resilient material.” To the extent that this limitation in the preamble is considered limiting, this limitation is taught in Colin.

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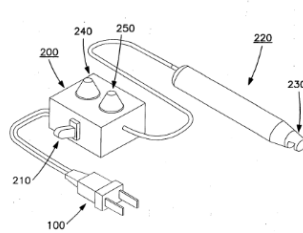
Colin discloses a “deformable eyelid interface . . . made from rubber, synthetic rubber, silicone rubber and like materials.” EX1008 8:28-32. As a PHOSITA will recognize, rubber, such as silicone rubber, is “not hard or firm” and is configured to shape to a surface when applied, but able to return to its normal state when removed. EX1010. Thus, Colin’s teaching of the eyelid margin being a deformable eyelid interface discloses a soft and resilient contact member. EX1002 ¶110

Therefore, it would have been obvious to combine the eyelid interface of the mechanical device in Grenon II with the deformable eyelid interface in Colin.

Thus, Grenon II in view of Colin discloses *a contact member comprising a soft and resilient material. See also* EX1002 ¶110.

c. “operably connected to an electromechanical device,”

Continuing in the preamble of the ‘621 Patent provides that its contact member is “operably connected to an electromechanical device.” Grenon II discloses that “[a]n apparatus for unplugging the obstructed gland channel C is schematically illustrated in FIG. 3a. . . . The controller 200 includes a means 220 for applying an external force to the gland to loosen the obstruction.” EX1006 ¶54.



EX1006

The power source is connected to the controller which is in turn connected to the probe. *Id.* More specifically, the power source is connected to the controller to provide power, and the controller is connected to the probe in order to control the means for applying an external force that is supplied via the probe. *Id.*

Thus, Grenon II in view of Colin discloses the limitation of *operably connected to an electromechanical device. See also* EX1002 ¶111.

d. “wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:”

The limitation of the preamble describing the eye having an eyelid margin, an eyeball, and removable debris is inherent within a human organism. EX1002 ¶¶66, 112. As this limitation appears to positively recite anatomical structures of an eye, which are not a portion of a device or the method and clearly not invented by the Patent Owner, this limitation is not subject to protection and should be given little to no weight in analysis. MPEP § 2105(III), Sect. 33(a) AIA.

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As a PHOSITA will recognize, eyeballs, and eyelid margins are known anatomical structures of eyes, and the presence of debris along these anatomical structures is well known in the art. EX1002 ¶¶66, 112. Nevertheless, Grenon II discloses that its method removes cells or cell materials that have overgrown the meibomian gland opening that are found on the eyelid margin. *Id.*, EX1006 ¶¶58, 61.

While an eyeball is a well-known component of the eye, Grenon II nevertheless illustrates its device in position on a patient near an eyeball in FIG. 11C.

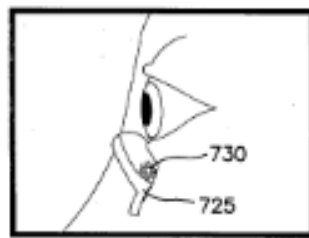


FIG. 11C

EX1006

Thus, Grenon II in view of Colin discloses *wherein the eye has an eyelid margin and an eyeball and includes a removable debris. See also* EX1002 ¶112.

e. “effecting movement of the contact member relative to the electromechanical device,”

Colin discloses “effecting movement of the contact member relative to the electromechanical device.” Like Grenon II, Colin discloses an electromechanical

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device, that is connected to the eyelid interface in order to provide rotation of a portion of the eyelid interface during use. EX1008 15:29-16:12. The electromechanical device is disclosed as “any device adapted to convert electrical energy to mechanical energy,” such as a motor. EX1008 6:9-21. Colin discloses one or more massaging nodules protruding from a disc surface to “push through the deformable eyelid interface.” EX1008 6:20-26. The motor is able to rotate the disc, and thus the massaging nodule pushes through the deformable eyelid interface, to effect movement on the eyelid interface. EX1008 7:1-7.

A configuration of Colin’s device is shown in FIG. 1, where the motor (5) is in communication with a circular disc (8) that provides support to the deformable eyelid interface (9). EX1008 15:29-16:12.

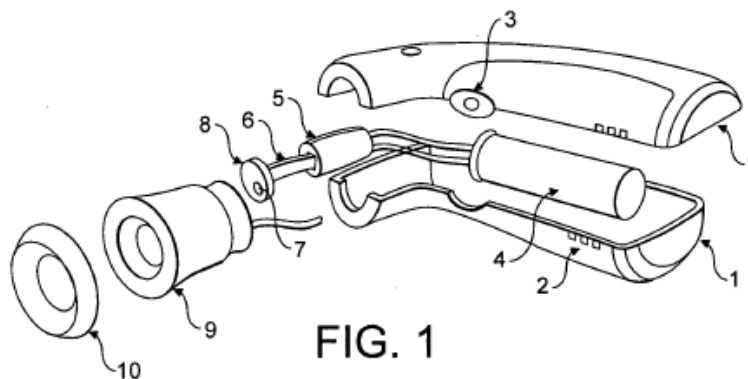


FIG. 1

EX1008

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As is plainly evident from the disclose in Colin, the motor effects movement of the deformable eyelid interface in order to rotate massaging nodules in contact with the eyelid. EX1008 16:4-8.

Thus, Grenon II in Colin discloses *effecting movement of the contact member relative to the electromechanical device. See also* EX1002 ¶113.

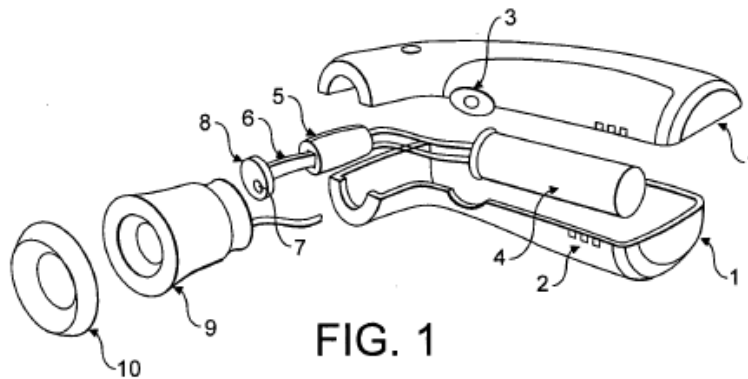
f. “the contact member having at least a portion thereof configured to access a portion of the eyelid margin,”

As discussed in Section VI.B.2.f, *supra*, Grenon II discloses “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid.” *See also* EX1002 ¶114.

g. “wherein the movement comprises electromechanical rotation of the contact member;”

As previously discussed, Colin discloses movement of the contact member, and more specifically the rotation of the contact member. EX1008 15:29-16:12. As described with reference to FIG. 1:

*The motor has an axle (6) representing the axis of rotation about which the massaging nodule (7) **rotates in use**. The massaging nodule is connected to the motor via a circular disc (8) which, in use, provides support to the portion of the deformable eyelid interface (9). Id.*



EX1008

The massaging nodule is disclosed as a protuberance that pushes through the deformable eyelid interface and is rotated during use. EX1008 6:20-26. The rotation of the massaging nodule results in rotation of the eyelid interface in contact with the eyelid and eyelid margin of the patient. EX1008 16:14-16.

Thus, Grenon II in view of Colin discloses *wherein the movement comprises electromechanical rotation of the contact member. See also EX1002 ¶115.*

h. “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid margin from the eye”

As discussed in Section VI.B.2.f, *supra*, Grenon II discloses “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid.”

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Thus, Grenon II in view of Colin discloses *while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid margin from the eye. See also EX1002 ¶116.*

i. “so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member”

Colin discloses “so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member.” Colin’s eyelid interface is disclosed as having a scrubbing element “positioned so as to displace debris from the base of the eyelashes in use.” EX1008 10:25-28. As a PHOSITA will recognize, the eyelash margin includes the eyelash base. EX1002 ¶¶66, 117. Thus, Colin discloses scrubbing a portion of the eyelid margin, namely eyelash bases, that comprises removable debris. EX1008 10:25-28.

One example of the scrubbing element is shown in FIG. 5, having deformable fingers integrally formed with the eyelid interface. EX1008 17:11-25. The deformable fingers are configured as part of the eyelid interface to contact the base of the eyelashes, and thus the eyelid margin, to dislodge any debris in that region. *Id.*

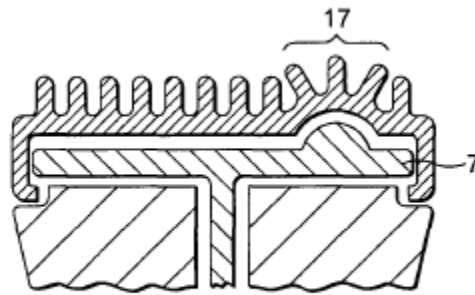


FIG. 5

EX1008

Thus, Grenon II in view of Colin teaches *scrubbing the portion of the eyelid margin that includes the removable debris with the contact member*. See also EX1002 ¶117.

j. “thereby impacting the debris with the contact member to remove debris from the eye.”

Colin further discloses “thereby impacting the debris with the contact member to remove debris from the eye.” As previously discussed, Colin discloses the use of a scrubbing element having fingers or bristles to dislodge debris on the eyelashes during use. EX1008 10:25-28. By dislodging the debris, Colin teaches that the debris may be removed from the eye. *Id.*

Thus, Grenon II in view of Colin discloses *thereby impacting the debris with the contact member to remove debris from the eye*. See also EX1002 ¶¶118-19.

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Claim 1 of the '621 Patent would have been obvious in view of the teachings of Grenon II and Colin in view of the general knowledge of an ordinary artisan.

3. Dependent Claim 2

a. “The method of claim 1, wherein removing debris further comprises at least one of:”

The preamble of Claim 2 provides “wherein removing debris further comprises at least one of.” To the extent this limitation limiting, it is disclosed in Grenon II in view of Colin as discussed in Section VI.C.2.j, *supra*. See also EX1002 ¶120.

b. “exfoliating the eyelid margin;”

As discussed in Section VI.B.3.b, *supra*, Grenon II discloses the limitation of “exfoliating the eyelid margin.” See also EX1002 ¶121.

c. “unroofing a plurality of meibomian glands along the eyelid margin;”

As discussed in Section VI.B.3.c, *supra*, Grenon II discloses “unroofing a plurality of meibomian glands along the eyelid margin.” See also EX1002 ¶122.

d. “buffing the eyelid margin; and”

Colin discloses “buffing the eyelid margin.” More particularly, Colin discloses “an apparatus for melting and expressing material from blocked glands in a mammalian eyelid having: a massager and a deformable eyelid interface having a

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heater and is arranged so that, in use, the massager causes the eyelid interface to massage the eyelid wherein the apparatus additionally comprises a scrubbing element.” EX1008 5:30-6:4. An ordinary artisan will recognize, buffing refers to making a surface smooth by rubbing it. EX1011. As Colin discloses scrubbing and massaging the eye to express obstructions, the obstructions blocking the glands are removed, resulting in an unobstructed and smooth eyelid margin. EX1008 1:29-30. *See also* EX1002 ¶123.

e. “breaking the debris free of the eyelid margin.”

As discussed in Section VI.B.3.e, *supra*, Grenon II discloses the limitation of “breaking the debris free of eyelid margin.” *See also* EX1002 ¶¶124-26.

Therefore, Grenon II in view of Colin discloses each limitation in Claim 2 of the ‘621 Patent.

4. Dependent Claim 3

Grenon II discloses the limitation of Dependent Claim 3. As discussed in Section VI.B.4, *supra*, Grenon II discloses *positioning the contact member near the eyeball along the eyelid margin; and targeting the debris with the contact member*. EX1006 ¶58. *See also* EX1002 ¶¶127-28.

5. Dependent Claim 5

- a. “The method of claim 1, further comprising repeating the effecting movement, the contacting the portion of the eye, and the impacting the debris with the contact member to remove the debris process of claim 1”**

Claim 5 of the ‘621 Patent includes repeating the limitations of Claim 1. The limitation of “effecting movement” is discussed in Section VI.C.2.e, *supra*, the limitation of “contacting the portion of the eye” is discussed in Section VI.C.2.h, *supra*, and the limitation of “impacting the debris with the contact member to remove the debris” is discussed in Section VI.C.2.j, *supra*. See also EX1002 ¶129.

Thus, as discussed with reference to Claim 1, Claim 5 is obvious over Grenon II in view of Colin.

- b. “after periodic intervals until the ocular disorder is sufficiently remedied.”**

Claim 5 of the ‘621 Patent further provides repeating Claim 1 at “periodic intervals until the ocular disorder is sufficiently remedied.” This is simply a repetition of the limitations of Claim 1 and is not a novel concept. Indeed, the “duplication of steps . . . is obvious absent a new and unexpected result brought about by the duplication.” *Ex Parte Gruetering*, No. 2017-011346 (P.T.A.B. 2020) (“It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced.”) (*citing In re Harza*, 274 F.2d 669,

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774 (C.C.P.A. 1960)); *See also Ex Parte Ward*, No. 2016-003204 (P.T.A.B. 2016) (“Claim 1 recites the mere duplication of the suspension of a first print job Here, we discern no new or unexpected result from the use of multiple suspensions of the first print job . . . and Appellants do not argue a new or unexpected result. Thus we do not find such duplication of steps to be non-obvious in view of the cited references.”).

As provided in the preamble of Claim 5, repeating the steps of Claim 1 is performed in order to further remedy the ocular disorder. Thus, it is abundantly clear that this limitation is obvious in view of Grenon II, Colin, and the knowledge of PHOSITA.

Nevertheless, Colin discloses that “the method of the invention is carried out by treatment of the eyelid twice per day for two weeks then to use a daily maintenance treatment on a permanent basis.” EX1008 18:30-19:2. As a PHOSITA will recognize, Colin discloses periodically treating an ocular disorder to sufficiently remedy the ocular disorder between other treatments. *See also* EX1002 ¶129.

Therefore, Grenon II in view of Colin and further in view of the knowledge of an ordinary artisan render every limitation of Claim 5 obvious.

6. Dependent Claim 9

Claim 9 is dependent on Independent Claim 1 and further recites “wherein the portion of the eyelid margin includes eyelashes on the eyelid margin.” As discussed in Section VI.B.6, *supra*, a PHOSITA will recognize that a *portion of the eyelid margin includes eyelashes*.

Nevertheless, Colin teaches that “[t]he massaging nodule presses upon the inside edge of the of the eyelid interface causing the deformable fingers (17) to move both radially (in the plane of the section) and perpendicular to the section shown in figure 5 so that they move against the base of the eyelash in use and dislodge any built up debris which has accumulated.” EX1008 17:21-26. As a PHOSITA will recognize, Colin discloses eyelashes as part of the eyelid margin. EX1002 ¶¶66, 130.

Thus, Claim 9 is obvious in light of the knowledge of a person of ordinary skill in the art. In the alternative, Claim 9 is obvious over Grenon II in view of Colin.

7. Independent Claim 12

a. “A method of treating an eye for an ocular disorder”

As discussed in Section VI.C.2.a, *supra*, the Grenon II in view of Colin demonstrated “a method of treating an eye for an ocular disorder” of Claim 1. *See also* EX1002 ¶131.

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b. “with a contact member comprising a soft and resilient material”

As discussed in Section VI.C.2.b, *supra*, Colin discloses “a contact member comprising a soft and resilient material.” *See also* EX1002 ¶132.

c. “operably connected to an electromechanical device,”

Continuing in the preamble of the ‘621 Patent provides that its contact member is “operably connected to an electromechanical device.” As discussed in Section VI.C.2.c, *supra*, Grenon II discloses “[a]n apparatus for unplugging the obstructed gland channel C is schematically illustrated in FIG. 3a. . . . The controller 200 includes a means 220 for applying an external force to the gland to loosen the obstruction.” EX1006 ¶54. Thus, Grenon II teaches the limitation of *operably connected to an electromechanical device* as demonstrated in Claim 1. *See also* EX1002 ¶133.

d. “wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:”

As discussed in Section VI.C.2.d, *supra*, Grenon II discloses an eye having an eyeball, eyelid margin, and removable debris. EX1006 ¶¶58, 61. *See also* EX1002 ¶134.

e. “effecting movement of the contact member relative to the electromechanical device,”

Colin discloses “effecting movement of the contact member relative to the electromechanical device.” As discussed in Section VI.C.2.e, *supra*, Colin includes a motor that is connected to the eyelid interface in order to provide rotation of a portion of the eyelid interface during use. EX1008 15:29-16:12. Thus, as discussed in Section VI.C.2.e, *supra*, Colin discloses *effecting movement of the contact member relative to the electromechanical device*. See also EX1002 ¶135.

f. “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid”

As discussed in Section VI.C.2.f, *supra*, Grenon II discloses “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid.” See also EX1002 ¶136.

g. “thereby impacting the debris with the contact member to remove debris from the eye”

Colin discloses a “thereby impacting the debris with the contact member to remove debris from the eye.” As discussed in Section VI.C.2.i and VI.C.2.j, *supra*, the device in Colin comprises a scrubbing element integrally formed with the eyelid

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interface and “positioned so as to displace debris from the base of the eyelashes in use.” EX1008 10:25-28. *See also* EX1002 ¶137.

h. “unroofing a plurality of meibomian glands along the eyelid margin.”

As discussed in Section VI.B.3.c, *supra*, Grenon II discloses *unroofing a plurality of meibomian glands along the eyelid margin*. *See also* EX1002 ¶138.

8. Dependent Claim 13

a. “The method of claim 12, wherein removing debris further comprises at least one of:”

The preamble of Claim 13 provides “wherein removing debris further comprises at least one of.” To the extent this limitation limiting, it is disclosed in Grenon II in view of Colin as discussed in Section VI.C.3.g, *supra*. *See also* EX1002 ¶139.

b. “scrubbing the eyelid margin”

Colin discloses “scrubbing the eyelid margin.” As discussed in Section VI.C.2.i, *supra*, Colin discloses an eyelid interface having a scrubbing element “positioned so as to displace debris from the base of the eyelashes in use.” EX1008 10:25-28. *See also* EX1002 ¶140.

Thus, Grenon II in view of Colin teach the limitation of *scrubbing the eyelid margin*.

c. “exfoliating the eyelid margin;”

Grenon II discloses the limitation of “exfoliating the eyelid margin.” As discussed in Section VI.C.3.b, *supra*, Grenon II discloses that “[a] second embodiment of the invention (FIG. 5) employs microdermabrasion or exfoliation to remove any cells or cellular material that may have overgrown the gland opening.” EX1006 ¶58. *See also* EX1002 ¶141.

d. “buffing the eyelid margin”

Colin discloses “buffing the eyelid margin.” More particularly, Colin discloses “an apparatus for melting and expressing material from blocked glands in a mammalian eyelid having: a massager and a deformable eyelid interface having a heater and is arranged so that, in use, the massager causes the eyelid interface to massage the eyelid wherein the apparatus additionally comprises a scrubbing element.” EX1008 5:30-6:4. As discussed in Section VI.D.3.d, *supra*, a PHOSITA would have found the limitation of “buffing the eyelid margin” obvious in light of the disclosure in Colin. EX1002 ¶142.

Therefore, Grenon II in view of Colin discloses *buffing the eyelid margin*.

e. “breaking the debris free of the eyelid margin.”

As discussed in Section VI.C.3.e, *supra*, Grenon II further discloses “breaking the debris free of the eyelid margin.” *See also* EX1002 ¶143.

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Therefore, Claim 13 is obvious according to the disclosures in Grenon II and Colin.

9. Dependent Claim 14

Claim 14 depends on Independent Claim 12 and further recites “wherein the portion of the eyelid margin includes eyelashes of the eyelid margin.” Claim 14 is substantially identical to Claim 9. EX1002 ¶144. Thus, for at least the reasons discussed in Section VI.C.6, *supra*, Colin discloses the limitation of Claim 14. *Id.*

10. Dependent Claim 15

Claim 15 depends on Independent Claim 12 and further recites “wherein the eye has an eyeball and further includes: positioning the contact member near the eyeball along the eyelid margin; and targeting the debris with the contact member.” Claim 15 is substantially identical to Claim 3. EX1002 ¶145. Thus, for at least the reasons discussed in Section VI.C.4, *supra*, Grenon II discloses the limitations of Claim 15. *Id.*

D. Ground 3: Obviousness of Claims 1-6 and 9-18 under 35 U.S.C. § 103 in view of Grenon II, Colin and Shabo

1. Motivation to Combine

An ordinary artisan would have found it obvious to combine the electromechanical device described in Grenon II with the eyelid interface and movement of Colin and the contact member in Shabo.

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As discussed in Section VI.C.1, *supra*, a PHOSITA would be motivated to combine Grenon II and Colin. It would have been further obvious to combine Grenon II and Colin with the teachings of a contact member in Shabo. Similar to Grenon II and Colin, Shabo is directed to a treatment method and apparatus for eye conditions, such as blepharitis. EX1009 1:7-23. The disclosure of Shabo provides for another contact member that can be used to scrub base of the eyelashes as described in Colin. EX1009 1:64-68, EX1008 5:10-21. *See also* EX1002 ¶¶146-47.

Therefore, it would have been obvious to a PHOSITA to combine the device in Grenon II with the teachings in Colin and Shabo.

2. Independent Claim 1

a. “A method of treating an eye for an ocular disorder”

To the extent the preamble is limiting, each of Grenon II and Shabo disclose this limitation. As discussed above under motivation to combine, Grenon II discloses that it is directed to “a method and apparatus for treating meibomian gland dysfunction wherein the flow of naturally occurring secretions from the meibomian gland is restored.” EX1006 ¶23. Likewise, Colin is directed to “an apparatus for melting and expressing material from blocked glands in a mammalian eyelid.” EX1008 5:30-32. Indeed, Shabo discloses that eye conditions, such as blepharitis, are “characterized by tenacious deposits on and around the eyelashes of an oily secretion (mild, simple blepharitis) and crusty desquamations or scales (seborrheic

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or squamous blepharitis). Blockage of the oil gland ducts at the eyelid margin may result in secondary infection with swollen, red-rimmed or ulcerated eyelids and styes (staphylococcal blepharitis).” EX1009 1:7-23. Thus, a PHOSITA would recognize that the disclosure of blocked glands in Colin is a disclosure of an ocular disorder according to the teachings of Shabo. *Id.*, EX1008 5:30-32. *See also* EX1002 ¶148.

Thus, Grenon II in view of Colin and Shabo teaches *a method of treating an eye for an ocular disorder*.

b. “with a contact member comprising a soft and resilient material”

The preamble further provides that the treatment occurs “with a contact member comprising a soft and resilient material.” To the extent that this limitation in the preamble is considered limiting, this limitation is taught in Shabo.

Shabo discloses a swab “formed of liquid absorbent material, and [having] a broad flat tip for optimal application to the eyelid margin. EX1009 2:11-12. As a PHOSITA will recognize, the swab disclosed in Shabo is generally understood to be a soft and resilient material.

Indeed, the ‘621 Patent discloses that “the swab 14 is a sponge. As described herein, ‘sponge’ broadly refers to any material that is soft, porous, and resilient.” EX1001 4:1-3. In light of the definition in the ‘621 Patent of the swab being “soft,

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porous, and resilient” it is plain that Shabo’s swab comprises soft and resilient characteristics, as would be understood by a PHOSITA. EX1002 ¶¶149-150.

c. “operably connected to an electromechanical device,”

As discussed in Section VI.C.2.c, *supra*, Grenon II discloses “operably connected to an electromechanical device.” *See also* EX1002 ¶151.

d. “wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:”

As discussed in Section VI.B.2.d, eyeballs and eyelid margins are known anatomical structures of eyes, and the presence of debris along these anatomical structures is well known in the art.

Nevertheless, Shabo discloses that its swab is formed to provide “move[m]ent near the **eyeball** along the **eyelid margin** to facilitate the application of liquid to the eyelids as well as the removal of **tenacious deposits**.” EX1009 2:1-3. As a PHOSITA will recognize, the tenacious deposits disclosed in Shabo are one form of removable debris that is found at the eye. *See also* EX1002 ¶152.

e. “effecting movement of the contact member relative to the electromechanical device,”

As discussed in Section VI.C.2.e, *supra*, Colin discloses “effecting movement of the contact member relative to the electromechanical device.” *See also* EX1002 ¶153.

f. “the contact member having at least a portion thereof configured to access a portion of the eyelid margin,”

Shabo discloses “the contact member having at least a portion thereof configured to access a portion of the eyelid margin.” As provided in Shabo, “[t]he applicator is formed so as to provide controlled, safe movement near the eyeball **along the eyelid margin** and to facilitate the application of liquid to the eyelid as well as the removal of tenacious deposits. . . . The swab is formed of liquid absorbent material, and has a broad flat tip for optimal **application to the eyelid margin**. . . . This, together with wrist movement to and fro, allows controlled **movement back and forth along the eyelid margin** without the danger of forward thrust toward the eyeball.” EX1009 1:69-2:33. Therefore, it is clear that the swab in Shabo is configured to access the eyelid margin. *See also* EX1002 ¶154.

Grenon II in view of Colin and Shabo therefore discloses the *contact member having at least a portion thereof configured to access a portion of the eyelid margin*.

g. “wherein the movement comprises electromechanical rotation of the contact member;”

As discussed in Section VI.C.2.g, *supra*, Grenon II discloses “wherein the movement comprises electromechanical rotation of the contact member.” *See also* EX1002 ¶155.

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- h. “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid margin from the eye”**

As discussed in Section VI.B.2.f, *supra*, Grenon II discloses “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid.” *See also* EX1002 ¶156.

- i. “so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member”**

As discussed in Section VI.C.2.i, *supra*, Colin discloses “so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member.” *See also* EX1002 ¶157.

- j. “thereby impacting the debris with the contact member to remove debris from the eye.”**

As discussed in Section VI.C.2.j, *supra*, Colin discloses “thereby impacting the debris with the contact member to remove debris from the eye.”

Claim 1 of the ‘621 Patent would have been obvious in view of the teachings of Grenon II and Colin in view of the general knowledge of an ordinary artisan. EX1002 ¶¶158-59.

3. Dependent Claim 2

As discussed in Section VI.B.3, *supra*, Grenon II discloses the limitation of Dependent Claim 2. EX1002 ¶¶160-166.

4. Dependent Claim 3

As discussed in Section VI.B.4, *supra*, Grenon II in view of Colin and further in view of Shabo discloses “exfoliating the eyelid margin; unroofing a plurality of meibomian glands along the eyelid margin; buffing the eyelid margin; or breaking the debris free of the eyelid margin.” EX1002 ¶¶167-68.

5. Dependent Claim 4

a. “The method of claim 1, wherein the movement of the contact member is at least one of:”

Claim 4 is dependent on Independent Claim 1 and further recites “wherein the movement of the contact is at least one of vibrating the contact member or reciprocating the contact member.” As claimed, the movement only requires that one “vibrating the contact member” and “reciprocating the contact member” and thus, only one of these limitations need to be taught. Nevertheless, the prior art references disclose both vibrating and reciprocating the contact member. EX1002 ¶169.

b. “vibrating the contact member”

Grenon II discloses “vibrating the contact member.” More particularly, Grenon II teaches that is probe “is adapted to vibrate at a preselected frequency.”

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EX1006 ¶54. For example, Grenon II discloses that the probe is “adapted to deliver ultrasonic vibrational energy through the skin into the obstruction P in order to loosen, liquefy, and/or fracture the obstruction.” EX1006 ¶55. EX1002 ¶170.

Thus, Grenon II in view of Colin and further in view of Shabo disclose *vibrating the contact member*.

c. “reciprocating the contact member.”

Shabo discloses “reciprocating the contact member.” Shabo discloses moving the applicator “to and fro” to remove tenacious deposits from the eyelid. EX1009 2:3-30. Reciprocating is moving an object back and forth, such as through a to and fro motion. EX1002 ¶171. Thus, Shabo discloses moving an applicator in a to and fro motion along the eyelid margin.

Therefore, Grenon II in view of Colin and further in view of Shabo discloses *reciprocating the contact member*.

6. Dependent Claim 5

As discussed in Section VI.C.5, *supra*, Colin discloses *repeating the effecting movement, the contacting the portion of the eye, and the impacting the debris with the contact member to remove the debris process of claim 1 after periodic intervals until the ocular disorder is sufficiently remedied*. EX1002 ¶172.

7. Dependent Claim 6

Claim 6 is dependent on Independent Claim 1 and further recites “wherein the contact member is a medical grade sponge for accessing the eyelid margin.” Shabo discloses that “[t]he swab can be formed of any liquid absorbent material, for example, a porous sponge material, or a cotton backing.” EX1009 4:3-5. As a PHOSITA will recognize, when contacting the eyelid margin with any material, it would be obvious to use medical grade materials. EX1002 ¶173. Therefore, it would have been obvious to an ordinary artisan that the sponge disclosed in Shabo to contact the eyelid margin is sterile, and thus, medical grade. *Id.*

8. Dependent Claim 9

As discussed in Section VI.C.6, *supra*, Colin discloses *wherein the portion of the eyelid margin includes eyelashes on the eyelid margin*. EX1002 ¶174.

9. Dependent Claim 10

Claim 10 is dependent on Independent Claim 1 and further recites “wherein the soft and resilient material is absorbent.” Shabo discloses that “[t]he swab can be formed of any liquid **absorbent** material, for example, a porous sponge material, or a cotton backing.” EX1009 4:3-5. Thus, Claim 10 is obvious over Grenon II in view of Colin and further in view of Shabo. EX1002 ¶175.

10. Dependent Claim 11

Claim 11 is dependent on Independent Claim 1 and further recites “wherein the soft and resilient material is porous.” Shabo discloses that “[t]he swab can be formed of any liquid absorbent material, for example, a **porous sponge material**, or a cotton backing.” EX1009 4:3-5. Thus, Claim 11 is obvious over Grenon II in view of Colin and further in view of Shabo. *See also* EX1002 ¶176.

11. Independent Claim 12

a. “A method of treating an eye for an ocular disorder”

As discussed in Section VI.D.2.a, *supra*, the Grenon II in view of Colin demonstrated “a method of treating an eye for an ocular disorder” of Claim 1. *See also* EX1002 ¶177.

b. “with a contact member comprising a soft and resilient material”

As discussed in Section VI.D.2.b, *supra*, Shabo includes a disclosure to “a contact member comprising a soft and resilient material.” *See also* EX1002 ¶178.

c. “operably connected to an electromechanical device,”

As discussed in Section VI.D.2.c, *supra*, Grenon II discloses that its contact member is “operably connected to an electromechanical device.” *See also* EX1002 ¶179.

d. “wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:”

As discussed in Section VI.D.2.d, *supra*, Shabo discloses an eye having an eyeball, eyelid margin, and removable debris. EX1009 2:1-3. *See also* EX1002 ¶180.

e. “effecting movement of the contact member relative to the electromechanical device,”

As discussed in Section VI.D.2.e, *supra*, Colin discloses “effecting movement of the contact member relative to the electromechanical device.” Colin includes a motor that is connected to the eyelid interface in order to provide rotation of a portion of the eyelid interface during use. EX1008 15:29-16:12. *See also* EX1002 ¶181.

f. “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid”

As discussed in Section VI.D.2.f, *supra*, Grenon II discloses “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid.” *See also* EX1002 ¶182.

g. “thereby impacting the debris with the contact member to remove debris from the eye”

Colin discloses a “thereby impacting the debris with the contact member to remove debris from the eye.” As discussed in Section VI.C.2.i and VI.C.2.j, *supra*,

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the device in Colin comprises a scrubbing element integrally formed with the eyelid interface and “positioned so as to displace debris from the base of the eyelashes in use.” EX1008 10:25-28. *See also* EX1002 ¶183.

Thus, Grenon II in view of Colin and further in view of Shabo discloses *thereby impacting the debris with the contact member to remove debris from the eye.*

h. “unroofing a plurality of meibomian glands along the eyelid margin.”

As discussed in Section VI.B.3.c, *supra*, Grenon II discloses *unroofing a plurality of meibomian glands along the eyelid margin.* *See also* EX1002 ¶184.

Therefore, Grenon II in view of Colin and further in view of Shabo discloses each limitation of the ‘621 Patent.

12. Dependent Claim 13

As discussed in Section VI.C.8, *supra*, Grenon II in view of Colin and further in view of Shabo discloses the limitations of Claim 13. *See also* EX1002 ¶185.

13. Dependent Claim 14

Claim 14 depends on Independent Claim 12 and further recites “wherein the portion of the eyelid margin includes eyelashes of the eyelid margin.” Claim 14 is substantially identical to Claim 9. Thus, for at least the reasons discussed in Section VI.D.8, *supra*, Colin discloses the limitation of Claim 14. EX1002 ¶186.

14. Dependent Claim 15

Claim 15 depends on Independent Claim 12 and further recites “wherein the eye has an eyeball and further includes: positioning the contact member near the eyeball along the eyelid margin; and targeting the debris with the contact member.” Claim 15 is substantially identical to Claim 3. *See also* EX1002 ¶187. Thus, for at least the reasons discussed in Section VI.D.4, *supra*, Grenon II discloses the limitations of Claim 15. *Id.*

15. Dependent Claim 16

Claim 16 depends on Independent Claim 12 and further recites “wherein the contact member is a medical grade sponge for accessing the eyelid margin.” Claim 16 is substantially identical to Claim 6. *See also* EX1002 ¶188. Thus, for at least the reasons discussed in Section VI.D.7, *supra*, Shabo discloses the limitations of Claim 16.

16. Dependent Claim 17

Claim 17 depends on Independent Claim 12 and further recites “wherein the soft and resilient material is absorbent.” Claim 17 is substantially identical to Claim 10. *See also* EX1002 ¶189. Thus, for at least the reasons discussed in Section VI.D.9, *supra*, Shabo discloses the limitations of Claim 17.

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17. Dependent Claim 18

Claim 18 depends on Independent Claim 12 and further recites “wherein the soft and resilient material is porous.” Claim 18 is substantially identical to Claim 11. *See also* EX1002 ¶190. Thus, for at least the reasons discussed in Section VI.D.10, *supra*, Shabo discloses the limitations of Claim 18.

VII. MANDATORY NOTICES PURSUANT TO 37 C.F.R. § 42.8(A)(1)

Pursuant to 37 C.F.R. § 42.8(a)(1), the mandatory notices identified in 37 C.F.R. § 42.8(b) are provided below as part of this Petition.

A. 37 C.F.R. § 42.8(b)(1): Real Parties-In-Interest

Petitioner certifies that NuLids, LLC is the real party-in-interest.

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

The '621 Patent is the subject of co-pending litigation: *Blephex LLC v. NuLids LLC*, Case No. 3:2023-cv-00578 (S.D. Cal.), the complaint in which was filed March 31, 2023, and served April 3, 2023.

U.S. Patent Applications 17/364,321 filed June 20, 2021, and 18/116,005 filed March 1, 2023, pending in the Office, both claim priority to the '621 Patent.

C. 37 C.F.R. § 42.8(b)(3) and (4): Lead And Back-Up Counsel And Service Information

Petitioner NuLids, LLC provides the following designation of counsel:

**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT
NO. 11,083,621**

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**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT
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VIII. CONCLUSION

As demonstrated above, it is more likely than not that at least one of the Challenged Claims are unpatentable. Accordingly, Petitioner respectfully requests inter partes review of the Challenged Claims.

Dated: April 3, 2024

Respectfully submitted,

By: /Serge Krimnus/

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**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT
NO. 11,083,621**

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for Inter Partes Review of U.S. Patent No. 11,083,621, including all Exhibits and the Power of Attorney, was served on Patent Owner Blephex, LLC, upon agreement of the parties via electronic delivery in accordance with 37 C.F.R. § 42.105(b), on April 3, 2024, directed to the attorneys for Patent Owner at the following email addresses:

- jasonlake@quinnemanuel.com;
- bowenzhang@quinnemanuel.com;
- matthewrobson@quinnemanuel.com; and
- dblatt@whe-law.com.

Dated: April 3, 2024

Respectfully submitted,

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NO. 11,083,621**

CERTIFICATE OF WORD COUNT COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Petition, including footnotes, contains as measured by the word-processing system used to prepare this paper, 12,839 words. This word count does not include the items excluded by 37 C.F.R. § 42.24(a).