

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*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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.”). Blephex, LLC (“Blephex” or “Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Upon consideration of the Petition and the Preliminary Response, we determine that Petitioner has established a reasonable likelihood of prevailing on the claims challenged in the Petition. For the reasons expressed below, we institute an *inter partes* review of claims 1–11 and 14–17 of the ’718 patent.

B. Additional Proceedings

Pain Point 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 off an eyelid margin of a patient. Ex. 1001, Abst., Fig. 1. 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.

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 the transmitted motion to the swab by electromechanical device 10 “may include, but is not limited to, a reciprocating movement 38*a*, a rotating movement 38*b*, or a vibrating movement 38*c*,” and that, “the speed of the movement 38 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.

E. The Alleged Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable on the following specific grounds.¹

References	Basis	Claims Challenged
AlgerBrush II ² , Seminara, ³ and Stevens ⁴	§ 103	1–11 and 14–17
AlgerBrush II and Hamburg ⁵	§ 103	1–11 and 14–17
Yamaura ⁶ and Stevens	§ 103	1–11 and 14–17
Prosecution history of U.S. Patent Application No. 13/949,365.	§ 103	1–11 and 14–17

II. CLAIM CONSTRUCTION

Independent claim 1 recites “[a] method of treating an eye for an ocular disorder with *a swab* operably connected to an electromechanical device.” (Emphasis added). According to Petitioner, the term “swab” should “be given its ordinary meaning, specifically: a piece of absorbent material capable of removing debris from the eye without harming the eye.” Pet. 11–12 (citing Ex. 1001, 4:1–10, Ex. 1007, Ex. 1008, Ex. 1009, Ex. 1010, Ex. 1011). Patent Owner argues that this proposed construction is

¹ Petitioner supports its challenge with a Declaration of Dr. William J. Benjamin, O.D., Ph.D. (Ex. 1002). *See infra*.

² 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).

³ Ex. 1016, US 2007/0049860 A1 (Pub. March 1, 2007).

⁴ Ex. 1017, Sue Stevens, *How to Clean Eyelids*, Community Eye Health Journal (Copyright 2011).

⁵ Ex. 1018, U.S. Patent No. 4,883,454 (iss. Nov. 28, 1989).

⁶ Ex. 1019, Japanese Unexamined Patent Appl’n. No. JP-A-Hei10-108801 (Pub. April 18, 1989).

unnecessarily narrow and that “[n]othing in the intrinsic evidence of the ’718 Patent suggests that the ‘swab’ must be made from ‘absorbent material.’” Prelim. Resp. 14.

The ’718 patent does state, as pointed out by Patent Owner, that “[i]t will be appreciated that the swab 14 may be manufactured of *any* material suitable for contacting the eye 15 without harming the eye 15.” *Id.* at 14 (citing Ex. 1001, 3:64–66) (emphasis added). Thus, at first blush it appears that according to the specification a “swab” is inclusive of both absorbent and non-absorbent materials. This differs, perhaps, from the ordinary meaning asserted by Petitioner, for example, that a swab is “[a] small piece of absorbent material (e.g. cotton).” *Id.* at 18.

Despite the parties’ differences of opinion, we are not persuaded that this term needs to be construed for purposes of this Decision. Each ground appears to rely upon at least one reference that discloses an absorbent material as a swab. For example, in Petitioner’s second ground, the Hamburg reference describes that “[t]he present invention relates to a new and improved medicinal instrument generically referred to as a swab type applicator made of polyurethane or similar flexible material capable of absorbing and holding a medicant.” Ex. 1018, 1:3–6. Because the asserted prior art discloses that a swab can be absorbent, and because there is no dispute between the parties that a swab can be an absorbent material, we need not construe explicitly any claim language to determine that there is a reasonable likelihood of Petitioner prevailing on its claim challenges. *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. ANALYSIS

A. *Threshold issue – 325(d)*

Patent Owner argues, initially, that Ground 1 of the Petition should be denied because the AlgerBrush II references were listed, and initialed as having been considered, by the Examiner during prosecution of the application that became the '718 patent. Prelim. Resp. 17–18. Further, Patent Owner contends that the Seminara and Stevens references are cumulative to prior art considered by the Examiner during prosecution. *Id.* (citing Ex. 1001, Reference Cited, Ex. 2001, 41–45, 180). Patent Owner asserts, therefore, that AlgerBrush II and the cumulative information disclosed by Seminara and Stevens has already been considered by the Patent Office and “[t]hus, Ground 1 does not present any new arguments not previously considered by the USPTO during the examination of the '718 Patent.” *Id.* at 19.

The statute gives the Director discretion to take into account whether, and reject a petition because, the same or substantially the same prior art or arguments previously were presented to the Office. *See* 35 U.S.C. § 325(d). That the primary reference, AlgerBrush II, was considered as prior art in the prosecution record of the '718 patent is a factor which the Board “may take into account” according to 35 U.S.C. § 325(d). Patent Owner, however, does not show that the Examiner of the application that became the '718 patent substantively considered AlgerBrush II in combination with the secondary references in the present Petition, nor does Patent Owner persuasively explain that the Examiner considered “substantially the same . . . arguments,” as Petitioner presents here, another factor which the Board “may take into account” according to 35 U.S.C. § 325(d). For example,

although AlgerBrush II was apparently listed in an IDS initialed by the Examiner, and arguably does not teach a swab for “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin,” as recited in claim 1 Petitioner, here, relies upon Seminara’s bullet shaped sponge as an appropriate “swab,” for the eyelid margin. Pet. 13. Motivation for such a combination is gleaned from the method of manually cleaning an eyelid margin with a swab described by Stevens. *Id.* Patent Owner’s evidence that AlgerBrush II was considered during prosecution and that common-place treatments and swabs were known to treat ocular conditions such as Blepharitis, does not show persuasively that the Examiner considered either the same arguments or a similar combination of references as presented here during prosecution of the application that became the ’718 Patent. In addition, we note that the prosecution history focused substantively on an anticipation rejection over a different reference, Grenon, U.S. Pub. No. 2007/0060988. *See* Ex. 1003, 154 (“Claims 1–8 and 21–22 are rejected . . . as being anticipated by Grenon.”).

With respect to Ground 2, the combination of AlgerBrush II and Hamburg, we are similarly unpersuaded that the listing of Hamburg in the automated Patent Linguistics Utility System (“PLUS”) search results carried out by the Scientific and Technical Information Center (Ex. 1003, 147), is evidence that the Examiner substantively considered either Hamburg or arguments relating to obviousness and the combination of AlgerBrush II and Hamburg. Although, Hamburg was listed in the PLUS search results there is no corresponding evidence that we can find, nor does Patent Owner point to any in the file wrapper history, that Hamburg was considered in any

substantive manner by the Examiner during prosecution. (Ex. 1003, 33–35, 39–41).

The Yamaura reference relied upon by Petitioner as the primary reference for Ground 3 was, like AlgerBrush II, considered during prosecution of the application that became the '718 Patent. *See* Ex. 1001, References Cited. As in Ground 1, Petitioner relies upon Stevens for motivation to use the Yamaura device to clean debris from eyelid margins instead of ear secretions and detritus. Pet. 38. Because neither Stevens nor any arguments relating to combination with Stevens were considered by the Examiner during the underlying prosecution of the '718 patent, we are unpersuaded that “substantially the same arguments” have been presented here by Petitioner. *See* 35 U.S.C. § 325(d).

We do not address Patent Owner’s § 325(d) arguments with respect to Ground 4, because, as set forth below, we do not institute a trial on that ground.

We turn now to Petitioner’s asserted grounds of unpatentability and Patent Owner’s arguments in its Preliminary Response to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a).

B. Claims 1–11 and 14–17—Alleged obviousness over AlgerBrush II in view of Seminara and Stevens

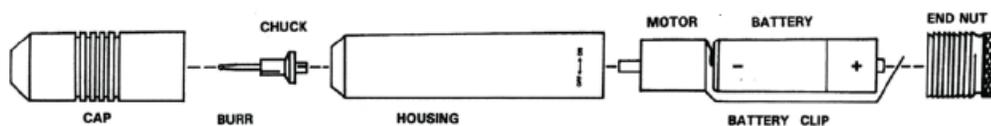
Petitioner asserts that claims 1–11 and 14–17 would have been obvious over AlgerBrush II in view of Seminara and Stevens. Pet. 12–26. Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–11 and 14–17 would have been obvious for the reasons explained below.

1. Overview of 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.



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.

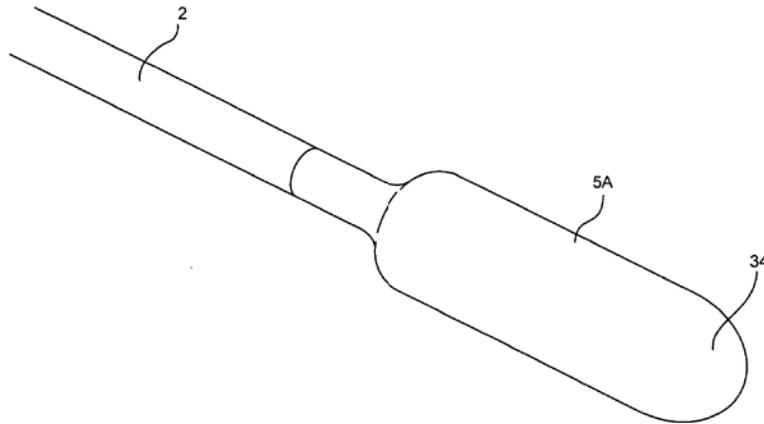


Above, a drawing from ALGERBRUSH II Operating Instructions illustrates a housing including a battery powered motor connected to a chuck and a shaft supporting a burr. Ex. 1014. Also, different sizes and types of burrs may be used with the device, for example carbide or fine grit diamond burrs. *Id.*

2. Overview of 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.

3. Overview of 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 description accompanying the above 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.

4. 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, at this

point, dispute this level of ordinary skill, but indicates that it may offer an alternative if *inter partes* review is instituted. Prelim. Resp. 12.

5. Discussion

Petitioner argues that the '718 patent, itself, admits that those of skill in the art would understand the AlgerBrush II electromechanical drive and replaceable instruments to be examples of the type of device that could be used to clean a patient's eyelid margins. Pet. 12–13 (citing Ex. 1001, 5:14–20). Petitioner admits that AlgerBrush II discloses the “burr” as being a carbide or a fine grit diamond. *Id.* (citing Exs. 1014, 1015.) Petitioner contends, however, that the burr could be replaced and that “[a]ny eye care specialist would recognize that a softer material can be used to remove such debris from the eyelid margin,” and points to Seminara's disclosure of a soft, bullet shaped, medical grade sponge as a suitable material for removing debris from a patient's eyelid margin. *Id.* at 13 (citing Ex. 1016 ¶ 0081, Fig. 20). Petitioner argues further that motivation to combine AlgerBrush II with Seminara's bullet shaped sponge to carry out the process of cleaning a patient's eyelid margin is provided by Stevens' description and steps that explain how “to remove crusting on the eyelid margins in cases of blepharitis using a swab soaked in a solution.”⁷ *Id.* (citing Ex. 1017, Figs. 8 and 10).

Patent Owner argues that the combination of AlgerBrush II, Seminara, and Stevens “fails to address every element of the challenged claims.” Prelim. Resp. 21. Specifically, Patent Owner contends that the combination

⁷ Petitioner's declarant, Dr. Benjamin, states that “blepharitis, [is] a condition characterized by chronic inflammation of the eyelid. Symptoms include redness, flaking of skin, and/or crusting at the eyelid margins, producing discomfort and vision impairment.”

appears directed to a device, rather than a method, and does not teach or disclose the claimed step of “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin” as required by claim 1. *Id.* at 21–22. Patent Owner argues further that the combination of AlgerBrush II and Seminara would have taught removing cornea tissue of a patient, not cleaning debris due to conditions such as blepharitis that occur on the vascularized tissue of the eyelid margin. *See id.* at 23–26 (citing Ex. 2002 ¶¶ 17–18).

We agree with Patent Owner that the claims at issue here are method claims. *See id.* at 21, and *see* Ex. 1001, 7:29–8:58. Patent Owner’s concern, however, that AlgerBrush II and Seminara disclose in combination a device as opposed to a method is misplaced. Claim 1, a method claim, specifically recites in each paragraph that the method is carried out by an “electromechanical device.” Although claim 1 is a method claim, Patent Owner fails to explain how or why “a swab operably connected to an electromechanical device,” as recited in claim 1, is not a limitation. Indeed, claim 1 also recites the structural limitation of “the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin.” We find it reasonable, if not necessary, for a proper obviousness analysis that Petitioner has looked to prior art apparatus and electromechanical devices such as AlgerBrush II and shaped swabs as in Seminara to meet certain apparatus-type limitations recited in the claims.

We are also not persuaded that the result of combining AlgerBrush II and Seminara would have been a device capable of only tissue removal, as opposed to cleaning debris. *See* Prelim. Resp. 25 (Patent Owner asserts that combining AlgerBrush II and Seminara “would yield a method of removing

tissue from the surface of the eye or a generic anatomical structure.”). This argument attacks these references in isolation, whereas the asserted combination is predicated on a combination of the teachings of three references, where Stevens is relied upon for teaching a method of cleaning debris from a patient’s eyelid margins. *See In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references”). Moreover, Patent Owner’s argument does not explain why one of ordinary skill in the art would not have understood, or considered, AlgerBrush II equipped with Seminar’s swab to be useful for cleaning a vascularized anatomical feature such as an eyelid margin with debris by, “impacting the debris with the swab to remove debris from the eye” as claim 1 recites. There is no requirement that a reference must recognize all features of its invention. *Ex parte Obiaya*, 227 USPQ 58, 60 (BPAI 1985), *aff’d mem.*, 795 F.2d 1017 (Fed. Cir. 1986) (holding that the recognition of another advantage flowing naturally from following the suggestion of the prior art cannot be the basis for patentability when the difference would otherwise be obvious).

With respect to the specifically claimed method steps, for example, “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin” as called for in claim 1, Petitioner has relied upon Stevens. Using pictures and other written description, Stevens teaches a series of steps that a care-giver should undertake when using a swab to clean the eyelid margins of a patient’s lower and upper eyelid. *See Ex. 1017, 7* (“With the swab or bud, clean gently along the lower eyelid margin in one movement from inner to outer canthus.”). Stevens explains that in a first

step, with the patient's eyes closed, the eyelashes are cleaned. *Id.* In second and third steps Stevens describes manually manipulating the patient's upper and lower eyelid to expose and clean the eyelid margin of both the lower and upper eyelid. *Id.* at 7–8. A reasonable reading of Stevens provides a similar if not the same understanding of “eyelid margin” as described and claimed in the '718 patent. We are persuaded, therefore, that the procedures and images in Stevens teach a method of using a swab to clean the eyelid margin by “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin” as recited in claim 1.⁸

Patent Owner argues also that Petitioner's Ground 1 fails to identify a motivation for modifying the references to result in the claimed method. Prelim. Resp. 30. We disagree. Petitioner explained that Stevens teaches using a swab to clean a patient's eyelid margin. Pet. 13. Petitioner argues, persuasively, that one of ordinary skill in the art would understand that AlgerBrush's fine grit diamond may be too abrasive for cleaning, and where softer swabs are known in the medical field, “[a]ny eye care specialist would recognize that a softer material can be used to remove such debris from the eyelid margin.” *Id.*

Petitioner has shown sufficiently at this point in the proceeding that a person of ordinary skill in the art would have the ability and motivation to undertake the steps of cleaning of a patient's eyelid margin with an electromechanically operated swab device rather than a manual procedure as

⁸ We understand from a plain reading of the claims in the '718 patent, “eyelid margin” to include the “portion of the eye between the eyelashes and the inner edge of the eyelid margin” as recited for example in claim 1. Our understanding appears consistent with Dr. Trattler's testimony. *See Ex. 2002 ¶ 18.*

shown in Stevens. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007) (“a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions”).

Accordingly, on the present record we are persuaded that there is a reasonable likelihood that Petitioner will prevail as to the obviousness of claim 1 of the ’718 patent over AlgerBrush II, Seminara, and Stevens. Additionally, we are persuaded that there is a reasonable likelihood of Petitioner demonstrating that the suggested combination of the references’ teachings meets the limitations of claims 2–11 and 14–17 which depend from claim 1. *See* Pet. 17–26.

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

1. Overview of 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.

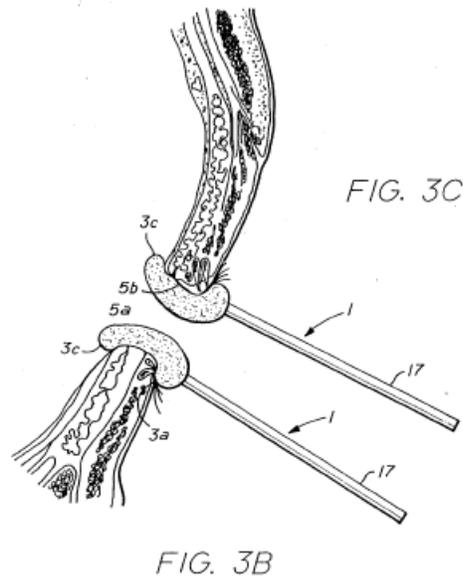


Figure 3 of Hamburg, above, depicts swab 1 being applied to an upper and lower eyelid margins. Hamburg describes that the concave nature of blotting means 5 facilitates cleaning the interior and exterior surfaces of the eyelid margin, and that “peak 3c is intended for contact with the upper or lower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

2. Discussion

Petitioner contends that all that is necessary to treat an ocular condition such as blepharitis, is simply to replace AlgerBrush II’s “burr” with Hamburg’s swab and use the swab and electromechanical device for the purpose of cleaning the eyelid margins as described by Hamburg. Pet. 26–27.

Patent Owner argues *inter alia* that Petitioner has failed to provide a motivation or “specify a rational basis for modifying the methods of the cited documents to result in the claimed method.” Prelim. Resp. 36–39. Patent Owner further asserts that Petitioner’s explanation that Hamburg’s swab could be simply substituted for the AlgerBrush II’s burr is

“impermissible hindsight reliance on the teachings of the ’718 patent” and changes the principle of operation of AlgerBrush II. *Id.* at 39.

We are persuaded by Petitioner’s evidence at this point in the proceeding that the substitution of a softer sponge or swab, for a burr, on the AlgerBrush II device would have been within the abilities of one of ordinary skill in the art and would not have altered the principle of operation of AlgerBrush II. Although we understand, as Patent Owner advocates, that AlgerBrush II describes a fine grit diamond burr for removing ocular tissue, we are persuaded that it would not have been outside the abilities of a person of skill in the art to substitute a different, e.g. softer swab, for cleaning tissue as described by Hamburg, as opposed to removing tissue. AlgerBrush II uses a “chuck” for holding the burr. At this early stage of the proceeding we are unpersuaded that replacing the AlgerBrush II burr with a softer swab in order to clean, rather than remove, human body tissue would have been beyond the skill or understanding of one of ordinary skill in the art. That the objective functional result is different, i.e. cleaning as opposed to removing material, does not persuade us that that the fundamental way in which the electromechanical AlgerBrush II device functions is changed.

Additionally, keeping in mind that the claims of the ’718 patent are method claims, Hamburg’s claims recite in functional terms how the claimed swab is used, for example independent claim 7 recites:

An improved swab for use on the eyelid margin for treatment of disease and/or irritation thereto by facilitating removal of cellular and sebaceous debris buildup along either the anterior or exterior lid margin and adjacent lashes with a mechanical action.

Ex. 1018, 5:25–29.

On this record, we are persuaded that such a substitution would have been nothing more than one of ordinary skill using his or her ordinary skill and creativity to automate a manual activity, and to make the necessary adjustments and modifications to result in a properly functioning cleaning device for cleaning an eyelid margin as recited in the '718 patent. *See KSR*, 550 U.S. at 418 (“the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”).

Patent Owner urges us to consider that the concave shape of Hamburg’s swab would not be effective for contacting the eyelid margin and cleaning debris when incorporated in AlgerBrush II, which spins, i.e. axially rotates, the swab. Prelim. Resp. 40. We are not persuaded at this point that the specific shape of any of the disclosed swabs, e.g. Hamburg’s concave swab, would dissuade one of ordinary skill in the art from using a swab, instead of a burr, with AlgerBrush II. As alleged by Petitioner, “all that is needed is to replace the burr with an appropriate contact element.” Pet. 27. We find it reasonable, on the record before us, that a person with ordinary skill in the art would have known to modify a swab’s shape to appropriately conform to an anatomical feature and accommodate the AlgerBrush II spinning motion.

Accordingly, on the present record, we are persuaded that there is a reasonable likelihood that Petitioner will prevail as to the obviousness of claim 1 of the '718 patent over AlgerBrush II and Hamburg. Additionally, we are persuaded that there is a reasonable likelihood of Petitioner demonstrating that the suggested combination of the references’ teachings

meets the limitations of claims 2–11 and 14–17 which depend from claim 1.
See Pet. 30–37.

D. Claims 1–11 and 14–17—Alleged obviousness over Yamaura and Stevens

1. Overview of Yamaura

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

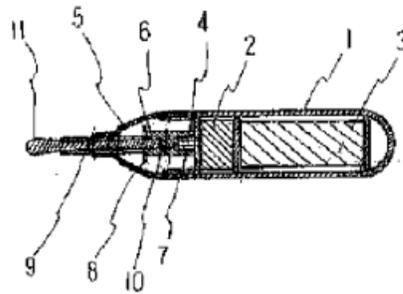


Figure 1 of Yamaura, above, illustrates an ear cleaning device including battery powered motor 2 for rotating shaft 4 connected to cotton swab holder pipe 9 having a cotton swab 11 inserted in pipe 9.

Yamaura explains that “[t]his invention was developed as a method for electrically-powered ear-cleaning, replacing the conventional manual method.” Ex. 1019 ¶ 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.* at ¶¶ 3–4.

Petitioner argues that ear canals, like eyelids, have sebaceous glands, and that Yamaura “could be used to clean the margins of the eyelid according to the method of the ‘718 patent with no modification.” Pet. 38. Petitioner contends, as in Ground 1, that motivation to use Yamaura to clean eyelid margins is provided by the procedure for cleaning eyelids with a swab described by Stevens. *Id.*

Patent Owner asserts that the combination fails to disclose all the steps recited in method claim 1, specifically that “the combination of the Yamaura (JPH10108801) with Stevens fails to address the elements of ‘contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin.’” Prelim. Resp. 41.

2. Discussion

As discussed *supra* we are not persuaded that the meaning of Stevens’ “eyelid margins” is substantively different from that in the ’718 patent. For similar reasons as set forth above relative to Stevens in combination with AlgerBrush II and Seminara, we are persuaded that Yamaura and Stevens disclose the method steps of claim 1. Although the images in Stevens may not clearly show a swab in contact with an eyelid margin, Stevens describes “[w]ith the swab or bud, clean gently along the lower eyelid margin,” and in context, is reasonably understood to mean cleaning along the length of the eyelid margin and between the lashes and inner edge of the eyelid margin. Ex. 1017, 7.

Patent Owner argues also that Petitioner has failed to provide evidence that one of ordinary skill in the art would use Yamaura’s motorized device in place of the manual cleaning procedure described by Stevens. Prelim. Resp. 43. We are persuaded at this point in the proceeding that a person of ordinary skill in the art would have had the ability and recognized to substitute a known electromechanically operated device which performs a commensurate mechanical action as a manual procedure and, to undertake the steps of cleaning a patient’s eyelid margins with such an electromechanically operated swab device, in the manner described by the manual procedure in Stevens. *See KSR*, 550 U.S. at 401 (“[I]f a technique

has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”), *see also Leapfrog Enterprises Inc. v. Fisher-Price Inc.*, 485 F.3d 1157 (2017) (generally obvious to automate a known manual procedure or mechanical device).

At this point we are also not persuaded by Patent Owner’s contention that Stevens teaches away from combination with Yamaura because Stevens’ procedure describes replacing the swab after cleaning along the length of the eyelid margin. Prelim. Resp. 44. Patent Owner’s argument that Stevens teaches away from “repeatedly cleaning the same location on the eyelid margin with a single swab, which is what occurs in the presently claimed method” is not commensurate in scope with the claims. We cannot find, nor has Patent Owner pointed to any, specific language in the challenged claims that the actions of “moving” or “contacting” the swab with the eyelid margin requires the swab to “repeatedly clean[] the same location” of the eyelid margin.” *Id.*, *see also* Ex. 1001, 7:30–43.

Accordingly, on the present record we are persuaded that there is a reasonable likelihood that Petitioner will prevail as to the obviousness of claim 1 of the ’718 patent over Yamaura and Stevens. Additionally, we are persuaded that there is a reasonable likelihood of Petitioner demonstrating that the suggested combination of the references’ teachings meets the limitations of claims 2–11 and 14–17 which depend from claim 1. *See* Pet. 40–48.

E. Claims 1–11 and 14–17—Alleged obviousness over Prosecution History of U.S. Patent Application No.: 13/949,365

With respect to the alleged obviousness of claims 1–11 and 14–17 over the prosecution history of U.S. Patent Application No.: 13/949,365, a continuation-in-part application of the underlying patent application that became the '718 patent, we exercise our discretion not to institute in light of our decision to institute review of these same claims on the grounds discussed above. *See* 35 U.S.C. §314(a); 37 C.F.R. § 42.108(b).

IV. SUMMARY

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail on at least one alleged ground of unpatentability with respect to each of claims 1–11 and 14–17 of the '718 patent.

The Board has not made a final determination on the patentability of any challenged claims.

V. ORDER

For the reasons given, it is

ORDERED that *inter partes* review of the '718 patent is hereby instituted as to claims 1–11 and 14–17 on the following grounds.

1. Claims 1–11 and 14–17 as obvious over AlgerBrush II, Seminara, and Stevens;
2. Claims 1–11 and 14–17 as obvious over AlgerBrush II and Hamburg; and
3. Claims 1–11 and 14–17 as obvious over as obvious over Yamaura and Stevens.

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FURTHER ORDERED that no ground other than those specifically granted above is authorized for the *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial on the grounds of unpatentability authorized above; the trial commences on the entry date of this decision.

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