

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

BLEPHEX, LLC,
Patent Owner.

Case IPR2016-01670
Patent 9,039,718 B2

Before MEREDITH C. PETRAVICK, SCOTT A. DANIELS, and
SCOTT C. MOORE, *Administrative Patent Judges*.

DANIELS, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Pain Point Medical Systems, Inc. (“Pain Point” or “Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–11 and 14–17 of U.S. Patent No. 9,039,718 B2 (“the ’718 patent”). Paper 1 (“Pet.”). Petitioner also filed a declaration by William J. Benjamin, O.D., Ph.D. (Ex. 1002). Blephex, LLC (“Blephex” or “Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). We instituted trial for claims 1–11 and 14–17 of the ’718 patent on certain grounds of unpatentability alleged in the Petition. Paper 10 (“Decision to Institute” or “Inst. Dec.”).

After institution of trial, Patent Owner filed a Patent Owner Response, (“PO Resp.”, Paper 21), along with a declaration by Blephex’s Declarant, Jerry R. Paugh O.D., Ph.D., (Ex. 2025), and also a declaration by Marguerite McDonald, M.D. (Ex. 2029). Petitioner timely filed a Reply (“Pet. Reply”, Paper 26). Subsequently, we authorized Patent Owner a Sur-Reply (“PO Sur-Reply”, Paper 32) to address alleged new arguments apparently raised for the first time by Petitioner in its Reply. Paper 28. Petitioner was authorized also to file a response to the Sur-Reply (“Pet. Resp. to Sur-Reply”, Paper 35). *Id.* Both parties have filed motions to exclude certain evidence in this proceeding. *See* Papers 29, 31.

A hearing for this proceeding was held on November 15, 2017. The transcript of the hearing has been entered into the record. Paper 43. (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a).

For the reasons that follow, we determine that Petitioner has not met its burden of showing by a preponderance of the evidence that claims 1–11 and 14–17 are unpatentable.

B. Additional Proceedings

Petitioner indicates that the '718 patent is also at issue in *Blephex LLC v. Pain Point Medical Systems, Inc.*, Case No. 3:16-cv-00410-N (N.D. Tex.).
Pet. 3.

C. The '718 Patent

The '718 patent (Ex. 1001), titled "Method and Device for Treating an Ocular Disorder," describes an electromechanically operated swab device, for swabbing for example, debris caused by an ocular malady, off an eyelid margin of a patient. Ex. 1001, Abst., Fig. 1. The '718 patent explains that debris on an eyelid can be the result of ocular disorders such as blepharitis, meibomitis, and dry eye syndrome. *Id.* at 1:15. Figures 1 and 2A of the '718 patent illustrating the electromechanical swab device and its application to a patient's eyelid margin are reproduced below.

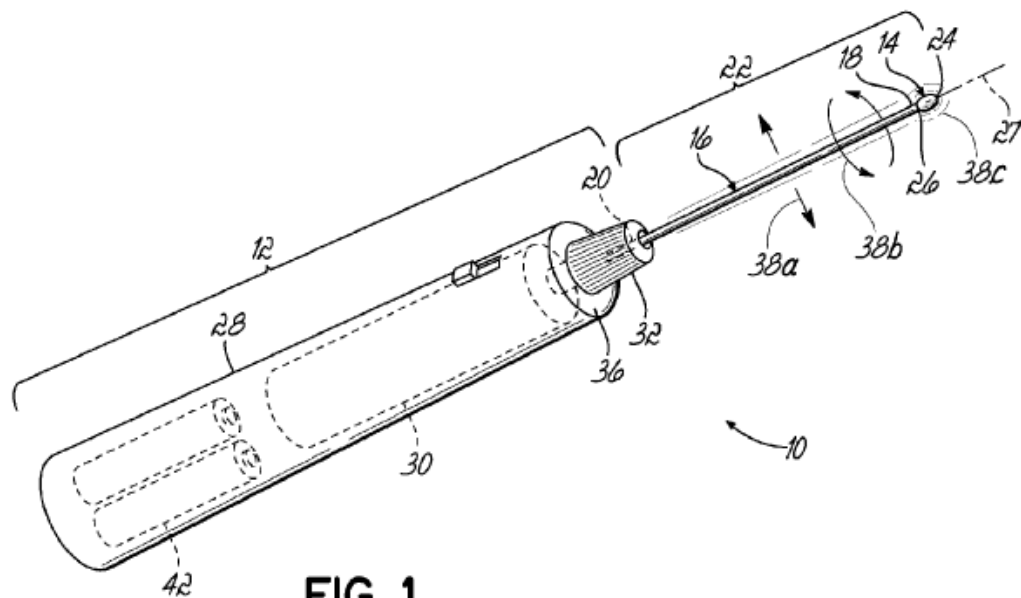


FIG. 1

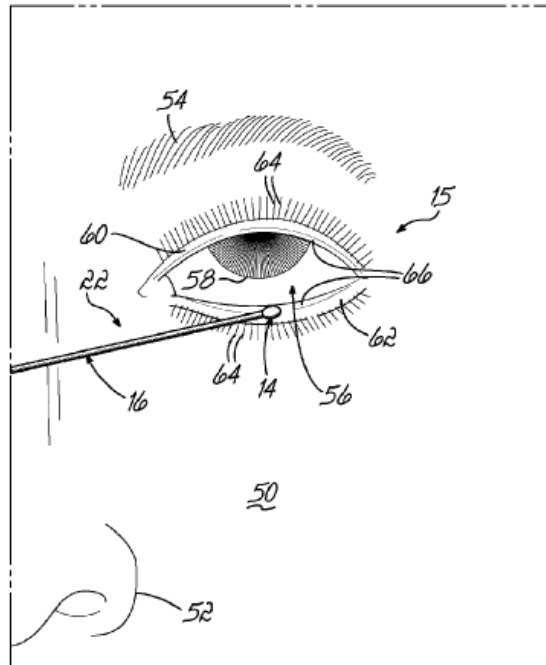


FIG. 2A

Figure 1 of the '718 patent, above, illustrates electromechanical device 10, drive unit 12, swab 14, and swab instrument 22. Ex. 1001, 3:35–44. Also depicted above, below Figure 1, Figure 2A depicts swab 14, in use on a patient's eyelid margin 62. Ex. 1001, 5:23–35.

The specification of the '718 patent explains that swab 14 is made of a material “suitable for contacting the eye 15 without harming the eye 15,” for example, “a sponge.” Ex. 1001, 3:65–4:1. Structurally, swab 14 is attached at the end of rigid member 16 that transmits motion from drive unit 12 to swab 14. *Id.* at 4:14–16. The specification further explains that motion of the swab by electromechanical device 10 “may include, but is not limited to, a reciprocating movement 38a, a rotating movement 38b, or a vibrating movement 38c,” and that, “the speed of the movement 28 of the swab 14 is any speed sufficient to remove debris from on the eye 15.” *Id.* at 4:53–59.

D. Illustrative Claim

Of the challenged claims, claims 1 and 17 are independent. Each of dependent claims 2–11 and 14–16 depend, directly or indirectly, from claim

1. Claim 1 illustrates the claimed subject matter and is reproduced below:

1. A method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device, wherein the eye has an eyelid margin and includes a removable debris, the method comprising;

effecting movement of the swab relative to the electromechanical device, the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin;

while the swab is being moved by the electromechanical device, contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.

1001, 7:30–43.

E. The Instituted Grounds of Unpatentability

We instituted trial on the following specific grounds.

| References | Basis | Claims Challenged |
|--|-------|-------------------|
| AlgerBrush II ¹ , Seminara, ² and Stevens ³ | § 103 | 1–11 and 14–17 |
| AlgerBrush II and Hamburg ⁴ | § 103 | 1–11 and 14–17 |
| Yamaura ⁵ and Stevens | § 103 | 1–11 and 14–17 |

Inst. Dec. 24.

II. CLAIM CONSTRUCTION

We determined in our Institution Decision that we need not construe explicitly any claim language. Inst. Dec. 5–6. Subsequently, neither party disputes the meaning of any claim terms for construction. *See generally* PO Resp.; Pet. Reply. Our review and analysis indicates that, beyond the plain meaning of the claim language itself, there is no need to provide any claim constructions in this Decision. *See* 35 U.S.C. § 314(a); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

III. MOTIONS TO EXCLUDE EVIDENCE

Pain Point and Blephex each move to exclude certain evidence proffered by their respective opponents. Papers 29 (“Pet. Mot.”), 31 (“PO Mot.”). The party moving to exclude evidence bears the burden of proving

¹ Ex. 1013, The Alger Company, Inc., ALGERBRUSH II, <http://www.algercompany.com/brush/product-info>, (Copyright 2012); Ex. 1014, ALGERBRUSH II, Product Specification Sheet (1998); Ex. 1015, ALGERBRUSH II, Operating Instructions (April, 2012). (“AlgerBrush II”).

² Ex. 1016, US 2007/0049860 A1 (Pub. March 1, 2007). (“Seminara”).

³ Ex. 1017, Sue Stevens, *How to Clean Eyelids*, Community Eye Health Journal (Copyright 2011). (“Stevens”).

⁴ Ex. 1018, U.S. Patent No. 4,883,454 (iss. Nov. 28, 1989). (“Hamburg”).

⁵ Ex. 1019, Japanese Unexamined Patent Appl’n. No. JP-A-Hei10-108801 (Pub. April 18, 1998). (“Yamaura”).

that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.20(c), 42.62(a). We address, below, each motion in turn.

Pain Point seeks to exclude certain portions of Dr. Paugh’s testimony (Ex. 2025) alleging his statements “improperly attempt to contradict admissions contained in the ‘718 patent concerning the prior art.” Pet. Mot. 2. These allegations fail to identify any applicable rule of evidence towards exclusion, and are most reasonably understood as directed to the evidentiary weight, or perhaps credibility, accorded such alleged contradictory evidence. *See id.*, *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,767. It is within our discretion to assign the appropriate weight to be accorded to evidence. *See, e.g., Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding Board has discretion to give more weight to one item of evidence over another “unless no reasonable trier of fact could have done so”). We are cognizant of the qualifications of Dr. Paugh in his respective field of expertise and have weighed his testimony on behalf of Patent Owner, Blephex, on specific subjects and in light of the prior art, accordingly. The alleged inconsistency of Dr. Paugh’s testimony, regardless of whether such testimony is in fact, inconsistent, is not sufficient reason to exclude his testimony. Any inconsistency simply would affect the weighing of the evidence.

Petitioner Pain Point moves also to exclude a paper written by James M. Rynerson and Henry D. Perry, titled “*DEBS – a unification theory for dry eye and blepharitis*,” from CLINICAL OPHTHALMOLOGY 10:2455–2467 (2016) (Ex. 2020), and also the Declaration of William B. Trattler (Ex. 2002). Pet. Mot. 6–8. Because our Decision does not rely upon either of

these references and exhibits, Petitioner's Motion is moot as to Exhibits 2002 and 2020.

For the foregoing reasons Pain Point's Motion to Exclude Exhibits 2002 and 2020 is *dismissed as moot*, and *denied* as to Exhibit 2025.

Patent Owner Blephex moves to exclude a paper by Caroline A. Blackie et al., *Nonobvious Obstructive Meibomian Gland Dysfunction*, CORNEA, Vol. 29, No. 12 (Dec. 2010) (Ex. 1021), as well as excerpts from another paper titled, *Make a Splash in Dry Eye,*" OPTOMETRIC MANAGEMENT (Feb. 2016) (Ex. 1025). PO Mot. 1–4. Patent Owner seeks as well to exclude portions of the deposition testimony of Dr. Paugh (Ex. 1026), and portions of the deposition transcript of Dr. Benjamin (Ex. 2028, 54:12–55:8, 83:20–86:21). PO Mot. 5–9. We do not rely in our Decision on any of the evidence objected to by Patent Owner, thus Patent Owner's Motion is moot as to these exhibits.

For the foregoing reasons, Blephex's Motion to Exclude Evidence is *dismissed as moot*.

IV. ANALYSIS

A. Claims 1–11 and 14–17— Obviousness over AlgerBrush II in view of Seminara and Stevens

Petitioner asserts that claims 1–11 and 14–17 would have been obvious over AlgerBrush II in view of Seminara and Stevens. Pet. 12–26.

A patent is invalid for obviousness:

if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a).⁶ Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). Courts must consider all four Graham factors prior to reaching a conclusion regarding obviousness. *See Eurand, Inc. v. Mylan Pharms., Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.)*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012). As the party challenging the patentability of the claims at issue, Petitioner bears the burden of proving obviousness by a preponderance of the evidence. *See* 35 U.S.C. § 316(e).

1. Scope and Content of the Prior Art

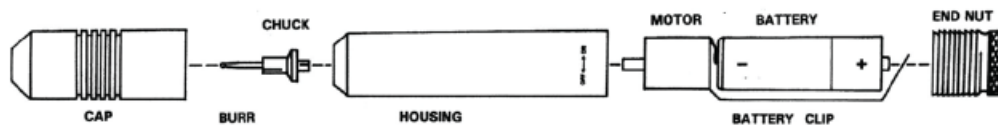
AlgerBrush II

AlgerBrush II discloses an electromechanical device having a low-power torque motor powered by a single AA battery that rotates a “burr” on the end of a shaft. Ex. 1013, 1. The device, pictured below, is used by physicians to brush away “rust rings” on the cornea of a patient’s eye often caused by a foreign ferrous object, such as a spark from a welding torch, striking the eye. Exs. 1013, 1014.

⁶ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), took effect on March 16, 2013, and amended 35 U.S.C. § 103. Because the ’718 patent has an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103.



The image from AlgerBrush II, above, depicts an electromechanical device having a shaft and burr that rotate during operation to facilitate removing rust rings from a patient's cornea. Ex. 1014. The drawing, below, of the AlgerBrush II device is reproduced from the reference titled "ALGERBRUSH II Operating Instructions." Ex. 1015.

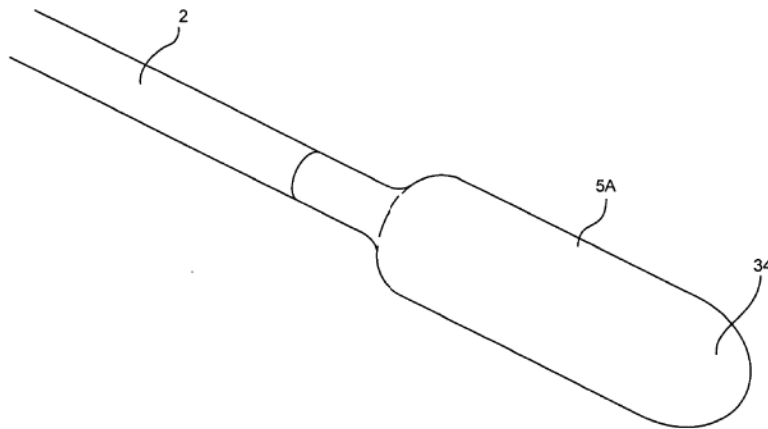


Above, a drawing from ALGERBRUSH II Operating Instructions illustrates a housing including a battery powered motor connected to a chuck and a shaft supporting a burr. Ex. 1015. Different sizes and types of burrs may be used with the device, for example carbide or fine grit diamond burrs. Exs. 1014, 1015.

Seminara

Figure 20 of Seminara, reproduced below, depicts one embodiment of a surgical sponge for use in medical procedures.

FIG. 20



Seminara’s Figure 20, above, illustrates handle 2 supporting surgical sponge 5A having taper 34 forming “essentially a bullet-shaped sponge” at a distal end. Ex. 1016 ¶ 81.

Stevens

Stevens is an internet article written by Sue Stevens, titled “How to clean eyelids,” from the Community Eye Health Journal, an online publication available on the World Wide Web. Ex. 1017. Figure 7 from Stevens, reproduced below, depicts in part, a method of cleaning the lower eyelid margin with a swab.



Figure 7 of Stevens, above, is an image showing a patient having their lower eyelid margin pulled down, and a swab. Stevens provides the following descriptive bullet points accompanying Figure 7:

- Ask the patient to look up.
- With one hand, take a new swab or bud and moisten it in the solution.
- With the index finger of the other hand, gently hold down the lower eyelid.
- With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8).
- Discard the swab or bud after use.

Ex. 1017, 7–8.

2. Differences Between the Prior Art and the Claimed Invention

Claims 1–11 and 14–17, AlgerBrush II, Seminara and Stevens

Our review of the prior art and the evidence presented by the parties informs us that AlgerBrush II, Seminara, and Stevens, individually, disclose certain of the claimed steps and apparatus limitations of independent claims 1 and 17. For instance, Stevens' figures and description explain how to

address Blepharitis by cleaning a patient's eyelid margin with a swab, thus teaching "[a] method of treating an eye for an ocular disorder with a swab" as recited in claim 1 and 17. Ex. 1017. AlgerBrush II discloses an electromechanical ophthalmology tool, which spins a burr and, for treating a patient's eye, is "used as a 'brush' rather than a drill and the rust ring is thus 'brushed' from the cornea." Exs. 1013, 1014. Also, Seminara teaches a bullet shaped sponge, i.e. a swab, on a handle, that can be used with a trocar or cannula. Ex. 1016 ¶ 42, Figs. 12, 20–22.

There is a lingering issue regarding the declarant's testimony with regards to whether Stevens discloses the "contacting" step as recited in both independent claims. *See* PO Resp. 31–35. Claims 1 and 17 recite, each somewhat differently, a step describing that the swab is "contacting" at least some portion of the eyelid margin. *Compare* Ex. 1001, 7:39–41 *with id.* at 8:55–56. Claim 1 recites the step:

contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris

And, claim 17 recites the step:

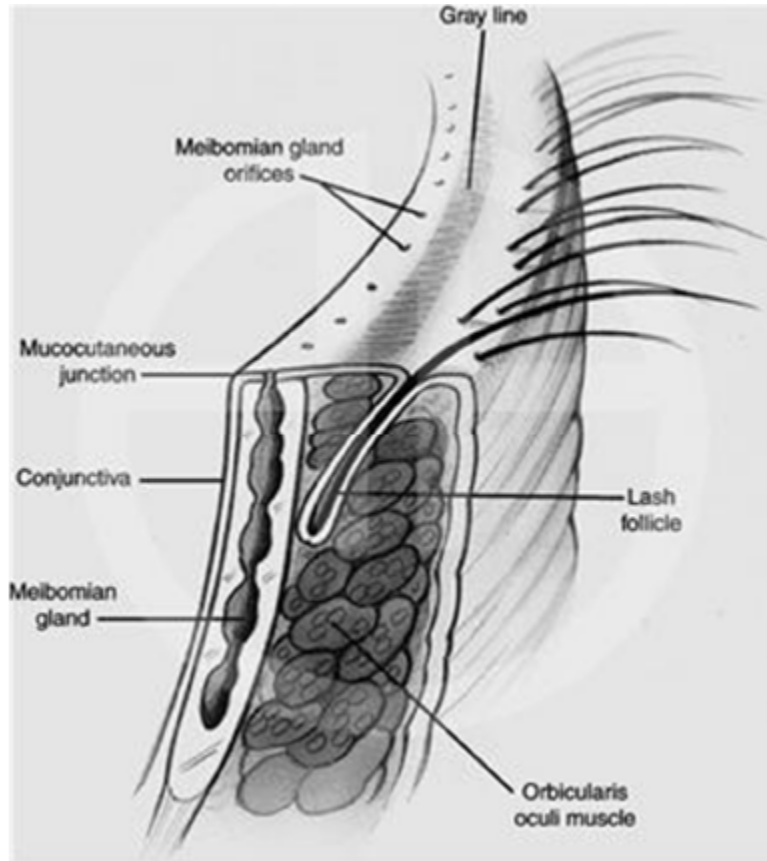
contacting at least an inner edge portion of the eyelid margin that includes the removable debris

The Stevens reference, in a bullet point reproduced below, directs how a caregiver should clean the eyelid margin (Ex. 1017, 7):

- With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus (Figures 7 and 8).

Patent Owner's Declarant, Dr. Paugh, referring to the figure reproduced below, explains that "the eyelid margin is divided into two regions demarcated by the gray line," an inner (posterior) eyelid margin including

the meibomian gland orifices, and an outer (anterior) eyelid margin including the eyelashes. Ex. 2025 ¶¶ 28–29.



The figure above, reproduced from the Declaration of Dr. Jerry Paugh, illustrates a cross-sectional anatomical view of an eyelid including the eyelid margin. *Id.* ¶ 29.

We credit Dr. Paugh’s testimony that oftentimes direct contact with the inner (posterior) eyelid margin was “highly disfavored among clinicians and viewed only as a last resort in cases where lid hygiene treatments and other indirect treatments were unsuccessful.” *Id.* ¶ 54. We also credit Petitioners Declarant, Dr. Benjamin, who testified under oath during his deposition that “a person versed in the art would not even need Stevens to know that you could take a swab and clean the eyelid margin and do what

you needed to do to focus on where the crusting was.” Ex. 2028, 28:9–13. The declarants’ testimony is not mutually exclusive. Although it may be easier, and safer, to treat only the outer (anterior) region of the eyelid margin, a reasonable understanding of Stevens’ directions, given the anatomical structure of the eyelid, above, is that a caregiver would have understood to clean gently the eyelid margin, and that could include the inner (posterior) and outer (anterior) eyelid margins. *See* Ex. 1017, 7 (Stevens instructs to “clean gently along the lower eyelid margin.”). This understanding and Dr. Benjamin’s testimony is confirmed by the Background section of the ’718 patent which explains that historically treatment included

attempts to remove the debris by physically scrubbing the eyelid margin, the base of the eyelashes, and the pores of the meibomian glands. This scrubbing is routinely attempted with either a generic cotton swab, a fingertip, or a scrub pad placed over the fingertip and applied against the eye. By cleaning debris and scurf free from the base of the eyelashes and unclogging the pores of the meibomian glands, the patient may improve the overall health of the eyelid margin; thereby reducing irritation, burning, and other symptoms related to the disorder.

Ex. 1001, 1:45–55. We determine that Stevens’ explanations, as they are directed towards cleaning the eyelid margin generally, reasonably include contact “between the eyelashes and the inner edge of the eyelid margin,” as called for in claim 1, as well as contacting “at least an inner edge portion of the eyelid margin,” as recited in claim 17. *See* PO Resp. 32 (Patent Owner concedes that “a person of ordinary skill in the art would have understood that the recited ‘inner edge portion’ of the eyelid margin refers to the posterior region of the eyelid margin.” (citing Ex. 2025 ¶ 82)).

As discussed in further detail below, because it is critical to addressing the issues of obviousness and Petitioner's burden, what we do not find in any of the prior art references is an express, or even inherent teaching, that one of skill in the art would have used an electromechanical device for debridement of a patient's eyelid.

3. The Level of Ordinary Skill in the Art

Petitioner asserts that the level of ordinary skill in the art is “a licensed eye care specialist such as an ophthalmologist (MD or DO) or a doctor of optometry (OD) and three to five years of training and practical experience in the field of eye care.” Pet. 5. Patent Owner does not dispute this asserted level of ordinary skill, but does contend in regards to the knowledge of a person of ordinary skill in that art, as discussed above, that “when direct contact was made to the eyelid margin, this contact was primarily limited to the anterior region of the lid margin.” PO Resp. 9 (citing Ex. 2025 ¶ 45).

In this case, Petitioner has set forth an undisputed, and what appears as a reasonable, articulation of the level of ordinary skill in the art. Also, the submitted prior art itself also reflects an appropriate level of skill that does not appear to conflict with Petitioner's assertion. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“[T]he absence of specific findings on the level of skill in the art does not give rise to reversible error ‘where the prior art itself reflects an appropriate level and a need for testimony is not shown’”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). Patent Owner's assertion with respect to the issue of contacting certain portions of the eyelid margin is not, as discussed above, untenable, and is consistent with the declarants' testimony.

What we do not infer from Patent Owner's position, however, is that it was unknown by those of skill in the art to contact and clean the inner (posterior) portion of the eyelid margin. Even if it was not a preferred treatment, we determine based on the evidence as a whole, that a person of ordinary skill in the art would have known that the entirety of the eyelid margin could be contacted and cleaned to remove debris depending on where the debris were located on the eyelid margin. *See e.g.* Ex. 2028, 28:9–13; *see also* Ex. 1017, 1 (Stevens explains the reason for cleaning eyelids is “to remove crusting on the eyelid margins.”).

4. *Secondary Considerations of Nonobviousness*

Patent Owner presents evidence of secondary considerations supported by a declaration from Dr. Marguerite McDonald, MD. PO Resp. 49–61; Ex. 2029. Patent Owner argues that the claimed invention has the required nexus with a commercial device known as BlephEx (the “BlephEx device”), and that there was long-felt need for such a method and device. *Id.* at 49–56 (citing Ex. 2029 ¶¶ 17–33, 35–36, 38, 41–45). Patent Owner asserts also that copying by competitors, commercial success, as well as academic and industry praise for its product and claimed invention is indicative of nonobviousness. *Id.* at 57–61 (citing Ex. 2025 ¶¶ 74–77; Ex. 2029 ¶¶ 47–53, 55–68; Ex. 2031). This evidence of secondary considerations of non-obviousness, when present, must always be considered en route to a determination of obviousness. *See Cyclobenzaprine*, 676 F.3d at 1075–76.

(a) *Nexus*

Dr. McDonald's testimony with respect to nexus addresses each limitation in claims 1 and 17, as corresponding to the BlephEx device. *See*

Ex. 2029 ¶¶ 25–36 (Dr. McDonald testifies for example that when using the BlephEx device “[t]o clean the patient’s eyelid margins, the swab of the BlephEx device is contacted to the patient’s eyelid margins from the lash line back to the orifices of the Meibomian glands in order to remove the debris present on the eyelid margin.” Ex. 2029 ¶ 30.).

From a standpoint of nexus, we disagree with Petitioner’s position that Dr. McDonald’s testimony does not focus on the unique characteristics of the claimed invention. Pet. Reply 23. Dr. McDonald testifies that she has incorporated the Blephex device into patient treatments in the same way as recited for each limiting step recited in claims 1 and 17. Ex. 2029, 27–36, 52, 66. We accord certain weight to Dr. McDonald’s unrebutted testimony with respect to nexus and find a strong correlation between the evidence highlighting the merits of the BlephEx device and the merits of the claimed invention. We are not persuaded that Petitioner has rebutted the presumption of nexus between the claimed invention as recited in the ’718 patent and the BlephEx device. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (A presumption of nexus exists for objective considerations when the objective evidence is tied to a specific product and that product “is the invention disclosed and claimed in the patent.”). We will consider evidence of the success and praise of the BlephEx device as direct evidence of the success and praise of the claimed invention. *See Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d 281, 306 (Fed. Cir. 1985) (holding that the weight attributed to the secondary evidence is proportional to its nexus to the merits of the invention, implying that a weak nexus requires some discount factor to the evidence, but a strong nexus does

not). We now turn to the evidence alleging commercial success and industry praise.

(b) Commercial Success

Patent Owner's evidence of commercial success includes a PR Newswire internet article, and a separate internet article, TheStreet, referring to, and linking to the PR Newswire article. Exs. 2005–2006. In the PR Newswire article, Dr. James Rynerson, the CEO of Blephex states that “[c]onsumers spend \$65 billion annually on semi-effective treatments for dry eyes.” Ex. 2005, 1. The PR Newswire article alleges that Blephex “is now available in more than 1,000 practices throughout the United States and worldwide.” *Id.* TheStreet states that “BlephEx is one of the fastest growing companies in the ophthalmic space, offering the first and only device to treat the root cause of dry eye disease and blepharitis.” Ex. 2006, 1. In addition, Patent Owner relies on testimony from Dr. McDonald who states that based on “widespread incorporation into the practices of many clinicians, it is my opinion that the BlephEx device has been commercially successful within the industry.” PO Resp. 60; Ex. 2029 ¶ 65. In addition, based on an email attributed in part to Mike Whitehurst, the CEO of Pain Point Medical System, Dr. McDonald testifies that Pain Point recognized the market and because of “the unique treatment method provided by the BlephEx device, Pain Point sought to introduce its own device into the industry.” *Id.* ¶ 67.

Although these exhibits indicate some circumstantial evidence of sales, and a potential market for the BlephEx device, what Patent Owner has not produced is any substantive evidence of market share. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1300 (Fed. Cir. 2012) (“An important

component of the commercial success inquiry in the present case is determining whether Applied had a significant market share.”). For instance, we are apprised of no corroborating evidence from Patent Owner that the BlephEx device has produced any revenue. *See* Ex. 2029 ¶ 65–68. We have before us simply press releases from Patent Owner that appear to be a product promotion, and uncorroborated testimony that “more than 1,000 ophthalmic practices worldwide had incorporated the device for treatment of dry eye and blepharitis.” *Id.* ¶ 66. Even if we take Dr. Rynerson’s statement from the PR Newswire article as true, that the market is “\$65 billion annually,” we have little, if any, evidence that the BlephEx device has any appreciative market share in this billion dollar industry. Without a more credible and corroborated basis for the BlephEx devices sales and revenue figures, we give little weight to these internet articles. We appreciate that Dr. McDonald has testified that she has apparently used the BlephEx device and knows colleagues “who have bought the BlephEx device as a treatment approach.” *Id.* However, even assuming there exists a certain level of sales and use of the BlephEx device, this alone does not define the market, nor tell us what portion of the market certain sales might account for, nor evidence any growth in market share or displacement of other treatment methods and devices. If simply sales and use was enough to show success, then virtually every product or service which is offered into the marketplace would be considered successful.

Our analysis of the commercial success evidence reveals, at best, and without any revenue, profit or even price point data, sales of 1,000 BlephEx devices in apparently a multi-billion dollar market. *See* Ex. 2005, 1. This does not provide competent evidence of market share, and instead relies on

vague numbers of products used in the market, and little, if any, evidence of actual sales. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1300 (Fed. Cir. 2012) (“[T]he more probative evidence of commercial success relates to whether the sales represent “a substantial quantity in th[e] market,”) *see also In re Huang*, 100 F.3d 135, 140 (Fed.Cir.1996) (“This court has noted in the past that evidence related solely to the number of units sold provides a very weak showing of commercial success, if any.”).

Patent Owner’s evidence of commercial success lacks sufficient detail linking sales of BlephEx devices to any significant market growth due to the merits of the claimed invention. Accordingly, this factor does not garner appreciable weight towards a finding of non-obviousness.

(c) Copying

Patent Owner contends that “[a]fter introduction of the BlephEx device into the industry in 2014, Pain Point attempted to develop its own competing device, the LidPro, which attempts to clean a patient’s eyelid margins in a similar manner as the BlephEx device.” PO Resp. 59 (citing Exs. 2018, 2022, 2031, 2029, ¶¶ 59–62). Mr. Whitehurst, Pain Point’s CEO, in his email of July 2015, expresses a desire to complete, and manufacture a product, to apparently compete with the BlephEx device. *See Ex. 2018* (“Blephex has no reason to be the only product like this on the market. Our price will be 1/3 of theirs. \$600.00 usd. Our mold maker is ready to start.”). Through Mr. Whitehurst’s emails, Patent Owner has provided certain evidence of competition, and perhaps some degree of copying. *See Ex. 2031* (Whitehurst immodestly conceding that “[t]hanks to Bl[e]phex we know we have a winner.”). As Petitioner points out, Dr. McDonald did not explicitly compare the LidPro device to the claims of the ’718 patent. Pet. Reply 15.

On the other hand, she testifies that “the LidPro device attempts to clean a patient’s eyelid margin in a similar manner as the BlephEx device,” Ex. 2029 ¶ 62, *see also* Ex. 2022 illustrating use of the LidPro device. Dr. McDonald points also to consistent testimony from Pain Point’s witness, Dr. Glenn Corbin, in the underlying district court litigation, confirming that “LidPro and BlephEx are both instruments that perform the same task, same procedure.” *Id.* (citing Ex. 2019, 8:19–20).

Patent Owner has provided at least circumstantial evidence from which we can infer some degree of copying by Pain Point, and to that end we give the evidence here some weight towards nonobviousness.

(d) Industry and Academic Praise

Patent Owner presents evidence of industry praise for the BlephEx device. PO Resp. 57–58. Patent Owner points out that BlephEx was a finalist for 2016 “Product of the Year” award by the Association of Optometrists. *Id.* at 57 (citing Exs. 2007, 1; 2008, 8–9; 2029 ¶ 48). Also, Patent Owner offers patient and physician testimonials, apparently from BlephEx’s website advertising material, relating to successful treatment of blepharitis and dry eye maladies with the BlephEx device. See Ex. 2016, 2–5. For example, the advertisement quotes Art Epstein, OD:

BlephEx has fundamentally changed the way we practice. Its become an essential element for managing blepharitis and I use it routinely for debridement of the lids prior to manual expression or LipiFlow for MGD. It has definitely improved outcomes and makes a tremendous difference in patient comfort. I could not practice without it.

Id. at 3. In addition, Dr. McDonald states that her personal experiences and feedback from patients and colleagues reveals that “treating patients with the

BlephEx device has led to significant, long-term improvement in symptoms associated with ocular disorders.” Ex. 2029 ¶ 51.

Petitioner’s argument that such praise is “based upon the Bleph[E]x device, not on praise for the claimed method,” is unpersuasive. Pet. Reply 24. Even the above noted examples indicate that that it is not simply the BlephEx device, but also patient treatment such as “debridement,” i.e. “contacting a portion of the eye between the eye lashes and the inner edge of the eyelid . . . thereby impacting the debris with the swab to remove debris from the eye” as recited in claim 1, which is occurring from use of the BlephEx device. Ex. 1001, 7:39–43.

Industry praise for an invention may provide evidence of nonobviousness where the industry praise is linked to the claimed invention. *See Geo. M. Martin Co. v. Alliance Mach. Sys. Int’l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008). Patent Owner has supplied credible evidence that the BlephEx device was praised and recognized as an innovative product. Giving credit also to clinical studies highlighted by Dr. McDonald that resulted in patient symptom improvement when treated, we determine that Patent Owner’s evidence of industry and academic praise along with recognition of the viable nature of the BlephEx device and treatment, as linked to the claims of the ’718 patent, is entitled to some weight. *See* Ex. 2029 ¶ 56 (citing Ex. 2017 (“The BlephEx provides a method of accomplishing lid debridement without using a surgical instrument.”)).

(e) Long-Felt but Unresolved Need

Patent Owner’s evidence of long-felt need is mainly the testimony of Dr. McDonald. PO Resp. 52–56 (citing Ex. 2029 ¶¶ 17–23, 38–46). To

summarize, a conventional out-of-office treatment plan for blepharitis, MGD, and dry eye can include daily application of “antibiotic ointments, omega-3 fatty acid supplementation, oral tetracyclines, and artificial tears or prescription-based eye drops,” and “relied heavily on patient compliance.” *Id.* at 53–54 (citing Ex. 2029 ¶¶ 19, 23). In-office procedures included “deliberate expression or surgical re-opening of the meibomian glands.” Ex. 2029 ¶ 40.

With respect to long-felt need, Dr. McDonald testifies specifically that there was a general interest in the industry to provide treatments that would provide long-lasting symptom relief with minimal reliance on the patient. Moreover, in addition to seeking a treatment that relieved the burden on the patient with respect to time, the industry also sought a treatment that relieved the financial burden on the patient as well.

2029 ¶ 39. According to Dr. McDonald, treatments using the BlephEx device are inexpensive and “typically in the range from \$100 to \$200 per treatment” and “provide[] immediate symptom relief that lasts for several months, freeing patients from the constraints of following a typical hygiene routine to abate symptoms.” *Id.* ¶¶ 41–42.

Evidence of long-felt and unresolved need may be helpful to assessing nonobviousness where “it is reasonable to infer the need would not have persisted had the solution been obvious.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016), cert. denied, 138 S. Ct. 420 (2017). We have evidence here of at least an alternative treatment to certain ocular conditions, apparently chronic, of blepharitis, MGD, and dry eye. Ex. 2029 ¶¶ 16–19. We also have evidence that the use of BlephEx device is effective and provides relief from the symptoms of these conditions. *Id.* ¶ 56.

Dr. McDonald's testimony is credible regarding treatment of blepharitis, for example, with the BlephEx device, but is fairly directed towards the efficacy of the device and treatment as an alternative to conventional in-home, as well as in-office surgical treatments, and is not specifically resolving a long-felt and unresolved need. *See* Ex. 2029 ¶ 56–57. Dr. McDonald points to a study of 20 patients who received treatment using the BlephEx device, and explains from the study that “researchers found that the patients’ TBUT improved by 65% and OSDI scores decreased by 54%.” *Id.* ¶ 56. Dr. McDonald also states that the use of the BlephEx device is “\$100 to \$200 per treatment, much less than the expenses associated with specialized heat applicators.” *Id.* ¶ 41. We have little doubt that these ocular conditions are an onerous physical malady. *Id.* ¶ 16–23. These results and costs, however apparently good they are, are not substantively compared to results and data from the other available treatments so as to provide a highly probative assessment of whether the BlephEx device is an improvement over the prior art that resolves or significantly improves the symptoms and conditions which apparently define the long-felt need, or is simply an alternative to conventional treatments.

We determine from the evidence before us that the BlephEx device is at least an effective, alternative for treating the noted ocular conditions and that there is interest and research in the industry striving for better treatment of such conditions. Therefore, whether or not the evidence pertaining to the BlephEx device and method ultimately satisfies a long-felt and unresolved need is neutral with respect to obviousness.

5. *Discussion and Analysis*

Petitioner argues that a person of ordinary skill in the art would have recognized that a softer swab, or sponge, such as disclosed by Seminara, could have been used in place of the diamond burr in a known electromechanical device, such as the AlgerBrush II. Pet. 13. Petitioner argues further that “motivation to combine the Alger Brush with Seminara is provided by Sue Stevens in the article “How to clean eyelids.” *Id.* Then, Petitioner asserts that the ’718 patent itself “admits that the Alger Brush is an obvious device to use for this purpose.” *Id.* at 14. This is, for all intents and purposes, the extent of Petitioner’s explanation for its combination of AlgerBrush II, Seminara, and Stevens. *See id.* at 12–13.⁷

Following this explanation for the prior art combination, Petitioner then provides a claim chart alleging where each limitation in the challenged method claims of the ’718 patent is found within one, or more, of the asserted references. *See id.* 14–26. We point out, also, that Petitioner relies to some extent on a declaration from Dr. William Benjamin, OD, Ph.D., with respect to explaining the known treatment of dysfunctional meibomian glands and resulting blepharitis, such as heat application, antibiotics, steroids and scrubbing and cleansing of the eyelid to remove debris. *Id.* at 4–5

⁷ During the oral hearing, we inquired as to testimony by Dr. Benjamin supporting Petitioner’s obviousness arguments, specifically the issue of whether replacing a manual procedure with an electromechanical device would have been obvious. Tr. 16:2–4. In response Petitioner’s counsel pointed us to paragraph 37 of Dr. Benjamin’s Declaration, which simply states, and without corroboration or support apart, from the ’718 patent itself, that in “the prior art . . . the use of electromechanical devices and swabs for debriding tissue and removing debris or buildup from the eye was well known to eye care professionals.” *Id.* at 16:5–9 (citing Ex. 1002 ¶ 37).

(citing Ex. 1002). Nowhere else in the Petition, however, do we find Dr. Benjamin's Declaration substantively relied upon, or cited to, in support of Petitioner's obviousness contentions. *See id.* at 6–49 (The Conclusion section of the Petition, on page 49, states “[f]or the reasons set forth above, and as supported by the technical expert testimony of Dr. Benjamin, claims 1–11 and 14–17 of the '718 patent are rendered obvious by the prior art cited in this Petition.”).

Patent Owner makes essentially three arguments with respect to Petitioner's combination of AlgerBrush II, Seminara, and Stevens. First, that Petitioner has failed to provide the necessary articulated reasoning explaining why a person of ordinary skill in the art would have combined these references so as to arrive at the claimed invention. PO Resp. 1–2, 17. Second, Patent Owner contends that the substantive evidence relied upon by Petitioner for motivation to combine the references to meet all the limitations of the claims is nonexistent in the case of Stevens. And third, Patent Owner asserts that the combination is unsupported by evidence taken from the teachings of the '718 patent itself, an analysis which amounts to improper hindsight. PO Resp. 15–17.

In an *inter partes* review, Petitioner has the burden of proving unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 326(e); *see also In re Magnum Oil Tools Int'l, Ltd.*, 892 F.3d 1364, 1380–81 (Fed. Cir. 2016) (holding that because “petitioner . . . bears the burden of proof,” the Board is not “free to adopt arguments on behalf of petitioners that . . . were not[] raised” and “must base its decision on arguments that were advanced by [petitioner], and to which [patent owner] was given a chance to respond”). “To satisfy its burden of proving obviousness, a petitioner cannot

employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *Magnum Oil Tools*, 892 F.3d at 1380 (citing *KSR*, 550 U.S. at 418).

Upon review of Petitioner’s evidence and analysis, we determine that Petitioner has not shown by a preponderance of the evidence that it would have been obvious to combine AlgerBrush II and Seminara to accomplish the method of eyelid margin cleaning described in Stevens. The most glaring gap in the asserted combination of references is the lack of reasoning and evidence pertaining to Stevens, along with Petitioner’s unexplained reliance on the ’718 patent itself. *See* Pet. 12–14 (Petitioner argues that “[t]he ’718 patent admits that the Alger Brush is an obvious device to use for this purpose.”).

Stevens describes, and depicts in several photographs, a manual procedure to “clean gently along the lower eyelid margin.” Ex. 1017, 7. And, in conjunction with the photographs of a caregiver applying hand held swabs to a patients’ eye, Stevens describes that, “extra care is needed when cleaning the upper eyelid margin.” *Id.* The Petition states:

Motivation to combine the Alger Brush with Seminara is provided by Sue Stevens in the article “How to clean eyelids” published by the Community Eye Health Journal and republished by the National Institute of Health. Stevens explains and illustrates how to remove crusting on the eyelid margins in cases of blepharitis using a swab soaked in a solution.

Pet. 13 (citing Ex. 1017, Figs. 8, 10). This recap of Stevens’ method is not persuasive of any evidentiary underpinning nor does it articulate a sufficient reason as to why one of ordinary skill in the art would have found “motivation” from any part of Stevens’ manual swab application to use an

electromechanical device. *See Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (“[O]bviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.”).

Moreover, Petitioner’s attempt to bridge this dearth of reasoning, by reliance on the ’718 patent itself is, at best, ineffective. Petitioner’s explanation that “[t]he ’718 patent admits that the Alger Brush is an obvious device to use for this purpose” is a misinterpretation of the ’718 patent, and, wrongly asserts an inference of support and reasoning for a combination of the prior art that appears simply as impermissible hindsight. *See Cyclobenzaprine*, 676 F.3d at 1073 (“[O]bviousness must be assessed at the time the invention was made.”).

The ’718 patent describes, in context, a known reusable mechanical drive unit, and that AlgerBrush II is an example “of such a professional mechanical drive unit.” Ex. 1001, 5:18–19. To the extent that this product was considered as a cited prior art reference during prosecution of the patent application which led to the ’718 patent, we understand that one of ordinary skill in the art would have known of AlgerBrush II. *See id.*, References Cited (“The Alger Co., Inc. [online retrieved on Dec. 22, 2014]. Retrieved from the internet at <[http://www.alg\[er\]company.com/brush/2013/01/02/the-algerbrush-ii-2/](http://www.alg[er]company.com/brush/2013/01/02/the-algerbrush-ii-2/)> Screen capture of page submitted herewith as ‘Algerbrush II Product Page.’”), *see also In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (“The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art.”). The inventor of the ’718 patent did not, however, admit that anything was

obvious, simply that AlgerBrush II was a known drive unit. *Id.* at 5:18–19. We cannot, without more, reasonably extend this knowledge to bolster the conclusory inference that one of ordinary skill in the art would have, prior to the filing of the '718 patent, combined AlgerBrush II with a softer swab in order to carry out the method described in Stevens as Petitioner argues. Using the solution to the problem as described in the '718 patent, is nothing less than hindsight. *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) (“The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.”).

In addition, this hindsight determination comports with our analysis and findings above with respect to secondary considerations. The evidence presented by Dr. McDonald is persuasive as to certain aspects of objective indicia which weigh in favor of nonobviousness. Secondary considerations “are crucial in avoiding the trap of hindsight[,]” *Leo Pharm. Products, Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013), and “may be the most probative and cogent evidence in the record[,]” *Apple Inc. v. Int’l Trade Comm’n*, 725 F.3d 1356, 1366 (Fed. Cir. 2013) (internal quotation marks and citations omitted).

To the extent Petitioner contends that using AlgerBrush II to perform the method described in Stevens is simply automating a manual process, we are not persuaded. *See* Pet. Reply, 19 *see also* Pet. 1 (The Petition stated that “[t]he only distinction in the ‘718 patent is the use of a simple electromechanical device to power movement of the swab.”). Petitioner points to alleged admissions by Dr. Paugh that AlgerBrush II as it is used to

remove rust rings from a cornea “is an example of the automation of a process that was previously performed manually.” Pet. Reply 6–7 (citing Ex. 2027; Ex. 1026, 156:11–157:3). This argument is not, however, persuasive evidence that a person of ordinary skill in the art would have used a spinning electromechanical device known for cornea tissue and pterygium removal, to supplant the gentle cleaning and wiping method of cleaning an eyelid margin as disclosed in Stevens. Patent Owner presents unrebutted testimony from Dr. McDonald that AlgerBrush II’s rapid rotary motion does not replicate Stevens’ treatment and such rapid rotary motion is inconsistent with Stevens’ admonition to “clean gently,” and that one of ordinary skill in the art would have understood such aggressive treatment “unnecessarily risked damage and caused further irritation to the delicate and inflamed eyelid tissue without providing any additional cleansing benefit.” Ex. 2025 ¶ 67.

As a whole, Petitioner’s assertions are not supported by persuasive evidence or facts and amount to simply a mere allegation that the combination would have yielded the claimed invention. Argument of counsel cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L’Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). The Petition lacks sufficient evidence and analysis to adequately support what amounts essentially to attorney argument for the asserted combination, and is insufficient in showing even the possible predictability of combining a conventional manual ocular medical technique as disclosed by Stevens with AlgerBrush II’s electromechanical tissue removing device. *C.f.*, see *KSR*, 550 U.S. at 416 (“The combination of familiar elements according to known

methods is likely to be obvious when it does no more than yield predictable results.”).

Lacking the necessary analysis, evidence and facts, Petitioner has failed to make the requisite showing of a sufficient rationale for the alleged combination. Petitioner has not met its burden to show by a preponderance of the evidence that claims 1 and 17 are unpatentable under 35 U.S.C. § 103(a) over AlgerBrush II, Seminara, and Stevens.

Dependent claims 2–11 and 14–16 at issue depend from claim 1. For the reasons discussed above, Petitioner has not met its burden to show by a preponderance of the evidence that claims 2–11 and 14–16 are unpatentable under 35 U.S.C. § 103(a) over AlgerBrush II, Seminara, and Stevens. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (“[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.”).

B. Claims 1–11 and 14–17— Obviousness over Yamaura and Stevens

Petitioner asserts that claims 1–11 and 14–17 would have been obvious over Yamaura and Stevens. Pet. 38–48.

1. The Prior Art

Yamaura

Yamaura discloses an electromechanical intra-aural (ear) cleaner as shown below in Figure 1. Ex. 1019, Fig. 1.

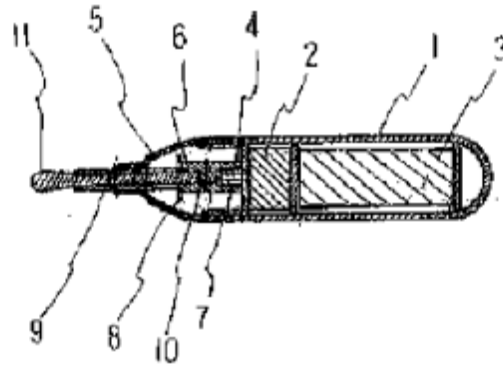


Figure 1 of Yamaura, above, illustrates an ear cleaning device including battery powered motor 2 for rotating shaft 4 connected to cotton swab holder pipe 9 having a cotton swab 11 inserted in pipe 9. Ex. 1019, [57]

Yamaura explains that “[t]his invention was developed as a method for electrically-powered ear-cleaning, replacing the conventional manual method.” *Id.* ¶ 4. Yamaura’s device uses a cotton swab so as not to damage the “delicate intra-aural skin” and yet removes earwax from the user’s ear. *Id.* ¶¶ 3–4.

2. Discussion and Analysis

Replacing AlgerBrush II and Seminara with Yamaura for this ground, Petitioner makes essentially the same errors with the combination Yamaura and Stevens as in the previous ground. Pet 38. Petitioner reiterates for this combination that “[m]otivation to use the Yamaura device to clean eyelid margins is provided by Sue Stevens in the article ‘How to clean eyelids.’” *Id.* Petitioner fails, apart from reliance on the ’718 patent, to explain why one of ordinary skill in the art would have used Yamaura’s electromechanical ear cleaning device on an eyelid margin based on the disclosure in Stevens. *See id.* (And, to tie Stevens to Yamaura, Petitioner

asserts that “[t]he ‘718 patent uses the same method, the only difference being the use of an electromechanical device to move the swab.” *Id.*).

Petitioner fails to provide persuasive evidentiary supported reasoning to adequately explain why a person of ordinary skill in the art would have combined Yamaura and Stevens, and employs a hindsight analysis from the ‘718 patent to fill in the gaps. *Id.* at 38. Lacking the necessary analysis, evidence and facts, Petitioner has failed to make the requisite showing of a sufficient rationale for the alleged combination.

A similar *Graham* factors analysis applies to this ground as in the previous ground, except for Yamaura is provided in place of AlgerBrush II and Seminara. As discussed above, this hindsight determination is supported by the evidence presented by Dr. McDonald that is persuasive as to certain aspects of objective indicia, and which together weigh in favor of nonobviousness. Petitioner has not met its burden to show by a preponderance of the evidence that claims 1 and 17 are unpatentable under 35 U.S.C. § 103(a) over Yamaura and Stevens.

Dependent claims 2–11 and 14–16 at issue depend from claim 1. For the reasons discussed above, Petitioner has not met its burden to show by a preponderance of the evidence that claims 2–11 and 14–16 are unpatentable under 35 U.S.C. § 103(a) over Yamaura and Stevens. *See In re Fritch*, 972 F.2d at 1266, (“[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.”).

C. Claims 1–11 and 14–17— Obviousness over AlgerBrush II and Hamburg

Petitioner asserts that claims 1–11 and 14–17 would have been obvious over AlgerBrush II and Hamburg. Pet. 26–37.

1. *The Prior Art*

Hamburg

Figure 3 of Hamburg, below, illustrates a swab-type applicator for cleaning “simultaneously [] the anterior and posterior lid margin surface, including the meibomian orifices.” Ex. 1018, 1:11–12.

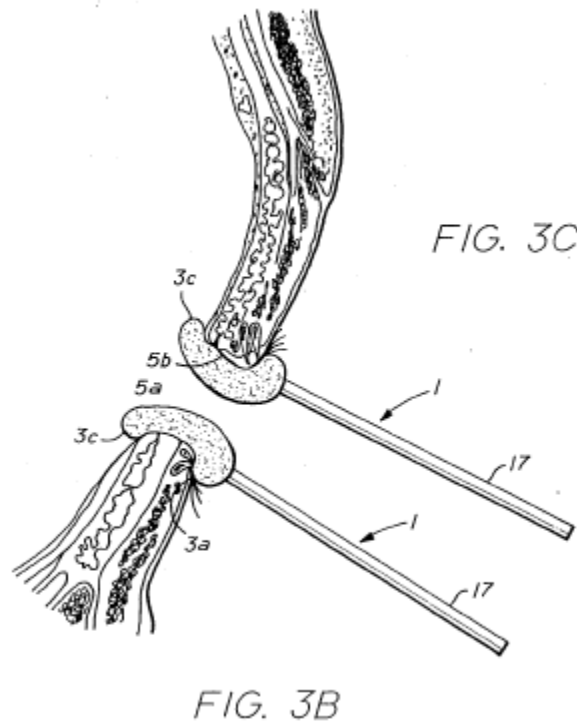


Figure 3 of Hamburg, above, depicts swab 1 being applied to an upper and lower eyelid margins. Hamburg describes that the concave nature of blotting means 5 facilitates cleaning the interior and exterior surfaces of the eyelid margin, and that “peak 3c is intended for contact with the upper or lower interior surface of the eyelid margin.” *Id.* at 3:4–6.

2. *Discussion and Analysis*

Petitioner relies on Hamburg, instead of Stevens, for this ground. Pet. 26–37. Clarifying why AlgerBrush II is the primary reference for this ground, Petitioner argues that “[t]he obviousness of adapting the Alger

Brush to clean eyelid margins is explicitly admitted by the Patent Owner.” *Id.* at 26 (citing Ex. 1001, 5:14–20). The reasoning offered for the combination of AlgerBrush II with Hamburg is that “[a]ny eye care specialist would recognize that a softer material can be used to remove such debris from the eyelid margin.” *Id.* at 27.

This combination suffers from a similar lack of reasoning and evidentiary rationale, as well as improper use of hindsight, as in the previous grounds. Arguably, as Petitioner contends, it is reasonable that a person of ordinary skill in the art would have known, under appropriate circumstances, to replace a harder material with a softer material, such as a replacing a diamond burr perhaps with a swab. This would be an example of a simple substitution. *See KSR*, 550 U.S. at 415—16 (a “patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men”) (*quoting Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152–153 (1950)). The claims of the ’718 patent are not, however, simply drawn to an electromechanical swab. *See Ex. 1001*, 7:30–8:58 (Independent claims 1 and 17 recite for example “[a] method of treating an eye for an ocular disorder.”). Petitioner’s argument falls short of explaining why, even assuming replacement of the burr with a softer swab, one of ordinary skill in the art would have undertaken the claimed “method of treating an eye for an ocular disorder with a swab operably connected to an electromechanical device” as called for in the independent claims. *Ex. 1001*, 7:30–31.

We recognize that Hamburg (like Stevens) teaches using a swab for contacting an eyelid margin with meibomian gland dysfunction. *See Ex.*

1018, 3:4–6 (Hamburg explains that the swab has a surface where “[t]he peak 3c is intended for contact with the upper or lower interior surface of the eyelid margin.”). Petitioner does not, however, persuasively address why one of ordinary skill in the art would have used an electromechanical drive device such as AlgerBrush II to perform such a medical treatment. Pet. 27. Petitioner argues that “[t]he motivation to combine the Alger Brush with Hamburg to treat a condition such as blepharitis is so obvious that it almost does not require explicit statement,” and then simply implicates the ’718 patent for the proposition “that the Alger Brush is an obvious device to adapt for cleaning eyelid margins.” *Id.*

Besides again relying improperly on a hindsight analysis gleaned from the teachings of the ’718 patent, Petitioner has failed to provide evidence or reasoning to suggest, for example, that the possible approaches to meibomian gland dysfunction are “known” and “finite” or that one of ordinary skill had “good reason to pursue the known options within his or her technical grasp.” *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (discussing the requirements of an “obvious to try”-type obviousness rejection).

Petitioner has the burden of proving a proposition of unpatentability by a preponderance of the evidence. 35 U.S.C. § 326(e); *see Magnum Oil Tools*, 892 F.3d at 1380–81. Upon review of the evidence and analysis in the Petition, we determine that Petitioner has not shown by a preponderance of the evidence that it would have been obvious to one of ordinary skill in the art to modify AlgerBrush II with a softer swab such as shown in Hamburg in order to contact an eyelid margin and treat an ocular medical condition such as caused by meibomian gland dysfunction. Patent Owner

also has presented persuasive evidence as to secondary considerations to which we accord some weight supporting the contention of an improper hindsight analysis. And, Petitioner does not sufficiently refute Patent Owner's evidence in this regard (Ex. 2025 ¶¶ 66–67, 90–98; Ex. 2029 ¶¶ 24–68). *See* Pet. Reply 21–22 (Petitioner responds with attorney argument that “a person skilled in the art would appreciate the benefits of automating a manual process.”).

Petitioner has not shown sufficiently that such a modification is “a mere design choice” or that one of ordinary skill in the art would be motivated to make the proposed modification because “[a]ll that is needed is to replace the burr with an appropriate contact element better suited to cleaning debris from the eyelid margin without irritating the tissue.” Pet. 27, *see Magnum Oil Tools*, 892 F.3d at 1380 (“The petitioner must . . . articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.”), *see also KSR*, 550 U.S. at 418 (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”).

Lacking the necessary analysis, evidence and facts, Petitioner has failed to make the requisite showing of a sufficient rationale for the alleged combination. Petitioner has not met its burden to show by a preponderance of the evidence that claims 1 and 17 are unpatentable under 35 U.S.C. § 103(a) over AlgerBrush and Hamburg.

Dependent claims 2–11 and 14–16 at issue depend from claim 1. For the reasons discussed above, Petitioner has not met its burden to show by a preponderance of the evidence that claims 2–11 and 14–16 are unpatentable

under 35 U.S.C. § 103(a) over AlgerBrush and Hamburg. *See In re Fritch*, 972 F.2d at 1266, (“[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.”).

V. CONCLUSION

Petitioner fails to show, by a preponderance of the evidence, that claims 1–11 and 14–17 of the ’718 patent are unpatentable under 35 U.S.C. § 103.

VI. ORDER

For the reasons given, it is
ORDERED that claims 1–11 and 14–17 of the ’718 patent have not
been shown to be unpatentable;

FURTHER ORDERED that Petitioner’s Motion to Exclude Evidence
is denied as to Exhibit 2025, and dismissed as to Exhibits 2002 and 2020;

FURTHER ORDERED that Patent Owner’s Motion to Exclude
Evidence is dismissed; and

FURTHER ORDERED that, because this is a Final Written Decision,
parties to the proceeding seeking judicial review of the decision must
comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2016-01670
Patent 9,039,718 B2

For PETITIONER:

Steven Ross
Christopher O'Hagan
Michael A. Rahman
Ross IP Group, PLLC
sross@rossipg.com
cpohagan@rossipg.com
mrahman@rossipg.com

For PATENT OWNER:

Michael Rosato
Matthew Argenti
Andrew Brown
WILSON SONSINI GOODRICH & ROSATI
mrosato@wsgr.com
margenti@wsgr.com
asbrown@wsgr.com