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

Declaration Of Dr. Robert Cykiert In Support of Petition for Inter-Partes Review of U.S. Patent No. 11,083,621

Declaration

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

By: _____

Robert Cykiert, M.D. 4/3/24

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v. "effecting movement of the contact member relative to the electromechanical device," 15

vi. "the contact member having at least a portion thereof configured to access a portion of the eyelid margin," 15

vii. "wherein the movement comprises electromechanical rotation of the contact member;" 15

viii. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid" 16

ix. "so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member" 16

x. "thereby impacting the debris with the contact member to remove debris from the eye." 16

C. Dependent Claim 2 17

i. "The method of claim 1, wherein removing debris further comprises at least one of:" 17

ii. "exfoliating the eyelid margin;" 17

iii. "unroofing a plurality of meibomian glands along the eyelid margin" 17

iv. "buffing the eyelid margin" 18

v. "breaking the debris free of the eyelid margin." 18

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i. "A method of treating an eye for an ocular disorder" 19

ii. "with a contact member comprising a soft and resilient material" 19

iii. "operably connected to an electromechanical device" 19

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:" 20

v. "effecting movement of the contact member relative to the electromechanical device." 20

vi. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid" 20

vii. "thereby impacting the debris with the contact member to remove debris from the eye" 20

viii. "unroofing a plurality of meibomian glands along the eyelid margin." 20

H. Dependent Claim 13 21

i. "The method of claim 12, wherein removing debris further comprises at least one of:" 21

ii. "scrubbing the eyelid margin" 21

iii. "exfoliating the eyelid margin" 21

iv. "buffing the eyelid margin" 21

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i. "A method of treating an eye for an ocular disorder" 22

ii. "with a contact member comprising a soft and resilient material" 22

iii. "operably connected to an electromechanical device," 22

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:" 23

v. "effecting movement of the contact member relative to the electromechanical device," 23

vi. "the contact member having at least a portion thereof configured to access a portion of the eyelid margin," 23

vii. "wherein the movement comprises electromechanical rotation of the contact member;" 24

viii. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid" 24

ix. "so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member" 24

x. "thereby impacting the debris with the contact member to remove debris from the eye." 24

C. Dependent Claim 2 25

i. "The method of claim 1, wherein removing debris further comprises at least one of:" 25

ii. "exfoliating the eyelid margin;" 25

iii. "unroofing a plurality of meibomian glands along the eyelid margin" 25

iv. "buffing the eyelid margin" 25

v. "breaking the debris free of the eyelid margin." 25

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i. "A method of treating an eye for an ocular disorder" 26

ii. "with a contact member comprising a soft and resilient material" 26

iii. "operably connected to an electromechanical device" 27

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:" 27

v. "effecting movement of the contact member relative to the electromechanical device." 27

vi. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid" 27

vii. "thereby impacting the debris with the contact member to remove debris from the eye" 27

viii. "unroofing a plurality of meibomian glands along the eyelid margin." 28

H. Dependent Claim 13 28

i. "The method of claim 12, wherein removing debris further comprises at least one of:" 28

ii. "scrubbing the eyelid margin" 28

iii. "exfoliating the eyelid margin" 28

iv. "buffing the eyelid margin" 28

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v. "effecting movement of the contact member relative to the electromechanical device," 30
vi. "the contact member having at least a portion thereof configured to access a portion of the eyelid margin," 30
vii. "wherein the movement comprises electromechanical rotation of the contact member;" 31
viii. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid" 31
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iii. "operably connected to an electromechanical device" 35
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I, Dr. Robert Cykiert, do hereby declare:

1. My name is Dr. Robert Cykiert. I have been retained by Petitioner NuLids, LLC ("Petitioner"), through its counsel, Bochner PLLC, as an independent expert witness in the Inter-Partes Review of U.S. Patent 11,083,621 ("the '621 Patent").

2. In preparing this Declaration, I reviewed the following materials:

(a) U.S. Patent No. 11,083,621 (EX1001)

(b) U.S. Patent Pub. No. 2007/0060988 (EX 1005);

(c) U.S. Patent Pub. No. 2007/0016254 (EX1006);

(d) U.S. Patent Pub. No. 2013/0331768 (EX1007);

(e) International Patent Pub. No. 2009/066077 (EX1008); and

(f) U.S. Patent No. 4,838,851 (EX1009).

3. I have also reviewed the Blephex product which I understand is publicly available.

4. I am familiar with the technology at issue as of July 24, 2012, the earliest filing date to which the '621 Patent claims priority.

I. Professional Background

5. Information concerning my professional qualifications, experience, and publications, and the matters in which I have served as an expert, are set forth in my *curriculum vitae*, attached as EX1003 and EX1004.

6. I received my M.D. from New York Medical College in 1976. After graduation, I was an Internal Medicine Intern at Lenox Hill Hospital from 1976-1977. I was a Resident in Ophthalmology at Albert Einstein College of Medicine from 1977-1980, including serving as Chief Resident in Ophthalmology from 1979-1980. Following residency, I served as the Heed

Ophthalmic Foundation Fellow in Corneal and External Disease at Wills Eye Hospital – Thomas Jefferson University from 1980-1981.

7. My accolades include recognition in the New York Magazine Best Doctors Issue from 2012-2021, the Heed Ophthalmic Foundation Fellowship in Cornea and External Disease from Wills Eye Hospital from 1980-1981, and recognition by Alpha Omega Alpha from New York Medical College in 1975.

8. Currently I serve as an attending surgeon at New York Eye and Ear Infirmary and an attending physician in Ophthalmology at Manhattan Eye, Ear & Throat Hospital.

9. From 1981-1990 I was a Clinical Assistant Professor of Ophthalmology at New York University Medical Center. Since 1991 I have served as a Clinical Associate Professor of Ophthalmology at New York University Medical Center.

10. I was a co-founder of New York Eye and Ear Infirmary IPA and Physician Hospital Organization (PHO) and served on the Board of Directors from 1998-2005.

11. I was a co-founder of the University Physicians Network, L.L.C. (UPN) and have served on the Board of Directors since 1996.

12. Currently I serve on the NYU Medical Center's Credential Committee of the Medical Board and the Medical Advisory Board of the New York Eye Bank for Sight Restoration.

13. I have written many peer-reviewed publications related to ocular diseases and disorders, including more than 30 publications, participated in over 160 lectures and presentations, and made over 40 multimedia appearances.

14. I have offered testimony in court during the last fourteen years, a list of which is provided in EX1004.

15. I have submitted declarations in the last fourteen years, a list of which is provided in EX1004.

II. Relevant Legal Standards

16. I have been asked to provide my opinions as to whether claims 1-6 and 9-18 ("Challenged Claims") of the '621 Patent are anticipated or would have been obvious to a Person Having Ordinary Skill in the Art (or "PHOSITA" or "an ordinary artisan") at the time of filing of the '621 Patent.

17. I am a doctor by training and profession. The opinions I express in this declaration involve the application of my technical knowledge and experience to the evaluation of certain prior art with respect to the '621 patent. In addition, I understand that the following legal principles apply.

18. It is my understanding that, in determining whether claims of the '621 Patent are anticipated or obvious in this proceeding, the claim terms are generally given their plain and ordinary meaning as understood by a person of ordinary skill in the relevant art. A person of ordinary skill in the art would read the claim terms in the context of the entire patent application in which they appear, as well as the prosecution history of the patent.

19. It is my understanding that a claim is anticipated under 35 U.S.C. § 102 if each and every element and limitation of the claim is found, either expressly or inherently, in a single prior art reference. I also understand that a reference must disclose all claimed elements as arranged in the claim, although identical terminology need not be used in the reference and claim elements.

20. It is my understanding that a claim is unpatentable under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I also understand that an obviousness analysis takes into

account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

21. In determining the scope and content of the prior art, it is my understanding that a reference is considered relevant prior art if it falls within the field of the inventor's endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering his problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

22. To assess the differences between prior art and the claimed subject matter, it is my understanding that 35 U.S.C. § 103 requires the claimed invention to be considered as a whole. This "as a whole" assessment involves showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

23. It is my further understanding that several rationales may be applied for combining references or modifying a reference to show obviousness of claimed subject matter. These rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would

have led one of ordinary skill to modify a prior art reference or to combine prior art teachings to arrive at the claimed invention.

24. It is my further understanding that a reference qualifies as a prior art printed publication as of the date it was "publicly accessible." *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016); *see also Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 13 at 32-33 (PTAB Dec. 20, 2019) (granting IPR petition based on prior art Service Manual and similar supporting evidence herein); *Roku, Inc. v. Universal Electronics Inc.*, IPR2021-00758, Paper 7 at 14 (PTAB Sep. 27, 2021) (granting IPR petition based on prior art HDMI Specification and similar supporting evidence herein).

III. Person of Ordinary Skill in the Art

25. It is my understanding that when interpreting the claims of the '621 Patent I must do so based on the perspective of one of ordinary skill in the art at the relevant priority date. My understanding is that the earliest claimed priority date of the '621 patent is July 24, 2012.

26. It is my opinion that one of ordinary skill in the art in the field of ocular devices, and more generally in the time period preceding and including 2012, would have had 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.

27. I am a person of at least ordinary skill in the art and was so at the time of the purported invention of the '621 Patent.

IV. The Subject Patent U.S. Patent No. 11,083,621 ('621 Patent)

28. The '621 patent is titled "Instrument for treating an ocular disorder." It was filed on October 1, 2019.

A. Overview

i. Field of Art

29. The stated field of the art is "to a method and apparatus for treating an ocular disorder, and more particularly, to treating eyelid margin disease." '621 Patent 1:17-20.

ii. Background – Description of the Prior Art and Admitted Prior Art

30. At least by the July 2012 priority date of the '621 Patent, the art of methods and apparatuses for treating an ocular disorder was decades old and well-established. It was a crowded art where concepts used in the field were well understood and predictable, with features regularly mixed and matched as needed to achieve a person of ordinary skill's design goals.

31. It is my understanding that the '621 Patent confirms several of these well understood and predictable features.

iii. Problem statement

32. The '621 Patent states that because of a patient's "anxiety, discomfort, and the inability to specifically target debris deposits" and the significant financial burden of treatment, there are existing challenges in treating ocular disorders. EX1001, 2:1-36. But the patent does not describe how it addresses these "challenges."

V. Prosecution History of the '621 Patent

33. I have reviewed the file history of U.S. Patent Application No. 16/590,228 ("the '228 Application"), from which the '621 Patent issued. The '228 Application is a continuation of U.S. Application No. 16/352,758 filed March 13, 2019, which is a continuation of U.S. Application 13/949,365, filed on July 24, 2013, which is a continuation-in-part of 13/556,729 filed July 24, 2012.

34. The '228 Application was ultimately allowed following a limitation to Independent Claims 1 and 12 to claim, "without lifting the eyelid margin from the eye."

VI. The Prior Art And Specific Grounds On Which The Challenge Is Based

A. The Prior Art

35. It is my understanding that all prior art relied on in this Petition was published before the '621 Patent's earliest priority date of July 24, 2012, and/or is a patent publication with a priority date prior to July 24, 2012, and is therefore, prior art to the '621 Patent under 35 U.S.C. § 102(a)(1-2).

36. It is my understanding the following patent literature is prior art to the '621 Patent at least under 35 U.S.C. § 102(a)(1-2):

(a) U.S. Patent Pub. No. 2007/0060988 to Grenon, *et al.* ("Grenon I", EX 1005), published March 15, 2007;

(b) U.S. Patent Pub. No. 2007/0016254 to Grenon *et al.* ("Grenon II", EX1006), published January 18, 2007;

(c) U.S. Patent Pub. No. 2013/0331768 to Nichamin ("Nichamin", EX1007), published December 12, 2013, with a priority date of Dec. 28, 2011;

(d) PCT Pub. No. WO 2009/066077 to Colin ("Colin", EX1008), published May 28, 2009; and

(e) U.S. Patent No. 4,838,851 to Shabo ("Shabo", EX1009), issued June 13, 1989.

VII. Summary of Prior Art

A. US2007/0060988; "Grenon I"

37. It is my understanding that Grenon I is directed to "treatment of mammalian eyes" by relieving obstruction of meibomian glands. EX1005 ¶4. Grenon I discloses a device including "the application of regulated heating to the eyelids for therapeutic purposes" and the application of "vibration, pulsation, and/or milking action of the eyelid to stimulate secretion from the meibomian glands." *Id.,* ¶¶4, 24, 128.

38. It is my understanding that Grenon I discloses a contact member comprising a soft and resilient material. Grenon I discloses an eyelid interface as a heat sink 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. It is my opinion that a PHOSITA reading Grenon I would find that flexible silicon is resilient as it is able to shape to a surface when applied, but able to return to its normal state when removed. Further, it is my opinion that flexible silicon is a soft material as it is able to conform to the shape of the eyelid.

39. It is my understanding that Grenon I discloses a "[p]ower source 34 [which] supplies power both to the heating element and the control processor 160, as well as to an alarm 176 and vibrator 136." EX1005 ¶128. Grenon I described that the power source, control processor, and the vibrator are in communication with the eyelid interface. EX1005 ¶115.

40. It is my understanding that Grenon I discloses movement of the heat sink in contact with the vibrator to "generate[] vibration, pulsation, and/or milking action" to "impart[] mechanical energy to the eyelid." EX1005 ¶¶34, 115.

41. It is my understanding that Grenon I discloses that its "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.

B. US2007/0016254; "Grenon II"

42. It is my understanding that 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. Grenon II discloses a mechanical device for applying a regulated force, regulated energy, regulated heat and/or chemical/pharmacological agent or combinations thereof to the eyelid to remove obstructions." EX1006 ¶23.

43. It is my understanding that Grenon II discloses placing an "abrasive tip 310 in contact over the gland orifice creating a seal between the tip and the skin." EX1006 ¶¶55-59. A PHOSITA will recognize that the meibomian gland opening is present on the posterior portion of the eyelid margin.

44. It is my understanding that Grenon II discloses a goggle-like device designed to position the electromechanical device proximate to the eyelids to apply heat and a massaging force to the meibomian glands. EX1006 ¶¶58-70. A PHOSITA will recognize that Grenon II's goggle-like device prevents access to, and the ability to lift, the eyelid margin during use.

45. It is my understanding that Grenon II discloses "exfoliation to remove any cells or cellular material that may have overgrown the gland opening." EX1006 ¶58.

46. It is my understanding that Grenon II discloses "rollers applying constant regulated pressure to the meibomian gland to apply a 'milking' type force to expel the obstructions." EX1006 ¶¶63-64.

47. It is my understanding that Grenon II discloses "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.

48. It is my understanding that 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.

49. It is my understanding that 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.

50. It is my understanding that Grenon II discloses vibrating its probe at a preselected frequency in order to loosen, liquefy, and/or fracture an obstruction in the meibomian gland. EX1006 ¶55.

C. US2013/0331768; "Nichamin"

51. It is my understanding that Nichamin discloses "a method of treating or preventing an eye condition in eye area tissue." EX1007 ¶30. Nichamin discloses an applicator extending from an electromechanical device to permit movement along the eyelid margin. EX1007 ¶¶48, 54.

52. It is my understanding that Nichamin discloses "chafing upper eyelid tissue, lower eyelid tissue, eyelid margin tissue, anterior eyelid margin tissue, posterior eyelid margin tissue, or eyelash follicle" to "clean margin surface and eyelash 44." EX1007 ¶¶31, 54. As debris builds up along the eyelid margin and Nichamin's disclosure of chafing the eyelid margin removes the debris built up along the margin.

53. It is my understanding that Nichamin discloses that an "applicator may rotate, rub, vibrate, or otherwise move to aid in the chafing process." EX1007 ¶65.

D. WO 2009/066077; "Colin"

54. It is my understanding that Colin is directed to "devices and methods for using such a device for therapeutic or prophylactic massage of mammalian eyelids." EX1008 1:7-9. Colin discloses "a device for heating and massaging the eyelid" to melt and extract obstructions from blocked meibomian glands. EX 5:10-32.

55. It is my understanding that Colin discloses "deformable eyelid interface . . . made from rubber, synthetic rubber, silicone rubber and like materials." EX1008 8:28-32. It is my opinion that a PHOSITA reading Colin would find that it discloses a deformable eyelid interface formed out of rubber as it is able to shape to a surface when applied, but able to return to its normal state when removed. Further, it is my opinion that rubber is a soft material as it is able to conform to the shape of the eyelid.

56. It is my understanding that Colin discloses a motor in communication with a circular disc provides support to the deformable eyelid interface. EX1008 15:29-16:26. It is my opinion that by the motor rotating the circular disc, the motor is moving the deformable eyelid interface.

57. It is my understanding that Colin discloses the circular disc having a massaging nodule that pushes through the deformable eyelid interface. EX1008 6:20-26. Colin discloses that the circular disc is rotated, causing the massaging nodule to be rotated, resulting in rotation of the eyelid interface in contact with the eyelid and eyelid interface. EX1008 16:14-16.

58. It is my understanding that Colin discloses a scrubbing element "positioned so as to displace debris from the base of the eyelashes in use." EX1008 10:25-28. The scrubbing element

is disclosed as deformable fingers formed with the eyelid interface to contact the base of the eyelashes to dislodge any debris. EX1008 17:11-25.

59. It is my understanding that 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.

E. US4838851; "Shabo"

60. It is my understanding that Shabo is directed to a treatment method and apparatus for eye conditions, such as blepharitis. EX1009 1:7-23.

61. It is my understanding that 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.

62. It is my understanding that Shabo discloses "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." A PHOSITA would recognize that tenacious deposits are one form of removable debris that is found at the eye.

63. It is my understanding that Shabo discloses an applicator "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.

64. It is my understanding that Shabo discloses that its "swab can be formed of any liquid absorbent material, for example, a porous sponge material, or a cotton backing." EX1009 4:3-5.

VIII. Claim Construction

65. In proceedings before the U.S. Patent and Trademark Office, I have been instructed that the claims are to be given the same interpretation that they would be given in the District Court under *Phillips v. AWH Corp*. In my opinion, the most reasonable interpretations of the claim terms of the '621 Patent are consistent with the ordinary and customary meaning of terms as one skilled in the art would understand them.

66. A PHOSITA knows that the eye inherently includes an eyelid margin and an eyeball. The eyelid margin includes the portion of the eye from a posterior sharp border of the lid margin to the eyelashes. The eyelid margin is separated into a posterior eyelid margin which includes meibomian gland openings and an anterior eyelid margin which contains the base of the eyelashes. The posterior and anterior portions of the eyelid margin are separated by a gray line. Further, in eyes with ocular disorders, such as blepharitis, debris often builds up along the eyelid margin and within the meibomian glands and is removed in order to treat the ocular disorder.

IX. Ground I – Grenon I, Grenon II, and Nichamin

A. Motivation to Combine

67. It is my opinion that a PHOSITA would have found it obvious to combine the teachings of Grenon I with Grenon II and Nichamin. Each reference is directed to an electromechanical device for removing obstructions in the meibomian glands. *See* EX1005 ¶34, EX1006 ¶¶69-70, 1007 ¶54.

68. It is my opinion that there should be no doubt whatsoever regarding the combination of Grenon I and Grenon II with the variety of different motions described in Nichamin to arrive at the claimed solution in the '621 Patent. EX1005 ¶34, EX1006 ¶56, EX1007 ¶65.

B. Independent Claim 1

i. "A method of treating an eye for an ocular disorder"

69. It is my opinion that Grenon I, Grenon II, and Nichamin each disclose "[a] method for treating an eye for an ocular disorder." See EX1005 ¶4; EX1006 ¶23; EX1007 ¶30.

ii. "with a contact member comprising a soft and resilient material"

70. It is my opinion that Grenon I includes "a contact member comprising a soft and resilient material." Grenon I discloses an eyelid interface made of a flexible silicon member that enables the eyelid interface to form to the patient's eyelid. Thus, it is my opinion that the eyelid interface in Grenon I comprises a soft and resilient material.

iii. "operably connected to an electromechanical device"

71. It is my opinion that Grenon I includes the contact member being "operably connected to an electromechanical device." Grenon I discloses a vibrator in connection with a power supply and a control processor EX1005 ¶128. The vibrator is disclosed as part of the eyelid interface and it is obvious that the power source, control processor, and vibrator are in connection with the eyelid interface. Thus, it is my opinion that the eyelid interface in Grenon I is operably connected to an electromechanical device.

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:"

72. It is my opinion that the limitation of "wherein the eye has an eyelid margin and an eyeball and includes a removable debris" is inherent within a human organism. Eyes, eyelid margin, and eyeballs are known anatomical structures of the eye. Moreover, the eye will generally accumulate removal debris.

73. It is my opinion that Grenon I further discloses an eye, an eyeball, an eyeball margin, and removable debris. EX1005 ¶¶12-15.

v. "effecting movement of the contact member relative to the electromechanical device,"

74. It is my opinion that Grenon I includes the limitation of "effecting movement of the contact member relative to the electromechanical device." Grenon I discloses the vibrator, and the eyelid interface are formed as part of a heating unit. As a PHOSITA will recognize, movement of the vibrator results in movement of the heating unit, including the eyelid interface. Thus, it is my opinion that Grenon I discloses effecting movement of the contact member relative to the electromechanical device.

vi. "the contact member having at least a portion thereof configured to access a portion of the eyelid margin,"

75. It is my opinion that Grenon II discloses a contact member having at least a portion thereof configured to access a portion of the eyelid margin. Grenon II discloses contacting a meibomian gland opening, which is a portion of the eyelid margin, with a tip of Grenon II's device. EX1006 ¶¶55-59. Thus, Grenon II discloses the contact member having at least a portion thereof configured to access a portion of the eyelid margin.

vii. "wherein the movement comprises electromechanical rotation of the contact member;"

76. It is my opinion that Nichamin discloses "wherein the movement comprises electromechanical rotation of the contact member." Nichamin discloses that its "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 rotation of the applicator as disclosed in Nichamin with the disclosures of vibration in Grenon I and Grenon I.

viii. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid"

77. It is my opinion that Grenon II discloses "contacting the eyelid margin with the contact member without lifting the eyelid." Grenon II discloses its electromechanical device being formed as part of a goggle-like device in order to contact the eye. EX1006 ¶69. A PHOSITA would have understood that the positioning of Grenon II's electromechanical device within the goggle-like device would prevent a patient from accessing the eyelid for lifting during use. Thus, Grenon II discloses the contacting the eyelid margin without lifting the eyelid.

ix. "so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member"

78. It is my opinion that Nichamin discloses scrubbing a portion of the eyelid margin that includes the removable debris with the contact member. Nichamin discloses "chafing posterior eyelid margin" to unblock and open meibomian glands. EX1007 ¶54. A PHOSITA will recognize that "chafing" is synonymous with scrubbing. Thus, it is my opinion that Nichamin discloses scrubbing a portion of the eyelid margin.

x. "thereby impacting the debris with the contact member to remove debris from the eye."

79. It is my opinion that Nichamin discloses impacting debris with the contact member to remove debris from the eye. Nichamin discloses chafing the eyelid margin to remove the debris built up along the eyelid margin and within the meibomian glands. EX1007 ¶54. Thus, it is my opinion that Nichamin discloses impacting the debris with the contact member to remove the debris.

80. It is my opinion that Grenon I, Grenon II, and Nichamin disclose each limitation of Independent Claim 1 of the '621 Patent for the reasons provided *supra*.

C. Dependent Claim 2

i. "The method of claim 1, wherein removing debris further comprises at least one of:"

81. It is my opinion that for at least the reasons provided in Section IX.B.x, Nichamin discloses removing debris.

ii. "exfoliating the eyelid margin;"

82. It is my opinion that Grenon II discloses "exfoliating the eyelid margin." EX1006 ¶58.

iii. "unroofing a plurality of meibomian glands along the eyelid margin"

83. It is my opinion that Grenon II discloses "unroofing a plurality of meibomian glands along the eyelid margin." A PHOSITA will recognize that unroofing meibomian glands refers to getting rid of hardened obstructions at the top of the meibomian glands. There are a variety of well-known 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. Thus, it is my opinion that Grenon II discloses unroofing meibomian glands along the eyelid margin.

iv. "buffing the eyelid margin"

84. It is my opinion that Nichamin discloses "buffing the eyelid margin." It would have been obvious to a PHOSITA that Nichamin's disclosure of rubbing the eyelid margin is synonymous with buffing the eyelid margin. Thus, it is my opinion that Nichamin discloses buffing the eyelid margin.

v. "breaking the debris free of the eyelid margin."

85. It is my opinion that "breaking the debris free of the eyelid margin" is well known in the art. In order to treat ocular disorders, such as blepharitis, a PHOSITA would recognize that the debris must be dislodged and removed.

86. It is my opinion that Grenon II discloses "breaking the debris free of the eyelid margin." Grenon II discloses removing obstruction in order to restore the natural flow of secretion from the meibomian gland. EX1006 ¶23. Thus, Grenon II discloses breaking the debris free of the eyelid margin.

87. It is my opinion that Grenon I, Grenon II, and Nichamin disclose Dependent Claim 2 of the '621 Patent.

D. Dependent Claim 3

88. It is my opinion that the limitations of Dependent Claim 3 are obvious as discussed in Section IX.B.viii and IX.B.x.

89. It is my opinion that "positioning the contact member near the eyeball" is inherent when positioning the contact member along the eyelid margin. The eyeball and eyelid margin are

in close proximity to one another. Thus, it is my opinion that positioning the contact member near the eyeball is obvious. Similarly, "targeting the debris with the contact member" is effectively synonymous with chafing the eyelid margin to remove the debris built up along the eyelid margin and within the meibomian glands, as disclosed by Nichamin. EX1007 ¶54. Thus, the limitations of this claim are disclosed by and obvious in view of the prior art.

E. Dependent Claim 5

90. It is my opinion that repeating the method in Independent Claim 1 at periodic intervals is obvious to remedy and treat ocular disorders. In ophthalmology, it is common to repeat a particular movement in treating an ocular disorder.

F. Dependent Claim 9

91. It is well known that eyelashes are a portion of the eyelid margin. Thus, a PHOSITA would recognize that the eyelid margin includes eyelashes.

G. Independent Claim 12

i. "A method of treating an eye for an ocular disorder"

92. As discussed in Section IX.B.i, *supra*, it is my opinion that Grenon I, Grenon II, and Nichamin disclose "a method of treating an eye for an ocular disorder."

ii. "with a contact member comprising a soft and resilient material"

93. As discussed in Section IX.B.ii, *supra*, it is my opinion that Grenon I discloses "a contact member comprising a soft and resilient material."

iii. "operably connected to an electromechanical device"

94. As discussed in Section IX.B.iii, *supra*, it is my opinion that Grenon I discloses "operably connected to an electromechanical device."

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:"

95. As discussed in Section IX.B.iv, *supra*, it is my opinion that Grenon I discloses "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising."

v. "effecting movement of the contact member relative to the electromechanical device."

96. As discussed in Section IX.B.v, *supra*, it is my opinion that Grenon I discloses "effecting movement of the contact member relative to the electromechanical device."

vi. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid"

97. As discussed in Section IX.B.viii, *supra*, it is my opinion that 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."

vii. "thereby impacting the debris with the contact member to remove debris from the eye"

98. As discussed in Section IX.B.iv, *supra*, it is my opinion that Nichamin discloses "thereby impacting the debris with the contact member to remove debris from the eye."

viii. "unroofing a plurality of meibomian glands along the eyelid margin."

99. As discussed in Section IX.C.iii, *supra*, it is my opinion that Grenon II discloses "thereby impacting the debris with the contact member to remove debris from the eye."

H. Dependent Claim 13

i. "The method of claim 12, wherein removing debris further comprises at least one of:"

100. As discussed in Section IX.C.i, *supra*, it is my opinion that Grenon I, Grenon II, and Nichamin disclose "removing debris."

ii. "scrubbing the eyelid margin"

101. As discussed in Section IX.B.ix, *supra*, it is my opinion that Nichamin discloses "scrubbing the eyelid margin."

iii. "exfoliating the eyelid margin"

102. As discussed in Section IX.C.ii, *supra*, it is my opinion that Grenon II discloses "exfoliating the eyelid margin."

iv. "buffing the eyelid margin"

103. As discussed in Section IX.C.iv, *supra*, it is my opinion that Nichamin discloses "buffing the eyelid margin."

v. "breaking the debris free of the eyelid margin."

104. As discussed in Section IX.C.v, *supra*, it is my opinion that Grenon II discloses "breaking the debris free of the eyelid margin."

I. Dependent Claim 14

105. It is my opinion that Claim 14 is substantially identical to Claim 9 and is thus obvious for the reasons provided in Section IX.F, *supra*.

J. Dependent Claim 15

106. It is my opinion that Claim 15 is substantially identical to Claim 3 and is thus obvious for the reasons provided in Section IX.D, *supra*.

X. Ground II – Grenon II and Colin

A. Motivation to Combine

107. It is my opinion that a PHOSITA would have found it obvious to combine the teachings of Grenon II with Colin. Both references are directed to electromechanical devices for heating and massaging eyelids in Grenon II. *See* EX1006 ¶¶69-70, EX1008 5:17-23.

108. It is my opinion that there should be no doubt whatsoever regarding the combination of Grenon II and Colin because they are part of a single line of innovation. It is my opinion that a PHOSITA would certainly look to both references that describe the similar inventions to arrive at the claimed solution of the '621 Patent.

B. Independent Claim 1

i. "A method of treating an eye for an ocular disorder"

109. It is my opinion that Grenon II and Colin both disclose "[a] method for treating an eye for an ocular disorder." EX1006 ¶23; EX1008 1:7-9.

ii. "with a contact member comprising a soft and resilient material"

110. It is my opinion that Colin includes "a contact member comprising a soft and resilient material." Colin discloses a deformable eyelid interface formed of rubber. EX1008 8:28-32. A PHOSITA will recognize that the rubber disclosed in Colin is soft and resilient. Thus, it is my opinion that the eyelid interface in Colin comprises a soft and resilient material.

iii. "operably connected to an electromechanical device,"

111. It is my opinion that Grenon II includes the contact member being "operably connected to an electromechanical device." Grenon II discloses a power supply connected to a controller, which is in turn connected to the probe which contacts the eye. EX1006 ¶54. Thus, it is my opinion that the eyelid interface in Grenon II is operably connected to an electromechanical device.

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:"

112. It is my opinion that the limitation of "wherein the eye has an eyelid margin and an eyeball and includes a removable debris" is inherent within a human organism. Eyes, eyelid margin, and eyeballs are known anatomical structures of the eye. Moreover, the eye will generally accumulate removal debris.

v. "effecting movement of the contact member relative to the electromechanical device,"

113. It is my opinion that Colin includes the limitation of "effecting movement of the contact member relative to the electromechanical device." Colin discloses a motor able to rotate a disc and a deformable eyelid interface. EX1008 7:1-7. Thus, it is my opinion that Colin discloses effecting movement of the contact member relative to the electromechanical device.

vi. "the contact member having at least a portion thereof configured to access a portion of the eyelid margin,"

114. As discussed in Section IX.B.vi, *supra*, it is my opinion that Grenon II discloses a "contact member having at least a portion thereof configured to access a portion of the eyelid margin."

vii. "wherein the movement comprises electromechanical rotation of the contact member;"

115. It is my opinion that Colin discloses "wherein the movement comprises electromechanical rotation of the contact member." Colin discloses rotating a circular disc that supports the eyelid interface. EX1008 15:29-16:12. Thus, it is my opinion that Colin discloses electromechanical rotation of the contact member.

viii. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid"

116. As discussed in Section IX.B.viii, *supra*, it is my opinion that Grenon II discloses "contacting the eyelid margin with the contact member without lifting the eyelid."

ix. "so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member"

117. It is my opinion that Colin discloses scrubbing a portion of the eyelid margin that includes the removable debris with the contact member. Colin discloses a "scrubbing element" positioned to displace debris from the base of the eyelashes in use. EX1008 10:25-28. Thus, it is my opinion that Colin discloses scrubbing a portion of the eyelid margin.

x. "thereby impacting the debris with the contact member to remove debris from the eye."

118. It is my opinion that Colin discloses impacting debris with the contact member to remove debris from the eye. Colin discloses the scrubbing element having fingers as part of the eyelid interface to dislodge the debris along the eyelid margin. EX1008 10:25-28. Thus, it is my opinion that Colin discloses impacting the debris with the contact member to remove the debris.

119. It is my opinion that Grenon II and Colin disclose each limitation of Independent Claim 1 of the '621 Patent for the reasons provided *supra*.

C. Dependent Claim 2

i. "The method of claim 1, wherein removing debris further comprises at least one of:"

120. It is my opinion that, for at least the reasons provided in Section X.B.x, Colin discloses removing debris.

ii. "exfoliating the eyelid margin;"

121. As discussed in Section X.C.ii. *supra*, it is my opinion that Grenon II discloses "exfoliating the eyelid margin."

iii. "unroofing a plurality of meibomian glands along the eyelid margin"

122. As discussed in Section X.C.iii. *supra*, it is my opinion that Grenon II discloses "unroofing a plurality of meibomian glands along the eyelid margin."

iv. "buffing the eyelid margin"

123. It is my opinion that Colin discloses "buffing the eyelid margin." It would have been obvious to a PHOSITA that Colin's disclosure of scrubbing the eyelid margin is synonymous with buffing the eyelid margin. Thus, it is my opinion that Colin discloses buffing the eyelid margin.

v. "breaking the debris free of the eyelid margin."

124. It is my opinion that "breaking the debris free of the eyelid margin" is well known in the art. In order to treat ocular disorders, such as blepharitis, a PHOSITA would recognize that the debris must be dislodged and removed.

125. As discussed in Section X.C.II., *supra*, it is my opinion that Grenon II discloses "breaking the debris free of the eyelid margin."

126. It is my opinion that Grenon II and Colin disclose Dependent Claim 2 of the '621 Patent.

D. Dependent Claim 3

127. It is my opinion that the limitations of Dependent Claim 3 are obvious as discussed in Section X.B.viii.

128. It is my opinion that "positioning the contact member near the eyeball" is inherent when positioning the contact member along the eyelid margin. The eyeball and eyelid margin are in close proximity to one another. Thus, it is my opinion that positioning the contact member near the eyeball is obvious.

E. Dependent Claim 5

129. It is my opinion that repeating the method in Independent Claim 1 at periodic intervals is obvious to remedy and treat ocular disorders.

F. Dependent Claim 9

130. It is well known that eyelashes are a portion of the eyelid margin. Thus, a PHOSITA would recognize that the eyelid margin includes eyelashes.

G. Independent Claim 12

i. "A method of treating an eye for an ocular disorder"

131. As discussed in Section X.B.i, *supra*, it is my opinion that Grenon I, Grenon II, and Nichamin disclose "a method of treating an eye for an ocular disorder."

ii. "with a contact member comprising a soft and resilient material"

132. As discussed in Section X.B.ii, *supra*, it is my opinion that Colin discloses "a contact member comprising a soft and resilient material."

iii. "operably connected to an electromechanical device"

133. As discussed in Section X.B.iii, *supra*, it is my opinion that Grenon II discloses "operably connected to an electromechanical device."

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:"

134. As discussed in Section X.B.iv, *supra*, it is my opinion that Colin discloses "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising."

v. "effecting movement of the contact member relative to the electromechanical device."

135. As discussed in Section X.B.v, *supra*, it is my opinion that Grenon II discloses "effecting movement of the contact member relative to the electromechanical device."

vi. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid"

136. As discussed in Section X.B.viii, *supra*, it is my opinion that 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."

vii. "thereby impacting the debris with the contact member to remove debris from the eye"

137. As discussed in Section X.B.iv, *supra*, it is my opinion that Colin discloses "thereby impacting the debris with the contact member to remove debris from the eye."

viii. "unroofing a plurality of meibomian glands along the eyelid margin."

138. As discussed in Section X.C.iii, *supra*, it is my opinion that Colin discloses "thereby impacting the debris with the contact member to remove debris from the eye."

H. Dependent Claim 13

i. "The method of claim 12, wherein removing debris further comprises at least one of:"

139. As discussed in Section X.C.i, *supra*, it is my opinion that Grenon II and Colin disclose "removing debris."

ii. "scrubbing the eyelid margin"

140. As discussed in Section X.B.ix, *supra*, it is my opinion that Colin discloses "scrubbing the eyelid margin."

iii. "exfoliating the eyelid margin"

141. As discussed in Section X.C.ii, *supra*, it is my opinion that Grenon II discloses "exfoliating the eyelid margin."

iv. "buffing the eyelid margin"

142. As discussed in Section X.C.iv, *supra*, it is my opinion that Colin discloses "buffing the eyelid margin."

v. "breaking the debris free of the eyelid margin."

143. As discussed in Section X.C.v, *supra*, it is my opinion that Grenon II discloses "breaking the debris free of the eyelid margin."

I. Dependent Claim 14

144. It is my opinion that Claim 14 is substantially identical to Claim 9 and is thus obvious for the reasons provided in Section X.F, *supra*.

J. Dependent Claim 15

145. It is my opinion that Claim 15 is substantially identical to Claim 3 and is thus obvious for the reasons provided in Section X.D, *supra*.

XI. Ground III – Grenon II, Colin, and Shabo

A. Motivation to Combine

146. It is my opinion that a PHOSITA would have found it obvious to combine the teachings of Grenon II with Colin and Shabo. Each reference relates to methods of treating ocular disorders caused by dysfunction of the meibomian glands. *See* EX1006 ¶23, EX1008 5:30-32, and EX1009 1:7-23.

147. It is my opinion that it would have been obvious to combine the electromechanical devices in Grenon II and Colin with the contact member of Shabo in order to arrive at the claimed solution in the '621 Patent.

B. Independent Claim 1

i. "A method of treating an eye for an ocular disorder"

148. It is my opinion that Grenon II, Colin, and Shabo each disclose "[a] method for treating an eye for an ocular disorder." EX1006 ¶23; EX1008 1:7-9; EX1009 1:7-23.

ii. "with a contact member comprising a soft and resilient material"

149. It is my opinion that Shabo includes "a contact member comprising a soft and resilient material." Shabo discloses a swab, which a PHOSITA will recognize is a soft and resilient

material. EX1009 2:11-12. Thus, it is my opinion that the swab in Shabo comprises a soft and resilient material.

150. It is my opinion that Shabo includes "a contact member comprising a soft and resilient material." Shabo discloses a swab which is described in the '621 Patent as being soft and resilient. EX1009 2:11-12, EX1001 4:1-3. Thus, it is my opinion that the swab in Shabo comprises a soft and resilient material.

iii. "operably connected to an electromechanical device,"

151. As discussed in Section X.B.iii, *supra*, it is my opinion that Grenon II includes the contact member being "operably connected to an electromechanical device."

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:"

152. It is my opinion that the limitation of "wherein the eye has an eyelid margin and an eyeball and includes a removable debris" is inherent within a human organism. Eyes, eyelid margin, and eyeballs are known anatomical structures of the eye. Moreover, the eye will generally accumulate removal debris.

v. "effecting movement of the contact member relative to the electromechanical device,"

153. As discussed in Section X.B.v, *supra*, it is my opinion that Colin includes the limitation of "effecting movement of the contact member relative to the electromechanical device."

vi. "the contact member having at least a portion thereof configured to access a portion of the eyelid margin,"

154. It is my opinion that Shabo discloses "the contact member having at least a portion thereof configured to access a portion of the eyelid margin." Shabo discloses moving an applicator

along the eyelid margin and thus a PHOSITA would recognize that Shabo's applicator can contact the eyelid margin. EX1009 1:69-2:33. Thus, it is my opinion that Shabo discloses the contact member accessing a portion of the eyelid margin.

vii. "wherein the movement comprises electromechanical rotation of the contact member;"

155. As discussed in Section X.B.vi, *supra*, it is my opinion that Colin discloses "wherein the movement comprises electromechanical rotation of the contact member."

viii. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid"

156. As discussed in Section IX.B.viii, *supra*, it is my opinion that Grenon II discloses "contacting the eyelid margin with the contact member without lifting the eyelid

ix. "so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member"

157. As discussed in Section X.B.ix, *supra*, it is my opinion that Colin discloses scrubbing a portion of the eyelid margin that includes the removable debris with the contact member.

x. "thereby impacting the debris with the contact member to remove debris from the eye."

158. As discussed in Section X.B.x, *supra*, it is my opinion that Colin discloses impacting debris with the contact member to remove debris from the eye.

159. It is my opinion that Grenon II, Colin, and Shabo disclose each limitation of Independent Claim 1 of the '621 Patent for the reasons provided *supra*.

C. Dependent Claim 2

i. "The method of claim 1, wherein removing debris further comprises at least one of:"

160. It is my opinion that, for at least the reasons provided in Section X.B.x, Colin discloses removing debris.

ii. "exfoliating the eyelid margin;"

161. As discussed in Section X.C.ii. *supra*, it is my opinion that Grenon II discloses "exfoliating the eyelid margin."

iii. "unroofing a plurality of meibomian glands along the eyelid margin"

162. As discussed in Section X.C.iii. *supra*, it is my opinion that Grenon II discloses "unroofing a plurality of meibomian glands along the eyelid margin."

iv. "buffing the eyelid margin"

163. As discussed in Section X.C.iv, *supra*, it is my opinion that Colin discloses "buffing the eyelid margin." .

v. "breaking the debris free of the eyelid margin."

164. It is my opinion that "breaking the debris free of the eyelid margin" is well known in the art. In order to treat ocular disorders, such as blepharitis, a PHOSITA would recognize that the debris must be dislodged and removed.

165. As discussed in Section X.C.II., *supra*, it is my opinion that Grenon II discloses "breaking the debris free of the eyelid margin."

166. It is my opinion that Grenon II, Colin, and Shabo disclose Dependent Claim 2 of the '621 Patent.

D. Dependent Claim 3

167. It is my opinion that the limitations of Dependent Claim 3 are obvious as discussed in Section X.B.viii.

168. It is my opinion that "positioning the contact member near the eyeball" is inherent when positioning the contact member along the eyelid margin. The eyeball and eyelid margin are in close proximity to one another. Thus, it is my opinion that positioning the contact member near the eyeball is obvious.

E. Dependent Claim 4

i. "The method of claim 1, wherein the movement of the contact member is at least one of:""

169. It is my opinion that Grenon II, Colin, and Shabo disclose the limitations of Dependent Claim 4.

ii. "vibrating the contact member"

170. It is my opinion that Grenon II discloses "vibrating the contact member." Grenon II discloses that its probe is adapted to vibrate. EX1006 ¶¶54-55. Thus, it is my opinion that Grenon discloses vibrating the contact member.

iii. "reciprocating the contact member."

171. It is my opinion that Shabo discloses "reciprocating the contact member." Shabo discloses moving its applicator in a "to and fro" movement along the eyelid margin. EX1009 2:3-30. Thus, a PHOSITA would recognize that Shabo discloses reciprocating the contact member.

F. Dependent Claim 5

172. As discussed in Section X.E, *supra*, it is my opinion that repeating the method in Independent Claim 1 at periodic intervals is obvious to remedy and treat ocular disorders.

G. Dependent Claim 6

173. It is my opinion that Shabo discloses "wherein the contact member is a medical grade sponge for accessing the eyelid margin." As a PHOSITA will recognize, the designation of medical grade means that the material is sterile. It would have been obvious to an ordinary artisan that any material being in close proximity to the eye should be sterile, and thus medical grade, to prevent infection in the eye. As Shabo discloses that its swab can be formed of a sponge, it is my opinion that Shabo discloses a medical grade sponge. EX1009 4:3-5.

H. Dependent Claim 9

174. It is well known that eyelashes are a portion of the eyelid margin. Thus, a PHOSITA would recognize that the eyelid margin includes eyelashes.

I. Dependent Claim 10

175. It is my opinion that Shabo discloses "wherein the soft and resilient material is absorbent." EX1009 4:3-5.

J. Dependent Claim 11

176. It is my opinion that Shabo discloses "wherein the soft and resilient material is porous." EX1009 4:3-5.

K. Independent Claim 12

i. "A method of treating an eye for an ocular disorder"

177. As discussed in Section XI.B.i, *supra*, it is my opinion that Grenon II, Colin, and Shabo disclose "a method of treating an eye for an ocular disorder."

ii. "with a contact member comprising a soft and resilient material"

178. As discussed in Section XI.B.ii, *supra*, it is my opinion that Shabo discloses "a contact member comprising a soft and resilient material."

iii. "operably connected to an electromechanical device"

179. As discussed in Section XI.B.iii, *supra*, it is my opinion that Grenon II discloses "operably connected to an electromechanical device."

iv. "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising:"

180. As discussed in Section XI.B.iv, *supra*, it is my opinion that Colin discloses "wherein the eye has an eyelid margin and an eyeball and includes a removable debris, the method comprising."

v. "effecting movement of the contact member relative to the electromechanical device."

181. As discussed in Section XI.B.v, *supra*, it is my opinion that Colin discloses "effecting movement of the contact member relative to the electromechanical device."

vi. "while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid"

182. As discussed in Section XI.B.viii, *supra*, it is my opinion that 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."

vii. "thereby impacting the debris with the contact member to remove debris from the eye"

183. As discussed in Sections XI.B.ix and XI.B.x, *supra*, it is my opinion that Colin discloses "thereby impacting the debris with the contact member to remove debris from the eye."

viii. "unroofing a plurality of meibomian glands along the eyelid margin."

184. As discussed in Section XI.C.iii, *supra*, it is my opinion that Grenon II discloses "unroofing a plurality of meibomian glands along the eyelid margin."

L. Dependent Claim 13

185. As discussed in Section XI.C, *supra*, it is my opinion that Grenon II, Colin, and Shabo render the limitations of Dependent Claim 13 obvious.

M. Dependent Claim 14

186. It is my opinion that Claim 14 is substantially identical to Claim 9 and is thus obvious for the reasons provided in Section XI.H, *supra*.

N. Dependent Claim 15

187. It is my opinion that Claim 15 is substantially identical to Claim 3 and is thus obvious for the reasons provided in Section XI.D, *supra*.

O. Dependent Claim 16

188. It is my opinion that Claim 16 is substantially identical to Claim 6 and is thus obvious for the reasons provided in Section XI.G, *supra*.

P. Dependent Claim 17

189. It is my opinion that Claim 17 is substantially identical to Claim 10 and is thus obvious for the reasons provided in Section XI.I, *supra*.

Q. Dependent Claim 18

190. It is my opinion that Claim 18 is substantially identical to Claim 11 and is thus obvious for the reasons provided in Section XI.J, *supra*.

XII. Summary

191. I am therefore of the opinion that Claims 1-6 and 9-18 of the ’621 Patent would be anticipated or rendered obvious to a person of ordinary skill in the art given the prior art references discussed above.